An Exceptional International Intellectual Property Law Solution for COVID-19: Spurring Innovation to Facilitate Access to Affordable Medicines

By:

David Enrique Betancourt Cruz

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There is no doubt about the role international law can play in order to face the current COVID-19 pandemic. The answer is crystal clear: reform the current International Intellectual Property Law regime in order to accelerate innovation and facilitate access to affordable medicines worldwide. This could include examining how to better use the current flexibilities of the patent system so as to allow for more innovation, and effective co-operation/coordination in the scientific world. This unprecedented crisis of international scope offers us a rare opportunity to galvanize support for stronger international co-operation among the World Health Organization (WHO), World Intellectual Property Organization

(WIPO), World Trade Organization (WTO),United Nations (UN), G20, and the European Union (EU) - as the top net exporter of pharmaceuticals. Reforming the international patent system and the Trade- Related Aspects of Intellectual Property Rights Agreement (TRIPS) is the type of real and pragmatic solidarity that we need to protect the most vulnerable individuals around the world.

This new pandemic hearkens back to debates in prior decades about whether certain essential medicines could be declared as global public goods through efforts such as compulsory licensing. It is time to reform the international intellectual property system, especially the patent regime, as we are in need of shared research and development(R&D). Most of the pharmaceutical discoveries and advances have been made with state investments, regardless this, several pharmaceutical multinationals in recent weeks have oriented their strategy towards filing new patents, test data and utility models aimed more at increasing royalties than at saving us from the onslaught of COVID-19. In other words, many patented inventions are based on publicly subsidized research in public institutions. It is, therefore, the global public that pays taxes that often finance many research activities. Consumers, in turn, have to pay higher prices for patented products and in this process of increasing profits there is a parallel loss of intellectual commons. This is why it is imperative to de-link R&D from the final cost paid by consumers. The prices of medicines and other health products should be set on the basis of accessibility by all those in need. This improved accessibility is essential in Least Developed Countries; to this end, a new legally binding international R&D treaty should include mechanisms to decouple the cost of R&D for all diseases and pandemic out-breaks from end consumer pricing mechanisms.

A legal system that allows the monopoly of transnational corporations brings more inequality and less growth. The lack of leadership and cooperation amongst international stakeholders is evident. However, not all is lost, the President of Costa Rica sent a letter to the WHO Director requesting that access and use of intellectual property covering technologies that help detect, prevent, control and treat the COVID-19 be allowed. This "pool" of technologies would include patents, copyrights, test data, research for diagnosis, treatment, medicines and vaccines, among others. This proposal has been endorsed by directors of global pharmaceutical companies as well as, different international

public health organizations and by the director of the WHO.

Hopefully, this opportunity for technology transfers, financing, shared R&D and global cooperation is not wasted and is supported by the governments of the world. Colombia must lead by following up on this issue since, as I will explain later. The price control strategy or the use of compulsory licenses in the framework of a national state of emergency are insufficient measures that require other urgent emergency actions. Before presenting the recommended strategy for Colombia, let's briefly review some measures that have been taken by different countries so far regarding patent law regulatory changes.

Chile and Israel, for instance, have requested the implementation of the compulsory licensing mechanism that would allow for the local development of low-cost medicines, better known as generics, upon payment of royalties to the holders of said rights. Ecuador has done the same; it has also requested access to test data for non-commercial public use. Canada and Germany seek by law to nullify patents. The ministers of science and technology of Spain, Australia, Brazil, Canada, France, Germany, India, Italy, Japan, New Zealand, South Korea, Portugal, Singapore and the United Kingdom have considered “the possibility of excepting global patent regulation, with the aim of speeding up technology licensing and transfer processes, so that we can manufacture certain products around the world quickly”.

The true wealth of countries should now be measured in their ability to respond effectively to the pandemic and to safeguard the life and health of all inhabitants without exception or exclusion. All lives have the same intrinsic value. Now, let us highlight some recent proposals on the roadmap of countries like Colombia facing this challenge of enormous ethical, legal and existential dimensions. Costa Rica's proposal should be the foundation both regionally and globally as it is beneficent to all countries involved. The use of compulsory licenses has been tried in the past in Colombia without success for various reasons. Recall the case of Lopinavir / Ritonavir to treat HIV/ AIDS ended in price regulation. Remdesivir is also being studied for the COVID-19, which is patented alongside other patents currently being reviewed. The same must be said regarding Hepatitis C drugs and more recently, the debate related to IMATINIB, which also ended up in price regulation and not in compulsory

licenses.

Compulsory licenses have been given in many countries like Thailand, Brazil, Mozambique, Zimbabwe, Zambia, Rwanda, Malaysia, Indonesia and recently India. Also, developed countries in Europe and the USA have used compulsory licenses in the past. According to estimates from the WHO, nearly 6.5 million people in low and middle income countries are in urgent need of ARV treatment. However, due primarily to patent protection and high prices charged by drug companies, only 1.3 million people actually receive treatment. Nearly 80% of the 3 million people who die each year from AIDS have no access to the available medicines. Brazil had to comply with the TRIPS Agreement in order to protect foreign technology and recognize minimum standards for the protection of pharmaceuticals and patents. Furthermore, the Brazilian government modified its domestic legislation even though the costs were too high for the Brazilian health budget.

There are many advantages of compulsory licenses for developing countries. The main benefit for society as a whole is making the drug product available at a reasonable cost and as a consequence, saving more lives as developing countries are able to access medicines that have become more affordable. At the same time, knowledge cartels and transnational interest blocks are challenged as governments may control dominant positions of firms. Also, voluntary licensing of patents can help create new solutions and promote access to medicines. Some have pledged to make intellectual property available free of charge for use in ending COVID-19 and minimizing the damage of the disease.

It is precisely in times like these that we must ask ourselves what is the overarching societal function of the contemporary Intellectual Property regime in the context of COVID-19? To what extent is that function attainable given the existing design of International Patent rules and associated domestic rules regarding pharmaceutical patents in developing countries?

There are different proposals in Colombia aimed at directing the policy of the national government to suspend the exclusive effects of patents to respond to this pandemic of international scope. That is, the temporary suspension of

intellectual property rights (monopolies) granted by patents, test data and utility models without this implying any infringement since a subsequent mechanism for the payment of royalties can be established. Also, proposed is the suspension of all patent procedures and other forms of intellectual property, utility models and protection of test data on technologies or information that could be useful to face the pandemic and request companies that have relevant industrial secrets for the development of mechanical ventilators, for example, to disclose such information that is of public interest. This would guarantee the supply of medicines that must be produced in Colombia in order to cover the needs for all citizens and residents in the national territory.

The Global South should use existing TRIPS flexibilities more aggressively combined with competition policy and better international coordination to face and solve this pandemic. There is a need to put life and human rights at the centre of the international institutional and regulatory system. Political cooperation is required now more than ever and international aid from the Global North is also essential. Subscribing to the “medicines patent pool of technologies” proposed by Costa Rica with WHO coordination is the key since representatives from developer companies have welcomed this solution so far. Patent pools significantly reduce the cost of research and it makes licenses available on a non-discriminatory, transparent, proportionate and non-exclusive basis to facilitate the production of an affordable solution vaccine. Other international organizations from the Global South recently proposed to make use of Article 73(b) of the TRIPS Agreement to suspend the enforcement of any intellectual property right including patents, designs and trade secrets on the grounds of the security exception.

Finally, there is a need to rewrite and reform the basic premises of the present Intellectual Property Law system one that constitutes a major legal tool of control since COVID-19 is a wake-up call that challenges mainstream views about the world economy, knowledge monopolies and market oriented incentives to innovate. The current international, regional and national architecture of Intellectual Property law confers privileges to foreign transitional interest blocks in order to profit from patents by extending, trademarks, copyrights and so on for longer periods of time. This legal enclave diminishes

the possibility of developing technologies, including diagnostics, medicines, vaccines and other medical supplies vital to treating patients infected by COVID-19 and it hampers efforts to distribute them in a timely manner to all the countries currently affected by the pandemic. However, the creative elements of a new global system are emerging now, one characterized by coordination between WIPO, WTO and WHO. A new system where R&D is de-linked from costs and prompt access for all the countries of the world is guaranteed since the Sustainable Development Goals shared mandate to work for good health and well-being for all.

By David Enrique Betancourt Cruz, LL.M., LL.M. Master of Laws- International Intellectual Property Law. C.E.O @ ElitSD.Org International Economic Law, Innovation and Trade for Sustainable Development.
https://www.linkedin.com/in/david-betancourt-ll-m-ll-m-1a278786/