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Big Pharma Strikes Back

On Monday, we, along with Achal Prabhala, had a column in the New York Times arguing in support of a resolution put forward before the WTO by India and South Africa, which would suspend intellectual property rights related to vaccines and treatments during the pandemic. The main point is that these rights are slowing the diffusion of life-saving medicines in a crisis. Furthermore, since much or all the cost of developing these vaccines and treatments were picked by up by various governments, the drug companies would still be earning back their investment, plus a healthy profit, even with this suspension.

Not surprisingly, the pharmaceutical industry is not letting this proposal go unchallenged in public debate. Thomas Cueni, the director-general of the International Federation of Pharmaceutical Manufacturers and Associations, had a column in the NYT on Thursday pushing the industry's line. Cueni argues that it would be unfair to the industry to suspend its patent rights in the pandemic. He also argues that it wouldn't help distribution in any case because of supply constraints and that it would be harmful in the long-run since companies would not invest in developing new drugs if they could not count on their patent rights being respected.

Starting with the issue of supply constraints, while the processes for manufacturing the leading U.S. vaccine contenders are complicated, there are sophisticated manufacturing facilities in India and elsewhere. While it clearly would take time for anyone to gear up to manufacture these vaccines, it is important to remember there were no vaccines to manufacture nine months ago.

Ideally, we would have had open-source research all along, so that any manufacturer anywhere in the world could have been preparing for large-scale production, but even if we started today it is still likely that additional facilities can be producing these vaccines well before the end of 2021. And no one thinks we will be anywhere close to having the world's population fully vaccinated for at least several years. This means production that comes on

line in six or eight months would be enormously valuable. Also, the issue is not just vaccines, but also effective treatments, like Regeneron, which are in very short supply even in the United States and other rich countries.

The pharmaceutical industry wants to be in a position to license these to whom they choose and argue that they will themselves resolve the manufacturing capacity constraints. But this is fraught with dangers. First, if the past is anything to go by, license agreements are limited to few producers and involve costs to producers that will inevitably increase the price of the drug. The WTO proposal will do away with these restrictions and allow anyone with the knowhow or capacity to produce at as low a price as possible under competitive conditions—and they can supply all over the world so that the pandemic is over sooner. If knowhow is a barrier and no one can ever develop the manufacturing capacity, countries should not worry about their IP.

An important aside here is the history which Cueni alludes to. One reason his piece is extraordinary is that it is the first time, to our knowledge that PHRMA has apologized for the role in the AIDS crisis. But what is not said is that the very same laws that allowed for that disaster and that are being challenged now, routinely prevent people from developing countries from accessing generic medicines for a whole host of other diseases (cancer for example), these are rolling and silent crises that the current system continues to perpetuate.

The next question is whether the companies are being treated fairly after their heroic efforts to develop vaccines in a record amount of time. First, while the researchers do deserve enormous credit, their performance here is not quite as exceptional as many seem to believe. China has several vaccines in the final stage of testing, one of which has already been approved in the United Arab Emirates after showing an 86 percent effectiveness rate. This doesn't denigrate the accomplishments of the scientists who developed the leading U.S.-European vaccines, it just means that the achievement wasn't quite as exceptional as it is often portrayed.

But getting to the issue of fairness, one of the main points we made in the piece is that Moderna and Pfizer have already been paid for their work on the vaccines. In the case of Moderna, the U.S. government paid the full cost of the research and clinical trials for the economy. If the vaccine turned out to be ineffective, the U.S. taxpayer would have been out the money, Moderna had been paid for its work.

In the case of Pfizer, the company has large advance purchase agreements with the U.S. and many other countries, which far more than cover its plausible research costs and allow for a generous profit. The Germany government also contributed several hundred million dollars to manufacturing facilities.

Of course, both vaccines rely heavily on taxpayer funded research through the National Institutes of Health. So, their reliance on government support is extensive.

But what about the issue that this could affect the incentives for the development of vaccines and drugs in the future… Hopefully, these sorts of events will be rare, so the impact on expected future profits should be limited. Furthermore, in any comparable situations in the future, presumably the government will again step in to put up money and absorb risk, so that companies will still be able to cover their costs and make a healthy profit if such a situation arises.

It is also important to note that limiting patent rights is already in the law. The TRIPS accords in the WTO allow for governments to issue compulsory licenses. This means that a patent holder can be required to let other companies produce its patented drugs for a set fee. U.S. law also explicitly allows for such limits, as we mentioned in our piece. At the height of the Anthrax scare in 2001, President Bush threatened to invoke Section 1498 of the Commercial Code to force Bayer to lower its price for large quantity of ciprofloxacin, the most effective treatment for Anthrax. (The threat worked.)

In short, the U.S. and other governments have always had the ability to restrict the patent monopolies they issue. Presumably the people who run the drug companies know this, so limited patent rights in a pandemic would not be an event that should have been unanticipated.

Finally, Cueni is dismissive of the idea that the government could directly fund the development of new drugs and vaccines, as it just did with Moderna. He tells us:

"Further, governments have neither the money nor the risk tolerance to take over the role of businesses in developing pharmacy-ready medicines."

This one is a real head scratcher. Governments don't have the money? The U.S. government is projected to spend over $5 trillion in 2021. The Bureau of Economic Analysis puts the pharmaceutical industry's research tab for 2019 at less than $90 billion, or 1.8 percent of the U.S. budget. Obviously, if we wanted to pick up the tab we have the money, especially since the savings from buying drugs at generic prices in government programs like Medicare and Medicaid would quickly swamp the research tab.

As far as "risk tolerance," the U.S. government spends over $40 billion a year on basic research at the National Institutes of Health. While much of this work has huge payoffs, like the discovered of the spike protein that is the basis for both the Moderna and Pfizer vaccines, much of it leads to dead ends. Apparently, the government has the risk tolerance for spending tens of billions annually on research with distant and uncertain payoffs, but somehow lacks the risk tolerance to put up the money for developing a specific drug or vaccine. Sorry, that doesn't make sense.

If we did go the route of direct funding there would be enormous advantages in addition to having all new drugs and vaccines available as cheap generics. First, we can make open-source research a condition of the funding. This means that any contractor or subcontractor that worked on publicly funded research would have to post any findings as quickly as

practical on the web. That way, other researchers would be able to promptly build on successes and learn from mistakes.

The other major advantage is that we would take away the perverse incentives created by patent monopolies. Since these monopolies allow drug companies to charge prices that can be many thousand percent above costs, they provide an incentive to promote their drugs as widely as possible. This often leads drug companies to exaggerate the effectiveness of their drugs or conceal evidence of harmful side effects. We saw this very clearly with the opioid crisis, where drug companies have paid billions of dollars in settlements over the allegation that they recklessly pushed their drugs.

There are very good reasons for thinking that direct public funding would be a better way to support the development of new drugs than the current system of patent monopolies. There are obviously better and worse ways to structure such a system. (This issue is discussed in chapter 5 of ***Rigged*** [it's free] and in some journal articles.) But it is absurd to argue that a system of direct funding is not a possibility, as Mr. Cueni would apparently like us to believe. We need a serious debate on the best mechanisms for financing the development of drugs and vaccines, even if the pharmaceutical industry doesn't want us to have one.

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This first appeared on Dean Baker's Beat the Press blog.