Articles

Uncertainty and Intellectual Property Rights

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In this time of uncertainty, innovation and technology have been rapidly evolving to find solutions for our global health care crisis. There are now over one million COVID-19 cases around the world[i], with a persistent increase in the number of deaths caused by a virus which has no cure. There are at least 500 clinical trials worldwide in an active investigation for new therapies and a vaccine for this virus[ii], but few if not only one therapy had advanced to be approved for alleviating severe COVID-19 cases.[iii]

The scientific community is united with the pharmaceutic industry to find a vaccine for a lethal virus that months ago was unknown to the scientific academy and the public and for which our immunity system has no defence. Transparency on clinical trials is crucial so that the population can be informed on the most updated and correct information on confirmed therapies. Some say COVID-19 is a game-changer for compulsory licenses on drug discovery. Before the 2001 Doha Declaration[iv], the right to use compulsory licenses to export or produce locally essential medicines was rarely used before.[v]

We have seen many jurisdictions updating their local intellectual property legislation to cope with the demand for novel medicine still to come to alleviate overwhelming hospitals and health care workers around the world. France, Israel, Ecuador, Chile, Germany are the policymaker's frontrunners enacting intellectual property legislation that allows compulsory licenses on patents and even price control to avoid a tragedy of unsurmountable proportions in which more human lives may be lost.[vi] Sound public policy should encourage access to essential medicines or vaccines at a reasonable price. It is well-known that compulsory licenses do not create a stimulus to find efficient therapies, but rather it may decrease the goodwill to find a solution.[vii]

Other elements that are pre-patent grant may be more useful, such as global clinical trials. Clinical trials are investigative by nature, interventional studies designed by phases to provide studies of potential drugs eligible for approval by regulatory agencies.[viii] Clinical trials may be conducted before the patent examination or after, but their results may affect the outcome of a patent application.[ix]

The clinical trial and its evaluation may produce variable results. A clinical trial is a costly, lengthy and unpredictable process for all stakeholders. The risk is that the conducted studies may not produce the outcome expected, so it is a risky project. On the other hand, clinical trials are of extreme importance

to intellectual property rights associated with them. That is because when the clinical trial confirms a useful drug, there is a profitable outcome. Novel drugs can be commercialized locally or worldwide if the local authorities certify the data compiled on a registered clinical trial. In a sense, it produces evidence in the form of data that will provide safety for the therapy. Clinical trials then become a crucial part of the patent framework, especially for novel drug compounds, because they validate the novelty of the medication and its claimed use. Clinical trials are not included expressly in the patentability principles, though. If a clinical trial is successful, the patentability of the subject-matter is validated by its results. Conversely, if a clinical trial does not result in a confirmation fora new drug, then the whole process and the research associated with the invention may be a failure.

It is a world of fierce competition; a patent application that discloses a claimed therapy, which has not materialized is an investment lost. In a nutshell, the world of pharmaceutical inventions, a global market that accrued in 2018 more than one trillion dollars, is risky.

The amount of investment required for such clinical trials, small or large, is not set in stone, because not all clinical trials are equal. It depends on the designed trial, on the number of patients, on the follow-ups and protocols designed to evaluate results. That is why COVID-19 changed the rules for drugs discovery and intellectual property rules to a fast-pacing and global effort to speed up clinical trials results to be approved rapidly. The nature of the virus does not allow any waste of time.

COVID-19 is a lethal virus that replicates inside a host living cell in hours, leaving research and development teams around the world working with an unknown sub-microscopic infectious agent that replicates with a fury not seen before with other lethal diseases as Ebola, SARS or HIV.[x]

That is where transnational intellectual property enters to assist the quest for an efficient therapeutic or an effective medicine to combat this plague. Transnational intellectual property may bring harmonization of intellectual property rules among different countries in which these research teams are located so that the information can run fast. Many research teams have started working together remotely, which will require more collaborative communication and feedback. Thus, transnational research means jointly work for a solution after the COVID-19 genetic code became public. Generally, the COVID-19 research has been grouped on four basic concepts for producing vaccines candidates: the virus itself, viral vector, nucleic acid and protein-based formulations.[xi]

With the dissemination of COVID 19, many individuals around the globe have been exposed to the virus, so an international commitment to share research and clinical trial results are imperative. The fact that many private and public institutions are joining efforts around the world is remarkable. A brief analysis of the regions racing on Research and

Development may indicate that North America, China, Europe and Australia are leading the race to find vaccines. Upon more detailed study, the transnationality of research teams is verifiable, for instance, an Indian manufacturer in full collaboration with an American research team may have the capacity to mass-produce a successful vaccine in a short period of time.[xii]

The public at large hopes that this opportunity to collaborate and produce a vaccine to save lives will avoid practicing prohibitive prices or restrict availability for poor and developing countries. There is hope that having a rich sample of volunteers around the world, one of the most extensive clinical trials ever conceived in our times, will be a game-changer. The pharmaceutical industry, health institutes and universities are working in various research projects unite for a viable vaccine instead of racing against each other to reach out to be granted a patent. That spirit of union in the scientific community allied with private biotechnology and pharmaceutical companies is an answer to the humanitarian crisis we are currently living in.

For private global companies, research institutes and universities globally to unite their efforts to find a solution for a pandemic that has killed more than 244K worldwide, the virus represents an excellent opportunity to revisit the meaning of collaboration. Joint research means spreading the costs among all stakeholders .Intellectual property rights have also an impact on the control of prices for exported goods. Any novel drug in the marketplace, particularly in the case of COVID-19 is beneficial for the whole population in the planet to be inoculated and achieve one of the established principles of intellectual property – to disclose the invention for the public.

In the case of COVID-19, a virus that kills the host rapidly, it is of extreme importance that a vaccine would be discovered in the short term to halt an increase in the number of deaths. For that matter, the versatility of intellectual property protection on arranging licenses for free dissemination of scientific information is crucial for sharing knowledge. This knowledge can be shared among researchers to be useful on technology and to inform the public. Our human ingenuity can find solutions, but the population must be informed of the benefits of receiving a vaccine for this malaise. It has been estimated that over 500 clinical trials are active for finding a cure for COVID-19, in which the Solidarity Trial is worth a mention.[xiii]The World Health Organisation has created the Solidarity Trial, which is a non-bureaucratic clinical trial that aims to speed up registration and certification of clinical trial results.

The Solidarity Trial is sponsored by the World Health Organisation, with a clear and fast procedure for hospitals, in which most of the COVID-19 severe patients are admitted for care and be monitored for clinical trials after enrolling in the program with no bureaucracy attached. This initiative demonstrates that less paperwork for

researchers and healthcare professionals on collecting consistent evidence will generate efficient treatment faster for all.[xiv]

Intellectual property can be of great help to halt this lethal virus. We are sharing information using free publications, shared data, allowing compassionate use requests, which are not elements of what the established principle of patent monopoly is understood.[xv] Compulsory licenses were used as the last resort for diseases such as the HIV that decimated lives in the 1980s until antiretroviral treatment was developed. Litigation for intellectual property rights does not reach a benefit for the population at large, but it demonstrates the antagonism of humanitarian values and principles. We have high hope that this time of COVID-19 it will be different with the help of a robust and innovative transnational intellectual property system.

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[i] For recent number of confirmed deaths which are updated daily. See, The World Health Organisation, Coronavirus disease (COVID-19) Pandemic, available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

[ii] This data is changing rapidly. See, TranspariMed, Working to End Evidence Distortion in Medicine, All COVID-19 Trials Clinical Trails See, the World Health Organization, "Solidarity" Clinical Trial for COIVD-19 Treatments, available at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

[iii] See, U.S. National Library of Medicine, Clinical Trials, Adaptive COVID-19 Treatment Trial (ACTT), available at <https://clinicaltrials.gov/ct2/show/NCT04280705>. See, National Institutes of Allergies and Infectious Diseases, NIH Clinical Trial shows REMDESIVIR accelerates recovery from advanced COVID -19, available at <https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>. See also Daniel O'Day, An Open Letter from our Chairman and CEO dated 29th April 2020 available at <https://www.gilead.com/stories/articles/an-open-letter-from-our-chairman-and-ceo-april-29>

[iv] See, World Trade Organisation, The Doha Declaration explained, available at <https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm>

[v] Compulsory licenses prior to Doha Declaration were connected to the HIV virus pandemic and the exorbitant prices practised by the developed countries pharmaceutical companies. In 1983, Brazil has its first diagnosed HIV case, from there the mortality increased exponentially because of restrict access to extensive drugs produced in the North hemisphere. Compulsory licenses to produce local medication that would be accessible to the large population was implemented by the Brazilian government, which influenced other developing countries to follow suit. See, , A Nunn, E. da Fonseca, and S. Gruskin, U.S. National Library of Medicine Institute of Health, Changing Global Essential Medicines norms to improve access to AIDS treatment: Lessons from Brazil, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2768722/> See, also the World Trade Organization, DS 199, Brazil - Measures Affecting Patent Protection, available at <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm>

[vi] See, The World Trade Mark Review, The key covid-19 compulsory licensing development so far, Adam Houldsworth, available at <https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far>

[vii] When the Brazilian government of Fernando Henrique Cardoso and the Minister of Health Jose Serra changed the Brazilian patent law in 1996, the United States commenced a procedure against Brazil in the World Trade Organisation arguing the illegality of the AIDS program and the production of generic drugs to save lives. The strategy backfired in the public opinion worldwide, which brought light to the economic power of patent protection. Patents were on the bad side of the public policy, particularly on public health for developing countries with no access to essential medicines. See, A. Nunn, E. da Fonseca and S. Gruskin,US National Library of Medicine National Institute of Health, Changing Global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2768722/> (for an account of the political struggle to bring control price on AIDS medicine which was contested by the United States in a trade dispute against Brazil at the World Trade

Organisation and other economic sanctions against developing countries using generic AIDS medicine).

[viii] See, U.S National Library of Medicine, ClinicalTrials, Glossary of Common Site Terms, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>. See also, The World Health Organisation, Clinical Trials, available at <https://www.who.int/health-topics/clinical-trials/#tab=tab_1>

[ix] See,Thorsten Baush, Kluwer Patent Blog, The Dilemma with Clinical Trials and Patent Law, available at <http://patentblog.kluweriplaw.com/2018/04/24/the-dilemma-with-clinical-trials-and-the-patent-law/>

[x] See, Marne C. Hagemeijer, Monique H. Verheije, Mustafa Ulasli, Indra A. Shaltiël, Lisa A. de Vries, FulvioReggiori, Peter J.M. Rottier, Cornelis A.M. de Haan, American Society for Microbiology, Journal of Virology, Dynamics of Coronavirus Replication-Transcription Complexes, available at <https://jvi.asm.org/content/84/4/2134>

[xi] See, Ewen Callaway, Nature, The Race for coronavirus vaccines: a graphical guide, available at <https://www.nature.com/articles/d41586-020-01221-y>

[xii] See, Ewen Callaway, Nature, The Race for coronavirus vaccines: a graphical guide, available at <https://www.nature.com/articles/d41586-020-01221-y>.

[xiii] See, The World Health Organisation, "Solidarity" Clinical Trial for Covid-19 treatments, available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>

[xiv] See, The World Health Organisation, "Solidarity" Clinical Trial for Covid-19 treatments, available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>

[xv] See, Gilead Sciences Update on the Company's Ongoing Response to COVID-19, available at <https://www.gilead.com/purpose/advancing-global-health/covid-19>