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EU RISKS GLOBAL PUBLIC HEALTH IN ITS PROTECTION OF BIG PHARMA MONOPOLIES

Coronavirus
Vaccine
COVID-19
Injection Only



Corporate
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Observatory

In response to global south calls for patent waivers for COVID-19 vaccines, testing materials, and treatments, the EU insists this is unnecessary as global trade rules already have ‘flexibilities’ built in. That is not just untrue, it is highly hypocritical. The EU has been waging a ‘war on cheap drugs’ for over two decades, and done everything in its power to strengthen patent rules. But its protection of big pharma profits could have dire consequences.

Will the risk of prolonging the pandemic change the EU’s approach?

It was inevitable that the pandemic would lead to powerful global disagreements over pharmaceutical patents.

These patents – on things like vaccines, medical equipment, and drugs – are about the protection of monopolies on behalf of private interests. This goes against not only a notion of sharing in solidarity during a public health emergency, it prevents a massive expansion of production by allowing others to manufacture vaccines and treatments, whether a company or a public institution. Yet a massive, urgent expansion of production worldwide is exactly what is needed to bring the pandemic to an end.

Now the fight has been taken to the World Trade Organization (WTO), where India and South Africa – with the backing of more than 100 countries – have proposed that international intellectual property rights should be put temporarily on hold to make way for the massive global production of pandemic-related vaccines and treatments. But the ‘waiver’ is set to be blocked this Spring by the European Union, the US, and a few other countries.

However outrageous it may seem – to choose to protect the profits of a few companies over a route out of the pandemic worldwide – this move is no surprise. For two decades the EU has fought hand in hand with big pharma for far-reaching intellectual property rights. The question is whether pandemic times will force the EU to change course in its stubborn defense of the international patent regime.

A universal common good

In the first phase of the pandemic, it did sound as if the European Union had finally had a change of heart in its approach to patents on pharmaceutical products. President of the European Commission Ursula von der Leyen [stated](#) solemnly at a WHO press conference in April 2020: “We need to develop a vaccine. We need to produce it and to deploy it to every single corner of the world. And make it available at affordable prices. This vaccine will be our universal, common good.”

However, given the EU’s behaviour since, this was purely rhetorical. EU representatives are crystal clear in their opposition to India and South Africa’s proposal at the WTO to waive patents. The two countries argue that for COVID-19 vaccines, testing equipment, and medicine to become available and affordable globally, patents will have to be suspended for a while.

This makes ethical, epidemiological, and economic sense. Such a move would save many lives, given we now have working vaccines and improved treatments. Secondly, if the virus continues to replicate unchecked anywhere in the world, this greatly increases the risk of new variants arising – perhaps even vaccine resistant ones. In the [words](#) of WHO Director Tedros Adhanom Ghebreyesus, “No one is safe until everyone is safe,” indeed a sentiment directly [echoed](#) by von der Leyen herself. Finally, ending the

pandemic as soon as possible makes economic sense for everyone, and should be prioritised over the profits of a few giant pharmaceutical companies.

Despite these compelling reasons, the Commission – with the backing of member state governments – has not hesitated: “Vaccine developers retain their intellectual property rights,” a Commission spokesperson told [EURACTIV Germany](#) in February this year: “We expect them to commit to the goal of universal and affordable access to diagnostics, treatments and vaccines.” In other words, the EU proposes the world rely on the voluntary goodwill of its pharma executives to end the pandemic.

Charity cannot do the job

This is the European Commission on classic form: **viewing patents – in effect monopolies on pharmaceutical inventions – as an unquestionable good.** Now more than ever this is a credo at odds with reality: billions across the globe are in peril of not getting access to a vaccine any time soon, in no small part because a few companies have been allowed to cling on to their monopolies. Despite the fact that the vaccines are all predominantly funded by [public money](#) from the very inception, a few companies are still allowed to decide whether others should be allowed to manufacture them.

The WHO's international vaccine-sharing programme COVAX will not be able to deliver much this year, and about [85 poor countries will not have widespread access to vaccines until 2023](#), as it stands. What is needed is extra production capacity and modestly-priced products, but patents stand in the way. Patent rules in hand, pharmaceutical companies are preventing generic manufacturers from producing vaccines, due to international rules under the TRIPS agreement of the WTO and due to national laws in many countries. And while [one company](#) has allowed some producers to take on manufacturing on their own, most have not. Incredibly, given the impact of COVID-19 on us all, [vaccine production capacity is still lying idle](#).

Meanwhile the WHO-led [COVID 19 Technology Access Pool](#), a feeble attempt to share technology globally, has failed to gain traction. In Europe, for instance, only five countries have signed up half-heartedly (Portugal, the Netherlands, Luxembourg, Norway, and Belgium), and the pool remains horribly empty.

That is the problem that India and South Africa have set out to address with a proposal to adopt a waiver that would **temporarily suspend rules on patents, industrial designs, and trade secrets** – all necessary to allow swift production of both vaccines, test equipment, and medicines.

Existing exceptions no solution

Still, such arguments are lost on the European Commission. Along with industry, they argue that charitable programmes are the way forward. However when pressured, they claim that existing rules already allow for patents to be waived, pointing to flexibility built into the TRIPS agreement. The WTO “allows for the necessary flexibilities in relation to intellectual property rights, including in health emergencies”, Vice President of the Commission Dombrovskis stated in a [reply to a question from the European Parliament](#). “If voluntary solutions fail and IP becomes a barrier to access to treatments or vaccines, the TRIPS Agreement provides for a possibility to grant compulsory licences.” So, if a pharmaceutical company will not cooperate, then a license can be issued by law and hence make way for another producer.

Compulsory licensing – the current way of sidestepping patents globally – are in large part the outcome of a clash between the global south and the global north over access to antiretroviral HIV/AIDS medicine between 2001 and 2003. In the face of millions of HIV patients dying for lack of medicine, the global north was forced to make concessions to enable generic production of affordable treatments.

But the current exceptions are limited in many ways. While they do make space for ‘compulsory licensing’ in times of emergency, in practice they stand in the way of the kind and scale of technology transfer necessary.

As international medical activist and expert on intellectual property law Ellen ‘t Hoen told Corporate Europe Observatory, “Compulsory licensing alone will not help in the case of vaccines. Vaccine producers will need [access to technology and knowhow](#), they will need to have information on production processes. That is not covered by the current exceptions”.

When it comes to medicine and equipment, compulsory licensing may be useful. But having the European Commission point to the existing option of compulsory licensing as an adequate response to the pandemic, sparks a strong pushback from Ellen ‘t Hoen: “That makes me laugh. Looking at what the European Union has done in the past decades to make compulsory licensing as difficult as possible, it is quite something to hear them use that argument.”

Narrowing the options

Since compulsory licensing exceptions were first fleshed out in 2001-2003, the EU in general and the European Commission in particular have waged a multifaceted campaign to reduce their scope, hand-in-hand with the pharmaceutical industry.

They have taken any opportunity to pile on constant pressure against these exceptions, for example pushing for introduction of rules on “data exclusivity” that would prevent most if not all generic producers from making use of the exceptions under the [TRIPS agreement](#).

“Data exclusivity” is a set of rules that allow patent holders to keep crucial data related to a drug secret, for example the results of clinical testing. This means information given to authorities for the purpose of approval for marketing by the company that launched the product in the first place cannot be handed over subsequently to a generic manufacturer to support its attempt to have a generic product approved. As generic producers rarely have the capacity even to conduct the tests, data exclusivity essentially renders a license fairly useless. Under the current circumstances, new testing either requires massive apparatus and huge resources, or it takes a huge amount of time – and to state the obvious, time is the scarcest of resources when confronted with a currently raging pandemic. According to one [investigation](#) the time needed to conduct such tests is 61 months on average.

So while it’s true that there may be rules under TRIPS that allow for compulsory licensing, in practice these can be rendered null and void by rules on data exclusivity for the duration of the time they cover. In the case of the European Union, data exclusivity can impede effective use of a license [for as long as eleven years](#). This may make the EU the

most difficult place on earth to make use of a compulsory license (in the US this data exclusivity use is five years). These time limits also demonstrate how effectively data exclusivity in practice prevents compulsory licensing from being a way to urgently produce vaccines and treatments in a sudden emergency such as an unfolding pandemic.

These impediments are the outcome of the powerful partnership between the European Commission and the main lobbying association for the pharmaceutical industry in Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA). The close alliance between the Commission and EFPIA was reflected in the words of [one Commission official](#): “They [EFPIA] know best in the end”, as told to an academic during an investigation of the file (the Directive on Data Exclusivity adopted in 2004, shortly after the adoption of the TRIPS exceptions in 2003).

Data exclusivity doesn't just affect developing countries. It is also a serious obstacle within the EU: for some countries, compulsory licensing historically has been a key strategy to keep prices down and secure supply. This was the case for Central and Eastern European accession states that were out-manoeuvred: the directive was put in place right before these countries joined the European Union in 2004, leaving them with no choice but to accept the measure. The consequences are clear, as in [a 2016 case](#) where

Romania tried to register a generic version of a drug against hepatitis C, but this proved to be impossible as the directive on data exclusivity rules out such a move [this side of 2022](#).

A global campaign at all levels

But both EFPIA and the Commission had bigger ambitions, and the first was to limit the scope of the very exceptions to the TRIPS agreement at the WTO itself. This was done by attempting to have rules on data exclusivity included in the texts – had they succeeded it would have cast doubt on the value of the concessions that were made to developing countries. The whole point with the negotiations were to make it easier to issue a compulsory license in times of emergency. The EU position went in the opposite direction.

At the time, data exclusivity was one of [EFPIA's](#) key priorities both globally and in the EU, and the European Commission brought this into the negotiations in 2001 in relation to the exceptions needed to secure access to antiretroviral medication in the global south, claiming that existing protection against “unfair commercial use” of data was equivalent to data exclusivity. [According to the EU](#), the best way forward would be “to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time”, a position

that was made part of the negotiation. However, at the time the rich and powerful countries in the WTO faced stiff resistance to their plans for the organisation, and in combination with the HIV/AIDS controversy, the EU, the US, and others had to give in and accept some flexibility.

But while provisions about data exclusivity were lost for now in the WTO, they were not abandoned by its proponents. This – and other so-called [TRIPS Plus proposals](#), ie proposals that suggests stronger protection of intellectual property rights than those in the TRIPS agreement – were pursued in a plethora of ways by the European Union, spurred on by EFPIA, the industry body that has worked closely with the European Commission all along to reduce the significance of the TRIPS exceptions.

Two failed attempts

One place where this campaign unfolded was in European ports. Since 2008, and on no less than 19 occasions, the Dutch authorities have [confiscated shipments of medicine en route to Brazil](#), including treatments for high blood pressure, HIV/AIDS, and dementia. Similar actions have been taken by French and German customs. In response, India and Brazil threatened to file a formal complaint at the WTO's Dispute Settlement Body. Following a [negotiated settlement](#), the EU accepted India had done nothing wrong under

international rules and accepted a rewrite of its Border Measures Regulation.

Also, the EU has sought ways to use the fight against counterfeiting as a means of attacking generic production. The Anti-Counterfeiting Trade Agreement was spearheaded by the EU and the United States to strengthen enforcement of intellectual property rights. It was to become an agreement among countries in the global north, but with an ambition of expanding it around the world at a later stage.

Several provisions of the agreement could have had dire consequences for the production and sale of generic drugs worldwide. It could, according to Health Action International, have had “a profoundly negative impact on the global production and distribution of quality generic medicines”, including by [criminalising any actor](#) in the generics supply chain. In the end, though, ACTA was voted down in 2012 in the European Parliament.

But other measures were to prove more successful for the proponents of strong IP rules on pharmaceuticals in the EU, first and foremost association agreements and bilateral trade agreements.

Agreements in the neighborhood

At the time of the discussions about TRIPS exceptions, the EU was involved in several negotiations with countries that were seeking a closer relationship with the EU, and these negotiations included a push from the EU to agree to data exclusivity rules.

For example take the 2004 process that was to bring Turkey closer to the EU, with the prospect of full membership. The EU highlighted a key priority in these negotiations: “In particular, the overall trade regime for pharmaceuticals remains problematical,” [the Commission noted](#) in its progress report. This was all about getting a large country that relied very much on generic producers to introduce data exclusivity in its laws EU-style: “Turkey should urgently adopt the relevant legislation.” This was to become a recurring agenda point in the years to come in the talks between the two sides.

As the Turkish case was about a country that sought membership of the EU, it is to be expected that introducing rules similar to those of the EU would be part of the bargain. But the case does illustrate how the EU singles out pharmaceuticals and data exclusivity as strategic areas. In a similar vein, the EU has made sure that agreements with [Albania](#), [Serbia](#), [Kosovo](#), and [Bosnia-Herzegovina](#) all ask for “a level of protection of intellectual, industrial and

commercial property rights similar to that existing” in the EU. In the cases of Georgia and Moldova, data exclusivity covers up to seven and eight years respectively.

A similar pattern can be spotted on the outskirts of the EU neighbourhood. According to one source, in 2003 [the EU tried to make the Ukraine adopt rules on data exclusivity](#) similar to those in force today in the EU, but before they were adopted internally. They were finally included in a 2016 agreement in which [Ukraine agreed](#) to adopt laws to ensure five years of data exclusivity – and vowed to align their rules with the EU at a later, non-specified date.

Success with few limits

Data exclusivity is no less important to the EU in bilateral trade negotiations outside the neighbourhood. One breakthrough was an agreement with [Colombia and Peru](#) in 2012, which grants patent owners five years data exclusivity. Similarly, the EU succeeded in persuading the Vietnamese Government to accept an agreement that promises “normally not less than five years” of data exclusivity.

Data exclusivity appears to have grown in importance for the EU over the years, given several big trade agreements which include strong provisions on the matter. In the last few years alone, three of the EU’s comprehensive trade

agreements include strong provisions on data exclusivity: with [South Korea](#) (2015, five years of data exclusivity), [Japan](#) (2019, six years), [Singapore](#) (2019, five years), and [the CETA Agreement](#) with Canada with eight years of data exclusivity.

The EU's astounding success in pushing for a 'new normal' – more far-reaching intellectual property rights – in a high-risk area such as pharmaceuticals make one wonder just how low they will go? It reached an extreme during negotiations for an EU-India trade agreement, in which the European Union pushed for years in an attempt to make India accept data exclusivity provisions. India hosts the most important generic producers globally – pharmaceutical companies that provide affordable medicine to many developing countries – and produces about 60 percent of the vaccines in the world. The EU's move put in peril access to affordable medicine for perhaps billions of people. In 2011 the EU [had to give in](#) for now, due to tenacity from the Indian Government and outcry from civil society in India itself as well as in many other countries. But in a similar vein, the EU pushed for the inclusion of data exclusivity at the negotiations on the Mercosur agreement with Brazil, Argentina, Uruguay, and Paraguay; again however, the EU had to fold.

Even the poorest

The less developed a country, the less likely they are to be fond of the demands of the EU. In the case of most African countries, there is no appetite for including strong provisions on intellectual property rights in trade agreements with the EU. The battle over HIV/AIDS antiretroviral medicines left a lasting impression. That does not mean the EU is powerless. In one incident, a fund for trade policy support, the Economic Partnership Agreement Related Trade and Private Sector Support (EPA-TAPSS) was used in an attempt to introduce [a new law against counterfeit products](#) that could have severely hampered Uganda's ability to import generic drugs. But the clash over access to HIV/AIDS medicine does mean that the EU's room for manoeuvre is smaller here than in middle-income countries.

Still, there are examples of the EU imposing data exclusivity on lower-income countries. The EU had the clear ambition to get Central American nations of Panama, Costa Rica, Nicaragua, El Salvador, and Guatemala to adopt data exclusivity rules. It ended up winning this by default: the trade agreement had a 'most-favoured-nation' clause, which means that any concession given to other trading partners must be given to the EU as well. The EU pointed out in an [annex](#) that since the Central American countries had agreed to a five year data exclusivity period with the US, this would automatically apply to the EU as well.

A constant eye all over the globe

The European Commission's monitoring of the development of intellectual property rights legislation across the globe has been systematic since 2004, with biennial reports that pinpoint 'positive' or 'worrying' developments. Once identified, the European Commission uses whatever leverage it has to keep the patent regime fortified, whether via a complaint under the terms of a trade agreement, diplomatic effort, or an offer of technical assistance to develop new procedures.

[The latest report](#) from January 2020, on the brink of the global pandemic, showed the Commission in campaign mode against generic drugs via an emphasis on data exclusivity. While three countries received a favourable mention of recent developments in the area (Canada, Vietnam, Russia), seven countries (Argentina, Brazil, India, Indonesia, Turkey, Malaysia, and Ukraine) were represented as problematic, the Commission noting a worrying "absence of an effective system for protecting undisclosed test and other data generated to obtain marketing approvals" for pharmaceutical products.

The way these cases are built is straightforward: IP enforcement can be seen as an advanced complaint box set up for industry, and pharmaceutical companies are among its most frequent users. To them, it is another day in the office. But the risks and terrible consequences of such excessive form of protection for corporate patents across the board are becoming clear.

Call off the dogs

In pandemic times, **the EU's role in blocking global access to affordable medicines deserves every criticism.** Along with the US, the EU is constantly on guard to protect the interests of big pharma, even in a situation that so obviously demands a different approach.

"The European Commission needs to call off the dogs now. They need to understand that we are in a very special situation, and that patents and other forms of intellectual property will have to be shared," as Ellen 't Hoen observes.

Having the Commission claim that the existing rules provide the necessary space to start generic production, is not only not true, it is also highly hypocritical. If anything, the EU has over the years engaged in a structured attempt to undo generic production entirely, in effect acting as a key obstacle to international access to affordable medicines.

That tide needs to be turned, and it is a job that needs to be done in the main by people in Europe. A push to change the stance of the European Union on patents on vaccines, testing equipment, and medicines is urgently needed. Whatever happens with the current proposal for a waiver in the short term, this crucial issue will not go away any time soon.

TAKE ACTION

The 'Right to Cure' campaign has launched a European Citizens' Initiative calling upon the EU to "make anti-pandemic vaccines and treatments a global public good, freely accessible to everyone". The campaign aims to collect one million signatures in EU member states, in order to pressure the European Commission to implement this crucial demand. Sign the initiative here: noprofitonpandemic.eu

Corporate Europe Observatory has filed several Freedom of Information (FOI) requests to the European Commission to throw light on the Commission's interactions with Big Pharma lobbyists on the issue of the TRIPS waiver for COVID-19 vaccines and treatments. We have requested access to documents from the European Commission on its exchanges with pharma lobby groups.

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Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the disproportionate influence that corporations and their lobbyists exert over EU policy-making. CEO works in close alliance with public interest groups and social movements in and outside of Europe to develop alternatives to the dominance of corporate power.

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