# COVID-19
## Vaccines, Patents and Human Rights

By David Carstens

The world is enduring the onslaught of COVID-19 and to date an estimated four million have died as a result. But parts of the world are moving into a post-pandemic state due to effective vaccines. The Pfizer, Moderna and Johnson & Johnson vaccines are each highly effective at preventing hospitalization and death from COVID-19. But the development of these vaccines required the outpouring of billions of dollars in research and testing - spent at an outlandish pace to bring the vaccines to market as quickly as possible.

Typically, companies that produce useful, novel and inventive substances such as these vaccines are awarded patents. Those patents allow the drug company to recoup those billions by excluding others from making, using or selling infringing knockoffs for a limited period of time.[1] When a competitor is stopped by the developer's patent rights, then the vaccine developer should be able to price its products higher.

Now, due to the human suffering being experienced in the third world from Covid-19, the Biden administration is endorsing a waiver of those patent rights to allow generic manufacturers to step in and produce with impunity vaccines that would infringe those patent rights. The logic goes that by converting the vaccine to an unprotected, commodity product, the vaccines will be more affordable to the third world. A few important issues should be considered first. Will a waiver of patent rights help those in need outside the US? Are foreign countries allowed to do the same under international treaty? Most importantly, does the waiver of US patent rights in this instance provide a disincentive to drug companies to produce a vaccine for the *next* pandemic? Is there a better model than waiver that still helps minimize the number who die from COVID-19?

### Patent Rights and Competitive Pricing

A United States patent gives its owner the right to exclude others from making, using or selling the claimed invention in the United States.[2] In other words, a US patent excludes a generic manufacturer from making the infringing vaccine in the US, selling the vaccine in the US or patients from using the infringing vaccine in the US. The US patent has very limited extraterritorial effect. The US patent does not prevent a generic manufacturer from making an infringing vaccine in India and selling it in India. Therefore, a US decision to invalidate a *US patent* for a COVID-19 vaccine will have no impact on a generic manufacturer in India or elsewhere from making its vaccines in a country other than the US and selling it outside the US.

Now, companies such as Pfizer and Moderna also obtain patents for their developments outside the US.[3] It is common to file for

[1] In most instances, a US patent is valid for 20 years from its date of filing. 35 USC 154(2).
[2] 35 USC 271
[3] A search reveals that Pfizer has over 250 US patents and published patent applications related to vaccines, and over 1600 when including all other countries.

patent protection in countries around the world. But unless India opts to block or otherwise invalidate those equivalent Indian patents, the US action will have little effect on increasing the number of potential producers.

Many have the misconception that a patent produces unbearable monopoly pricing for essential goods such as vaccines. This mistake requires the assumption that only one solution can exist for a problem. The Covid-19 vaccines help prove this assumption is false as at least five effective distinct vaccines have been produced. In a normal marketplace, when several alternatives each produce essentially the same benefit, then normal price competition should exist, with each company reducing its price to increase sales and maximize profit.[4] Therefore, the assumption that waiving patent rights will produce lower pricing is wrong. A greater number of equivalent options will produce lower pricing and hopefully greater penetration to those in need.

## Impact of International Treaties

Most countries are members of the World Trade Organization (WTO). To join the WTO, a country must also adopt the terms of TRIPS - Trade Related Aspects of Intellectual Property - an international agreement that establishes minimum standards for intellectual property protection in each member country. So, for instance, Article 27 of TRIPS requires that all member countries have legislation that allows for patents for vaccines. But Article 27 also allows countries to exclude protection in instances to "protect public order or to "protect human life…or health." The waiver of vaccine patent rights might fit into those categories. Therefore, members of the WTO should have the right to waive protection of patents related to vaccines.

A "waiver" under TRIPS was first proposed by India and South Africa – two countries with robust generic pharmaceutical manufacturing capacity – in October 2020 as one method of improving availability of COVID-19 vaccines. But if generic manufacturers are allowed to produce identical vaccines, how will they price them? If the pricing is identical to that charged by patent holders, then the only result is re-distribution of the profits to the generic producers with no meaningful increase in demand or supply.

With apparent US approval of a waiver, Pfizer and others will lose the right to exclude generic manufacturers from producing additional doses of vaccines that are covered by any patents. This should allow more doses to be produced assuming generic manufacturers lower prices and have the skill to produce them.[5] But where will those doses go. A rational economic answer is that they will go to the *highest bidder*. So, instead of going to the poorest in the third world, the net result could only be a lowering of the price for the developing world. This may sound like a heartless conclusion, but the history of AIDS drugs provides some evidence to support "pharmaceutical arbitrage."[6]


## Long Term Impact of Waiving Patent Rights

When SARS was a concern in 2003, very few politicians thought forward about the potential for COVID-19. Likewise, those proposing a waiver may not be thinking forward to a potential COVID-24 or similar virus which could be even more deadly. Will drug companies be as quick to respond to that threat after having their patent rights waived this time? Probably, but government subsidies might be required to incentivize a company to develop that next vaccine. Of course, a subsidy simply shifts the cost from the vaccine user who pays a premium for the patented vaccine to the taxpayer who pays for the subsidy.

There are alternatives to simply waiving patent rights in the name of human rights. Another path to consider is a compulsory licensing

[4] Marginal benefit refers to the maximum amount a consumer is willing to pay for an additional good. It tends to decrease as consumption increases. However, life extending drugs do not follow normal pricing models because most people in need will spend an unlimited amount to extend their life if only by a little amount. Also, in the case of the Pfizer and Moderna vaccines, once you have the first dose, you are locked into using the same brand for the second dose. There is no competitive market with alternatives for the second dose.

[5] Up to 15 million Johnson & Johnson vaccine doses were ruined by a manufacturing error.

[6] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Pol'y L. & Ethics (2005).

scheme. [7] For example, if a US company has a patent in India, the US company must actually make the product in India within a set amount of time. If it does not "work" the invention in India, then India can grant a compulsory license to third parties. Section 83(b) of the Indian Patent Act allows a license to be granted to a local company at a license fee that is determined by an Indian tribunal. While this takes the freedom to contract out of the hands of the patent owner, it is at least compensated for the use of its innovative vaccines. It is difficult to watch suffering. But it is essential to have a clear vision of what motivates companies to produce vaccines to alleviate that suffering. Waiving patent rights strikes at the very profit motive that drives innovation. Innovation is the ultimate answer to improving the lives of billions of humans and the extension of life span and the reduction in preventable suffering. Long term human rights are not served by short term abuse of the rights of patent owners.

[7] Article 31 of TRIPS allows a member country to have laws that provide for "working requirements" and mandatory licensing.

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