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Public Health Security COVID-19 & Its Impacts

Intellectual Property: Shift in Global IP Power?

By Hannah Elyse Sworn

SYNOPSIS

Where once the US and EU dominated global trade negotiations, their grip on intellectual property regulations and pharmaceutical production are weakening amidst the COVID-19 pandemic.

COMMENTARY

TWENTY YEARS after the HIV/AIDS crisis, the world faces a new pandemic but a familiar problem. Technology needed to produce life-saving drugs remains fiercely guarded by the Western pharmaceutical companies who develop it. But there are signs that their tight grip may be loosening.

In the mid-1990s, a course of anti-retroviral drugs (ARTs) was priced at <u>US\$10,000</u>. This was an impossible sum in Southeast Asia and Sub-Saharan Africa, where more than <u>90 per cent</u> of new HIV infections in 1995 were recorded. But governments of developing countries were blocked from supplying their HIV-affected citizens with affordable, generic alternatives by strict global intellectual property (IP) regulations.

Patents: Power and Regulations

In the negotiation of IP regulations, the world's most powerful states use their economic clout to establish rules that disproportionately benefit them. Introduced at the behest of the United States and European Union, stringent IP standards protect high-value patented drugs developed by Western pharmaceutical companies.

Eventually recognising that HIV/AIDS could <u>destabilise</u> entire regions of the globe, the US and EU backed the 2001 World Trade Organisation (WTO) <u>Doha Declaration</u>. This allowed governments to overrule IP regulations in the interest of public health. Facing competition from generic versions, the price of patented ARTs dropped to US\$700 a year.

But after Doha, Western governments reverted to their <u>old ways</u>. Unable to work through the WTO, these powers <u>shifted</u> to threats of sanctions and narrower trade agreements to extinguish the IP flexibilities provided by the declaration.

In 2021, most IP related to COVID-19 vaccines is owned by pharmaceutical giants based in the US and EU who have reaped <u>tens of billions of dollars</u> in sales. Struggling to access immunisations, just under <u>four per cent</u> of people in low-income countries are fully vaccinated.

This contrasts with the much higher 69 percent vaccination rate in high-income nations, an inequality that is prolonging the pandemic with new strains of the virus. Once again, developing countries are beseeching the WTO to waive IP protections. But the review process has been hamstrung for more than a year.

Big Pharma vs Generic Drug Makers

Drafted in 2015, the then Trans-Pacific Partnership (TPP) was a 12-member megaregional free-trade agreement that would have required many less-developed signatories to <u>increase</u> IP protections — including for pharmaceuticals — beyond what was already mandated by the WTO.

The Anti-Counterfeiting Trade Agreement (ACTA) was another controversial and ambitious US-driven arrangement that would have allowed countries to seize in-transit shipments of generic drugs suspected of IP infringements.

The rules embodied in these agreements once again bestowed advantages on Western pharmaceutical companies, while generic drug manufacturers based in countries like India, Brazil and Thailand were restricted in what they could produce.

Fearing the loss of precious access to the US and EU's enormous markets, developing countries were prepared to capitulate to these IP regulations, all the while arguing that open access to knowledge was necessary for education, public health and economic development in their countries.

But since the 1990s, a tiger has joined the table. China has now overtaken both the US and the EU in GDP (PPP), positioning it to influence global IP regulations. While China has been <u>reluctant</u> to directly challenge the economic system that enabled its rise, it has <u>endorsed</u> flexible IP regulations advocated by the developing countries who are its most important economic partners.

Rival Camps in Global IP

Trends in recent trade agreements suggest that the US-EU regulatory hegemony may not be as robust as was presumed. Beijing has placed ASEAN at the centre of the Regional Comprehensive Economic Partnership (RCEP), a mega-regional trade agreement <u>rivalling</u> the TPP that does not include the US and EU.

The agreement, which will enter into force in a few weeks on 1 January 2022, has emerged with flexible, development-friendly IP provisions that contrast starkly with the TPP. When in 2017, Donald Trump withdrew the US from the TPP, RCEP became the world's biggest free-trade agreement. Left to pick up the pieces, the remaining TPP members unveiled the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) a year later.

The CPTPP <u>eliminated</u> all but one of the original IP chapters — including those related to pharmaceuticals — while leaving the rest of the agreement intact. Suddenly, the global landscape of IP regulation appeared very different.

Thailand has now expressed interest in joining the CPTPP, <u>citing</u> a reduced threat to access to medicines, and China formally <u>filed</u> a bid to join in September 2021. If the CPTPP advances in its current form, global IP regulations will be even further cemented away from the US and EU's preferences, giving generics manufacturers greater scope to produce affordable medicines.

Asia Steps Up its Pharmaceutical Game

Even without an IP waiver from the WTO, vaccine competition is heating up as Asia's pharmaceutical companies leverage high demand and an injection of funds into R&D to put alternative immunisations on the market. With the <u>second and third highest</u> number of COVID-19 vaccine developers in the world, China and India are leading the challenge to the West's vaccine monopoly.

While Chinese vaccines suffer bad publicity from <u>questionable</u> efficacy rates, generics giant India has seen Baharat Biotech's <u>Covaxin</u> recently obtain WHO emergency approval and has another immunisation hot on its tail from Zydus Cadila.

<u>South Korea</u> and <u>Japan</u> are investing billions of dollars in local vaccine development, with multiple candidates in clinical trials in both countries. Another high-profile generics manufacturer, Thailand, has two promising vaccines in the pipeline — one <u>mRNA</u> and another <u>protein-based</u> — as well as two <u>nasal sprays</u> beginning human trials.

Asia's home-grown vaccines could drive down prices globally by increasing <u>supply</u>. They could also produce valuable <u>spillover effects</u> for the development of other innovative drugs, rendering Asian firms more <u>competitive</u> against their Western counterparts in the long run.

A Fractured Western IP Camp

The West's IP dominance has not only been weakened by the changing balance of power, but also from within. The US and EU's powerful partnership came under strain as the latter found it increasingly <u>difficult</u> to achieve agreement between the European Commission and European Parliament on IP issues.

In 2012, the European Parliament rejected ACTA, sealing its political death. Even the

US' special partner, the United Kingdom, has begun <u>negotiations</u> to join the CPTPP, further indicating the pact's viability with countries that have traditionally been firmly in the US and EU's IP camp.

But the trajectory of IP regulations is far from settled. Property protections are key for encouraging innovation, especially given the high R&D costs for pharmaceuticals. As countries develop and produce more innovations, they are likely to demand higher IP standards.

China is shifting from a dependence on trade in goods toward high-technology sectors that benefit from more stringent IP regulations. If history repeats itself, developing countries may once again find themselves at the mercy of these great power interests.

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