The role of IP in a new post crisis world

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Report Encounter nº3

International IP and Access to Pandemic Treatments

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Moderator and Speakers:

Prof. Rochelle **DREYFUSS** (New York University)
Prof. Henning **GROSSE RUSE-KHAN** (Cambridge University)
Prof. Laurent **MANDERIEUX** (Bocconi University) acting as Moderator

This **third Encounter** took a novel – Socratic – approach and departed from the "presentation, then Q&A session" structure, giving the speakers the opportunity to answer the same questions – initially from the Moderator, and then from the audience – and, moreover, to build on each other´s answers.

Prof. MANDERIEUX (Moderator) stressed that the 2020 Health crisis has put the spotlight on the international IP system: in its views, it is at stake whether there is an appropriate balance in the IP system's role as innovation incentivising tool, on the one hand, and its promoting access and dissemination function, on the other. The current Global Digital Encounter is therefore analysing whether the focus must be changed from the former to the latter and if so, whether the current system, tools and principles are able to tackle this challenge or, on the contrary, an in-depth reform is needed.

1. **What are the lessons learnt by the international IP system as a result of the COVID? Is the current system workable enough to face this challenge?**

Prof. DREYFUSS set the basis by analyzing the underlying duality of the TRIPS Agreement: TRIPS in its enabling function, setting minimum standards of protection that level the playing field vs. TRIPS, empowering the right holders with exclusive rights that conflict with the diffusion of R&D results. The recent WTO AB decision in the Australia Plain Packaging case has confirmed the Doha Declaration's interpretative role in interpreting TRIPS. The states' policy space is further limited by FTAs and Investment Agreements.

Two sets of problems shall be distinguished: (1) impact of TRIPS, FTA, and IAs, when inventing a new medicine (e.g. use of genetic material, other research materials, use of patented drugs and medical equipment); and (2) impact of TRIPS, FTA and IAs on the access to developed, then patented vaccines and treatments.

Prof. GROSSE RUSE-KHAN reminded that international law mostly regulates IP protection – incentivizing function – and not that much the access side – dissemination function -, which is regulated primarily by domestic law. Art. 7 TRIPS, however, focuses on the utilitarian motivation for IP protection: not only by giving incentives to innovate; but also by promoting the dissemination and transfer of technology – hence serving as potential basis also for coordination of access within the international IP regime. Certain examples of coordinated actions with regards to access do exist: the Marrakesh VIP Treaty; and, within the EU, mandatory exceptions for user-generated content in the European Digital Single Market Directive.

Also, Art. 31bis TRIPS for compulsory licenses for exports can be understood in that context, but rather serves as a tool for bilateral actions. In the COVID-19 context (where no-one is safe until we all are safe), both utilitarian and humanitarian motivations militate for the globalizing access to medicine.

2. Are initiatives such as patent pledges, the accelerator system or the Research Data Alliance guidelines enough?

Although them are positive steps – according to **Prof. DREYFUSS** – these initiatives are limited inasmuch they are mostly referred to (research) data. In addition, most of these initiatives are driven by NGOs, such as the Bill & Melinda Gates Foundation, and they have not been decisively supported by individual pharma generators.

Prof. GROSSE RUSE-KHAN, recalled the importance of technology transfer agreements – notably pull and push arrangements – to promote an effective exchange of information while maintaining the incentives for companies. Another interesting (non IP-related) initiative was the WHO Pandemics Influenza Preparedness (PIP) framework, aimed at the exchanging viruses´ genetic information against commitments to receive technology (such as vaccines) developed on the basis of that genetic information. However, this mechanism might not be that attractive as it does not enforce its quid pro quo – hence reducing incentives for participation – and since it does not directly address private actors holding the relevant technology.

3. What could the governments do to promote (COVID-related) research?

Prof. DREYFUSS suggested various tools, in hands of the governments, such as publicly funding the research, so that the governments could later assert their rights to patented inventions. In case of privately funded research, governments may make use of research exceptions. COVID-19 pandemic teaches us that the patent exceptions should be broader, but new exceptions may raise the question as to whether they are TRIPS/FTAs/IAs compatible.

Prof. GROSSE RUSE-KHAN added that Art. 30 TRIPS was given a narrow interpretation in WTO "Canada – Patent Protection" dispute, but this was done prior to the adoption of the Doha Declaration. FTA provisions are not particularly problematic on this specific issue, but IAs can give rise to investment disputes.

4. What are the available tools to protect access to medicines against vaccine (or funding) nationalisms?

Prof. DREYFUSS replied that, although there are some soft law efforts at the WTO level, the issue is ultimately left to the states, who shall act within the international law framework.

Prof. GROSSE RUSE-KHAN referred to the WHO Assembly Resolution, which calls for an equitable and timely access to health technologies, in line with TRIPS flexibilities. He explained the functioning of the Art. 31 bis TRIPS mechanism, which contemplates the possibility of compulsory license for exporting purposes, and was introduced as a result of the HIV crisis as an attempt to address domestic manufacturing capacity constraints in the pharmaceutical sector. So far, this mechanism has only been used once, so there is limited experience about its effectiveness. Other TRIPS flexibilities, including ordinary compulsory licenses or not allowing patents for secondary medical use, can also be used by governments.

Prof. DREYFUSS developed the argument further by citing certain national measures (such those recently adopted in Israel and Canada) which allows the Ministry of Health to use patented inventions in cases of medical emergencies. The question persists as to whether it would be consistent with states obligations under IAs.

Prof. GROSSE RUSE-KHAN elaborated on lessons learned from previous investment disputes, potentially relevant for prospective COVID-19 litigation. Investors may invoke the expropriation or the fair and equitable treatment (FET) standards of protection to challenge negative impacts on individual IP rights, or changes in the broader legislative environment. Law firms are already pointing out at potential investment disputes, which might cause a chilling effect on the states.

5. **Should the flaws of the current system be addressed from a systemic perspective or at application level?**

For **Prof. GROSSE RUSE-KHAN**, the IP system is just a small part of a broader framework which shapes the dynamics and incentives of companies. So the answer to this depends on the individual circumstances, and IP's relative role vis-à-vis other factors.

Prof. DREYFUSS believes that the expansion of IP protection stemming from FTAs is more a systemic problem. COVID might teach countries the danger of ever-raising protection and bring more exceptions, less scope of patentable subject matter to newer FTAs.

6. **Are there IP issues related to tracing apps?**

Prof. GROSSE RUSE-KHAN does not observe any IP-specific issues, but privacy-related ones.

Prof. DREYFUSS sees that, just as in the situation with patents, COVID-19 is challenging our perception of privately-owned personal data. In particular whether the appropriability of personal data can be severely challenged by the public interest in accessing such data.

7. **How to prevent opportunistic behaviours of Patent Assertion Entities in relation to COVID 19- related technologies?**

Prof. DREYFUSS argues that it is important to control who gets access to public funded inventions – and how they are monetised by middlemen. She seems more concerned overall with the aggressive enforcement of very wide – and potentially invalid – patents in the IT sector, which can be addressed by providing for cheaper means to challenge validity.

8. **Is the opportunistic use of bilateral investment disputes – as opposed to WTO Disputes Settlement Mechanisms – a threat to effective access to medicines?**

Prof. GROSSE RUSE-KHAN reminded of the necessity to distinguish between IP provisions in FTAs, which are problematic on the norm-setting level – here mostly diplomatic pressure to implement FTAs arise; and prospective investment-state disputes, which can arise under IAs. Past cases show that latter are certainly something states might have to worry about – but one would also hope that ISDS tribunals duly recognize the state's right to regulate, especially in the COVID context.

9. **Might a grace period for COVID-related disputes be an appropriate measure to promote dissemination of research results?**

Prof. DREYFUSS confirmed that the period to file for patent protection has been extended in the past on the bilateral level between Germany and the US, as part of post-war settlements. Such mechanism is not regulated in TRIPS, but, once again, COVID-19 will challenge our perception of TRIPS and the ways of changing it.

In turn, **Prof. GROSSE RUSE-KHAN** believes that we should also search for solutions outside of the IP system to promote incentives to innovate.

Anastasiia KYRYLENKO
Vicente ZAFRILLA DÍAZ-MARTA