
THE ETHICS OF INTELLECTUAL PROPERTY LAW IN THE AREA OF PHARMACEUTICAL DRUGS AND VACCINES DURING TIMES OF PANDEMICS

Peeraput Thiendej and John Giordano

ABSTRACT

The course of the Covid 19 pandemic, has demonstrated the serious obstacles to the availability and access to vaccines for many less-developed countries. One obstacle involves the pharmaceutical patents which limited the ability of many countries to afford the necessary vaccines. For many, the intellectual property laws created by the World Trade Organization and TRIPS agreement has shown itself to be unfair to less-developed countries. This is also seen as a problem in global justice. There is an increasing belief that pharmaceutical patents should be waived in times of emergency. But the question is how to justify these waivers? One approach might be the idea of the commons which underlies intellectual property in its most basic form. This paper explores ways of reforming intellectual property law in light of the recent problems connected to the Covid pandemic.

Keywords: Intellectual Property Rights; Vaccine Patents; Intellectual Commons; Pandemics

Introduction

It is the very nature of pandemics that research on cures and vaccines and their distribution needs to be accomplished very quickly.

During the covid-19 global pandemic countries around the world had to rush to ensure that their citizens were fully vaccinated. This placed the pharmaceutical companies in a position of great power. It allowed them to dictate prices of vaccines which created problems in vaccine access. Wealthier countries were able to secure large vaccine contracts, while low-income countries often had difficulty accessing these vaccines. This highlighted a serious problem concerning intellectual property in relationship to the distribution of vaccines in times of serious pandemics. There is an increasing belief that pharmaceutical patents should be waived in times of emergency. But the question is how to justify these waivers? One approach might be the idea of the commons which underlies intellectual property in its most basic form. This paper explores ways of reforming intellectual property law in light of the recent problems connected to the Covid pandemic.

Pharmaceutical Patents

Nicol and Nielsen, in their article “Humanity cannot afford a COVID-19 patent battle,” explained the necessity of pharmaceutical patents. According to them, pharmaceutical companies have always protected their patents over their medical innovations. Their justification is the high expense of research and testing to prove the medicines are safe, effective, and useful. It means that there needs to be a certain period of control once they are on the market in order to gain a good return on their initial investment. But the result of these strict patent laws often leads to monopolies over production and distribution, and makes new drugs and vaccines expensive and less accessible.¹

So it is often argued that to solve this problem of accessibility during times of serious pandemics, there should be a temporary waiver of intellectual property protection. The pharmaceutical companies have argued against such waivers based upon the same arguments they

use to defend strict intellectual property laws. They argue that patent waivers would reduce the return for patent holders on their R&D investment in the vaccine; they argue that the research and development of vaccines involves heavy investment in highly specialized equipment, technologies and infrastructure. If vaccine patents are waived in the condition of a public emergency, would firms be willing to invest next time there is a similar emergency?

In addition, they argue that the waiver of patent rights would create chaos, and even lead to the increase in fake vaccines. That it is a matter of production safety standards, and it is not easy for just any country to have the infrastructure available to produce vaccines with reliable medical technology.²

Critics of a patent waiver also claim that it would not give an immediate increase in supply, as establishing production of a new type of vaccine would take months. Another concern is that waivers would jeopardize existing supply chains. For example, during the Covid 19 pandemic the Pfizer-BioNTech vaccine requires 280 components from 86 suppliers in 19 countries. Competition for access to the raw materials could slow net production and result in an even lower supply. In addition, the waiver would discourage future innovation. Most importantly, the mRNA technology utilized by the Pfizer-BioNTech and Moderna vaccines were only possible through years of research and development from the public and private sector.

Jecker and Atuire have attempted to investigate ethical arguments for vaccine waivers. They looked at both sides of the argument. At one point they cite the industry argument which contends that if companies have no profit incentive to create these new health care products, the investments in the pharmaceutical industry drop. This could lead to a decline in new technologies, leaving us unprepared for the next pandemic.³

Yet as Jecker and Atuire show, there have been good arguments for such waivers. They argue that a pandemic is a global public health problem, and that strict patent laws slow the production of vaccines to meet demand. During the Covid-19 crisis there were many manufactures

with the capacity to produce vaccines at factories in Bangladesh, Denmark, Canada, Israel, and India. Unfortunately, these countries were unable to contribute to the production of vaccines because they did not have the right to the patents. In addition, such waivers would give governments the freedom to collaborate on technology transfers and exports. It would enable governments around the world to be prepared for a long-term response to future pandemics. A mechanism for waiving intellectual property rights could help to build diverse regional manufacturing hubs and protect the rest of the world from future pandemics.

So this becomes an ethical question; how to balance the rights of investors in research and technology with the needs of the world population during times of pandemics. A possible clarification of this ethical problem involves understanding what lies at the very basis of patent law, that is, intellectual property. And to understand the ethics of intellectual property is to investigate the very essence of property itself and how it is related to the commons.

The Commons

Locke has created the way we usually think of private property. In his attempt to defend the very idea of private property, Locke affirms that all humans are equal under God, and all have ownership over their own bodies, or property in their own person. A person's labour is an extension of their bodies, and so, whenever a person mixes their labour with nature, he thereby makes it their property. The nature available to be claimed through a person's labour and transferred into private property is called the commons.

Locke created two limitations on this claim over the commons. We claim only "where there is enough, and as good left in common for others" and "As much as anyone can make use of to any advantage of life before it spoils, so much he may by his labour fix a property in." In other words, individuals can have a right to their claims of property as long as there is enough left for others, and if the property can be used without a loss of benefit for the general public.

These two limitations are to help to create a balance between the interests of individuals who have gained access to properties from commons and for society in general.⁴ Yet , as Locke recognized, a complication comes in with the introduction of money that allows unequal control over resources. Locke accept this accumulation of property, but it must be remembered that during Locke’s time, there was considered to be an unlimited commons available for appropriation. Locke sometimes uses the term ‘America’ to refer to this unlimited commons.

It is important in a society for provisions to ensure the access to the commons. This should be the role of the government. A particular government should provide its citizens with public goods. Public goods are nonexcludable and nonrivalrous. That means that it is wrong to exclude someone from using the good. Therefore, this shows that the very idea of the commons implies a certain public good. And certainly in the case of vaccines during the time of pandemics, they can be considered as a public good.⁵

Similarly, In the book *A Philosophy of Intellectual Property*, Peter Drahos shows complications in the meaning of intellectual property. Drahos suggests that Intellectual Property Rights are often rights of exploitation of information. Information is becoming “the prime resource” in modern economics these days. To Drahos, there are two frameworks in intellectual property rights. Drahos suggests that intellectual property rights considered within the framework of “proprietaryism” as it is today gives too many advantages to the ownership. The owner of rights can hold this monopoly and can take advantage of the infinite nature of the intellectual property rights. Intellectual property in the framework of “proprietaryism” is therefore inappropriate and creates a negative effect on the society.⁶

So Drahos contends that viewing intellectual property rights from the framework of “Instrumentalism” is more appropriate. Such an approach gives more importance to society. It shows the role of intellectual property in enabling society to operate properly. The instrumental view is supported by the very idea of the commons which makes property

possible. Drahos distinguishes a ‘negative’ idea of the commons or the community reliant on the commons, and a ‘positive’ idea. The negative idea is that the commons exists to be exploited by whoever can lay claim to it. The positive idea is that the claim to the commons needs to be shared or balanced with the interests of the citizens.

Our question, then, is whether there are reasons to favour one of the models of community we have identified when it comes to making decisions about the relationship between community and the intellectual commons. One assumption we make without defending it is that communities have an interest in encouraging the creativity of their members. A way to proceed to an answer is to come to some understanding of the role that the intellectual commons has in aiding creativity of all kinds.⁷

This idea of the commons and the community which relies upon it, forms the very possibility not only of property, but of the creativity and innovation which issues from it. Therefore a strict adherence to intellectual property laws not only limits creativity and innovation, it also leads to exploitation.

The dangers of negative community for the intellectual commons come when technology makes new kinds of appropriation possible or when the regulatory conventions protecting it for one reason or another cease to work. The intellectual commons then becomes a hunting ground for the economically strong and the technologically capable.⁸

This emphasis on creativity and indebtedness is also described by Jecker and Atuire. They cite the words of a physician, who received the Pfizer COVID-19 vaccine who acknowledge all the work that made his work possible:

My gratitude starts with scientists who years before this pandemic, perfected the ability to extract DNA from viruses, sequence it and transcribe it to RNA... the scientists who identified the segment of that DNA that codes for the spike proteins that the virus uses to invade our cells; those who made the mRNA that corresponds to that DNA sequence, and those who figured out how to create a lipid womb to protect that precious mRNA payload during its perilous journey from factory floor to the depths of our deltoid musculature.⁹

Therefore, both Jecker and Atuire and Drahos, recognize that every innovation is indebted to what has been prepared for by the researchers of the past. So for the sake of fostering innovation for the benefit of humanity, intellectual property rights need to be considered in relationship to the benefit of humanity as a whole and the idea of a positive sense of community.

The Commons and Public Health

The ethics of intellectual property is now becoming increasingly important. But it is especially important with regards to the pharmaceutical industry during pandemics. The discipline of bioethics can help determine ethical choices through four key principles which are: autonomy, beneficence, nonmaleficence, and justice. The principle of autonomy is about respecting people and their free will. Beneficence and nonmaleficence are doing what is helpful, and not doing what is harmful. Justice has to do with being fair.¹⁰

How to fairly allocate vaccines is one of the critical ethical issues in the times. It will violate the bioethical principles, if the vaccines are made available fairly to all. For example, elites can receive a vaccine in hospitals sponsored by the government, while many patients in the poor and middle-class were turned away from hospitals without treatment in Bangladesh.¹¹

In addition, developed countries have taken control over the creation and distribution of vaccines, making the global distribution of such vaccines unequitable.¹² Yet this exclusion creates dangers. The longer a pandemic spreads among humans, the higher the chance that it can lead to new mutations. Such mutant viruses lead to the possibility that vaccines will become obsolete. Moreover, areas of the world denied access to vaccines will become the breeding ground for new strains. Therefore, it is not a question of should wealthy nations help developing and poor nations get vaccinated? It's a question of how to serve the interests of the world's people.

During pandemic situations, both developed and developing countries must have provisions to make intellectual property rights more flexible. The Covid-19 outbreak is a world crisis and could cause millions of deaths. Intellectual property rights are supposed to be based on the idea of a positive community or commons. Therefore, the health of the commons must be given priority over the profit from the commons.

Conclusion

The issue of vaccine patents has now become a symbol of a fragmented society. A patent system is a government-supported, guaranteed monopoly on commercial products. The only possible reason for governments to support this is that small groups of investors will benefit. Yet a pandemic is a worldwide health crisis.

All the concerns over Covid-19 vaccine patents are far less important than the lives of millions of people. The patent systems may be neither clearly positive nor negative from the perspective of social responsibility. However, what is more relevant is how much more we benefited from the vaccines through saving lives, reducing suffering, and opening the economy. The patent system should be ethically judged by its impact on humanity as a whole.

Therefore, vaccines should be considered in relation to the commons as Locke would insist we should use only "where there is enough, and as good left in common for others." Medical innovation and

ethics are related to one another in pharmaceutical industries. The impact of covid-19 pandemic shows the importance of balancing intellectual property rights and service to the community at large during times of crisis.

Large pharmaceutical companies have the right to protect their investments through patents. However, the question may remain, if the companies deserve such rigid rights during a global crisis. The Covid-19 crisis seems to have passed. But what of the next pandemic? An ethical procedure for the waiver of patents is desperately needed. The first step in deciding such a procedure is understanding how the world's population is a positive community which make certain demands upon the use of the commons, both for property in general and for intellectual property.

ENDNOTES

¹ Nicol, D. and Nielsen, J, “Humanity cannot afford a COVID-19 patent battle,” (International science council, 2020).

² Siripurapu, A, “The Debate over a patent waiver for covid 19 vaccines. What to know.” accessed 7 June 2021. <https://www.crf.org>.

³ Jecker and Atuire, “What is yours is ours: Waving intellectual property protections for Covid-19 vaccines”, accessed 10 May 2021. <https://www.jme.bmj.com>

⁴ Locke, J, *Two Treatises of Government*, (Cambridge U.P, 1960).

⁵ Boyce, P, “What are Public Goods.” accessed 8 December 2021. <https://www.boycewire.com>

⁶ Drahos, P, *A Philosophy of Intellectual Property*, Hampshire, (Ashgate Publishing Limited, 1996).

⁷ Ibid, 60

⁸ Ibid, 66

⁹ Jecker, N, “What is yours is ours: Waving intellectual property protections for covid-19 vaccines,” accessed 10 May 2021. <https://www.jme.bmj.com>.

¹⁰ Clark, D. et. al., “Biomedical ethics and clinical oversight in multisite Observational neuroimaging studies with children and adolescents: The ABCD experience,” (*Developmental Cognitive Neuroscience*, 2018),32,143-154

¹¹ Siraj, M. S., et. al., A, “The Infectious Diseases Act and resource allocation during the COVID-19 pandemic in Bangladesh” (*Asian Bioethics*, 2020), Review, 12(4), 491-502.

¹² McMahon, A, “Global equitable access to vaccines, medicines and diagnostics for Covid-19: The role of patents as private governance,” (*Journal of Medical Ethics*, 2020), 47, 142.

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