Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity

*We are living through a humanitarian crisis, yet design faults in intellectual property mechanisms and a faith-based approach to patents is steering governments into what the WHO has called 'a catastrophic moral failing', writes **Siva Thambisetty**. To explain patents and vaccines in the context of recent developments we need larger frameworks that are not contingent on the current crisis. Right now, the UK should show moral leadership in a post-Brexit world by supporting the intellectual property waiver on patents related to COVID-19 vaccines and treatments proposed by India and South Africa at the WTO.*

Major pharmaceutical companies are central to combatting COVID-19 through prevention and treatment. Yet It is not unprecedented to find them acting in their own self-interest as patent holders, and for this disposition to be baked into global intellectual property rules. We hang our entire innovation system on the peg of individual patent holders working to take their invention to market and maximise their returns on the rights held. A patent is a property right, to be used mostly as the property holder wishes to.

Self-interest

The EU president has said that Europe invested billions to help develop the world's first COVID-19 vaccines and create a global common good, and that companies must deliver and honour their obligations. But unless strings were attached to the initial investment that carried over to any patented inventions, there is no such thing as a 'global common good' when such goods may be appropriated via patents. The human genome was declared a symbolic 'heritage of mankind', yet that did not prevent a single gene patent from being granted.

According to one study, all 210 drugs approved in the US between 2010 and 2016 benefitted from public grants that supported early or indirect research. The proportion is likely to be as much or higher in Europe and the UK. Apparently, South Africa are paying more per dose for the Pfizer vaccine than the EU is, in return for the early public investment of the latter in the technology. Yet, the pharmaceutical industry has assiduously worked to deny any public claim on patents that have grown from public money. It is hard therefore not to see the explanation of higher dose price for South Africa as just cynical word play. It is much more likely that the lower price in the EU reflects a tougher negotiating partner with choices.

If the lower EU price is indeed a reflection of public investment, then governments must begin to recalibrate the public cost of risk in research and development, and privatisation of profit. If all drugs could be marked lower to reflect public investment, we would be on our way to solving the access to medicines problem. Unfortunately, for many pharmaceutical corporations price-gouging from desperate poorer countries during a humanitarian crisis seems to be part of business as usual.

Patents reward 'inventors' and in doing so often privilege individual initiative over collaborative or cumulative effort. The system rewards the first to file the application not the achievement itself. The law also assumes that extrinsic incentives on the part of the inventor is essential to the inventing process at the cost of non-instrumental motives. Both these aspects – the valorisation of individual effort and the invisibility of intrinsic motivation – is a form of civic damage. Our patent incentives rely on self-interested behaviour to propel innovation and in doing so it undermines altruism, collaboration and any notion of intellectual labour to further the common good.

Scarcity

Once the invention is created, the patent in effect generates an artificial scarcity allowing the value of the vaccine or drug to be maintained, managed, and even increased. The scarcity feeds on under-investment in capacity-building and reluctance to transfer technology and manufacturing know-how. Scarcity and the consequent deprivation (either because the vaccine is not affordable or because you are using money for it that could pay for other things) is at the heart of our innovation systems. It allows the patent holder to orchestrate the manufacture of the product through restrictive licensing.

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While it is true that the AstraZeneca vaccine has been licensed to India's Serum Institute, this is a restrictive arrangement. From what we know (in the public domain), AstraZeneca controls ultimate recipients. The deal has given India an ability to supply developing countries. Yet there are many other companies in India and elsewhere that could be upgraded to start producing the vaccine. However, this would need a non-exclusive deal directly between these manufacturers and AstraZeneca, something that is not currently forthcoming.

In November the *Wall Street Journal* published a piece that claimed developing countries do not have the capacity to produce complex vaccines that rely on mRNA technology. Decades of examples prove otherwise. In response, Tahir Amin writes about Shanta Biotechnics in India producing Hepatitis B vaccines at a dollar a dose that went on to become the mainstay of a UN-led drive to vaccinate people globally despite being denied technology transfer. Tamiflu was produced in a short space of time in India in 2005 after claims it involved a complex process that could not be easily replicated. And more recently, Hetero and CIPLA have produced Remdesivir in India after similar claims about lack of manufacturing competences were made.

There is a darker element to claims about firms' limitations in developing countries. Even if some do not currently have the technology necessary, it is in everyone's interest that capacity be built up and technology transferred to enable current and future production of vaccines or drugs be ramped up. If not now, when? In fact, Article 66.2 of the global Trade Related Intellectual Property Rights Agreement obliges governments in developed countries to provide incentives to 'enterprises and institutions' to enable technology transfer and a 'sound and viable technological base'. The reluctance to share not just in the products (drugs or vaccines) but in technology has always been essential to maintain the capacity to manipulate scarcity globally.

Property begets property

Public accounts of patent law tend to convey the idea that one product or drug usually corresponds to one patent for a duration of 20 years. The reality is that over the last few decades the pharmaceutical industry has gradually pushed legal boundaries to allow for an intricate 'evergreening' of patent rights. What this means is that many drugs often have multiple patents on them. i-MAK have a very useful score card that lists some particularly egregious examples. Humira, the world's number one drug has 247 patent applications. Cancer drug Imbruvica has 165 patent applications associated with it, 'over half of which cover different diseases it can treat and formulations of the drug, all of which are already mentioned in the first patent covering the original invention of the active ingredient.' In effect this increases the duration of protection to successive patent terms beyond 20 years.

When one company holds hundreds of patents on the same product it greatly complicates the possibility of other companies entering the market when the patent has expired. And it's not just patents that ring-fence technologies. Other rights such as exclusivity of data around clinical safety and drug testing, and technical know-how kept as trade secrets also make it difficult for competitors to enter the market.

One possible solution here is the compulsory license – where a license would be granted without the authorisation of the patent holder. In fact, efforts at the World Trade Organisation to provide equitable access to patented technologies is often met with the claim that existing measures, including compulsory licenses must be used first.

Canada has adopted a measure that will allow the Commissioner of Patents to make a decision on compulsory licenses without first negotiating with the patent holder, a requirement under international rules. France has amended its patent law to say that there is no need to evidence 'amicable negotiations' with the patent holder if there is urgency. Germany has allowed for the Federal health minister to take executive action to make medicines available in return for adequate compensation. These pandemic-related measures are all acknowledgements that even wealthy governments may not have the upper hand when negotiating with pharmaceutical companies during a crisis. So why do we think this is an easy solution for developing countries with much greater asymmetry of information about how the patents involved are being worked? All of this adds up to a well-known dynamic where initial property rights granted are gradually built on and strengthened, such that a complex of rights develops around initial entitlements. Navigating these complexes requires time, money and legal expertise.

Legal code as capital

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The complexity of law and regulations around the patent protection, manufacture and supply of patent protected technologies is in itself the most efficient way to hoard and ring-fence such technologies. Compound this with restricted regulatory sovereignty due to global rules and it translates to very little agency on the part of governments of low- and middle-income countries to navigate the law.

Tackling structural inequality therefore requires us to make processes related to drugs and vaccines transparent, so we can see how legal complexity can create both wealth and inequality. The entire ecosystem of patents, manufacture, supply, restrictive technology transfer, and the difficulty of injury-specific solutions (like compulsory licenses) have all contributed to a techno-legal complex that is in itself both a source of wealth for some and deprivation for others.

Solidarity: Where Art Thou?

In a barely credible move, the EU states in its Transparency and Authorisation Mechanism for the export of COVID-19 vaccines that international solidarity requires that vaccines must be made available in low- and middle-income countries during a humanitarian crisis. If the EU was truly interested in solidarity it would support the intellectual property waiver at the WTO proposed by India and South Africa. The waiver would suspend patents relevant to drugs and vaccines allowing developing countries with the manufacturing capacity to do so to produce them. More than just a waiver will be needed in the case of vaccines – technical know-how, and further technology transfer may also be necessary. But rather than upset the pharmaceutical apple cart, it appears the EU may buy Chinese and Russian vaccines and as per recent indications Canada, Singapore, and New Zealand may draw on the Covax vaccines procurement pool designed for equitable access for poorer countries.

For decades, western governments have done as little as they possibly can globally to resolve the problem of access to medicines. They peddle an unmitigatedly positive view of patents as incentives that ignores both critique and problems, often bamboozling less experienced nations with high-sounding talk of innovation, incentives, and investments. All this does is maintain the vast majority of developing countries as consumers while a handful of developed economies function as producers of consumable technology. What happens now at the WTO will be remembered for years.

And this brings me to my final point. A low-hanging fruit of moral leadership that the UK can pick in a post-Brexit world would be to support the intellectual property waiver at the WTO so we may build up resilience for the future globally while ramping up vaccine supply now. This is unlikely to be the last pandemic, or the only context where financial gains have distorted our ability to respond in solidarity. The waiver is only the first, but an important step. If we can do this, there might well be a silver lining to these dark times.

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