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# PATENTLY ILL-SERVED

## Patent protections are pushing medicines out of patients' reach

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**The proliferation of patents is blocking affordable access to essential medicines.** 11



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# Notes from a vanishing shore

Amid overfishing, urbanisation and climate change, Filipino artisanal fishing communities are fighting to maintain their way of life.

**Sigrid Marianne Gayangos**

*This story originally appeared in* Earth Island Journal.

Bernard Spragg

**More than 85% of the Philippines' two million fisherfolk are small-scale fishers who depend on coastal waters for both income and food.**

THE ferry slipped out of Dumaguete's city port just before dawn. On the roof deck, I joined the scattered silhouettes of morning people, each of us drawn there by an unspoken desire to greet the sea. I breathed deeply, greedily, each inhale a cool balm easing the back of my throat and each exhale exiting as a faint fog. I was heading back home, to Zamboanga, a city on another island some 16 hours south of the Philippines' Central Visayas region, where I had once lived.

This particular return weighed heavily on me. As the ferry cut through the waves, I found myself thinking of my ancestors who had once travelled these same waters, moving from one coastal home to another across the country's islands in search of better fishing grounds – guided only by knowledge passed down among navigators in their communities and the very real need to provide food for the family. The whisper of the breeze and the gentle rocking of the ferry seemed to carry echoes of their existence, drifting like the sea's own breath, reminding me of the threads that still bound me to them.

I grew up immersed in seafaring tales. I heard stories of how, once, after enduring days with no substantial catch, my maternal grandfather and his brother ventured out on the cold, open waters off their fishing village in Cotabato, on the island of Mindanao. When they returned, my great-uncle developed a fever and severe cough. By the time they sought help, it was too late. A month after he died, news spread through their fishing village that those who ventured farther south to the Zamboanga Peninsula were met with bountiful catches. The same news had reached my paternal grandparents in the village of Iloilo, in the Western Visayas, which inspired them to make the journey as well. In the 1950s, both families settled in Zamboanga, unaware that they would be among the last generations of artisanal fisherfolk in their lines.

As the ferry hummed along, I wondered how these landscapes had shaped us – and what it means to stay rooted when those very landscapes begin to vanish.

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The Philippines is an archipelago of 7,641 islands located at the heart of the Coral Triangle – the richest and most diverse marine ecosystem in the world, which also spans parts of Indonesia, Malaysia, Papua New Guinea, the Solomon Islands and Timor-Leste. Its vast, discontinuous coastline – totalling 36,289 kilometres – is one of the longest in the world. Fishing has long been a vital source of livelihood in the triangle, and our culture remains deeply entwined with the sea.

More than 85% of the country's two million fisherfolk are artisanal: small-scale fishers who depend on coastal waters for both income and food. In fact, these fishers supply nearly half of the Philippines' total fish catch, a market valued at around $981 million. Yet, according to research by the marine conservation organisation Rare Philippines, these fishing families are also among the country's most marginalised. They typically live below the poverty line

and are often buried in debt.

My maternal grandfather's life was no different: relentless labour, long hours, unpredictable catches, and a constant battle against the elements. Determined to spare his children such hardship, he had discouraged anyone from following in his footsteps. My grandparents managed to put all their children through college, and in time, his wish was fulfilled. None of them would go on to fish for a living.

On my father's side, nearly everyone in the family had worked as fishers, fish truck drivers or ferry porters. My father's youth was spent balancing studies with shifts in a fish-processing warehouse. He was the only one among 13 siblings to earn a university degree. He, too, vowed that none of his children would endure the struggles he had faced. My father became a schoolteacher, and my mother, a fulltime homemaker. Though my parents briefly dabbled in buying and selling fish when I was in grade school, my siblings and I never truly knew the physical toll or the precariousness that had defined their labour.

These days, this way of life has become even more precarious due to decades of environmental degradation, chronic overfishing and rapid urbanisation of the country's coastlines. Climate change and its knock-on effects – unpredictable weather patterns, stronger typhoons and ocean acidification – which are further eroding marine ecosystems and shifting fish migration routes, have added another layer of vulnerability to the life of coastal fishers.

A few months before I got on this ferry, I visited six coastal communities in Dumaguete to meet with villagers opposing a proposed 174-hectare land-reclamation project on the island. The project, marketed by the city mayor's office as a 'smart city' with mixed-use development, promised to upgrade Dumaguete from a 'Third-Class City' to a 'Highly Urbanised City'.

We gathered in huts by the port and on *bancas* (small boats) bobbing in the shallows, sharing meals, exchanging stories and reflecting on how coastal life had changed.

'I used to dive for sea urchins with my father,' an elderly fisherman in Binisaya told me. He asked to remain anonymous, like many others I spoke with. Many people in these communities relied on seasonal jobs from the city mayor's office and feared that speaking out could cost them work. The elder fisher talked of his first taste of the briny, buttery custard-of-the-sea, a flicker of wonder still in his voice. 'There used to be tide timetables printed on the calendars we hung in our homes. But even without those, I learned to read the tides by watching how the water licked the mangroves.'

A mother of four shared: 'When I was a girl, we used to jump from boats into clear water, swim until our limbs grew tired, then go home to cook the day's catch. There was always enough. We even had extra to sell.'

Though not a Dumaguete local myself, my family's life in Zamboanga mirrored theirs. Much like my family, many here too had moved from one coast to another in search of better catches.

As people in these communities welcomed me into their homes, I shared stories in return: of how my grandparents journeyed to Zamboanga; of growing up in a family compound that smelled strongly of brined fish drying in the sun; and of how, for a couple of years, I'd carry pails of fish through the neighbourhood in my pristine white school uniform to help my parents sell their stock. I may have gone on to pursue a different path entirely, but these memories tether me still.

Today, one doesn't see too many overflowing pails of fish being carried around neighbourhoods. Small-scale fishers around the country manage to catch only 5 kg of fish a day on average, according to the Philippine Statistics Agency. That's a 90% decline from the 50 kg a day they used to pull up from the sea in the 1970s and 1980s, when the Philippines' coral reefs were healthy and highly productive. Fishers are now forced to venture farther out at sea and spend more hours and resources just to secure a modest catch. Various studies estimate that not only have 70% of the country's waters and major fishing grounds been overfished, but several species have also disappeared altogether.

'Illegal commercial fishing inside municipal waters and overfishing have long plagued Philippine waters, depleting fish stocks and degrading marine ecosystems,' Gloria Estenzo Ramos, vice president of the marine conservation group Oceana Philippines, said in a February statement raising alarm about the state of the country's fisheries. 'These practices threaten biodiversity and can trigger the collapse of essential fish populations,' she added. 'The unabated exploitation of these resources and the often aggressive, destructive and illegal fishing practices of commercial operators endanger the future of our fisheries and the communities that rely on them.'

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I had always felt an unshakable connection to the sea and fisherfolk. Growing up in Zamboanga, we would buy the day's catch directly from fishermen returning to shore, their pump-boats heavy with the scent of salt, fish and gasoline. The seaside was where I wandered after lighting candles at the nearby Fort Pilar, a place to grieve in private, to whisper my deepest wishes to the wind. It was where I stood, time and again, to say too many goodbyes, watching loved ones disappear over the horizon and hoping they would find their way back.

We've been taught to think that this kind of subsistence lifestyle

Judgefloro

**Nearly half of the Philippines' total fish catch is supplied by artisanal fishers.**

might soon be a thing of the past, but my heart finds it hard to believe that a whole way of being that has been for eons the mainstay of this country's socioeconomic culture can disappear in a matter of years.

But the fact is, the disenfranchisement of fisherfolk did not happen overnight. Small-scale fishers began being pushed to the margins decades ago, as commercial fishing took hold in the Philippines. In the 1950s to 1970s, artisanal fishing had still been a viable livelihood, but by the 1980s, it was nearly impossible for independent fishers to compete with industrial fishing vessels that monopolised the waters. Many had no choice but to leave the trade and find other means of survival. It was not by choice that the line of fisherfolk in my family ended a generation or two before me; it was by necessity.

When I asked my mother what moment solidified for her that our family's fisherfolk life had truly come to an end, she paused before recalling the day the family *kamalig* (fish-processing warehouse) was finally torn down in 2015, a year after my grandmother passed.

'When the last columns of the *kamalig* fell, we found seahorses and coins stashed in them. For good luck,' she said. 'But the luck only lasted a few decades, it seems. The *kamalig* had to shut down. Just like your Lolo's [grandfather's] entire fishing line.'

Built in the 1960s within our family compound, the warehouse had once been a vital space, not just for us but for many fishers in the community. They'd lay out their fish to dry there, and stored their catch in labelled boxes in the shared space. At a time when few homes had refrigeration, dried fish was in constant demand. But by the 1990s, the entire fish trade was already running at a loss. The dismantling of the building, two decades later, felt to her like a quiet farewell to a lineage of wandering, sea-bound lives. It was painful, she admitted, but also came with a complicated sense of relief. 'Perhaps it's for the better,' she told me. 'Maybe the next generations won't have to live such hard lives.'

Among those who hung on to this way of life, many began to resort to blast fishing – hurling handmade bottle bombs into the sea to stun or kill a large number of fish quickly. While this did help them harvest more fish, the practice is highly destructive. It kills the entire marine food chain, including juvenile fish, plankton and the coral reefs that the fish depend on.

By 1998, when a combination of unregulated fish-bombing and commercial fishing had wrecked significant portions of the country's 10,500 square miles of coral reefs and severely depleted coastal fish populations, the Filipino government introduced the Philippine Fisheries Code. The law bans the use of explosives and poisonous substances like sodium cyanide, and the use of fine mesh nets, trawling and purse seine techniques, as well as gill nets, air compressors and tuna longlines within municipal waters.

These waters, extending 15 kilometres from shore, are among the most productive marine zones. They are home to coral reefs, seagrass beds and mangroves that serve as breeding grounds for marine life. The goal of the ban was to protect near-shore spawning areas, which would in the long run benefit not only the environment but also fishers. However, enforcing these regulations across the country's vast coastline proved difficult.

The situation got so bad that in 2013, the European Union issued a stern warning to the Philippines: It would be banned from exporting to the bloc (which at the time brought in about $165 million in revenue) unless its fishing activities were better regulated. In response, the country produced a new fisheries code that called for stricter measures against illegal methods and commercial overfishing and stipulated that only artisanal fishers could fish inside the country's municipal waters.

While this has had some positive impact, curbing illegal fishing continues to be a challenge for authorities. A recent joint

report by the Philippines Bureau of Fisheries and Aquatic Resources and the USAID Fish Right programme estimates that illegal fishing costs municipalities 257,000 to 402,000 metric tons of catch per year, valued at $482.4 million to $756.8 million.

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As the Philippines works to address overfishing, another threat is quietly remapping its shores: land reclamation. These projects – which create new land by dredging up sediment and depositing it into coastal waters – have surged in recent years, putting further pressure on fragile marine ecosystems and displacing coastal communities.

Under the administration of President Rodrigo Duterte (2016–22), reclamation efforts saw unprecedented expansion. At least 45 projects were approved, mostly through public-private partnerships. This surge was partly enabled by an executive order that transferred the authority to approve reclamation projects from the Department of Environment and Natural Resources to the Philippine Reclamation Authority under the Office of the President.

The move raised concerns among environmental and fisherfolk groups, including Pamalakaya-Pilipinas, the National Federation of Small Fisherfolk Organization in the Philippines, which warned that fast-tracking these approvals would accelerate the destruction of marine habitats and the eviction of shoreline communities. Today, there are over 187 reclamation projects across the country, both proposed and ongoing. Of these, only 16 have been officially approved. The rest are in varying stages of planning or development.

The scope of these projects is wide: New land is being created to make room for housing, malls, airports, luxury hotels and business districts, and they are often marketed as solutions to urban congestion and economic stagnation. But environmentalists warn that these initiatives threaten to erase coastal biodiversity.

Patrickroque01 (CC BY-SA 4.0)

**The Manila Bay reclamation project has drawn backlash for its potential to displace fishing families and disrupt marine life.**

In Metro Manila, for instance, the highly contested Manila Bay reclamation project envisions new commercial and residential zones but has drawn backlash for its potential to displace fishing families and disrupt marine life. Contrary to claims by local officials that Manila Bay is 'dead', its waters remain a vital habitat for fish, mangroves and migratory birds – and a lifeline for thousands of fishers. Commonly caught species like sardines, mackerel, squid and blue crab rely on the bay's spawning grounds, which these dump-and-fill projects risk obliterating. According to Oceana Philippines, the fisheries industry alone accounts for 67% of Manila Bay's total economic value. Similar proposals have surfaced in other cities and provinces around the Philippines, including Cavite, Cebu, Bacolod and Bulacan.

At a November 2024 meeting of the Association of Southeast Asian Nations' Parliamentarians for Human Rights, Bong Binosa, a fisherfolk leader from a coastal community in Cavite province, described how drastically life has changed since reclamation projects began in the area.

'Life in our community used to be really good. Abundant fish catch and a peaceful environment,' he shared. 'Now, with these reclamation projects, the fish supply at the market has become seasonal.' Cavite, once the biggest supplier of mussels, oysters and other shellfish to Metro Manila and much of Luzon island, where Manila is located, is now seeing a sharp decline in harvests.

Critics of the projects say they also increase the risk posed to coastal communities from flooding and storms linked to climate change by depleting coastal wetlands and mangrove forests that slow storm surges and soil erosion. At the same time, research has linked increased groundwater extraction due to the developments to subsidence in the urban sprawl around Manila Bay, which is home to the country's capital and some 23 million people.

Even relatively small projects, like Dumaguete City's own ferry

port in Barangay Looc, have caused irreversible damage to the marine ecosystem. Built in stages between the 1910s and the 1930s, the Dumaguete pier was one of the city's earliest and most ambitious infrastructure projects, connecting Dumaguete to 11 nearby islands and facilitating regional commerce. But its legacy is complicated. Its construction led to the degradation of coastal habitats, and its continued expansion has further altered the seafloor and disturbed coral and seagrass ecosystems that used to be abundant in the area.

'Reclamations damage not just the areas being backfilled but those from where the backfilling materials are sourced as well,' Gary Rosales, a representative of the environmental groups Kinaiyahan and Friends of the Environment in Negros Oriental, told me via email. 'When done along coastal areas, especially when no meaningful discussion and public consultation is conducted, reclamation projects not only destroy adjacent marine habitats but also result in social inequity wherein artisanal fishermen and their families are deprived of either their fishing or gleaning grounds and the nursery of commercially important marine species.'

While strong community opposition has successfully halted some high-profile proposals – like Dumaguete's 174-hectare 'Smart City' – many reclamation efforts across the country have continued under other names. In recent years, some places have been reclaiming coastal areas by building boardwalks and calling it shoreline protection, a practice flagged multiple times by the Philippine Reclamation Authority. And even in Dumaguete, after the smart city proposal was shelved, officials quietly repackaged parts of the plan as piecemeal coastal defence projects.

But environmental groups remain vigilant. They continue to resist what they see as the slow erasure of people and places deemed disposable in the name of progress.

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Last year, a Philippine Supreme Court ruling dealt a further blow to artisanal fishers. In August 2024, the court upheld a lower court decision allowing commercial fishing vessels to operate within 15 kilometres of the coastline, waters that had long been reserved for small-scale fishers under the Fisheries Code.

With municipal waters now at risk of exploitation by commercial fleets, the consequences are dire: dwindling fish populations, destruction of spawning grounds, displacement of artisanal fishers and worsening poverty among already-marginalised communities. The ruling also stripped local governments of key regulatory powers, undermining their ability to curb illegal fishing, and it threatens the tourism industry, which relies heavily on healthy coastal ecosystems and vibrant coral reefs.

In response, fisherfolk across the country have begun mobilising. On 4 February this year, small-scale fishers from across the Philippines gathered in Quezon City to consolidate their demands and build a common agenda. The assembly called for the protection of municipal waters and stronger recognition of fisherfolk rights, while also addressing broader concerns such as climate impacts, dwindling fish stocks and exploitative market conditions. Weeks later, on 27 February, fishermen marched to the Supreme Court in Manila to contest the court ruling, while at the same time, fluvial protests swept through five towns in Zambales, with demonstrators sailing along municipal waters to assert their claims. Across these coordinated actions, the movement rallied under the cry #AtinAngKinse ('The 15 Kilometres Are Ours').

These struggles also resonate beyond Philippine shores. In late 2024, Pamalakaya joined 28 other organisations at the World Forum of Fisher Peoples' general assembly in Brazil, calling for food sovereignty, sustainable fisheries and systemic change. The issues faced by Filipino fishers are shared by small-scale fishing communities around the world.

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The ferry let out a long, low horn as it neared Zamboanga's port, the city's evening skyline emerging beyond the wharf. It was pitch dark but the night sky was streaked with a scattering of lights, like stars flickering on land. The briny smell of the dock wrapped around me like a memory – Zamboanga did still smell like Dumaguete after all. After more than 16 hours at sea, I was finally home.

For children like me who grew up in seaside communities, the sea was this unspoken presence that shaped the rhythm of everyday life. Some of us chose to drop anchor elsewhere and built lives away from the coast. But the identity formed by the sea – its fluidity and quiet, unrelenting force – had always stayed with us.

Perhaps this was why I strive to capture the sea in all its beauty and terror in my stories, to immortalise some semblance of that life on paper. To capture the coastal lives in my writing is one thing, to have them endure – not as relics of a forgotten world, but as lived realities, protected by those who understand their worth – is quite another.

On the shore of Zamboanga, I watched the waves as they rolled in, their motion steady and calm. The waters have been here long before us and will outlast us all. They have given us so much – the least we can do is fight for what remains. ◆

*Sigrid Marianne Gayangos was born and raised in Zamboanga City, Philippines. Her debut collection,* Laut: Stories*, was published by the University of the Philippines Press in 2022. In the Malayo-Polynesian language of seafarers,* laut *is the name of the vast ocean, whose shifting currents carried them across countless islands.*

# Tax the rich and corporations to close the climate finance gap

By righting rigged tax systems, governments will be able to fund global climate solutions and still have billions left to invest in domestic development.

**Franziska Mager**


Global Alliance for Tax Justice (CC BY-NC 2.0)

**Governments have weakened their ability and willingness to tax those most responsible for fuelling the climate crisis.**

AS the climate crisis accelerates, global faultlines are widening. Wealthy nations are gutting aid budgets while pouring fortunes into their militaries. Their climate finance commitments ring empty, masked by claims that public funds have run dry. But the reality is different: The money is there, and a bold tax justice agenda can unlock it. Reclaiming tax sovereignty – the power to decide how wealth is taxed and where it goes – can shift resources away from billionaires and corporate giants to fund real climate solutions.

This isn't a funding gap. It's a sovereignty gap.

New analysis by the Tax Justice Network shows that governments could raise an additional $2.6 trillion each year by applying a modest wealth tax to the richest 0.5% of households and ending corporate tax abuse. That would be more than enough to meet global climate finance needs and still leave most countries with billions to invest in care, education and green jobs at home.

The climate crisis is accelerating. Floods, heatwaves and crop failures are pushing more people into precarity. The costs of climate adaptation, mitigation, and loss and damage are projected to reach $9 trillion per year by 2030. Yet the global community is still scrambling to honour a $100 billion pledge first made over 15 years ago.

Climate finance remains a structural void that policy declarations alone cannot fill. On the road to this November's COP 30 United Nations climate conference in Belém, governments face a critical choice: Keep chasing inadequate voluntary climate finance handouts, or finally confront the rigged tax systems that let the superrich and big polluters amass obscene wealth while the planet burns.

The Tax Justice Network reveals that fair taxation of extreme wealth combined with measures to curb cross-border tax abuse by multinational corporations could raise $2.6 trillion each year – enough to more than double the $1.3 trillion annual climate finance goal that UN member countries are aiming to reach by 2030. The real issue isn't where new money will come from, but why governments keep letting existing public resources leak through the cracks of a broken tax system.

By applying a minimal annual wealth tax of 1.7–3.5% and reclaiming tax revenue from multinationals that underpay tax, countries could unlock additional tax revenue equivalent to 2.4% of global GDP. This is money that could be raised today if governments stopped letting it slip away through loopholes and inaction.

We modelled what countries could raise and contribute based on historical responsibility for emissions. The results are striking. If countries were to contribute to a global climate finance fund sized at $300 billion – the lower end of the current debate – then 89% of countries could cover their share and still have billions left over for public services. Even if the fund were scaled up to $1.5 trillion, 58% of countries would still contribute their fair share and have billions to spare.

Take the United States. It could raise enough additional revenue to contribute $365 billion

a year towards climate finance and still be left with $412 billion to spend at home. China, India, the United Kingdom and Brazil follow the same pattern.

This is the core message of our climate finance slider tool (https://tax-justice-network.github.io/slider_climate_finance/slider_protected.html). Taxing extreme wealth and curbing tax abuse does not pit climate justice against development. It enables both. The interactive tool shows how much countries could raise and how much they could contribute if tax rules were rebalanced in favour of people and planet.

So why are countries still acting like climate finance is unaffordable?

The answer lies in decades of eroded tax sovereignty. Countries have signed away their taxing rights through outdated and unfair treaties, allowed wealth to flow into secrecy jurisdictions, and catered to corporate demands for tax cuts and incentives – often under conditions of debt dependence and economic coercion. In the process, governments have weakened their ability and willingness to tax those most responsible for fuelling the climate crisis.

Today, 61% of countries were found to have an 'endangered' level of tax sovereignty or worse – meaning they are failing to collect tax revenue worth at least 5% of what they already raise, largely from their richest households and from multinational corporations that underpay tax. Nearly a fifth of countries (19%) fall into the 'negated' category, missing out on the equivalent of 15% or more of their annual tax revenue. These are not natural constraints. They are political outcomes shaped by an unequal global financial system.

Across the Global South, the consequences are particularly acute. Many governments face impossible tradeoffs – between education and climate adaptation, between debt service and disaster response. As

Moniruzzaman Sazal/Climate Visuals Countdown (CC BY-SA 2.0)

**Reclaiming tax sovereignty can shift resources away from billionaires and corporate giants to fund solutions to the climate crisis.**

UN independent expert Attiya Waris has warned: 'Across the Global South, care and climate responses are being sacrificed to servicing debts that dwarf the funds we need for a just transition. These sacrifices reflect an international financial order that prioritises creditor claims over human and planetary well-being.'

Climate finance cannot be separated from this wider context of fiscal injustice. When governments are forced to borrow for every disaster or rely on discretionary aid pledges, they lose both agency and time. The race to build resilience becomes a race against the clock – one they cannot win without revenue.

It is time to reframe the debate. Climate finance must not rely on broken promises or voluntary pledges. It must be embedded in systems that are fair and redistributive. That means tax systems – ones that reflect both capacity to pay and responsibility for emissions.

The upcoming UN Tax Convention offers a once-in-a-generation opportunity to rebalance global tax rules. If done right, it could help all countries reclaim the power to tax their richest residents and corporations fairly. It could end the era of tax havens, profit shifting and billionaire impunity.

But we do not need to wait for negotiations to conclude. Countries can act now by introducing wealth taxes, renegotiating exploitative tax treaties, increasing transparency, and aligning fiscal policies with climate goals. These reforms are not only possible. They are popular. Polling consistently shows widespread support for taxing extreme wealth to fund public goods.

Extreme wealth fuels climate inaction, rising debt and inequality. In a world on fire, refusing to tax those who profit most is no longer neutral – it's a global risk.

By reclaiming tax sovereignty, governments can do what markets and private finance have failed to deliver: fund climate solutions at scale, protect the most vulnerable, and make those most responsible pay their fair share. Refusing to tax isn't sovereignty – it's surrender to the idea that tax is a tool for catering to the desires of the superrich, rather than a tool for protecting people's well-being, the planet and our collective survival. ◆

*Franziska Mager is a senior researcher and advocacy lead for climate and inequalities at the Tax Justice Network. This article is reproduced from Common Dreams (www.commondreams.org) under a Creative Commons licence (CC BY-NC-ND 3.0).*

# Steering AI towards the public interest

A recent paper provides a blueprint for fostering innovation in artificial intelligence outside the dictates of Big Tech.

**Lean Ka-Min**

AS countries rush to embrace the potential of artificial intelligence, they must take care not to fall into the clutches of dependency on the powerful technology corporations. A tech policy expert has outlined how governments may seek to build AI systems that are not beholden to Big Tech but more aligned with the public interest.

In a recent paper, Burcu Kilic charts a course that countries can take towards the development of an independent and resilient AI sector using the tools of industrial policy, which can be defined in simple terms as 'any state intervention promoting specific industries or activities'.

Kilic is a tech and human rights fellow at the Carr Center, Harvard Kennedy School, and a senior fellow with the Canada-based Centre for International Governance Innovation (CIGI), which published her paper in March. The paper, entitled 'AI, Innovation and the Public Good: A New Policy Playbook', is available on the CIGI website at https://www.cigionline.org/publications/ai-innovation-and-the-public-good-a-new-policy-playbook/

Currently, Kilic notes, most AI strategies end up being AI adoption strategies reliant on the digital infrastructure developed by major tech companies like Amazon, Google and Microsoft. It is not difficult to see why: the design, training and running of AI systems require vast amounts of computing power and data and sophisticated cloud-based infrastructure – resources controlled by Big Tech.

Yet many countries, desperate not to miss the AI boat, aim to jump on in a big way, going for large-scale implementation. Being more resource-intensive, this 'bigger is better' approach, cautions Kilic, only reinforces dependency on the dominant platforms.

Instead of adding to the imbalance of power, countries can develop more autonomous AI models with the right mix of industrial policies focused on spurring innovation in line with national priorities.

Domestic innovation capabilities can be enhanced, Kilic says, through cooperation between local researchers, universities, technologists, companies and investors to 'build an equitable infrastructure that provides access to compute power and clean data sets. This framework would promote a collaborative model, empowering civil society, local communities, researchers and local innovators to participate in designing and developing AI systems. In the long run, this would reduce reliance on big tech companies for infrastructure, public services and technological needs'.

'Government demand,' stresses Kilic, 'can be a powerful driver of local innovation, whether by procuring new AI systems or investing in infrastructure.' Accordingly, government procurement policies should be crafted to support local innovation where feasible and prioritise domestic players while bearing in mind any constraints thereon under the country's trade agreements.

The government is also key to supporting AI research and development (R&D). Its role has become all the more crucial given that Big Tech is now investing heavily in basic research in this field – and therefore increasingly influencing research priorities – departing from the traditional arrangement where industry would look to the universities for fundamental research. Beyond basic research, suggests Kilic, public R&D initiatives should also 'support applied research, foster collaboration with the local industry, and address broader societal and economic dimensions of AI development'.

It is precisely such social concerns that stand to be given short shrift by industry-backed research, which pays less attention to issues of robustness, interpretability, fairness and security despite the public's strong interest in ensuring AI models are trustworthy, says Kilic. She thus calls for public funding to 'prioritise areas that align with broader societal needs, including interpretability, defensive cybersecurity, benchmarking and evaluations, and privacy-preserving machine learning', which are 'essential for ensuring AI systems are reliable, equitable and secure in their applications'.

There is also an imbalance in access to specialised computing resources, data sets and top human talent between the major tech companies and universities, especially non-elite universities. This gap, warns Kilic, 'threatens to undermine the long-term research and training functions traditionally performed by universities, hobbling

their ability to sustain innovation and educate the next generation of AI talent'.

To bridge the computing divide between industry and academia, proposals have been put forward for governments to invest in a 'national research cloud'. Such infrastructure, Kilic emphasises, must remain independent of tech companies and promote public-interest research free from corporate influence, without the investment ending up as a research subsidy for the tech firms.

The success of industrial and innovation policy demands coordination in government policymaking beyond innovation agencies to encompass multiple policy domains and sectoral ministries in a 'whole-of-government' approach, underlines Kilic. Governments, she says, should not give up in the face of the current Big Tech dominance but should 'embrace these complexities as opportunities to shape policies that rebuild the AI ecosystem from the ground up'. In this regard, the whole-of-government approach can be complemented by 'participatory policymaking, where civil society, local communities, workers and researchers can help design AI policies'.

The policy journey can begin by focusing on smaller AI models, which Kilic says provides a more practical and achievable foundation for AI development. 'Rejecting the blind replication of the US tech model characterised by data extraction, commodification and market concentration creates a space for responsible, equitable and democratic innovation that prioritises productivity and social goals. … Ultimately, it all comes down to balancing the need to foster innovation with serving the public interest.'

The industrial policy measures discussed above will also need to be supported by a country's competition and trade policies, says Kilic. Competition policy comes into play when dealing with the market power of the tech giants. Antitrust laws can be invoked to investigate and prohibit unfair and anti-competitive practices such as self-preferencing, tying, exploiting customers and restricting access to key inputs, thereby allowing the entry of new players, greater choice for businesses and consumers, and more scope for innovation. Structural interventions like blocking anti-competitive mergers and requiring asset divestments, Kilic says, are more effective than behavioural remedies that seek to regulate a company's behaviour instead of changing its structure.

According to Kilic, competition policy should strike 'a balance between short- and long-term priorities, price effects versus investment incentives and consumer interests versus local industries'. However, she contends that conventional competition policy may not be up to the task, as it is rooted in a neoliberal framework that prioritises productive efficiency and seeks to maximise the 'narrow concept' of consumer welfare at the potential expense of the broader national interest in promoting productive and dynamic industries.

Competition policy thus needs to be aligned with a country's national innovation strategy. 'When carefully designed, industrial and competition policies can work together to foster innovation, market fairness and sustainable development,' asserts Kilic. 'Without such efforts, countries risk remaining participants rather than creators in the digital economy.'

As with competition policy, trade policy in its neoliberal incarnation is not conducive to industrial policy success. International trade agreements often restrict government actions to build up domestic industry, viewing such measures as trade barriers that impede the workings of the free market. When it comes to AI, the current global regime for trade in digital goods and services 'fails to support AI industrial policy; instead, it reinforces structural dependencies and increases reliance on big tech companies', Kilic laments. In place of this constricting framework, she recommends that countries revisit their trade commitments and reclaim the policy space to implement measures to effect more inclusive digital development.

Such space would necessarily cover all areas of the digital economy. It would encompass not only the AI industrial policies discussed in Kilic's paper but also other, broader policy initiatives aimed at securing digital sovereignty – the capacity to 'steer the development of science and technology, so citizens can access, understand, and produce technology that truly improves their lives'.[1] Proposals towards this end have envisioned open and decentralised public digital infrastructure, and include calls for a 'Digital Non-Aligned Movement' of nations collaborating on digital transformation beyond the sway of the tech powers.[2]

Whether it's AI or other digital innovations, escaping the stranglehold of Big Tech will not be easy, but the need to ensure technology empowers, not subjugates, demands nothing less. ◆

*Lean Ka-Min is editor of* Third World Resurgence.

## Notes

1. Democratic and Ecological Digital Sovereignty Coalition (2024), 'Reclaiming digital sovereignty: A roadmap to build a digital stack for people and the planet' (lead authors: Cecilia Rikap, Cédric Durand, Edemilson Paraná, Paolo Gerbaudo and Paris Marx), https://www.unige.ch/sciences-societe/dehes/files/7417/3329/9105/Reclaiming-Digital-Sovereignty_whitepaper.pdf
2. Kai-Hsin Hung (2025), 'Beyond Big Tech geopolitics: Moving towards local and people-centred artificial intelligence', in *State of Power 2025: Geopolitics of Capitalism*, Transnational Institute, https://www.tni.org/en/publication/geopolitics-of-capitalism

# TRIPS@30: Thirty years of widening inequities in access to medicines

The TRIPS Agreement, the treaty that sets international standards for the protection of intellectual property, turned 30 this year. In its three decades of implementation, the stringent patenting requirements imposed by the agreement have often thwarted affordable access to medicines in developing countries.

**K.M. Gopakumar**

PATENT protection for pharmaceutical products was introduced in developing countries to comply with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). As a result, pharmaceutical producers in developing countries lost the freedom to produce generic versions of new medicines. The elimination of freedom of operation has considerably compromised the ability of countries to make available the latest efficacious medicines to the people at affordable prices, widening disparities in access between countries.

The COVID-19 pandemic laid bare these contradictions. It not only highlighted the significant inequity in accessing vaccines, therapeutics and diagnostics but also exposed the fallacy of justifying patents as a mechanism to recoup investment in research and development (R&D). Despite the almost 100% public funding, vaccine manufacturers were not ready to license their products widely to facilitate rapid access. Consequently, while high-income countries had vaccinated 68% of their populations by October 2021, only 2.31% of people in low-income countries had received a dose.

This is just one of many examples of how a patent is used as a tool to maximise profit at the cost of inequitable access. The United Nations Committee for Development Policy has stated that intellectual property rights 'are biased towards rewarding innovators over users. Intellectual property protection often far exceeds what would be necessary to incentivise innovation, leading to high prices and an undersupply of public goods and reducing the global dissemination of the benefits of innovation, which contributes to new inequalities'.[1]

At the global level, this regime has a clear origin. The 30-year history of the TRIPS Agreement, which came into force in 1995, is a history of institutionalising inequitable access to medicines, barring a few exceptions such as treatments for HIV/AIDS, tuberculosis (TB) and malaria. But even access to new HIV/AIDS and TB therapeutics is threatened by patents. Initiatives to facilitate access, such as the Global Fund to Fight AIDS, TB and Malaria (GFATM) and the US President's Emergency Plan for AIDS Relief (PEPFAR), have been disrupted by the withdrawal of funding from the Trump administration. Meanwhile, a new medicine which can effectively prevent HIV infection has been approved by the US Food and Drug Administration (FDA), bringing with it a possible end to new infections, but patent restrictions could hinder its breakthrough potential. Similarly, more efficacious medicines introduced for the treatment of cancer, rare diseases and other conditions are priced beyond the reach of people in developing countries, largely as a result of patent protections.

It is therefore a matter of pressing urgency to examine the options for developing countries in the light of the widening gap in access to medicines.

## Market concentration

The universal introduction of product patent protection by 2005 as required by the TRIPS Agreement, except in least-developed countries (LDCs), helped transnational pharmaceutical corporations to consolidate their market power by eliminating any possibility of competition from generic companies with regard to new medicines. In the absence of competition from generics, the patent holders could charge very high prices in developed countries without the possibility of any comparative pricing. Compulsory product patent protection also allowed the originator companies to obtain patents in developing countries without any obligation to market the product there. After being granted the patents, especially in those developing countries with manufacturing capabilities like China and India, the originator firms could prevent generic

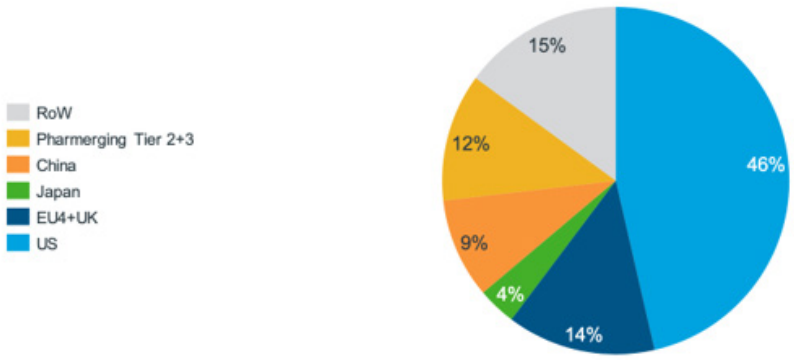
manufacturers from producing new medicines.

Figure 1 shows the pharmaceutical (excluding vaccines) market distribution among regions. The market is dominated by developed countries: in terms of value, the US, Europe and Japan account for some 64%. This highlights how patent holders have not launched most of the new medicines in developing countries. For the few products which are launched, the high prices make them inaccessible to people and governments in those developing countries. Thus, patent holders can extract the maximum price from developed-country markets through universal pricing (a single price applied globally) and effectively exclude people in developing countries from accessing these patented medicines.

Concentration in the vaccine market is even more severe. Ten manufacturers account for 73% of vaccine dose volumes and 85% of global financial value. Manufacturers affiliated with the developing-country vaccine manufacturers' network account for 50% of vaccine doses procured globally, but only 11% of the global financial value. In contrast, manufacturers affiliated with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) account for 34% of the volume but 85% of the financial value. On a country basis, high-income countries account for 72% of the financial value of the $77 billion global vaccine market.[2]

The global spending on medicine in 2024 was at $1.7 trillion, and developed countries accounted for $1.4 trillion.[3] The shares of countries with increasing health expenditure ('pharmerging' countries)[4] and low-income countries were $312.2 billion and $16.1 billion respectively. Out of the $1,421.5 billion spent in developed countries, $1,091.6 billion was on original brands. The high spending on originator brands is generally due to spending on patented medicines, which are not affordable to the governments and people in developing countries.

**Figure 1: Projected pharmaceutical market share (excluding vaccines) between regions (2027)**




RoW: Rest of the world
Pharmerging tier 2+3: Countries with increasing health expenditure

**Source**: Global Pharmaceutical Market 2022–27: IQVIA Quarterly Update, November 2023

The high prices emanating from product patent protection have resulted in the denial of access to new medicines in developing countries. According to a report by health analytics firm IQVIA, out of the 1,005 novel active substances (NAS) introduced in the last 20 years, 81% were launched in the US, followed by 65% in Europe and 60% in Japan.[5] Though China accounted for 59%, nearly 40% of it was launched only in China. The study does not even mention the percentage of new launches in developing countries. However, citing another IQVIA report, it states that only Brazil and Mexico saw the launch of at least 30% of the most recent NAS (see Figure 2). This clearly shows that originator companies are not launching the majority of their products in many developing countries, which are less attractive from a profitability perspective.

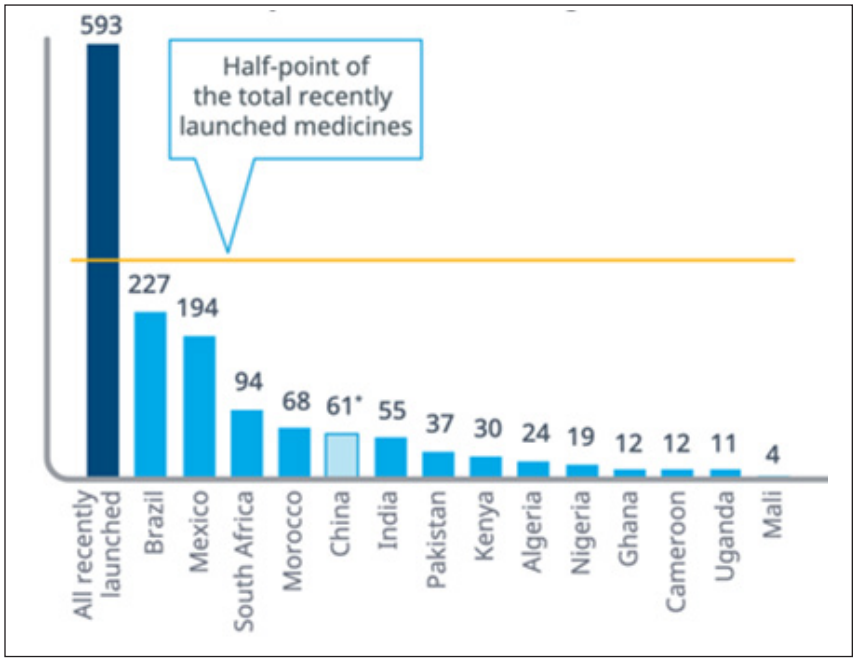
The US, Europe and Japan account for 86.8% of the sales of new medicines launched between 2018–23.[6] The share of the pharmerging market, which includes China and India, is 3.8%. The rest of the world, including Australia and Canada, accounts for 9.4%. It is clear there is a denial of access to new medicines to people in developing countries. Most patients and governments in these countries are unable to buy these products, irrespective of the actual need.

The pharmaceutical market concentration is also reflected in R&D priorities. The pharmaceutical companies focus on the health needs of developed-country markets rather than developing countries. The product patent regime has therefore resulted not only in the denial of access but also in the denial of investment to develop products for diseases disproportionately affecting developing countries. Among those overlooked by this market rationale are the 1.65 million people who require treatment for neglected tropical diseases.[7]

To make matters worse, over the years, originators have devised various strategies to extend their monopoly beyond the expiry of the original patents:

- Product hopping – when an originator slightly modifies a medicine before its patent expires, either by replacing the old version or by promoting the new one, to delay generic competition and extend its

**Figure 2: Number of local registrations of recently launched medicines by country (2013–22)**




**Source**: IQVIA Key Access Pathways and Bottlenecks for Medicines in LMICs, July 2025

market monopoly

- Evergreening – when a pharmaceutical company makes minor or incremental changes to a drug, such as a new formulation, dosage, delivery method or combination, often near the end of the patent term, in order to obtain a new patent and extend its market exclusivity without significant therapeutic improvement or actual innovation.

In the absence of any legally compulsory measure to market the product at an affordable price in developing countries, the TRIPS Agreement legitimises denial of access to new medicines in the pursuit of intellectual property (IP) protection. It allows originator companies to extract maximum profit from developed-country markets without fear of a comparative generic price. It widens inequity in access and directly compromises the ability of governments, particularly in developing countries, to fulfil their international obligations on the right to health and the right to science. This effectively results in the denial of access to new medicines for the vast majority of people living in developing countries, especially in low- and middle-income countries, where 80% of the world population live.

## Law and policy response

The standard law and policy response to address concerns emanating from product patent protection is the use of TRIPS flexibilities. The policy flexibilities allowed under the TRIPS Agreement, which are available during the pre- and post-grant stages of patent protection, can be used to facilitate availability of generics at an affordable price.

The flexibilities available during the pre-grant stage provide the freedom to set a high threshold for meeting patentability criteria. This can be used to curb the practice of seeking multiple patents on the same molecule and to restrict the number of patents (ideally, one patent per molecule). However, this approach has only had limited success in reining in the practice of extending monopolies.

The flexibilities available during the post-grant stage include compulsory and government-use licences to facilitate the production of affordable generic versions of patented products. A government can issue such licences to authorise the production or import of generics without the patent holder's consent, on the grounds of protecting public health. This policy option can be invoked, for example, during emergencies or when negotiations with the patent holder fail. The patent holder will still receive royalties when such a licence is issued.

Another TRIPS flexibility, parallel importing, allows a country to import a patented medicine from another country where it is sold at a lower price, without needing the patent holder's permission. Though parallel importation is considered an important flexibility, its actual efficacy is doubtful because of the universal pricing policy of originator companies.

The use of TRIPS flexibilities to mitigate the adverse effects of product patent protection gained political consensus through the adoption by WTO member states of the Doha Declaration on the TRIPS Agreement and Public Health in 2001. The Declaration affirms that the TRIPS Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose'.

However, countries face many practical challenges in making use of the TRIPS flexibilities, especially compulsory licensing. In the absence of domestic manufacturing capabilities, a country issuing a compulsory licence has to depend

**Figure 3: Grounds for compulsory licensing**

| Provisions of law | Compulsory licence for non-working of patent | Compulsory licence for dependent patent | Compulsory licence to correct patent abuse | Compulsory licence for public interest | Separate provision on government use | Separate provision implementing the 30 Aug 2003 decision of the WTO General Council |
|---|---|---|---|---|---|---|
| Yes | 97 | 82 | 50 | 83 | 52 | 18 |
| Not explicitly provided | 16 | 32* | 63* | 30 | 61 | 95 |
| No | 1 | 0 | 1 | 1 | 1 | 1 |
| Total countries | 114 | 114 | 114 | 114 | 114 | 114 |

* Slovakia provides for compulsory licensing for dependent patents with regard to plant varieties and compulsory licences to correct patent abuse with regard to semiconductors.

**Source**: World Intellectual Property Organization, 'Database on Flexibilities in the Intellectual Property System', https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html (accessed 14 July 2025)

on a manufacturer outside its borders to supply the product. Even if producers within the country are able to manufacture a particular pharmaceutical product, they may need to obtain the active pharmaceutical ingredients (API) from elsewhere. Patent protection on the required API could block the supply and therefore render the compulsory licence ineffective.

The TRIPS Agreement was amended in 2017 with a view to facilitating the effective use of compulsory licensing by countries with no domestic manufacturing capacities in the pharmaceutical sector. However, the system put in place under the amendment is riddled with cumbersome procedures and is especially difficult for countries with small markets to utilise, due to lack of economies of scale.

As a result of the various challenges, most developing countries cannot use the compulsory licensing option effectively. This is further complicated when voluntary licences are issued by patent holders to generic manufacturers on terms that prevent them from supplying to middle-income countries like Brazil or Malaysia.

In addition, the TRIPS flexibilities are often not fully incorporated into national or regional patent laws. For instance, Figure 3 illustrates the state of implementation of various grounds for compulsory licensing in 114 countries. The table shows that many countries do not explicitly provide grounds for the issuance of a government-use licence. The lack of explicit mention of the grounds could put the countries under undue pressure from patent holders. Further, there may be a lack of institutional and policy measures to make the most of the flexibilities. For example, there is no effective institutional mechanism in most developing countries to monitor the impact of medicine patents on access. As a result, the governments in those countries are not in a position to take timely action to facilitate access to new medicines.

Another area where TRIPS flexibilities are seldom utilised is trade secrets. Under Article 39 of the TRIPS Agreement, there is an obligation to keep confidential certain information contained in the dossiers submitted for the marketing approval of medicines. However, an exception to this general rule is provided for in case there is a need to protect the public. This Article allows regulatory authorities to share confidential information to protect public health. However, most countries do not incorporate exceptions to the confidentiality clause for dossiers submitted for marketing approval.

Policy space with regard to the use of TRIPS flexibilities is also being circumscribed by free trade agreements (FTAs). FTAs which incorporate 'TRIPS-plus' provisions – obligations that go beyond those established in the TRIPS Agreement – eliminate or limit the use of flexibilities. Although some of the new agreements do include language stating that their IP provisions do not affect the freedom to make use of flexibilities, FTAs often contain provisions on providing new-use patents, patent term extensions as

well as patent linkage. New-use patents allow companies to extend their monopoly rights by patenting a new use of an existing drug, even when the original patent is about to expire. Patent term extensions prolong a company's exclusive rights beyond the standard patent period of 20 years, usually to compensate for the time taken for market approval to be granted. Patent linkage ties the drug approval process to patent status, preventing health authorities from approving generic versions until all patents on the originator drug have expired, even if those patents are weak or not directly related. These provisions delay the entry of generic medicines.

One of the most important barriers to deploying the TRIPS flexibilities to facilitate access to medicines is bilateral political pressure exerted against their use. Well-documented instances of such pressure led the UN Secretary-General's High-Level Panel on Access to Medicines to observe that 'political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement, as reaffirmed by the Doha Declaration. This pressure undermines the efforts of states to meet their human rights and public health obligations.'[8]

A stark example is the annual 'Special 301' report on the global state of IP protection, published by the Office of the US Trade Representative (USTR), the US government agency concerned with trade issues. Countries that make use of TRIPS flexibilities may get listed in the report and be subjected to sanctions by the US.

Most recently, the 2025 Special 301 report published under the Trump administration discouraged the use of compulsory licensing, saying that 'actions by trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses raise serious concerns. Such actions can undermine a patent holder's IP, reduce incentives to invest in research and development for new treatments and cures, unfairly shift the burden for funding such research and development to American patients and those in other markets that properly respect IP ... Such licenses should not be used as a tool to implement industrial policy, including by providing advantages to domestic companies, or as undue leverage in pricing negotiations between governments and right holders'.

To evade bilateral political pressure, developing countries like India generally avoid granting compulsory licences and signal their preference for voluntary licences issued by patent holders. However, a voluntary licence not only often excludes middle-income countries but may also impose restrictive conditions to prevent the licensee from supplying to non-licensed territories even under a compulsory licence. The United Nations High Commissioner for Human Rights has noted how this approach undermines equal access to medicines. Seen in this light, voluntary licences are used as a tool to protect profits rather than promote access.

## Human rights challenges

Bilateral political pressures have deterred the issuance of compulsory licences by developing countries. In turn, the inability of developing countries to make optimal use of TRIPS flexibilities compromises their capacity to meet their human rights obligations relating to the right to health and right to science. Further, the TRIPS patent regime in effect leads to discrimination in enjoyment of these rights based on nationality. As shown above, the people in developing countries are denied access to new medicines due to the high prices emanating from product patents.

The international human rights framework recognises the adverse implications of the global IP regime, especially with regard to accessing the benefits of scientific research, which include medicines. In its General Comment No. 25 adopted in 2020, the UN Committee on Economic, Social and Cultural Rights (CESCR) highlights how IP is not innate but rather a social product that should be subjected to the rights to health, food and education.

However, most national patent laws do not establish any process for patients or patient groups to initiate a compulsory licensing procedure. Therefore, enjoyment of the right to health and the right to science in the context of patented medicines is dependent on the business models of pharmaceutical firms or the discretion of national governments.

Left to government discretion, the duty to protect the right to health – which is enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights – is seriously undermined. The CESCR's General Comment No. 14 states that countries must not only be active promoters of the right to health, but also act to guarantee that the right to health is not interfered with by third parties, like private entities. When it comes to private healthcare systems, says the CESCR, the state's intervention is required to guarantee 'the availability, accessibility, acceptability and quality of health facilities, goods and services', and to 'control the marketing of medical equipment and medicines by third parties'.

However, there are no direct means available within the IP framework, especially in national and regional patent laws, for affected people to remedy the lack of affordable access to patented medicines. At the national level, the administration of patents often falls under the industry or commerce ministry, which may view the use of flexibilities as an option and not a mandatory measure to facilitate access to medicines. Taking note of this situation, the UN Special Rapporteur in the field of cultural rights has stated: 'Whereas from the perspective of trade law, exclusions, exceptions and flexibilities under international intellectual property law, such as the World Trade

**Figure 4: Medicines covered by the compulsory licensing litigation in India**

| Name of medicine | Therapeutic use | Price (US$) | Originator company |
|---|---|---|---|
| Abemaciclib & ribociclib | HR+, HER2- breast cancer | 558–1,104 per month 744 per month | Eli Lilly & Novartis |
| Risdiplam | Spinal muscular atrophy | 7,208.59 per bottle | Roche |
| Trikafta | Cystic fibrosis | 320,000 per year | Vertex |

Conversion rate: US$1 = INR85

Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, remain optional, from the perspective of human rights, they are often to be considered as obligations.' The optional approach within the IP framework has resulted in the exclusion of individuals or patients from seeking compulsory licences as a remedy against abuse of patent monopolies.

Against this backdrop, activists are pushing for realisation of the right to health. In India for example, at least three sets of petitions are pending in two high courts seeking remedy against violation of the fundamental right to health through issuance of government-use licences. These petitions argue that the Indian government has no discretion when it comes to facilitating access to critical patented medicines because lack of access infringes fundamental rights under Article 21 of the Indian Constitution. Article 21 guarantees the right to life, which now extends to the right to live with dignity, including the right to health. Therefore, it is argued, the government should take measures under the country's Patents Act to facilitate access, like the issuance of a government-use licence. The courts are yet to hear the merits of the petitions and to provide a verdict. Figure 4 gives details of the particular medicines that are the subject of these petitions.

## Conclusion

The TRIPS Agreement, in its three decades of implementation, has entrenched significant inequities in access to medicines, particularly disadvantaging developing countries. While TRIPS flexibilities, such as compulsory licensing, offer legal avenues to mitigate these challenges, practical obstacles, including political pressures, limited manufacturing capacity and cumbersome regulatory frameworks, have severely limited their effectiveness.

All these factors have created a chilling effect on the effective use of TRIPS flexibilities. However, the turbulence created by the policies of the Trump administration has once again trained the spotlight on the use of these flexibilities to facilitate affordable access to medicines. The use of flexibilities such as compulsory licensing to remedy abuse of patents offers an effective tool to retaliate against unilateral trade measures unleashed by Washington.

Addressing the inequities wrought by medicine patents requires an urgent global commitment to reform the intellectual property regime with a stronger emphasis on public health and human rights obligations. At the same time, there should be renewed efforts to generate the political will to make use of the TRIPS flexibilities to urgently arrest the widening inequity in accessing efficacious medicines and treatments. Towards this end, the international community should actively push back against the political and corporate pressures that undermine the right to health and the right to science. The best way is to empower people individually or collectively with legal remedies against the abuse of patents, such as exorbitant pricing of patented products, by adding appropriate provisions to that effect in patent laws. Only through such comprehensive efforts can the promise of equitable access to medicines and other scientific advances be realised. ◆

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*The author acknowledges comments and inputs from Chetali Rao, Rajnia de Vito and Srinath Namboodiri.*

## Notes

1. https://documents.un.org/doc/undoc/gen/n24/096/02/pdf/n2409602.pdf?utm_medium=email&utm_source=sendpress&utm_campaign
2. https://www.who.int/publications/m/item/global-vaccine-market-report-2024
3. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicines-outlook-through-2029/iqvia-institute-global-use-of-medicines-06-25-forweb.pdf
4. Pharmerging refers to a group of developing countries experiencing rapid growth in healthcare expenditure. These countries include: Algeria, Argentina, Bangladesh, Brazil, Colombia, Chile, China, Egypt, India, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, Russia, Saudi Arabia, South Africa, Turkey and Vietnam. At times, China is mentioned separately along with pharmerging markets.
5. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicines-outlook-through-2029/iqvia-institute-global-use-of-medicines-06-25-forweb.pdf
6. https://efpia.eu/media/2rxdkn43/the-pharmaceutical-industry-in-figures-2024.pdf
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# WHO Pandemic Agreement: A win for multilateralism, a missed opportunity for public health?

The imperative of access to medicines and other essential health products was made painfully evident during the COVID-19 pandemic when unequal global distribution of vaccines wrought devastating consequences. A milestone agreement was adopted in May to improve international cooperation in tackling such health crises but, as the following *Third World Network* analysis reveals, fails to sufficiently plug gaps in access and in other areas of pandemic prevention and response.

Surya Edy Gautama (CC BY-SA 4.0)

**The Pandemic Agreement falls far short of the ambition and solidarity needed to address the stark inequities exposed during the COVID-19 crisis.**

A LANDMARK Pandemic Agreement (PA) setting norms for international cooperation in dealing with global health emergencies was adopted by member states of the World Health Organization (WHO) at the 78th annual World Health Assembly (WHA) held in Geneva on 19–27 May.

While its adoption may be viewed as a symbolic win for multilateralism in a fragmented world, the agreement falls far short of the ambition and solidarity needed to address the stark inequities exposed during COVID-19 and to ensure effective prevention, preparedness and response to future global health crises.

The agreement had been finalised after 20 sessions of the Intergovernmental Negotiating Body (INB) held between February 2022 and April 2025, which saw often tense negotiations marked by sharp North-South divides.

The INB was set up in 2021 by a special session of the WHA following the world's traumatic experience of COVID-19 which forced WHO members to rethink the global health emergency regime, especially the lack of equity and solidarity in the context of pandemic prevention, preparedness and response (PPR).

Decision SSA2(5) that established the INB set out reasons for a PA, including to 'address gaps in preventing, preparing for, and responding to health emergencies, including in development and distribution of, and unhindered, timely and equitable access to, medical countermeasures such as vaccines, therapeutics and diagnostics, as well as strengthening health systems and their resilience with a view to achieving universal health coverage'.

The decision also recognised the commitment of WHO member states to develop a new instrument for PPR 'with a whole-of-government and whole-of-society approach, prioritising the need for equity'. It stressed that development of the PA should be guided by 'the principle of solidarity with all people and countries, that should frame practical actions to deal with both causes and consequences of pandemics and other health emergencies'.

However, a closer examination of the adopted PA reveals that this ambitious vision remains largely unfulfilled. Except for a pending annex on pathogen access and benefit sharing (PABS), the agreement relies heavily on ad hoc, voluntary commitments – particularly in critical areas such as technology transfer, production diversification, and equitable access to pandemic-related health products.

The forthcoming negotiations on the PABS annex – a linchpin component of the PA that will govern how countries share

pathogen samples, genetic sequence data and the vaccines, therapeutics and diagnostics developed using such samples and data – will therefore be critical. The PA can be signed and ratified only after the PABS instrument is also adopted by the WHA, whose next session will be in 2026.

Crucially, the PABS instrument must deliver rapid and timely equitable access to vaccines, therapeutics and diagnostics by ensuring legally binding commitments on manufacturers which access materials and genetic sequence information of pathogens with pandemic potential. Without such specificity, there is risk of repeating the stark inequalities witnessed during previous health crises, where sharing of materials and sequences from the Global South failed to result in fair or timely access to vaccines, therapeutics and diagnostics.

The main part of the PA that was adopted by the WHA in May contains three chapters. The introductory Chapter 1 consists of three articles – on 'use of terms', 'objectives' and 'principles and approaches'. Chapter 2, titled 'The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response', contains 15 articles. Chapter 3, which deals with institutional arrangements and final provisions, comprises 17 articles.

The key provisions which had been central to the INB negotiations and often the source of prolonged debate and tension, are highlighted below.

## Articles 4 and 5: Pandemic prevention, surveillance and One Health

Article 4 on 'pandemic prevention and surveillance' has six paragraphs that address: (i) progressive strengthening of prevention and surveillance measures and capacities through international collaboration, in bilateral, regional and multilateral settings; (ii) national pandemic prevention and surveillance plans, programmes and actions, such as zoonotic spillovers, antimicrobial resistance, community-level detection, water and sanitation, immunisation etc.; (iii) factors increasing risk of pandemics; (iv) provision of mandate to the Conference of the Parties to the PA (COP, the body that will oversee implementation of the PA) to develop non-binding guidance for the implementation of provisions under paragraphs 1 and 2; (v) mandate to the COP to facilitate access to resources and tools for prevention and surveillance; and (vi) obligation on WHO to provide technical support upon request of Parties for the implementation of the PA.

Article 5 focuses on the One Health approach – which recognises that the health of people is interconnected with animal health and the environment – for PPR. Paragraph 1 calls on Parties to promote a One Health approach for PPR, while paragraph 2 is on Parties taking measures to address drivers of pandemics and the emergence and re-emergence of infectious disease at the human-animal-environment interface by introducing and integrating interventions in PPR plans. Paragraph 3 calls for measures to promote human, animal and environmental health including by reflecting the One Health approach in relevant policies and strategies and multisectoral training and education of the workforce.

Both Articles 4 and 5 are framed to provide policy space to Parties to act in accordance with national or domestic laws and based on their national public health priorities. The obligations are subject to availability of resources. In other words, Parties can calibrate the implementation of Articles 4 and 5 by taking into account national circumstances, availability of resources and public health priorities.

These elements were finally agreed on in the INB negotiations following a standoff with developed countries that were pushing for a detailed annex that would address the One Health approach. Facing opposition from the Global South, developed countries then repackaged their demand and called for an annex to elaborate on Article 4 on pandemic prevention and surveillance. This suggestion was also vehemently opposed by most developing countries. As a result, the compromise is Article 4, paragraph 4 which provides for development of non-binding guidance.

In future, the COP is mandated to work on means of implementation, in particular for provisions in Article 4, including with full consideration to developing countries taking into account the different capacities and capabilities of Parties (paragraphs 4 and 5). Despite such a mandate, it is clear from the text of Articles 4 and 5 that there is no assurance of additional resources being made available for prevention and surveillance measures. Any technology-sharing provision is subject to 'mutually agreed terms'.

It is also imperative to note that application of Articles 4 and 5 is at the national level and does not obligate cross-border transfer such as of biological samples and related sequence data or information relating to public health events. Implementation is also based on national and international laws. Hence, crucially, caution should be exercised to ensure that conditionalities (rejected during the negotiations and other discussions) are not reintroduced/added when implementing Articles 4 and 5.

## Article 9: Research and development (R&D)

Article 9 promotes collaboration of Parties in R&D, with obligations which fall into four

areas: (i) building diversified R&D capacities, including in developing countries; (ii) encouraging research collaboration and information sharing; (iii) clinical trials for pandemic-related products; and (iv) publicly funded R&D.

Article 9 focuses on actions by Parties; it does not contain actions for WHO. The provisions outlining Party actions are framed in open-ended language with numerous caveats, creating potential loopholes that allow for non-compliance. Under paragraph 2, Parties are required to promote sustainable investments, research partnerships, access to evidence synthesis, knowledge translation, sharing of information on research agenda etc., all 'within means and resources at their disposal and in accordance with national and/or domestic laws and policies'.

Each Party, 'in accordance with their national or domestic circumstances and law', also undertakes to promote well-designed clinical trials in their jurisdiction during public health emergencies of international concern (PHEICs) and pandemics – by ensuring representative populations, sharing comparator products, and improving access for trial participants and their communities. Parties are also, 'in accordance with their national or domestic circumstances and law', obligated to 'support the rapid and transparent publication of clinical trial protocols'. These as well as other provisions depend on available resources and applicable laws.

Similarly, though paragraph 5 mandates Parties to incorporate provisions in R&D funding agreements that the recipients of funds would have to comply with to facilitate access to pandemic-related vaccines, therapeutics and diagnostics, it does not provide for definite commitments. Instead, it also allows each Party to decide which provisions to include in such agreements.

Accordingly, the paragraph provides a non-exhaustive list of clauses that may be reflected in the funding agreements, such as non-exclusive licensing especially to developing-country manufacturers, affordable pricing policies, technology access to facilitate R&D and diversify production, and adherence to WHO product allocation frameworks. The approach taken dilutes the effect of the provision as a Party can include minimal commitments in an R&D funding agreement.

## Article 10: Sustainable and geographically diversified local production

Under this article, Parties are to take measures for three key objectives: (i) achieve more equitable geographical distribution and rapid scale-up in production of pandemic-related health products; (ii) increase sustainable, timely and equitable access to such products; and (iii) minimise supply-demand gaps during pandemic emergencies.

Paragraph 2 of the article requires Parties, in collaboration with WHO and other relevant organisations, to commit to supporting and strengthening national and regional production of pandemic-related health products, especially in developing countries. This includes promoting sustainable manufacturing through skills development, capacity building, transparency in value chains, and technology transfer. Parties are also to incentivise investment and partnerships, support WHO-led production initiatives, and encourage procurement from developing-country manufacturers. During pandemics, if existing capacity is insufficient, measures will be taken to rapidly scale up production through additional manufacturing contracts. However, the commitment under paragraph 2 is qualified with the terms 'as appropriate' and 'subject to national and/or domestic law'.

In paragraph 3, WHO is tasked with supporting facilities mentioned in paragraph 2, including through training, capacity building and timely support for product development, especially in developing countries. However, such assistance is to be extended only on request of the COP, arguably weakening its utility. In contrast, in the recently amended International Health Regulations 2005 (IHR), WHO can act upon request from 'any State Party'.

## Article 11: Transfer of technology and cooperation on related know-how for the production of pandemic-related health products

Article 11 contains six paragraphs, with paragraph 1 having six sub-paragraphs. And yet the provision fails to shift the status quo – technology transfer still hinges on the consent of rights holders, even in pandemic emergencies. The commitments are soft and non-binding.

Paragraph 1 outlines six flexible commitments of Parties: (i) promoting technology transfer as mutually agreed; (ii) taking measures to enhance availability of licences for pandemic-related health technologies; (iii) publishing licensing terms for equitable access; (iv) encouraging royalty waivers or reductions for developing-country manufacturers; (v) promoting technology transfer as mutually agreed to multilateral hubs; and (vi) encouraging sharing of manufacturing-related information.

'As mutually agreed' is defined as 'willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements'.

Additionally, paragraphs 2 to 6 address the following: capacity building for technology transfer (e.g., absorption capacities); cooperation in relation to time-bound measures agreed in other

fora (e.g., intellectual property waivers) to accelerate or scale up the manufacturing of pandemic-related health products; reaffirmation of the right to use to the full TRIPS flexibilities and Parties respecting such use; development or strengthening of technology transfer initiatives; and reviewing national laws to enable implementation.

(TRIPS is the Agreement on Trade-Related Aspects of Intellectual Property Rights administered by the World Trade Organization.)

Article 11 was one of the most contentious articles in the PA negotiations. Since the start of the negotiations, developing countries had been hoping for concrete commitments relating to transfer of technology. In the end, all references to technology transfer were qualified with 'as mutually agreed'. Effectively the technology transfer commitments are voluntary in nature, albeit without prejudice to the right of governments to use measures allowed under international law such as compulsory licensing to facilitate technology transfer.

Developed countries were opposed to any text that could improve the status quo. For example, with respect to 'time-bound measures', developed countries opposed references to cooperation for the 'adoption and implementation' of such measures. The text also does not create any new pathways for addressing intellectual-property-related barriers to access, beyond providing assurance of the right to use TRIPS flexibilities.

(For more on the PA's technology transfer provisions, please see the following article in this issue.)

## Article 12: PABS system

Article 12 establishes a PABS system for promoting the rapid and timely sharing of 'materials and sequence information on pathogens with pandemic potential' and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the use of such materials and sequence information. As mentioned above, the operational details, including scope and definitions, are deferred to a future PABS instrument to be annexed to the PA through further negotiations.

Nevertheless, unlike in other provisions of the PA, there is clear indication in Article 12 on securing equitable access to health products through legally binding contracts signed between participating manufacturers and WHO. Without prejudice to further detailed benefits to be set out in the PABS instrument, at least one specific benefit has been reflected in Article 12.

Paragraph 6 provides that in the event of a pandemic emergency, each participating manufacturer shall make available to WHO, pursuant to legally binding contracts signed with WHO, rapid access to a targeted 20% of their real-time production of vaccines, therapeutics and diagnostics (VTDs), with a fixed 10% to be provided to WHO as a donation and the remaining percentage, with flexibility based on the nature and capacity of the manufacturer, to be reserved for WHO at affordable prices.

Other benefits are reflected in general terms, such as VTD access in the event of a PHEIC (paragraph 7); VTD access during pre-PHEIC stages of disease outbreak [paragraph 8(c)]; licences for manufacturers in developing countries to produce VTDs [paragraph 8(d)]; and annual monetary contributions [paragraph 5(a)].

The exact modalities of these benefits are expected to be finalised during development of the PABS instrument. Importantly, even though paragraphs 7 and 8 say 'including options', the underlying fact is that access to VTDs under these paragraphs is guaranteed – but through various options. These options are purportedly for maximising the benefits by enabling various types of manufacturers to participate in PABS, according to developed countries which insisted on this phrase.

The text is not explicit about when the contracts are to be signed, owing to pressure from developed countries. This will only be settled during the PABS annex negotiations. Similarly, key terms such as 'participating manufacturer', 'pathogens with pandemic potential', 'PABS Materials and Sequence Information', and 'affordable prices' are undefined.

Several legal and institutional elements of the PABS system, such as a WHO-coordinated network of laboratories and PABS sequence database, modalities and legal certainty for access and benefit sharing including standard material transfer and data access agreements, etc., are yet to be designed. Any dilution in these elements will affect the legal enforceability of PABS benefits as well. Fortunately, Article 12 agrees that the PABS instrument shall also 'address' traceability measures along with open access to data (paragraph 3), indicating possibilities for better accountability.

The relationship between national and international access and benefit-sharing laws will also become a critical element in the design of the PABS annex. This is because paragraph 5(d)(ii) of Article 12 currently risks eroding the national access and benefit-sharing laws of developing countries by requiring their alignment with the still-unwritten annex.

## Articles 13 and 14: Supply chain and logistics; procurement and distribution

Articles 13 and 14 create a framework for procurement, allocation, distribution and delivery of pandemic-related health products, and supply chain coordination, mainly downstream (supply of

health products from manufacturer) although upstream (supply of ingredients to manufacturer) elements are also addressed. While Article 13 establishes the Global Supply Chain and Logistics (GSCL) Network, Article 14 focuses on procurement and distribution by Parties.

The GSCL Network will be a WHO-coordinated mechanism to improve equitable, timely and affordable access to pandemic-related health products during and between PHEICs. Its structure, functions and modalities are to be defined by the COP. Subject to the decisions of the COP, the GSCL Network could be tasked with identifying supply sources, barriers and stockpiling needs; promoting procurement coordination; and ensuring product allocation, distribution, delivery and assistance with utilisation including those secured by WHO through the PABS system.

One of the major concerns with Article 13 is that the functions of the GSCL Network are to be discharged by organisations best suited to carrying them out [paragraph 2(b)]. This approach risks creating a fragmented pandemic response as well as undermining accountability. The Access to COVID-19 Tools Accelerator (ACT-A) during the COVID-19 pandemic stands as a clear example of how a multistakeholder model can compromise both accountability and effective service delivery. Unfortunately, the INB appears not to have fully absorbed the lessons from the ACT-A experience.

Article 14 is notably weak, containing mostly non-binding language such as 'consider' and 'endeavour', offering limited accountability. The only partial exception is paragraph 5, which introduces a relatively stronger obligation for Parties to promote the rational use of health products and reduce waste, with support from the GSCL Network. However, even this commitment is diluted by the qualifier 'as appropriate'.

Article 14 contains provisions for each Party to 'endeavour' to publish relevant terms of its purchase agreements with manufacturers for pandemic-related health products at the earliest reasonable opportunity and to exclude confidentiality provisions that serve to limit such disclosure. Parties are also to 'consider' including in publicly funded purchase agreements provisions to promote access to developing countries such as donations, licensing and global access plans. While transparency in procurement contracts is promoted, the provision does not rule out confidential clauses.

The article also calls on Parties to reserve a share of procurement for countries with unmet needs, but with no defined thresholds. Similarly, Parties are to avoid maintaining excessive national stockpiles beyond national need. A provision on sharing products stresses the need for the shared products to have sufficient shelf-life and be accompanied by necessary ancillaries and relevant information.

## Article 18: Sustainable financing

Article 18 acknowledges the need for sustainable and predictable financing for pandemic prevention, preparedness and response. Parties are under a soft commitment to maintain or increase domestic funding and mobilise international resources, especially for developing countries. The article also promotes innovative financing, including financial reprogramming for countries facing fiscal constraints.

The article further establishes a Coordinating Financial Mechanism (CFM), but the specifics of its function and power remain subject to future decisions by the COP. Also, the CFM established under the amended IHR shall be utilised as the mechanism to serve the implementation of the PA, in a manner determined by the COP.

The CFM functions are largely identified as financing gap assessments and developing a five-year financial and implementation strategy for the PA for the consideration of the COP; promoting coordination of financial pandemic prevention, preparedness and response; identifying sources of financing and maintaining a dashboard of such funding sources; and supporting national applications for financial resources for PPR. Essentially the CFM is a mechanism for tracking, mapping, coordinating and advising on financial resources, rather than a fund for financing implementation. A worrying downside of this approach is the likelihood of external agencies undermining the decision-making role of Parties by determining the areas to be financed and therefore prioritised in the implementation of the PA.

Unlike in the amended IHR, which mandates the CFM to support the national priorities of recipient states, particularly developing countries, no such commitment exists in the PA. This marks a clear step backwards from the IHR.

On a more positive note, the PA leaves open the possibility for the COP to explore 'additional financial resources to support the implementation of this Agreement, through all sources of funding, existing and new' (Article 18, paragraph 5). Another potential avenue to influence international financial flows is through the adoption and updating of a financial and implementation strategy. Yet, even here, the commitment is weak – Parties are merely encouraged to 'endeavour to align', as appropriate, with the strategy when providing external financial support.

The implication of Article 18 is clear: financing for implementation of the PA will largely rely on ad hoc donors and agendas, which will be shaped by geopolitics and private sector priorities rather than by equity, public health needs or even realisation of the objectives of the PA. – *TWN*

# No assurance of technology transfer during pandemic outbreaks

The Pandemic Agreement does not guarantee provision of technology for the manufacture of health products, undermining prospects of broadening production and availability of these items in times of emergency.

**Nithin Ramakrishnan**


Arie Basuki (CC BY-SA 4.0)

**Without guaranteed commitments on technology transfer, it will be challenging to diversify production of pandemic-related health products like vaccines.**

THE WHO Pandemic Agreement (PA) does not secure technology transfer for when it is most critically needed – during health emergencies, despite its objective 'to prevent, prepare for and respond to pandemics'.

All references to transfer of technology in Article 11 and elsewhere in the Agreement are qualified with the clause 'as mutually agreed', which is defined in a footnote as 'willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements'.

Without guaranteed commitments on technology transfer, it will be challenging to diversify production of pandemic products.

Contrary to persistent media criticism over the three years of negotiations in the Intergovernmental Negotiating Body (INB) that Global South demands for the pathogen access and benefit-sharing system would make or break the PA deal, it was developed countries' push to make technological cooperation voluntary that nearly derailed the talks. The final text of the PA was agreed only after difficult negotiations that stretched beyond the original schedule.

It is clear that Article 11 of the Agreement, which addresses technology transfer, including knowledge, skills and expertise, does not mandate sharing by technology holders but rather remains contingent on the consent of the technology holder, even during pandemic emergencies. However, the footnoted definition leaves open the possibility for Parties to utilise rights that they have under other international agreements, such as compulsory licensing, to require the transfer of technology.

Article 11 is also riddled with other qualifier clauses such as 'as appropriate', 'where and as feasible', and 'subject to applicable law'. It also relies on best-effort language like 'encourage', 'promote' and 'facilitate' – a regrettable dilution of what could have been stronger, enforceable commitments.

The problems extend beyond Article 11. The INB introduced the 'as mutually agreed' clause into Articles 4, 12 and 19 (Article 17, after renumbering post-INB) as well as paragraph 17 of the preamble (paragraph 16, after renumbering post-INB), further weakening key provisions. An attempt was also made to introduce the footnote into Article 9.5; however, a last-minute intervention replaced 'technology transfer' with a broader clause (iii): 'provisions enabling access to technology to facilitate research and development and geographically diversified local production.'

Article 4 (on prevention measures like early containment and immunisation) and Article 10 (on sustainable, geographically diverse production) both deal with issues that rely on access to technology. But with weakened text, meaningful

technology transfer remains elusive, likely to significantly affect Articles 4 and 10 as well as undermine pandemic prevention, preparedness and response activities.

## Content of Article 11

The final title of Article 11, 'Transfer of technology and cooperation on related know-how for the production of pandemic-related health products,' was accepted only following prolonged debate in the INB negotiations.

Over the last several INB sessions, another title, 'Transfer of technology and know-how for the production of pandemic-related health products', had been under consideration. The change was made due to consistent objection from the Russian delegation to accepting any obligation to transfer or share know-how along with technology. According to Russia, they could only cooperate in this regard.

Paragraph 1 of Article 11 outlines six soft commitments:

a) To promote and facilitate, 'as mutually agreed,' technology transfer, including relevant knowledge, skills, expertise and know-how;
b) To enhance access to licences for government-held technologies and encourage private holders to do the same;
c) To improve transparency around licensing terms that impact equitable technology access;
d) To encourage rights holders to forgo or reduce royalties, particularly for developing-country manufacturers, during pandemics;
e) To promote voluntary transfers by private holders to WHO-coordinated hubs;
f) To encourage manufacturers to share production-related information during emergencies.

Additionally, paragraphs 2–6 cover the following: capacity building for technology transfer (e.g., absorption capacities); cooperation in other fora to adopt time-bound measures (e.g., intellectual property waivers); reaffirmation of TRIPS flexibilities; development or strengthening of technology transfer initiatives; and reviewing domestic laws to enable implementation.

Yet, none of these ensure that technology or know-how will actually be transferred. The phrase 'as mutually agreed' offers a clear exit route for technology holders, who can stall or reject deals citing lack of consensus. No binding obligation exists to compel private rights holders to cooperate. Parties are merely asked to 'encourage' them.

Russia also raised concerns over inequity in obliging Parties to share only government-held or funded technologies. This, it argued, would disproportionately affect Russia, where state ownership is high, while countries like the United States could evade sharing by pointing to private sector control.

Thus, what remains is whether the Parties to the PA will exercise their rights and obligations under other international agreements – including legal tools available in these agreements such as flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – to trigger sharing of technologies with developing-country manufacturers.

## The road to defining 'as mutually agreed'

Since the start of the INB negotiations, a major sticking point in Article 11 had been the developed countries' insistence that technology transfer occur only on 'voluntary and mutually agreed terms.'

Knowing this position beforehand and to overcome it, developing countries initially proposed a WHO-led technology access programme and mandatory technology transfer clauses in publicly funded research and development (R&D) contracts. However, this proposal was split across Articles 9.5 and 11.5 and significantly diluted during negotiations from the very beginning.

As the debate progressed, developed countries pushed to insert 'voluntary and mutually agreed terms' across Articles 9, 11 and 19 (post-INB Article 17) wherever transfer of technology was mentioned, while developing countries called for 'voluntary' to be dropped as a compromise.

After the newly installed Trump administration announced in January that the US was withdrawing from WHO, it was Germany which led the G7 developed countries' position to continue opposing any binding language on technology transfer. A proposed workaround was to define 'technology transfer' in a way that avoided compulsory measures. But developing countries rejected defining the term, fearing this would narrow its interpretation and set a bad precedent.

In February, the INB Bureau proposed to the 13th meeting of the INB (INB13) the following definition that did not refer to the term 'voluntary': 'For the purposes of this Agreement, Transfer of Technology is understood to be on fair and most favourable terms, including on concessional and preferential terms, and in accordance with mutually agreed terms and conditions. In the case of technology subject to patents, such transfer shall be provided on terms which recognize and respect protection of intellectual property rights.'

Both developed and developing countries did not like this proposal. The former wanted reference to 'voluntary', while the latter wanted to include a 'without prejudice' clause to safeguard the compulsory measures that may be undertaken by Parties based on rights in other international agreements.

From this point onwards, it became clear that the INB process would not lead to any advancement over the existing international legal framework on technology transfer. Much of the developing countries' efforts subsequently focused on resisting regressive standards.

After INB13 was suspended on 21 February, another definition was proposed by the INB Bureau: 'For the purposes of this Agreement, transfer of technology refers to a mutually agreed process where technology is transferred on mutually agreed terms. This understanding is without prejudice to and does not affect the measures that Parties may take in accordance with their domestic or national laws and regulations, and compliant with their international obligations on intellectual property.'

Developing countries did not accept this proposal because 'mutually agreed process' was synonymous with 'voluntary'. After informal meetings, the Bureau circulated yet another proposal on 25 March with a further tweak dropping the word 'mutually' from the definition, but that too failed to gain traction.

When INB13 resumed in April, the Ambassador of Mexico, not a regular participant in the INB negotiations, appeared in person on 11 April and proposed an alternative to the terms 'voluntary' and 'mutually agreed process'. She proposed to use 'willingly undertaken' in the definition instead of 'agreed process', and pleaded for the INB to agree, in the interest of time and to conclude the PA negotiations. However, developing countries were not willing to accept this proposal either.

Late in the night of 11 April, a proposal to define 'mutually agreed' instead of 'technology transfer' was officially tabled. The proposal was to add 'as mutually agreed' to the text wherever technology transfer was mentioned in Article 11 and elsewhere, and to insert a footnote defining 'as mutually agreed' as follows: 'For the purposes of this agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.'

According to certain diplomatic sources, the idea of defining 'as mutually agreed' as opposed to defining 'technology transfer' seems to have evolved from a meeting held outside of WHO premises, and some non-state actors had also been involved in detailing and promoting the idea. But for the majority of the delegations in the INB, this came up as a late-night solution on 11 April, emerging from the personal initiatives of a group of delegates making their best efforts to conclude the PA negotiations. Brazil reportedly proposed this definition.[1]

The phrase 'willingly undertaken' was particularly unpopular amongst several developing countries. Despite this dissatisfaction, compromise-seeking delegates, supported by the WHO Director-General and Secretariat, urged acceptance. Members from WHO's developing-country regions were reportedly lobbied to support it. Some civil society and academic voices from the Global North also promoted the compromise, without fully considering its long-term implications.

Most developing countries reluctantly accepted the definition after marathon negotiations that lasted over 20 hours, ending on 12 April. However, the European Union (EU) and Canadian delegations expressed reservations, saying they needed to consult their capitals, prompting an extension of INB13 to 15 April.

## Limited discussions on 'as mutually agreed' definition on 15 April

When INB13 resumed on 15 April, INB Co-Chair Ambassador Anne-Claire Amprou (France) opened the session by proposing that the phrase 'as mutually agreed' be added alongside 'transfer of technology' and be applied to several articles, specifically Articles 4.6, 9.5, 11.1(a), 11.1(e), 11.5, 12.8(e) and 19 (post-INB Article 17), as well as preambular paragraph 17 (post-INB paragraph 16).

This proposal surprised many delegations, as the compromise had initially been suggested only for Articles 11 and 19 (post-INB Article 17), not for Articles 4, 9 and 12. Delegations from the Africa Group, Malaysia, Bangladesh, Indonesia and others contested the automatic transposition to these additional articles. They insisted that such an approach should only be accepted after a detailed consideration of the relevant provisions.

The Co-Chair insisted on adopting the approach uniformly across all provisions and reiterated several times that the compromise deal among INB members was to use the phrase 'as mutually agreed' with a footnote wherever 'technology transfer' was used.

Several developing-country delegations confirmed on anonymity that there had been no such deal beyond Articles 11 and 19 (post-INB Article 17). Under Article 9, there was a note which allowed for coming back to consider the language of paragraph 5 taking holistically the outcomes of the Article 11 negotiations. This was not to indicate automatic transposition of the approach adopted in Article 11 to Article 9. Certainly Articles 4 and 12 had been agreed without any notes and conditions.

Some delegations, including Eswatini, Kenya and India, pointed out that the phrase 'as mutually agreed' also appeared in provisions unrelated to technology transfer. For instance, Article 21.4 read: 'The Parties shall protect, as mutually agreed, any confidential information that is exchanged.' The phrase 'for the purposes of this agreement' in

the footnote definition could cause confusion in the implementation of this provision. Hence, those delegations argued that this was 'inappropriate' and should be removed. In response, the Bureau and Secretariat clarified that for provisions like Article 21.4, there would be no footnote.

## Implications of 'as mutually agreed'

**Trivialising pandemic emergencies and preparedness:** The PA's reliance on the phrase 'as mutually agreed' for technology transfer undermines the urgency of pandemic emergencies by making technology transfer dependent on voluntary negotiations between technology holders and recipients. This approach reduces pandemic situations to normal market conditions, overlooking the exceptional nature of such crises, and diminishes the primacy of public health and the right to life over pharmaceutical companies' intellectual property rights and profits. Although the definition is without prejudice to 'the rights and obligations of the Parties under other international agreements', it sends a problematic message that emergencies do not warrant exceptional responses, effectively trivialising pandemic preparedness.

**No concessional terms for developing countries:** Unlike other international agreements such as the Convention on Biological Diversity (CBD), this definition as well as other parts of Article 11 of the PA fail to acknowledge the special status of the developing countries and to provide access to technologies on fair and concessional terms.

For instance, Article 16.2 of the CBD states: 'Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed.…'

Unlike in the above stipulation, there is no call in Article 11 of the PA, or in the footnote definition of 'as mutually agreed', for fair or concessional terms for developing countries.

## Limited cooperation on time-bound measures for technology transfer

Paragraph 3 of Article 11, addressing cooperation among Parties within international and regional organisations to accelerate or scale up production of pandemic-related health products through time-bound measures, was another contentious provision. An illustrative example of such measures is the TRIPS decision adopted by the World Trade Organization (WTO) during the COVID-19 pandemic.

Initially, on 10 April, INB member states reached tentative agreement on paragraph 3 as follows: 'The Parties shall cooperate, as appropriate, to implement time-bound measures where agreed within the framework of relevant international and regional organisations to which they are a party, to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability, accessibility and affordability of pandemic-related health products during pandemic emergencies.'

However, late-night negotiations on 11 April saw developed countries, led by the EU, retreat from this position. They proposed changing the text to: 'The Parties shall cooperate, where deemed as appropriate, with regard to time-bound measures....'

The Africa Group opposed this new proposal made by the EU and allies. It also objected to the phrase 'where agreed,' arguing it could be interpreted to remove the obligation to cooperate in adopting such measures in other organisations.

Botswana, representing the Africa Group, emphasised on 15 April that limiting cooperation solely to measures already adopted elsewhere was redundant and would create unnecessary delays, referencing the two-year negotiation delay experienced by India and South Africa's TRIPS waiver proposal at the WTO.

India tried to weigh in supporting the Africa Group proposals and proposed to add 'adoption and implementation' and also delete the EU proposal of 'where deemed'. The Indian proposal would have read: 'The Parties shall cooperate, as appropriate, with regard to adoption and implementation of time-bound measures where agreed within the framework of relevant international and regional organisations....'

However, the INB Co-Chair did not reflect the same in the on-screen text, despite support from Botswana (speaking on behalf of the Africa Group) and South Africa. Meanwhile the phrase 'where agreed' was replaced with 'to which they have agreed' as proposed by the EU.

After many rounds of back and forth, finally paragraph 3 was agreed as follows: 'The Parties shall cooperate, as appropriate, with regard to time-bound measures to which they have agreed within the framework of relevant international and regional organisations to which they are a party, to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability, accessibility and affordability of pandemic-related health products during pandemic emergencies.'

The compromise was achieved by explaining that the clause 'with regard to' is open-ended and could mean both adoption and implementation of measures available within the framework of other international organisations.

## Transfer of publicly funded technologies

Article 9.5 of the PA addresses the inclusion of technology transfer conditions in publicly funded R&D agreements for pandemic-related

products. Developed countries attempted to insert the phrase 'as mutually agreed' specifically into clause (iii) of Article 9.5 that calls for inclusion of conditions for technology transfer.

Developing countries, led notably by Malaysia, Kenya and Botswana, strongly opposed this insertion. They argued that adding 'as mutually agreed' was inappropriate here, since the clause explicitly refers to obligations on Parties themselves who are funding the R&D, to include clear and effective technology transfer provisions in their public financing agreements.

Malaysia emphasised that the type and scope of technology transfer conditions in public financing agreements must be left to the discretion of the funding Parties, allowing them flexibility and autonomy to ensure equitable and timely access to pandemic-related health products, particularly for developing countries. Any reference to mutual agreement with technology holders, Malaysia argued, would constrain Parties' ability to set effective terms to achieve the intended public health outcomes.

To develop a compromise, Norway proposed replacing 'technology transfer' with a broader clause (iii): 'provisions enabling access to technology to facilitate research and development and geographically diversified local production.' This eventually made it into the final text. ◆

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## Notes

1. P. Patnaik (2025). Nearing a Deal: Countries Converge Closer to Consensus [Pandemic Treaty Negotiations]. *Geneva Health Files.* https://genevahealthfiles.substack.com/p/nearing-a-deal-countries-converge-closer-consensus-pandemic-agreement-geneva-world-health-organization-pabs-tech-transfer-prevention-multilateralism-global-health

# Protecting profits, endangering lives

The new drug lenacapavir marks a breakthrough in the fight against HIV/AIDS but manufacturer Gilead's aggressive use of the patent system to prolong its monopoly on production is impeding access.

LENACAPAVIR (LEN), a groundbreaking medication for both HIV treatment and pre-exposure prophylaxis (PrEP), marks a significant advancement in the fight against HIV. Its long-acting formulation – requiring just two doses per year – improves adherence, reduces the burden of frequent dosing, and offers a more convenient, effective option for both prevention and long-term management.

However, priced exorbitantly by Gilead at $42,250 per patient per year, LEN remains out of reach of most patients. A 2024 expert study led by Andrew Hill of Liverpool University estimates that a generic version of LEN could be produced for as little as $40 while still maintaining a 30% profit margin, exposing the stark contrast between production costs and market price.[1] Ensuring widespread, affordable access to long-acting treatments like LEN is critical to preventing new infections and advancing the global fight against HIV/AIDS. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), with the LEN breakthrough, the world has a shot at ending AIDS.[2]

Yet, Gilead is aggressively working to extend its monopoly on LEN through patent 'evergreening' strategies, delaying competition and keeping prices high.

Arne Hoel/World Bank (CC BY-NC-ND 2.0)

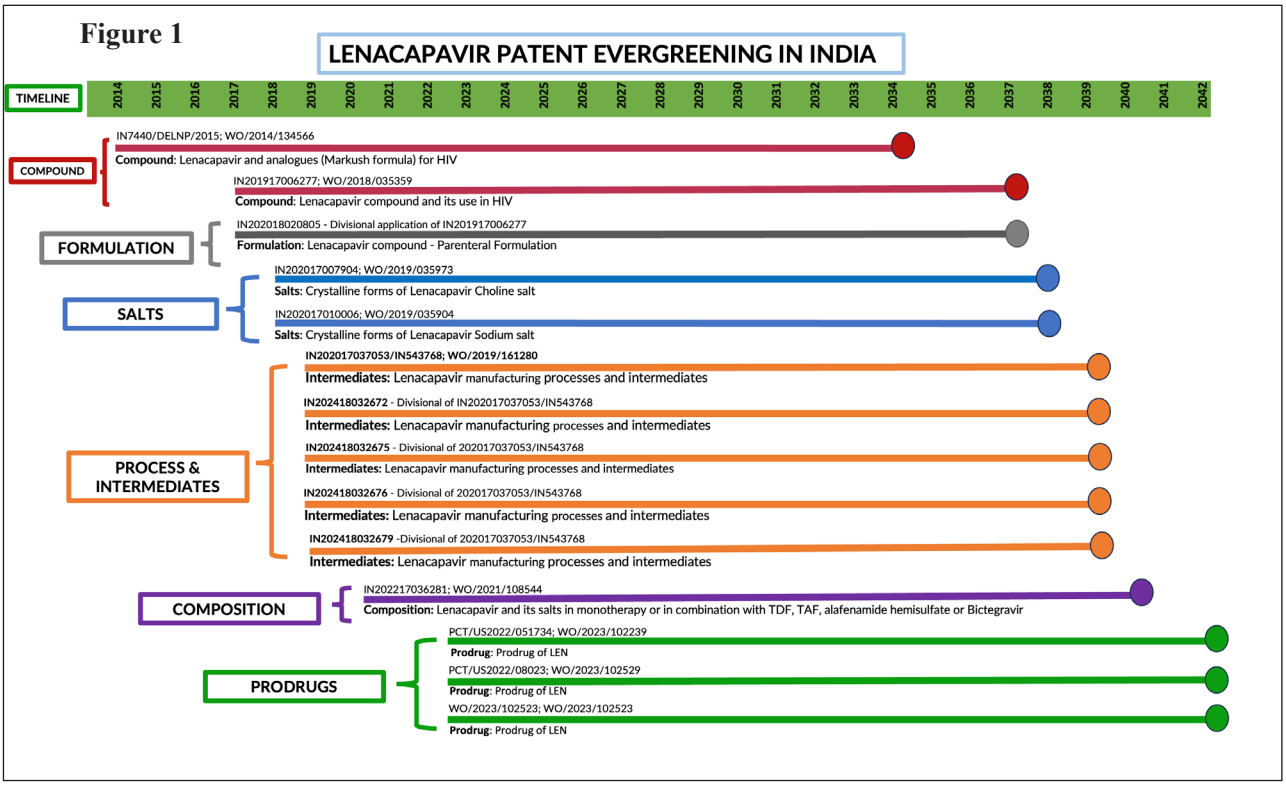
**Testing for HIV. Extension of the patent monopoly on lenacapavir, a potential breakthrough anti-HIV drug, will hinder competition from generics and keep prices prohibitively high.**

## PrEP access and affordability barriers

Globally, 40 million people are living with HIV, yet only about 30 million have access to life-saving treatment. According to UNAIDS, more than 3,500 people acquire HIV every day, and over the past five years, reductions in new infections have been marginal.[3] More than 60% of new infections occur within marginalised communities, yet access to PrEP remains severely limited. In 2023, only 3.5 million people used oral PrEP to prevent HIV transmission – far below the 10 million target for 2025, which is crucial for meaningfully curbing new infections.

New long-acting treatments have the potential to revolutionise HIV prevention, allowing people at high risk to protect themselves with just a few injections per year. LEN is currently approved for the treatment of multi-drug-resistant HIV infection in adults.[4] In 2025, the United States Food and Drug Administration accepted a new drug application for LEN as a twice-yearly injectable HIV-1 capsid inhibitor for use in HIV prevention as PrEP.[5] The PURPOSE 1 trial for PrEP, conducted among cisgender women in sub-Saharan Africa, demonstrated 100% efficacy, with no HIV infections reported.[6] In PURPOSE 2, a multicentre trial in high-risk populations, LEN reduced HIV infections by 96% compared with background HIV incidence (bHIV), with only two incident cases among 2,179 participants.[7] Further, the CAPELLA and CALIBRATE trials showed that LEN helps to control HIV in both treatment-experienced individuals with multi-drug-resistant HIV and

**Figure 1**




treatment-naïve individuals living with HIV.[8]

These results underscore lenacapavir's potential as a game-changing, long-acting PrEP option. However, Gilead's patent power play – specifically its evergreening strategies to extend market monopoly – allows it to impose excessively high prices and hinder competition from generics, delaying widespread, affordable access and putting millions at risk.

## Patent evergreening: Extending Gilead's monopoly over lenacapavir

Gilead is employing patent evergreening tactics to extend its monopoly on lenacapavir. This common strategy among pharmaceutical companies involves staggering patent filings and securing additional patents on modifications, different forms or new uses of an existing compound to prolong exclusive rights beyond the expiration of the primary patent (Figure 1). By leveraging these secondary patents, Gilead can delay generic competition and continue to keep prices artificially high, consequently restricting affordable access.

Between 2014 and 2022, Gilead filed 14 patent applications for LEN in India. The latest of these applications, if granted, is set to expire in 2042 – nearly 28 years after the first application was filed. Notably, patent filings continue unabated, with the submission of an additional patent application recently (IN20211700214) though its specifics are yet to be disclosed. Granting these patents would legitimise Gilead's evergreening strategy of extending its patent monopoly beyond the standard 20-year period, which, in this case, will

**Figure 2**

**Categorisation of Gilead's patent applications for lenacapavir in India**

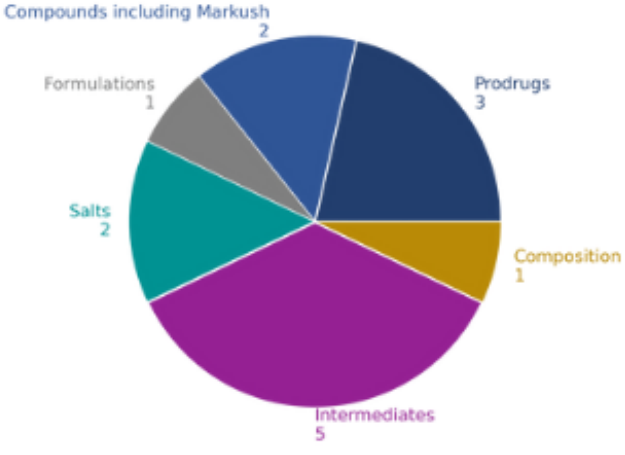


**Figure 3**

**Patent Oppositions / Third Party Observations**

| Title / Description of Invention | Application / Publication Number | Jurisdictions Where Opposition / TPO Filed |
|---|---|---|
| Lenacapavir and analogues (Markush formula) for HIV | PCT/US2014/019663; WO/2014/134566 | India, Thailand, Argentina |
| Lenacapavir compound and its use in HIV | PCT/US2017/047416; WO/2018/035359 | India, Argentina, Thailand, Vietnam, Indonesia |
| Lenacapavir compound (parenteral formulation) | IN202018020805 (divisional of IN201917006277, India) | India |
| Crystalline forms of lenacapavir choline salt | PCT/US2018/000248; WO/2019/035973 | India |
| Crystalline forms of lenacapavir sodium salt | PCT/US2018/000172; WO/2019/035904 | India |
| Prodrug of lenacapavir | PCT/US2022/051734; WO/2023/102239 | Colombia, Eurasian Patent Organization |

end in 2034, when the first patent expires.

Gilead's aggressive patent strategy employs a multi-faceted approach designed to strengthen its exclusive rights over LEN and erect entry barriers to Indian manufacturers capable of producing affordable generic alternatives. Figure 2 categorises Gilead's 14 patent applications based on the types of claims.

The first application (IN7440/DELNP/2015) contains patent claims with a Markush structure, a type of broad patent claim commonly used by pharmaceutical companies to seek patent protection over a large number (often millions) of compounds, rather than a specific chemical structure, in a single patent. In this first application that features a Markush structure, the LEN compound was not specifically disclosed, although complete disclosure is a prerequisite for anyone seeking patent protection.

The second application (IN201917006277) specifically claims the LEN compound as well as formulations and intermediates for the preparation of lenacapavir. Additionally, it also claims a few compounds that are not related to LEN and are structurally distinct from lenacapavir.

A subsequent patent application (IN202018020805) includes a parenteral formulation (a pharmaceutical preparation which is designed for administration via means like injection and infusion). This application is a divisional application stemming from the original compound application (IN201917006277).

Further applications have been filed on different forms of salts (choline and sodium) and polymorphs of LEN (IN202017007904 and IN202017010006). By patenting different salts and polymorphs, Gilead is strategising to extend its patent monopoly over LEN until 2039. Gilead has also filed at least five patent applications covering the manufacturing process and intermediates of lenacapavir, with the last four of such applications being divisional of a single granted patent (IN202017037053/IN543768).

Additionally, Gilead has also filed an application (IN202217036281; WO/2021/108544) which was originally filed as a method-of-treatment patent application in Europe and the US. However, the claims were entirely amended to composition claims, presumably to circumvent Section 3(d) and (i) of India's Patents Act 1970 which disallows patents being granted on treatment methods.

Gilead has also submitted multiple prodrug patent applications in India (WO2023102239; WO2023102529; WO2023102523), reinforcing its broader strategy to extend patent protection and maintain market exclusivity for lenacapavir.

Figure 2 clearly illustrates how Gilead is strategically manipulating the patent system to secure extended market monopoly over LEN – enabling it to control the production and supply of lenacapavir, dictate market prices and maximise profits.

In an apparent effort to deflect criticism of its evergreening and monopolistic tactics, Gilead announced on 2 October 2024 that it would grant voluntary licences (VLs) to six manufacturers from developing countries to produce and supply generic versions of LEN to 120 low- and middle-income countries. While the company claims this move is aimed at expanding access, the details of the licence tell a different story. The licence explicitly excludes many upper-middle-income countries (UMICs) as classified by the World Bank – despite these countries accounting for 41% of new HIV infections and 37% of the global population living with HIV.[9] Notably, supply to these excluded countries is prohibited even in cases of compassionate use, the absence

of patents, or where compulsory licences have been issued.

The VL also includes several restrictive and anti-competitive clauses, including stringent anti-diversion provisions and limitations on sourcing active pharmaceutical ingredients. These terms strongly suggest that Gilead's VL is less about public health and more a calculated move to suppress criticism, maintain market control and protect its LEN monopoly – especially as its patent claims face growing legal challenges worldwide.

## Global oppositions to Gilead's patent applications

Gilead's patent claims are being actively challenged in several countries, such as detailed in Figure 3.

Recently Argentina's National Institute of Industrial Property (INPI) rejected Gilead's patent application for the LEN compound (Application No. ARP170102299) on the grounds that the compound had already been disclosed in the Markush patent claims and therefore violates Argentina's patent law, making it unpatentable.[10]

Prior to the rejection, INPI had raised its objections to the grant of the patent with Gilead but did not receive an adequate response within the stated timeframe. In its pre-final rejection order, INPI cited prior art including the earlier Markush disclosure encompassing LEN. The examiner emphasised that the disclosure of a class of compounds through a Markush structure constitutes prior art as it inherently includes all compounds that fall within the scope of that structure. Thus, even if a compound is not explicitly named, it is considered to be disclosed if it fits within the parameters of the Markush structure. Gilead did not respond to the objection within the prescribed timeframe, resulting in the rejection of the application.

## Challenging LEN patent applications in India

As shown in Figure 3, pre-grant oppositions have been filed in India against key patent applications. These applications include the very first patent application filed by Gilead, claiming LEN through a Markush structure. Further, pre-grant oppositions have been filed against the patent applications claiming the LEN compound as well as two patent applications claiming different salt forms of LEN. The major grounds for the pre-grant oppositions are as follows:

**Novelty:** The first patent application claims the LEN compound through a Markush structure, as shown in Figure 1. Regardless of the broader debates around the patentability of a Markush structure, it is a well-established fact that this initial application discloses the LEN compound, thereby compromising the novelty claims of subsequent applications on LEN. Gilead has cited a technical ground to bypass the novelty objections, claiming that the patent applications covering salt forms of LEN were filed prior to the publication of the LEN compound patent application.

**Inventive step:** Though LEN is the first capsid inhibitor approved by the regulatory agencies, it is not the first capsid inhibitor molecule. Capsid inhibitors have been known to the scientific community since 2003, and numerous efforts have since been made to bring compounds in this class to market. The core of LEN is based on a capsid molecule developed in 2010 by Pfizer known as PF-3450074. The pre-grant oppositions argue that changes made by Gilead are obvious to a person skilled in the art and therefore lack inventive steps. At the time of these applications, capsid technology was known and scientists commonly used docking techniques, a method where computer simulations predict how well a molecule binds to a target (like the HIV capsid). This made it easier to identify potential inhibitors, reducing the element of invention.

**Insufficient disclosure:** The first application containing the Markush structure covers many possible chemical structures and the applicant is expected to provide detailed steps to show the enablement of each of the structures, i.e., how these structures actually work. However, the application does not disclose clear steps to make the claimed compounds, nor does it include specific synthetic routes, experimental data or biological activity details for all claimed compounds or proof that all the claimed compounds work. This makes it unclear whether all the compounds covered in the patent can actually be made and used as intended. Without this information, the claims are too broad and uncertain, failing to meet the requirement that a patent must fully explain how the invention is carried out. Similarly, the descriptions in other patent applications for the compound also do not provide enough information for someone with basic knowledge in organic chemistry to make the claimed compounds, such as lenacapavir compound or its salts and crystals.

**Section 3(d):** One of the important safeguards against patent evergreening is Section 3(d) of the Indian Patents Act. This section contains a list of elements that are excluded from patent protection. It states: 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of

isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy'.

According to Section 3(d), any new form of a known substance is patentable only if the new form results in enhanced efficacy. None of the subsequent applications, including the applications on salts, have shown any evidence of enhanced efficacy compared with the base compound. In addition, it is also important to note that the voluntary licence issued by Gilead explicitly lists multiple patent applications (as detailed in Appendix 2 of the VL), and states that they all pertain to a single product – lenacapavir.

This clearly indicates that the subsequent applications do not meet the requirements of Section 3(d), as they fail to demonstrate significant enhancement in efficacy over the original disclosure.

## Conclusion

Gilead's evergreening strategy for LEN reflects a broader pattern of delaying access to improved treatment options while prioritising profit maximisation at the expense of timely affordable care for patients. The large number of patent applications filed in India is a deliberate tactic to restrict the freedom to operate for generic manufacturers. This layering of patents is about creating a thicket of legal obstacles, significantly raising the costs and risks for generic producers and delaying the availability of more affordable alternatives. The resulting uncertainty around patent validity discourages generic companies from investing in the development of cost-effective alternatives, thereby weakening competition and ultimately limiting access to life-saving treatment.

Addressing these monopolistic practices requires a combination of legal challenges, patent oppositions and policy reforms. The situation of LEN underscores the enduring relevance of the Indian Supreme Court's landmark ruling in the Novartis case.[11] In that decision, the Supreme Court stated: 'We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.'

The granting of excessive patents on LEN risks stifling fair competition and delaying the entry of affordable alternatives – highlighting the urgent need for stronger scrutiny when granting patents and for pro-competition policies to safeguard global access to life-saving medicines. – *TWN*

*The above was first published as a Third World Network Briefing Paper (May 2025, https://twn.my/title2/briefing_papers/twn/TWN%20Briefing%20Paper_Abusing%20the%20Patent%20System.pdf).*

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# The ever-present threat of evergreening

Apart from lenacapavir, other crucial medicines have also been the target of patent evergreening by Big Pharma. *Kanaga Raja* looks at the case of the tuberculosis drug bedaquiline in Thailand.

THE practice of evergreening patents has always been a 'common trick' used by multinational pharmaceutical companies to extend their monopolies, with the case of bedaquiline, a key drug in treating multi-drug-resistant tuberculosis (MDR TB) in Thailand, being just one such example, according to the Thai Network of People Living with HIV/AIDS (TNP+).

In a post on its website on 27 May, the Make Medicines Affordable (MMA) campaign, led by the International Treatment Preparedness Coalition (ITPC) and partners, quoted Chalermsak Kittitrakul, TNP+'s Project Manager for Access to Medicines, as saying: 'Evergreening has always been used as a common trick by multinational pharmaceutical companies to extend their monopolies that hinders the public's access to essential medicines.'

'This tactic also causes heavy and unnecessary workload on the DIP's [Thai Department of Intellectual Property] patent examiners,' he said.

'The case of bedaquiline is just one example, where a single drug has multiple patent applications to extend the unjustified monopolies,' Kittitrakul pointed out.

Filing multiple patent applications is a common strategy used by pharmaceutical companies to block generic competition. In the absence of opposition and weak examination by patent offices, 20-year patent monopolies are often granted for each application.

According to MMA, for over five years, TNP+ and the AIDS Access Foundation have been advocating for the removal of barriers to access to MDR TB drugs by filing oppositions to patent applications for bedaquiline in Thailand. It said that after lengthy efforts, the patent applications have been rejected and there is now no patent barrier to bedaquiline in Thailand, allowing the country to import generic versions at an affordable price and provide them to patients under the national health insurance schemes at no cost.


Vysotsky (CC BY-SA 4.0)

**Applications filed by Janssen Pharmaceuticals, a Johnson & Johnson subsidiary, to effectively extend its patent monopoly on the TB drug bedaquiline in Thailand have been rejected.**

Providing some background, MMA said Janssen Pharmaceuticals N.V., wholly owned by Johnson & Johnson (J&J), filed five patent applications for bedaquiline in Thailand. The first, which was for the base compound, was granted and later expired in June 2023, while the other four were evergreening applications. In 2020, the AIDS Access Foundation and TNP+ filed information with the DIP to oppose and request that all four patent applications be rejected.

In June 2023, the DIP decided to reject two applications, which were applications filed for the use of bedaquiline for the treatment of MDR TB and latent TB. However, in September 2023, J&J appealed the decision. The DIP ruled on the appeal in February 2024, upholding the first ruling and dismissing both applications as they did not qualify for patents under Thai law. This ruling is final and if J&J disagrees,

the company may file a lawsuit with the Intellectual Property Court.

In April 2024, J&J decided to drop the other two applications, which were related to the fumarate salt and the paediatric formulation of bedaquiline.

MMA pointed out that bedaquiline has been approved for inclusion in Thailand's National List of Essential Medicines for the treatment of MDR TB since 2019. From 2020 to 2024, the national health insurance systems purchased and imported the original bedaquiline from J&J at an average cost of 35,672 baht per six-month treatment (about $1,100) for 724 patients per year on average. From 2024 to 2025, J&J reduced the price to 11,734 baht per treatment.

However, from 2025 to 2026, Thailand is able to purchase generic bedaquiline from India for only 5,348 baht per treatment (about $160), increasing access to treatment in Thailand to almost 1,000 cases per year.

In its post, MMA quoted Kittitrakul of TNP+ as saying: 'The civil society's movement on opposing the patent applications for bedaquiline started at the 50th Union World Conference on Lung Health in Hyderabad, India in 2019. Civil society representatives from various countries met and agreed to join hands in campaigning for access to … bedaquiline by filing oppositions to the patent applications related to bedaquiline.'

Kittitrakul noted that in the following years, oppositions began to be filed in India, Brazil, Thailand, Ukraine, Belarus, Moldova, Kyrgyzstan, Vietnam and Indonesia.

Of the Thai DIP's ruling on the two patent applications, he said it indicated that both applications did not violate Section 9(4) of the country's Patent Act, which does not grant patents to inventions on methods of diagnosis, treatment or cure of human and animal diseases. This had been one of the main arguments cited by civil society to reject the applications.


Photo by CEphoto, Uwe Aranas (CC BY-SA 4.0)

**A travel medicine clinic in Chiang Mai, Thailand, where tuberculosis, among other diseases, is treated. With no more patent barrier to bedaquiline, Thailand can now provide generic versions at no cost under its national health insurance scheme.**

Instead, the DIP rejected both the applications on the grounds that they violated Sections 5(1) and (2) because the inventions concerned were not 'new inventions' and were not 'inventions with an inventive step'.

'The chemicals referred to in the applications were chemicals that had been previously disclosed. The treatments of drug-resistant TB and latent TB with the same group of drugs had also been disclosed before,' said Kittitrakul. 'This invention is still a process of using the same compounds to produce drugs to treat tuberculosis as before, and it is still a composition of drugs with the same compounds to treat new diseases only.'

The DIP's ruling was consistent with the information and reference documents that civil society had submitted to consider rejecting the applications, Kittitrakul pointed out.

However, he noted that J&J filed an additional application in late 2024 for the long-acting formulation of bedaquiline. TNP+ submitted a letter and information to the DIP asking the Department to consider rejecting the application because the application is against the Thai patent law and the subject matter does not qualify for patent protection.

'Many of these evergreening patent applications seek patent protection on the therapeutic methods, which is clearly against our law,' said Kittitrakul. 'However, the applications are written deceptively in a way that makes it look like they are not for therapeutic use. And they also include claims on chemical compounds and manufacturing processes that were previously stated in other applications already filed or publicly disclosed.'

Such patent applications, Kittitrakul suggested, should be rejected from the earliest stages of consideration and not be allowed to remain in the process.

He said the current patent system has been repeatedly abused and does not truly promote innovation and access to medicines, but rather is exploited by the multinational pharmaceutical industry to increase monopoly and profit on people's lives and health.

'This system creates and extends inequalities in access to medicines and should be reformed by [putting] public health interests before trade benefits,' said Kittitrakul. ◆

*Kanaga Raja is the Editor of* SUNS (South-North Development Monitor)*, which is published by the Third World Network. This article first appeared in* SUNS *(No. 10237, 9 June 2025).*

# Colombian civil society's fight for access to affordable medicines

Civil society groups in Colombia have long championed greater accessibility of patented medicines, culminating in a historic move by the country to break the patent monopoly on a key HIV drug.

**Juliana López Méndez**

COLOMBIA has a significant track record in using the flexibilities established under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure access to medicines.

The TRIPS Agreement in the World Trade Organization (WTO) obliges all WTO member states to recognise patents in respect of medicines, thereby enlarging and entrenching the rights of patent holders at the expense of consumers. The effect of such all-encompassing patents has been to confer monopoly rights on international drug companies in the production and distribution of their patented drugs. By shutting out competition, the TRIPS Agreement gives drug companies the ability to charge high monopoly prices for their drugs.

The crux of the issue is how to make medicines more affordable to more people who need them. HIV/AIDS drugs are just one high-profile example. Many other drugs for tuberculosis, malaria, cancer, asthma, diabetes and rare diseases, among others, are made unaffordable simply because drug companies have been able to block competition from other firms and products through the use of patents.

While the TRIPS Agreement obliges WTO members to provide patent protection for drugs, it also allows them to take certain measures (e.g., government use of patents, compulsory licensing, parallel importing and exceptions to patent rights) which override or limit patent rights under certain conditions. These measures have, in fact, been introduced as a means of balancing patent rights with the public interest of encouraging competition, consumer protection and, in the case of drugs, access to affordable medicines.

Developing countries also pushed for an interpretation of the TRIPS Agreement which guaranteed the right of WTO members to use measures such as compulsory licences and parallel imports. The result is the Ministerial Declaration on the TRIPS Agreement and Public Health, adopted by the WTO members at the Doha Ministerial Conference in November 2001. The Doha Declaration states that the TRIPS Agreement 'does not and should not prevent members from taking measures to protect public health'. It also reaffirms the right of members to issue compulsory licences (and the freedom to determine the grounds on which the licences are granted) and confirms their right to make use of parallel importing. The Doha Declaration is significant because it recognises the negative impacts of an inflexible implementation of the TRIPS Agreement, and therefore, the need to balance commercial interests in patent rights with public interest in ensuring access to medicines.

In this context, in Colombia, civil society organisations such as the IFARMA Foundation have played a key role in leading or backing several requests for declarations of public interest to support compulsory licensing. Under Colombian law, such declarations enable the Superintendence of Industry and Commerce (SIC) to then issue compulsory licences for the relevant patented products.

The first of the civil society initiatives dates back to July 2008, when a declaration of public interest was requested for the HIV/AIDS drug Kaletra. At that time, the SIC returned the file, arguing its lack of competence according to Decree 4302 of 2008, which establishes the procedure for issuing declarations of public interest. Additionally, Kaletra's patent holder, Abbott Pharmaceuticals, filed a right of petition and a tutela action requesting (a) the rejection of the request and (b) its participation in the process in case the request was successful.

Subsequently, in March 2010, IFARMA, Fundación Misión Salud and Mesa de Organizaciones con Trabajo en VIH/SIDA filed a direct request before the SIC with the purpose of initiating an administrative procedure to obtain a compulsory licence for Kaletra, invoking reasons of social emergency in health. However, the SIC reiterated its incompetence to suspend granted patents or intervene in pending applications related to products involved in the declaration of social emergency.

In September 2012, the Administrative Court of Cundinamarca ordered the Ministry of Health to regulate the price of Kaletra and urged the SIC to open investigations to determine

whether Abbott had respected the reference prices. As a result of these actions, the SIC sanctioned the pharmaceutical company for marketing the drug at above the maximum price allowed. This pressure resulted in the inclusion of Kaletra in the direct price control regime.

In November 2014, several civil society organisations filed a request for a declaration of public interest in relation to the cancer drug imatinib, produced by the Swiss pharmaceutical firm Novartis under the Glivec brand name. In March 2015, the Ministry of Health notified that the process was underway. However, towards the end of May, the Swiss government sent an official communication opposing the measure. In response, IFARMA, together with other organisations, issued an open letter to the Swiss government, supporting the right of the Colombian state to grant compulsory licences in accordance with international law. As a result of these actions, imatinib became the first drug to be declared of public interest by the Ministry of Health and a significant reduction in its price was achieved.

In October 2015, IFARMA requested that all direct-acting antivirals for the treatment of hepatitis C – including telaprevir, boceprevir, sofosbuvir, simeprevir, daclatasvir, faldaprevir and ledipasvir – be declared of public interest, arguing that their high prices threatened the financial sustainability of the health system. However, pressures exerted by the international pharmaceutical industry caused an unusual delay in the process. Only in 2019 did the Technical Committee meet to analyse the request and issue its recommendation. Finally, the Ministry of Health opted to implement an alternative mechanism: centralised purchasing through the Strategic Fund of the Pan American Health Organization (PAHO).

## Compulsory licence for dolutegravir

The above developments can be seen as paving the way for the landmark achievement in 2023 when Colombia navigated a complex web of legal, political and industry hurdles to become the first country in the Americas to issue a government use license (a form of compulsory licence). The licence was for the HIV treatment dolutegravir.

Dolutegravir is a cornerstone in modern HIV therapy due to its superior efficacy, tolerability and resistance profile compared with older treatments. However, its high cost has historically limited access in many low- and middle-income countries, including Colombia.

According to the Colombian government, the estimated cost of treatment with dolutegravir, as sold by ViiV under the brand name Tivicay, was approximately $1,224 per patient per year in 2023 in Colombia. The international medical humanitarian organisation Médecins Sans Frontières (MSF) said this was an exorbitant mark-up when compared with the price of $22.80 or $44 per patient per year for generic versions of dolutegravir offered in 2023 through the Global Fund and PAHO respectively.

Now, under the government use licence, the price available to the Ministry of Health, $44 per patient per year, has enabled affordable access to generic dolutegravir.

Formal implementation of the government use licence materialised with the issuance of Resolution 20049 of 2024, which establishes the regulatory framework for its execution. With the licence, and through a centralised purchasing process, 819,346 vials of the pharmacological combination dolutegravir 50 mg + lamivudine 300 mg + tenofovir disoproxil fumarate 300 mg, produced by APL Health Care Limited (India), were acquired. This acquisition was financed with resources from the Global Fund and managed by the Administradora de los Recursos del Sistema General de Seguridad Social en Salud (ADRES).

The direct beneficiaries of this measure include Venezuelan migrants living with HIV, recently diagnosed patients, as well as people requiring post-exposure prophylaxis. In operational terms, the distribution of the medicine by the Ministry of Health is currently in the logistical conditioning phase. However, the units assigned to the territory have already begun to be distributed to the target populations.

The issuance of the government use licence by Colombia has been widely praised by global health advocates and organisations such as MSF, Public Citizen and Global Humanitarian Progress Corporation Colombia. The World Intellectual Property Organisation (WIPO) has stated that Colombia's pursuit of a compulsory licence for dolutegravir shed light on the complexities of intellectual property licensing schemes and pricing of medicines globally.

However, the implementation of the compulsory licence has encountered obstacles: on the one hand, pressure from pharmaceutical companies who argue that this licence may discourage innovation, and on the other hand, they consider the issuance of the licence illegitimate and illegal, which has generated intense debate in the country. The measure has faced strong opposition from the pharmaceutical industry trade body AFIDRO, as well as from the patent holders – ViiV Healthcare, GlaxoSmithKline and Shionogi – who have filed multiple legal and administrative actions in different institutional settings in order to reverse the decision. In this context, IFARMA has taken a leading role in defending the compulsory licence and the legitimacy of its implementation in accordance with the principles of international public health law.

Further, there is a lack of

clarity about the regulations on the use of compulsory licences, which has created uncertainties for both healthcare providers and patients. The Benefit Plan Administration Companies (EAPB) in Colombia have taken advantage of this lack of knowledge to set up additional administrative barriers that have resulted in patients not being able to access even the treatments covered by the licence.

The EAPB act as intermediaries between the state, citizens and providers for the country's universal health coverage system. They are responsible for managing public health resources and ensuring that the services under the Health Benefits Plan (PBS), a public social security health insurance plan, are provided to users.

Although the Ministry of Health has encouraged the necessary dialogues with healthcare providers, they have been reluctant to implement the changes necessary to facilitate the delivery of treatment. This state of affairs lays bare the lucrative and privatised nature of the current system, which perpetuates the vision of health as a business.

The Colombian health system faces numerous challenges, which require responses that prioritise equity and access to affordable treatment. The implementation of compulsory licensing for dolutegravir represents a crucial step towards guaranteeing access to antiretroviral drugs, but strong political commitment is needed to overcome current obstacles. In any future strategy, guaranteeing the right to health for all Colombians should be the main goal. ◆

*Juliana López Méndez is a social worker and epidemiologist with 10 years of experience in community work and human rights advocacy. As director of the IFARMA Foundation, she has led research projects related to the Foundation's objectives and, together with her team, has monitored the implementation of the compulsory licence for dolutegravir.*

# Rare diseases and roadblocks to affordable treatment

## Policy gaps and the unrealised potential of compulsory licences

Medicines for rare diseases are among the most expensive pharmaceuticals – costing up to millions per treatment – due in large part to patent protections. Compulsory licensing can offer a way out of the price trap.

**Chetali Rao**

RARE diseases, often referred to as orphan diseases, affect a small percentage of the population, yet their impact on individuals and families is profound. To date there are more than 7,000 known rare diseases affecting more than 300 million people globally, with 70% of these conditions starting from childhood.[1] Children account for more than 50% of those affected and 3 in 10 of them normally die before the age of 5.[2] These diseases are frequently progressive, chronic and disabling and can cause significant mortality and morbidity. While individually rare, there are common challenges and a huge unmet medical need faced by patients suffering from rare diseases globally.

Historically, the development and approval of drugs targeting rare diseases was largely neglected by the pharmaceutical industry. However, spurred by regulatory incentives like the Orphan Drug Act in the US (1983), the Orphan Drug Regulation in the EU (1999) and similar policies elsewhere, a shift in the landscape of new drug approvals for rare diseases has taken place in recent years. Prior to 1983, only 38 drugs were approved to treat rare diseases; however, by the end of 2022, the US Food and Drug Administration (FDA) had approved 882 different drugs for use in the treatment of 392 rare diseases.[3] In 2024, approximately 52% (26 out of 50) of new drugs approved by the FDA were for rare diseases.[4]

These advances are encouraging and reflect increasing recognition of the need for treatments targeting rare diseases, yet they are insufficient, considering that more than 95% of rare diseases still lack an FDA-approved treatment. This stark reality leaves millions of people living with a rare disease (PLWRD) clinging to hope for a cure or even basic disease management, and underscores the need for sustained innovation, increased investment and robust policy support to address the substantial gaps and unmet needs in this area.

One of the most formidable challenges in addressing rare diseases is the scarcity of reliable epidemiological data, which hampers the translation of research findings into real-world interventions. The actual determination of rare diseases prevalence is challenging primarily due to the fragmented and non-standardised nature of available data. Information is derived from patchwork sources – ranging from published reports to registries, systemic reviews and anectodal evidence, each employing different methodologies and lacking uniform diagnostic criteria or coding systems.[5]

These inconsistences are greatly pronounced in the case of developing countries, due to limited clinical information, lack of universal health coverage and registries, and inadequate diagnostic capabilities.[6] These factors significantly contribute to substantial underreporting and gross underestimation of the true burden of rare diseases. India is a striking example – prevalence and incidence data are available only for a limited number of relatively more common rare diseases like Duchenne muscular dystrophy (DMD) and spinal muscular atrophy (SMA). For many lesser-known rare diseases like Okur-Chung neurodevelopmental syndrome, there are no available prevalence or incidence estimates.[7] Even for relatively better-known conditions like cystic fibrosis, there is a huge disparity in the data – the estimated number of diagnosed cases in India is 600, while research findings suggest that the patient population in the Indian subcontinent is greater than that of the United States – concrete epidemiological data remain scarce.[8] Some estimates indicate that as many as 3,600 infants could be born with cystic fibrosis annually.[9]

Due to the diverse, complex and uncommon nature of rare

diseases – compounded by the scarcity of epidemiological data – PLWRD have limited political visibility and are often deprioritised in the allocation of healthcare resources, including diagnostics and treatments. This lack of prioritisation has a detrimental effect not only for PLWRD but also for their families and caregivers who shoulder the emotional, financial and practical burden. A recent global estimate based on 3,585 rare diseases suggests that they affect nearly 3.5–5.9% of the world's population corresponding to 263–446 million people,[10] but when the broader ripple effect on family members and caregivers is taken into account, the figure reaches 1.05–1.4 billion people globally.[11]

The challenges faced by this community are exacerbated by experiences of discrimination and psychosocial consequences including social isolation, stigmatisation and limited opportunities for social inclusion.[12] These hardships are often intensified by pervasive lack of public awareness and knowledge, which perpetuates misconceptions. Addressing these challenges therefore requires not only scientific and medical innovation but a concerted effort to raise awareness, foster inclusion and ensure that the voices of PLWRD and their families are heard and prioritised within health policy agendas.

Recognising the collective impact rare diseases have on patients and their caregivers and the fact that this area has long remained on the periphery of health policy, the 78th World Health Assembly in May, in a historic milestone, saw member states of the World Health Organization (WHO) unanimously adopt the resolution 'Rare diseases: a global health priority for equity and inclusion'.[13] The resolution – the first of its kind within the WHO framework – mandates WHO to craft a comprehensive 10-year global action plan to improve


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**Trikafta is the brandname of a fixed-dose combination medication for treating cystic fibrosis. Researchers have found that the drug could be produced for less than $6,000 per patient per year, yet it is sold at an astonishing $326,000 PPPY.**

diagnosis, treatment, access and equity, with the plan slated for presentation at the 81st World Health Assembly in 2028. Moving beyond symbolism, the resolution urges member states to incorporate rare diseases into their national health systems, enhance access to timely diagnosis and treatments, and establish robust registries and data systems.

Though the resolution emphasises the financial burden of rare diseases, taking into cognisance the high cost of treatment and catastrophic out-of-pocket expenditure, it falls short of proposing specific funding mechanisms or global financial commitments to support its goal. The resolution mentions mobilising resources and exploring innovative funding models but lacks details on how to achieve this, especially for developing countries.

A funding mechanism for rare diseases is a priority area as the majority of therapies developed for rare diseases come with an exceptionally high price tag, presenting a formidable barrier to accessibility and affordability. This challenge is compounded by the advent of newer cell and gene therapy treatments which have become some of the most expensive treatments introduced by the pharmaceutical industry. For example, Libmeldy, a gene therapy for the treatment of metachromatic leukodystrophy (MLD), is priced at nearly $4.3 million, while Elevidys for the treatment of DMD costs around $3.2 million per treatment. Without dedicated funding, the WHO resolution's call for equitable access to medicines and assistive technologies may remain merely aspirational.

In times of resource and budget constraints, health systems are struggling to make drugs for rare diseases accessible to PLWRD. High drug prices, driven by market exclusivity and limited competition, restrict access particularly for developing countries. A significant challenge lies in the inability of countries to address the monopolistic control pharmaceutical companies

hold over rare disease medications due to their patent ownership. In numerous cases, these companies have prioritised patenting and monopolising their drugs over making them accessible to PLWRD. For instance, despite being available elsewhere, the drug Trikafta for treatment of cystic fibrosis has not been registered for marketing in India, although multiple patent applications have been filed for it.

Most of the international discussions around rare diseases have failed to address the entrenched intellectual property barriers that render these critical life-saving medicines inaccessible. However, the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does contain several provisions that empower WTO member states to place public health priorities above intellectual property protections. Notably, the WTO's 2001 Doha Declaration reaffirmed that the TRIPS Agreement should not impede WTO members from implementing measures necessary to safeguard public health and ensure access to affordable medicines.

The adoption of the declaration was a monumental achievement for developing countries since it recognised the need to address their public health concerns and confirmed the right to use certain critical public health safeguards like compulsory licences (CLs) and parallel import flexibilities allowed under the TRIPS Agreement. Such provisions were incorporated to balance intellectual property rights with public health to ensure affordable access to life-saving drugs in resource-constrained settings. Although the declaration specifically referred to HIV/AIDS, tuberculosis and malaria, it covered all diseases, including non-communicable diseases.[14]

CLs enable governments to override patent exclusivities, yet, 30 years after the TRIPS Agreement's entry into force, they remain underutilised, with only 65 documented cases of CLs and government use globally, which fails to systematically address drug affordability.[15] Most governments have not fully leveraged the opportunities provided under the TRIPS Agreement to advance public health interests, particularly in the context of rare diseases. This reluctance can be attributed to the intense political and economic pressures exerted by the developed countries and pharmaceutical firms, which clearly prioritise the interests of the pharmaceutical patent holders.

The situation is worsened by bilateral and regional free trade agreements (FTAs) which impose many 'TRIPS-plus' provisions that exceed the intellectual property protections under the TRIPS Agreement, limiting CL use. For example, many bilateral FTAs mandate a five-year data exclusivity period. This can block competition from generic drugs in the pharmaceutical market even after patent expiration or even in the absence of patent protection.[16] Thus, even if a CL is granted to override a patent, generic manufacturers may still be prevented from entering the market until the data exclusivity period expires.

Given the generic manufacturing capabilities of countries like India, China and Argentina, the drugs for rare diseases can be produced at a fraction of the current prices if patent encumbrances are addressed. However, patent protections have led to an absence of local production and have consequently kept these life-saving treatments out of reach of most patients suffering from rare diseases. Critics argue that compulsory licensing reduces incentives to undertake drug research and development (R&D), yet the sales of patented drugs, including those for rare diseases, are overwhelmingly concentrated in high-income countries such as the US and Europe, which together account for the vast majority of the revenue,[17] suggesting that developing-country generics have minimal impact on profits. Studies clearly show that granting of CLs does not/has not hurt innovation.[18]

The high prices of drugs often far exceed R&D costs, thus clearly elucidating how business models place profit margins before patient well-being. A study by Dr Melissa Barber on the small molecule oral drug risdiplam for treating SMA reveals how the pharmaceutical industry often prioritises shareholders' interests above patient needs. Despite its high market price of around $80,000 per patient per year (PPPY), risdiplam could be manufactured by a generic manufacturer at a fraction of the current cost.[19] A generic manufacturer in India has produced the drug and has offered to sell it for a price as low as $4,000 PPPY. A similar pattern has emerged for Trikafta – where researchers have found that the drug could be produced for less than $6,000 PPPY, yet it is sold at an astonishing $326,000 PPPY.[20] If a CL is granted for such a drug, it would significantly improve access for rare disease patients not only in India but globally. However, the launch of such generic drugs has been mired in legal disputes, resulting in prolonged delays for patients who urgently need access to these life-saving treatments.

Despite recognising the potential to make rare disease drugs affordable and accessible, governments have refrained from pursuing compulsory licensing measures that would allow local generic manufacturers to produce these drugs. Similarly, governments have been largely silent on price transparency and pool procurement of such drugs. As a result, the promise of equitable access to treatments for patients with rare diseases remains largely unfulfilled and these life-saving medicines remain out of reach for those who

need them most.

Addressing these challenges in securing access to rare disease drugs requires not only political will but also a concerted effort to reform global intellectual property frameworks in a manner that prioritises public health over profits. No family should have to endure the heartbreak of seeing their child suffer from a disease for which a cure or treatment is available, simply because the drug is inaccessible. A few bold, targeted decisions can dramatically improve the lives of PLWRD and offer them the promise of a bright and equitable future. ◆

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**Explore more**

Watch interviews with experts **Chetali Rao** (*Third World Network*) and **James Love** (*Knowledge Ecology International*) on the legal, economic, and policy dimensions of rare disease medicines.

# 30 years of TRIPS and 20 years of patenting in Egypt: Why access to medicines might still be a challenge

In the face of strict, internationally imposed patenting requirements, Egypt continues to prioritise affordable medicines for its people.

**Heba Wanis**


Ashashyou (CC BY-SA 3.0)

**Egypt's per capita pharmaceutical expenditure is among the lowest in the Middle East and North Africa region.**

DRUG policies in Egypt have historically prioritised access and affordability. To this end, two key measures were established in the mid-20th century amid the growth of an ambitious pharmaceutical industry: a government (compulsory) drug pricing mechanism, and a patent law (132/1949) which protected the pharmaceutical process but not the product. Until the early 2000s, Egyptians enjoyed low medicine prices, thanks to government controls and competition from generics, with a fair number of producers per product. Given the high proportion of spending on health and medicines in Egypt paid for out of pocket, currently estimated to be 62.75%,[1] a no-product-patent industry combined with price controls meant that medicines remained accessible.

When the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into being, Egypt prepared itself for the new global paradigm starting from 2005 when the Agreement would come into force after a five-year transition period. The now famous Law 82/2002 on the Protection of Intellectual Property Rights has deliberately incorporated all possible safeguards against potential public health implications of the new Agreement, benefiting from the far-sightedness and expertise of its drafters.

The Law applied the minimum protection standards of the TRIPS Agreement and incorporated all its flexibilities, interpreting it in accordance with the principles and objectives stated in Articles 7 and 8 of the Agreement. The flexibilities related to public health protection include exceptions and limitations to patentability (Article 2 of the Law); compulsory licensing in cases of patent misuse or failure of exploitation (Articles 23 and 24); international exhaustion; and regulatory review (Bolar) exception (Article 10). The Law does not allow for patent linkage as it clearly demarcates the mandates of the patent office vis-à-vis the drug regulatory authority, so that the drug registration process is independent of the patent status. Nevertheless, transnational pharmaceutical corporations often exert pressure on regulatory authorities to prevent the registration of generic versions of their marketed products during their patent term, with some of the cases taken to court by the generic companies.[2]

Similarly, the Law does not recognise data exclusivity as a form of protection for test data submitted for registration in order for the regulatory authority to register generic versions of medicines utilising previously submitted clinical trial results. Test results are, however, protected by rules of unfair competition, but are not to be withheld when generic medicines

need to be registered.

Meanwhile, the Egyptian Patent Office has gained the global reputation of being a proponent of public health and development. Over the years, its team of pharmaceutical examiners has accumulated expertise based on thorough understanding of both international and national law. The Office applies absolute novelty as a patentability criterion, thus setting high standards as to which patent applications pass the examination process.

Intellectual property (IP) law and examination practices in Egypt both create ample policy space for the generic-medicine industry to flourish. This was clearly demonstrated when the local pharmaceutical industry contributed to the success of Egypt's viral hepatitis treatment programme following the launch of the Plan of Action for the Prevention, Care and Treatment of Viral Hepatitis 2014–2018.

At the time, the US Food and Drug Administration (FDA)'s approval of sofosbuvir (SOF) in December 2013 marked new hope for treating the disease. A longstanding public health problem in Egypt, viral hepatitis C chronic infection prevalence rates had reached 10% among 15–59–year–olds and more than 25% among 50–60–year–olds by 2012, with an estimated 150,000 new infections annually, making the country a key global market for SOF.

The deal with the manufacturer, the US-based pharmaceutical giant Gilead, was set at $300 per box, that is, $900 per 12-week treatment course – low compared with the exorbitant globally announced price of $84,000 at the time, and yet too high for Egypt's modest national health budget, and certainly much higher than the calculated manufacturing cost of $68–136.[3]

The agreed price was valid until the Patent Office issued a decision rejecting the SOF patent application, indicating that the 'invention' failed to meet the patentability criteria of novelty and inventive step. This decision opened wide the door for local generic producers which produced SOF among other direct-acting antivirals (DAAs) at fractions of the global prices, thereby enabling the medicine to be made more accessible to the country's hepatitis patients, both under the national treatment programme or privately for those who could afford to buy it out of pocket.

Patent examination practices in Egypt not only play a crucial role in protecting the population from unnecessary pharmaceutical patents, which would lead to expensive medicines, but also create a wide operational space for local pharmaceutical companies with research and development (R&D) capacity to expand their portfolio. There is a great, as yet untapped, potential in the information made available in all patent applications filed and in a broad public domain. This goldmine of patent information has been strongly promoted by the Egyptian Patent Office among researchers in academic circles and in the local generic industry.

Compulsory licensing of patented medicines is another means to enhance their accessibility and affordability. While compulsory licensing is provided for by the IP Law 82/2002 (Articles 23 and 24) as a protection for public health, it has never been utilised. One reason is purely procedural: the 2002 Law states that a compulsory licence is to be approved by a Ministerial Committee, but this Committee was only established in 2020, that is, 18 years after the Law. The Committee is mandated with approving compulsory licences issued by the Patent Office; determining the financial rights of the patent holder when compulsory licences are issued; and revoking of patents.

Patents are only one, albeit significant, determinant of access to medicines. Pricing policy; local production capacity; health insurance coverage and private spending on health are among the other factors. Despite the high out-of-pocket expenditure on health (62.75%, as mentioned above), of which nearly half goes to medicines, Egypt's per capita pharmaceutical expenditure remains among the lowest in the Middle East and North Africa region, and is expected to decrease. The demand for generic medicines is surging in the market.[4] Such trends cannot be examined in isolation of the economic situation which has had an impoverishing effect on whole segments of the population.

Despite the claimed self-sufficiency in medicines, Egypt is a net drug-importing country, with imported finished products comprising 73% of products on the market, and 90–95% of the components of locally produced medicines being imported.[5] Arguably, certain therapeutic groups such as oncology medicines and biological products continue to be primarily imported, hence exhibiting high prices.

There are local pharmaceutical companies with far-sighted R&D plans. Such companies have developed their own strategies to navigate local, regional and global markets through ambitious partnerships and pharmaceutical alliances with resulting voluntary licensing agreements and joint technological ventures. However, on the domestic front, there continue to be challenges as the relatively newly established Egyptian Drug Authority, now operating independently from the Ministry of Health, reviews and updates its mandate after the restructuring of national drug regulation and national drug procurement.[6]

While operating in a complex environment, the pharmaceutical sector in Egypt has demonstrated resilience, thanks to its large manufacturing base and to legislative safeguards. In the period since the TRIPS Agreement came

into force, time and experience have shown that the national IP regime has still got wide, as yet unutilised, policy space for the pharmaceutical industry to build upon, including a vast public domain created by patent information and rejected patents. These are learning and production opportunities for local manufacturers whose presence and sustainability in a developing-country market are fundamental for access and affordability of medicines. ◆

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# Resistance works

## How small groups took on great powers and won a victory for decolonisation, Africa, indigenous peoples and more

For over half a century, a small Indian Ocean archipelago has been the focus of a David-and-Goliath struggle against British colonialism and US militarism – a struggle that has now yielded a positive outcome.

**David Vine**

Anne Sheppard (CC BY 3.0)

**Salomons Atoll in the Chagos Archipelago. A Mauritius-UK treaty in May gives up British control of the Chagos Islands and allows the exiled Chagossian people to return home to all but one of them.**

AT a time when many may feel that good news has gone the way of the dodo, look no further than the homeland of that long-extinct bird – Mauritius – for a dose of encouragement. There, among the islands of the Indian Ocean, news can be found about the power of resistance and the ability of small groups of people to band together to overcome the powerful.

Amid ongoing slaughter from Gaza and Ukraine to Sudan and the Congo, the news also offers a victory for resolving conflicts through diplomacy rather than force. It's a victory for decolonisation and international law. And it's a victory for Africa, the African diaspora, and indigenous and other displaced peoples who simply want to go home. To the shock of many, US President Donald Trump actually played a role in making such good news possible by bucking far-right allies in the US and Britain.

The news came in late May when the British government signed a historic treaty with Mauritius giving up Britain's last African colony, the Chagos Islands, and allowing the exiled Chagossian people to return home to all but one of them. The British also promised to pay an estimated £3.4 billion over 99 years in exchange for continuing control over one island, the largest, Diego Garcia. Though few in the US even know that it exists, the Chagos Archipelago, located in the centre of the Indian Ocean, is also home to a major US military base on Diego Garcia that has played a key role in virtually every US war and military operation in the Middle East since the 1970s.

Diego Garcia is one of the most powerful installations in a network of more than 750 US military bases around the world that have helped control foreign lands in a largely unnoticed fashion since World War II. Far more secretive than the Guantánamo Bay naval base, Diego Garcia has been, with rare exceptions, off-limits to anyone but US and British military personnel since that base was created in 1971. Until recently, that ban also applied to the other Chagos islands from which the indigenous Chagossian people were exiled during the base's creation in what Human Rights Watch has called a 'crime against humanity'.

While the victories the Chagossians, a group numbering less than 8,000, finally achieved in May are anything but perfect, they wouldn't have happened without a more-than-half-century-long struggle for justice. A real-life David-and-Goliath story, it demonstrates the ability of small but dedicated groups to overcome the most powerful governments on Earth.

### A history of resistance

The story begins around the time of the American Revolution when the ancestors of today's Chagossians first began settling on Diego Garcia and the other uninhabited Chagos islands. Enslaved at the time, they were brought from Africa, along with

indentured labourers from India, by French businessmen from Mauritius who used the workers to build coconut plantations there.

Over time, the population grew, gaining its emancipation, while a new society emerged. First known as the Ilois (the Islanders), they developed their own traditions, history and Chagossian Kreol language. Although their islands were dominated by plantations, the Chagossians enjoyed a generally secure life, thanks in part to their often militant demands for better working conditions. Over time, they came to enjoy universal employment, free basic healthcare and education, regular vacations, housing, burial benefits and a workday they could control, while living on gorgeous tropical islands.

'Life there paid little money, very little,' one of the longtime leaders of the Chagossian struggle, Rita Bancoult, told me before her death in 2016, 'but it was the sweet life.'

## 'The Footprint of Freedom'

Chagos remained a little-known part of the British Empire from the early 19th century when Great Britain seized the archipelago from France until the 1950s when Washington grew interested in the islands as possible military bases.

Amidst Cold War competition with the Soviet Union and accelerating decolonisation globally, US officials worried about being evicted from bases in former European colonies then gaining their independence. Securing rights to build new military installations on strategically located islands became one solution to that perceived problem. Which is what led Stuart Barber, a US Navy planner, to find what he called 'that beautiful atoll of Diego Garcia, right in the middle of the ocean'. He and other officials loved Diego Garcia because it was within striking distance of a vast region, from southern Africa and the Middle East to South and Southeast Asia, while also possessing a protected lagoon capable of handling the largest naval vessels and a major airbase.

**US and UK soldiers in a training exercise at the US base in Diego Garcia. Diego Garcia has been, with rare exceptions, off-limits to anyone but US and British military personnel since the base was created in 1971.**

In 1960, US officials began secret negotiations with their British counterparts. By 1965, they had convinced Britain to violate international law by separating the Chagos Islands from the rest of its colony of Mauritius to create the 'British Indian Ocean Territory'. No matter that UN decolonisation rules then prohibited colonial powers from chopping up colonies when, like Mauritius, they were gaining their independence. Britain's last created colony would have one purpose: hosting military bases. US negotiators insisted Chagos come under their 'exclusive control (without local inhabitants)' – an expulsion order embedded in a parenthetical phrase.

US and British officials sealed their deal with a 1966 agreement in which Washington would secretly transfer $14 million to the British government in exchange for basing rights on Diego Garcia. The British agreed to do the dirty work of getting rid of the Chagossians.

First, they prevented any Chagossians who had left on vacation or for medical treatment from returning home. Next, they cut off food and medical supplies to the islands. Finally, they deported the remaining Chagossians 1,200 miles to Mauritius and the Seychelles in the western Indian Ocean.

Both governments acknowledged that the expulsions were illegal. Both agreed to 'maintain the fiction' that the Chagossians were 'migrant labourers', not a people whose ancestors had lived and died there for generations. In a secret cable, a British official called them 'Tarzans' and, in a no less racist reference to *Robinson Crusoe*, 'Man Fridays'.

In 1971, as the US Navy started base construction on Diego Garcia, British officials and American sailors rounded up people's pet dogs, lured them into sealed sheds, and gassed them with the exhaust from Navy vehicles before burning their carcasses. Chagossians watched in horror. Most were then deported in the holds of overcrowded cargo ships carrying dried coconut, horses and guano (bird shit). Chagossians have compared the conditions to those found on slave ships.

In exile, they effectively received no resettlement assistance. When the *Washington Post* finally broke the story in 1975, a journalist found Chagossians living in 'abject poverty' in the slums of Mauritius. By the 1980s, the base on Diego Garcia would be a multibillion-dollar installation. The US military dubbed it the 'Footprint of Freedom'.

## An epic struggle

The Chagossians have long demanded both the right to go home and compensation for the theft of their homeland. Led mostly by a group of fiercely committed women, they protested, petitioned, held hunger strikes, resisted riot police, went to jail, approached the UN, filed lawsuits, and pursued nearly every strategy imaginable to convince the US and British governments to let them return.

In the late 1970s and early 1980s, Chagossian protests in Mauritius won them small amounts of compensation from the British government (valued at around $6,000 per adult). Many used the money to pay off significant debts incurred since their arrival. Chagossians in the Seychelles, however, received nothing.

Still, their desire to return to the land of their ancestors remained, and hope was rekindled when the Chagos Refugees Group sued the British government in 1997, led by Rita Bancoult's son, Olivier. To the surprise of many, they won. Over several tumultuous years, British judges ruled their expulsion illegal three times – only to have Britain's highest court repeatedly rule in favour of the government by a single vote. Judges in the US similarly rejected a suit, deferring to the president's power to make foreign policy. The European Court of Human Rights also ruled against them.

## A strategic alliance

Despite the painful defeats, Chagossian prospects brightened when the Chagos Refugees Group allied with the Mauritian government to take Britain to the International Court of Justice. Aided by Chagossian testimony about their expulsion, which an African Union representative called 'the voice of Africa', Mauritius won. In 2019, that court overwhelmingly ruled that Mauritius was the rightful sovereign in Chagos. It directed the UK to end its colonial rule 'as rapidly as possible'. A subsequent UN General Assembly resolution ordered the British 'to cooperate with Mauritius in facilitating the resettlement' of Chagossians.

US Navy photo by Mass Communication Specialist 3rd Class Caine Storino (CC BY-SA 2.0)

**The airfield at the US military base in Diego Garcia. The base has played a key role in virtually every US war and military operation in the Middle East since the 1970s.**

Backed by the US, the British initially ignored the international consensus – until, in 2022, Prime Minister Liz Truss's government suddenly began negotiations with the Mauritians. Two years later, a deal was reached with the support of the Joe Biden administration in Washington. The deal recognised Mauritian sovereignty over Chagos but allowed Britain to retain control of Diego Garcia for at least 99 years, including the continued operation of the US base. The Chagossians would be allowed to return to all their islands except, painfully, Diego Garcia and receive compensation.

The Chagos Refugees Group and other Chagossian organisations generally supported the deal, while continuing to demand the right to live on Diego Garcia. Some smaller Chagossian groups, especially in Britain (where many Chagossians have lived since winning full UK citizenship in 2002), opposed the agreement. Some still support British rule. Others seek Chagossian sovereignty.

Right-wing forces in Britain and the United States quickly tried to kill the deal. Former Prime Minister Boris Johnson, Brexit protagonist Nigel Farage and then-Senator Marco Rubio campaigned for continued British colonial rule, often spouting bogus theories suggesting the agreement would benefit China.

Donald Trump's election and the appointment of Rubio as US secretary of state left many fearing they would kill the treaty. Instead, when Prime Minister Keir Starmer visited Washington, Trump indicated his support. A finalised treaty was in sight.

## An imperfect victory?

In the last hours, the deal was briefly blocked by a lawsuit that a judge later dismissed. 'I've been betrayed by the British government,' Bernadette Dugasse, one of two Chagossians who brought the suit, said of the treaty. 'I will have to keep on fighting the British government till they accept for me to settle' on Diego Garcia (where she was born).

Dugasse's suit and plans for additional legal action are being funded by a shadowy 'Great British PAC' that won't disclose its donors. The group is led by right-wing political figures still trying, in their words, to 'Save Chagos'. However, 'saving Chagos' doesn't mean saving Chagos for the Chagossians, but 'saving' it from the end of British colonial control. In other

words, right-wing figures are cynically using Chagossians to try to uphold the colonial status quo. (Even Dugasse fears she's being used.)

On the other hand, the Chagos Refugees Group and many other Chagossians are celebrating, at least partially. For the first time in more than half a century of struggle, they can go home to most of their islands, even if they, too, criticise the ban on returning to Diego Garcia and the shamefully small amount of compensation being offered: just £40 million earmarked for a Chagossian 'trust fund' operated by the Mauritian government (with British consultation). Divided among the entire population, this could be as little as £5,000 per person for the theft of their homeland and more than half a century in exile. (People in car accidents get far more.)

'I'm very happy after such a long fight,' Sabrina Jean, leader of the Chagos Refugees Group UK Branch, told me. 'But I'm also upset about how the UK government continues to treat us for all the suffering it gave Chagossians,' she added. '£40 million is not enough.'

The Mauritian government should benefit more unambiguously than the Chagossians: The treaty formally ends decolonisation from Britain, reuniting Mauritius and the Chagos Islands. Mauritius will receive an average of £101 million in rent per year for 99 years for Diego Garcia plus £1.125 billion in 'development' funds paid over 25 years.

'The development fund will be used to resettle' Chagossians on the islands outside Diego Garcia, said Olivier Bancoult, now the president of the Chagos Refugees Group, about a commitment he's received from the Mauritian government. 'They have promised to rebuild Chagos.'

Bancoult and other Chagossians insist they also should receive some of the annual rent for Diego Garcia. 'Parts of it need to be used for Chagossians,' he told me by phone from Mauritius.

The continuing ban on Chagossians living on Diego Garcia clearly violates Chagossians' human rights as well as the International Court's ruling and that UN resolution of 2019. Human Rights Watch criticised the treaty for appearing to 'entrench the policy that prevents Chagossians from returning to Diego Garcia' and failing to acknowledge US and British responsibility for compensating the Chagossians and reconstructing infrastructure to enable their return.

'We will not give up concerning Diego,' Olivier Bancoult told me. For those born on Diego Garcia and those with ancestors buried there, it's not enough to return to the other Chagos islands, at least 150 miles away. 'We will continue to argue for our right to return to Diego Garcia,' he added.

While US and British officials have long used 'security' as an excuse to keep Chagossians off the island, they could, in truth, still live on the other half of Diego Garcia, miles from the base, just as civilians live near US bases worldwide. Civilian labourers who are neither US nor British citizens have lived and worked there for decades. (Chagossians will be eligible for such jobs, although historically they've faced discrimination getting hired.)

That the US military has ended up a winner in the treaty could explain Donald Trump's surprising support. The treaty secures base access for at least 99 years and possibly 40 more.

Which means the treaty is a setback for those Mauritians, Americans and others who have campaigned to close a base that has cost US taxpayers billions of dollars and has been a launchpad for catastrophic wars in the Middle East, which a certain president claimed to oppose.

While many Chagossians are privately critical of the base that caused their expulsion and occupies their land, most have prioritised going home over demanding its closure. The campaign to return has been hard enough.

Ultimately, I'm in no position to decide if the Chagos treaty is a victory or not. That's for Chagossians and Mauritians to decide, not a citizen of the country that, along with Great Britain, is the primary author of that ongoing, shameful crime.

Let me note that victories are rarely, if ever, complete, especially when the power imbalance between parties is so vast. Chagossians, backed by allies in Mauritius and beyond, are continuing their struggle for the right to return to Diego Garcia, for the reconstruction of Chagossian society in Chagos, and for full, proper compensation. The Mauritian and British governments can correct the treaty's flaws through a diplomatic 'exchange of letters'.

'We are closer to the goal' of full victory, Olivier assured me. 'We are very near.'

Having won the right to return to most of their islands after 50 years of struggle, Olivier has been thinking a lot about his mother, longtime leader Rita Bancoult. 'I would like that my mom would be here, but I know if she would be here, she would be crying,' he said, 'because she always believed in what I do, and she always encouraged me to go until the destination, the goal.'

For now, inspired by the memory of his mother and too many Chagossians who will never see a return to their homeland, Olivier told me, '*lalit kontin*'. The struggle continues. ◆

*David Vine is a regular contributor to TomDispatch (tomdispatch.com), where this article was originally published. He is the author most recently of* The United States of War: A Global History of America's Endless Conflicts, from Columbus to the Islamic State*. He is also the author of* Island of Shame: The Secret History of the US Military Base on Diego Garcia *and* Base Nation: How US Military Bases Abroad Harm America and the World*, part of the American Empire Project.*

# Haiti's political impasse

Haiti's current form of 'chokepoint governance' represents a structural transformation in how politics works in the country.

**Greg Beckett**

IN Port-au-Prince today, roadblocks and barricades carve up nearly every neighbourhood. Residents who haven't already fled wake each morning wondering what dangers they'll face simply trying to move through their own city. They swallow their rage at the armed groups holding the country hostage, carefully navigating the gang-controlled chokepoints that now define urban life.

The insecurity stems not just from the gangs, but from the state's near-total disappearance as well. Haiti has had no elected national government for years. Since April 2024, a Transitional Presidential Council (CPT) – created by international actors to manage the crisis and shepherd new elections – has held nominal power and been mired in scandals. Yet for many residents, the gangs and the CPT are *marasa* – twins, two faces of the same failed system.

For decades, Haiti has been described as a country at a crossroads. But crossroads suggest choice, possibility, movement forwards. What defines Haiti now is something different: an impasse – a condition of blockage and immobility that traps millions in place. This impasse is both concrete and metaphorical, connecting the physical roadblocks fragmenting Port-au-Prince with the political deadlock preventing any resolution to the ongoing crisis. The impasse represents more than political breakdown – it's a transformation in how politics works. Controlling who moves where has become the main source of political power in Haiti today.

## The 'gangsterisation' of the Haitian state

The current stranglehold didn't emerge overnight. Its roots stretch back to the post-2010 earthquake reconstruction, when donors, the state and local actors all made politics about infrastructure, promising to build houses, roads, hospitals and schools. These were all urgently needed after the earthquake, but the reconstruction period was defined more by its failures than its successes, including the introduction of cholera to Haiti by UN soldiers or the displacement of residents from their neighbourhoods.

This infrastructure politics often served as more of a cover for resource extraction and outright graft rather than genuine development. By 2018, growing awareness of corruption in reconstruction projects – particularly the theft of billions meant for development and reconstruction – sparked massive protests against the government of then President Jovenel Moïse.

These protests evolved into a movement against what civil society groups have called the 'gangsterisation' of the state – the increasing collusion between officials and armed gangs. As protests continued through 2019, demonstrators adopted tactics known as *peyi lòk* (country lockdown), using strikes, marches and road blockages to shut down the capital. The protests were some of the largest in the country's history, though they did little to weaken the international and elite support of Moïse's government.

President Moïse's assassination in July 2021 created a constitutional vacuum that accelerated a transformation of the Haitian state. With no clear succession process and most elected officials' terms expired, political authority became increasingly detached from formal government institutions. The international community's backing of Ariel Henry as acting prime minister – despite his lack of electoral mandate or constitutional legitimacy – further gutted Haiti's already fragile state institutions.

This period also saw the consolidation of gang power. In the summer of 2020, former police officer Jimmy Chérizier, known as 'Barbecue', announced the formation of the G9 Family and Allies – a federation of nine powerful gangs. This marked a shift from neighbourhood-based groups to coordinated entities with national political ambitions. Gang federations signalled a new phase where armed groups could effectively challenge both state and international authority.

By March 2024, the transformation of Haitian political power was complete. Gangs prevented Prime Minister Henry's return from Kenya, where he'd gone to arrange an international policing mission. Armed gangs demonstrated their ability to dictate terms to what remained of the government. They showed no interest in taking over the state but made clear they could decide whether any government would govern.

## Life under 'chokepoint governance'

In Martissant, a neighbourhood of Port-au-Prince where I've conducted research for two decades, immobility has become the defining feature of daily life. Once a relatively accessible neighbourhood connecting southern regions to the capital, Martissant has become one of the most contested zones in the metropolitan area. Armed gangs have established numerous checkpoints along Route Nationale 2, the main road traversing the neighbourhood, effectively controlling movement between the capital and southern Haiti.

Roadblocks – *barikad* in Haitian Creole – have a long history as tools of protest. But current deployments represent something fundamentally different: semi-permanent features that mark boundaries and create zones of control. Major gangs target what logistics experts call 'chokepoints' – strategic locations in the city's circulation system where movement can be controlled with minimal resources.

The late-2022 blockade of the main fuel terminal provides the clearest example. By controlling access to this single facility that processes most of Haiti's imported fuel, gangs paralysed the entire country for months. The blockade demonstrated how vulnerable national infrastructure had become to localised control and ushered in a form of rule that I term 'chokepoint governance' – power that works not by controlling territory but by controlling the flow of essential goods and people.

For Port-au-Prince residents, navigating this fragmented urban space takes more than good luck – it requires strategies for moving through the city that account for gang territories, checkpoint schedules, personal connections and real-time information sharing. Many rely on informal networks to share information about passable routes. Others develop complex detour systems, sometimes travelling hours through mountainous terrain to bypass gang-controlled areas.

## The global architecture of immobility

While the impasse manifests most visibly in Port-au-Prince's blocked streets, it's fundamentally shaped by transnational dynamics that extend far beyond Haiti's borders. As the late Haitian-American anthropologist Michel-Rolph Trouillot noted, Haiti represents 'the longest experiment in neocolonial rule'. The current crisis continues this pattern through new experiments in political control.

The United States has historically shaped Haiti's political landscape through military interventions, economic policies and backing favourable political figures. More recently, the United States influences the situation by controlling what moves in and out of Haiti, making it easy for weapons to flow in while blocking people from leaving.

The flow of firearms into Haiti exemplifies this selective permeability. Despite having no domestic weapons manufacturing, gangs have acquired sophisticated arms, mostly from the United States. Meanwhile, the ability of Haitians to emigrate faces increasing restrictions. The Dominican Republic has kept its border closed to Haitians since September 2023 and has launched a mass deportation programme targeting Haitians and Dominicans of Haitian descent. The United States, too, has continued aggressively deporting Haitians – including migrants who had previously received parole – despite UN recommendations against returning people to such an insecure country. The Trump administration also recently included Haiti in its list of countries under a travel ban.

This asymmetrical mobility management – weapons flowing in while people are prevented from exiting the crisis or are sent back into the fray – intensifies the experience of mobility many Haitians now feel. International actors, particularly the United States, play a decisive role in determining who holds political power. The support for Ariel Henry after Moïse's assassination, despite Henry's constitutional illegitimacy and possible implication in the assassination, exemplifies how external recognition substitutes for internal democratic processes.

The recent US designation of certain Haitian gangs as terrorist organisations further complicates this dynamic. While the move is popular in Haiti, where residents are weary of living amid gang violence, the designation may function more as migration management than addressing the roots of the crisis. As analyst Jake Johnston of the Washington-based Center for Economic and Policy Research notes, the designation risks creating an effective embargo on Haiti, since conducting any business in gang-controlled territories, now including much of Port-au-Prince, could violate US anti-terrorism laws.

## Politics as survival

The current impasse represents more than a breakdown of governance – it deepens blockages that have long defined Haitian politics. In his analysis of Haiti's history, Trouillot identified a political system blocked in two ways: first, by keeping the peasant majority out of politics entirely, and second, by limiting political competition to elite fights over state resources.

When a political system is completely blocked, traditional politics is replaced with rivalries between individuals, parties and interest groups. Haiti's deep social problems, rather than being

addressed through real political engagement, have historically been fought out through elite competition for control of the state.

The gangsterisation of the state, followed by the takeover of much of the country by the gangs, represents a new version of this old pattern. But where the old blockages kept political rivalry within formal state institutions, the new impasse has pushed politics beyond the state entirely. Politics is no longer about administration or governance, but about what we might call 'life itself' – the daily work of just trying to survive.

In this context, ordinary Haitians engage in politics not through voting or protest, but through the constant work of getting by, around and through – navigating roadblocks, finding safe routes and securing basic necessities. Every trip to the market, every journey to work, every attempt to access services becomes a political act of resistance against imposed immobility. This represents a fundamental shift: politics as navigation rather than participation, politics as survival rather than representation.

The question facing Haiti is whether these new forms of political practice can ultimately break through the blockages that created them, or whether they will simply reproduce patterns of domination in new forms. The answer lies not with gangs or international actors, but in the everyday practices of resistance and survival that ordinary Haitians continue to develop as they navigate an impossible present while working towards a different future. ◆

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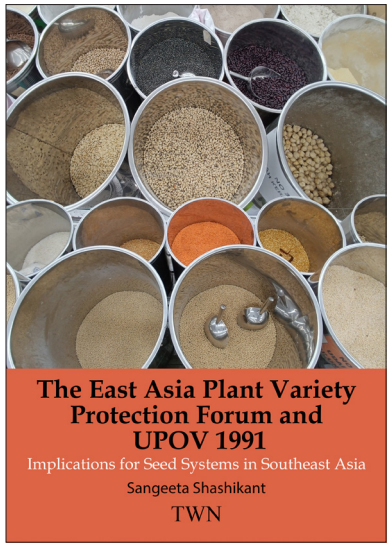
# The East Asia Plant Variety Protection Forum and UPOV 1991

## Implications for Seed Systems in Southeast Asia

*Sangeeta Shashikant*




Publisher: TWN
Year: 2025 Pages: 32

THIS paper critically examines the growing pressure on Southeast Asian (SEA) countries to adopt the rigid 1991 Convention of the International Union for the Protection of New Varieties of Plants (UPOV 1991) designed for the commercialized farming structures of industrialized nations.

It reveals how the East Asia Plant Variety Protection Forum, initiated by Japan under the guise of cooperation, has evolved into a key platform for aggressively promoting UPOV 1991 standards, sidelining national agricultural priorities and farmers' rights. Through detailed analysis, the paper exposes the commercial motivations driving this agenda and the pivotal role of developed countries and their allied entities, who stand as the primary beneficiaries of the UPOV system and regional harmonization based on it. It highlights how the Forum's pro-UPOV activities threaten to erode national sovereignty, undermine food security, and entrench a rigid, inappropriate plant variety protection (PVP) system across the region – one designed to serve the commercial interests of Japan and other developed nations, particularly the Netherlands, Germany, France and the United States.

It calls on SEA countries to critically reassess their participation in the Forum, advocate for meaningful reforms to safeguard their policy space, and, if necessary, withdraw to protect their national interests and ensure implementation of a PVP system that is aligned with domestic agricultural needs and that safeguards the interests of farmers and food sovereignty.

Available at: https://twn.my/title2/books/EAPVP_Forum_and_UPOV_1991.htm

# Comics and graphic novels can empower refugees to tell their stories on their own terms

The growing genre of 'refugee comics' is disrupting a media landscape that tends to reduce migrants to either threats or victims.

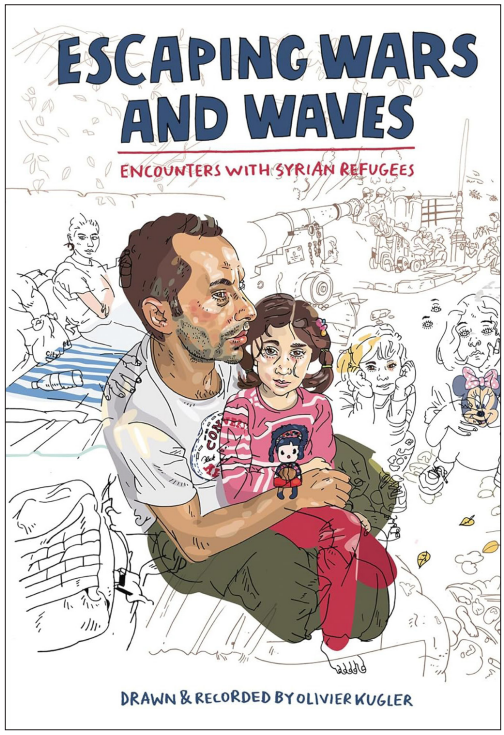
**Dominic Davies and Candida Rifkind**

THERE are more refugees in the world today than at any other point in history. The United Nations estimates that there are now more than 120 million people forcibly displaced from their homes. That is one in every 69 people on Earth. Some 73% of this population are hosted in lower- or middle-income countries.

From the legacies of European colonialism to global inequality, drone warfare and climate instability, politicians have failed to address the causes driving this mass displacement. Instead, far-right parties exploit the crisis by inflaming cultures of hatred and hostility towards migrants, particularly in high-income Western countries.

This is exacerbated by visual media, which makes refugees an easy target by denying them the means of telling their own stories on their own terms. Pictures of migrants on boats or climbing over border walls are everywhere in tabloid newspapers and on social media. But these images are rarely accompanied by any detailed account of the brutal experiences that force people into these situations.

In our new book *Graphic Refuge: Visuality and Mobility in Refugee Comics*, we show how a growing genre of 'refugee comics' is challenging this visual culture through a range of storytelling strategies and innovations in illustration. Comprised of multiple images arranged into sequences and interspersed with speech bubbles and caption boxes, refugee comics disrupt a media landscape that tends to reduce migrants to either threats or victims.




Many different kinds of visual storytelling live under the umbrella of refugee comics. They include short strips and stories, such as *A Perilous Journey* (2016) with testimonies from people fleeing the civil war in Syria, and *Cabramatta* (2019), about growing up as a Vietnamese migrant in a Sydney suburb. They also include codex-bound graphic novels, such as *The Best We Could Do* by Thi Bui (2017), and interactive web-comics such as *Exodus* by Jasper Rietman (2018).

They include documentaries made by journalists about the specific experiences of individual refugees. They also include fiction by artists who combine elements of several refugee testimonies into representative stories. Additionally, there are both fictional and non-fictional artworks made by migrants and refugees themselves.

Refugee comics address different forced mass displacements over the 20th and 21st centuries. These include the 1948 Nakba in Palestine, the 1970s flight of refugees from Vietnam, and the 2010s displacement of people from Syria and other countries across sub-Saharan Africa and the Middle East.

These refugee comics challenge anti-migrant images in at least three ways. First, they often integrate the direct testimonies of refugees. This is enhanced by the combination of words and pictures that comprise the comics page, which allows refugees to frame the way we see and respond to images


of displaced people.

For example, in *The Unwanted* by Joe Sacco (2012), familiar images of migrants crossing the Mediterranean on small boats are narrated by a refugee called Jon. Jon's testimony turns our attention to the fears and desires that drive people to attempt dangerous sea crossings.

A second way comics challenge anti-migrant images is by allowing refugees to tell their stories without disclosing their identities. Because comics are drawn by hand and use abstract icons rather than photographs, refugees can tell their stories while also avoiding any unwanted scrutiny and maintaining personal privacy. This reintroduces refugee agency into a visual culture that often seeks to reduce migrants to voiceless victims or security threats.

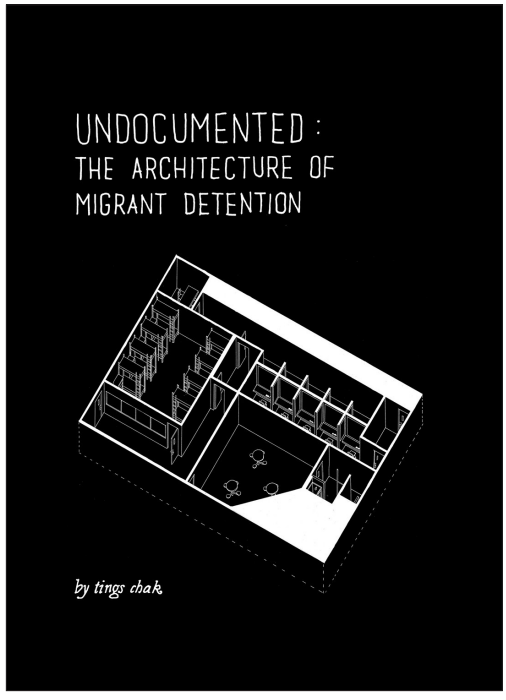
For example, in *Escaping Wars and Waves: Encounters with Syrian Refugees* (2018), German comics journalist Olivier Kugler dedicates two pages to a man he calls 'The Afghan' because he didn't want his name or identity revealed. Kugler presents this man's testimony of failed attempts to get to the UK, but he never draws his face or refers to him by name.

The third way comics challenge anti-migrant images is by shifting our attention from refugees themselves to the hostile environments and border infrastructures they are forced to travel through and inhabit. Refugee researchers describe this different way of seeing as a 'places and spaces, not faces' approach.

For instance, in *Undocumented: The Architecture of Migrant Detention* (2017), Tings Chak walks her readers through migrant detention centres from the perspective of those who are being processed and detained.

## Drawing displacement

This emphasis on place and space is built into the structure of our own book, *Graphic Refuge*. We begin by focusing on graphic stories about ocean crossings, particularly on the Mediterranean Sea. We then turn to comics concerned with the experience of refugee camps, and we also ask how interactive online comics bring viewers into virtual refugee spaces in a variety of ways.




It is the obliteration of homes that forces people to become refugees in the first place. Later in the book, we explore how illustrated stories document the destruction of cityscapes across Syria and also in Gaza. Finally, we turn to graphic autobiographies by second-generation refugees, those who have grown up in places such as the US or Australia but who must still negotiate the trauma of their parents' displacement.

Where most previous studies of refugee comics have focused on trauma and empathy, in *Graphic Refuge* we take a different approach. We set out to show how refugee comics represent migrant agency and desire, and how we are all implicated in the histories and systems that have created the very idea of the modern refugee.

As critical refugee scholar Vinh Nguyen writes in our book's foreword, while it is difficult to truly know what refugee lives are like, those of us who enjoy the privileges of citizenship can at least read these comics to better understand 'what we – we who can sleep under warm covers at night – are capable of'. ◆

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# Ten years after Ni Una Menos: Feminism, resistance and the future

*Maisa Bascuas* traces the trajectory of the popular feminist movement seeking to unify the struggle against social injustice in Argentina and beyond.

## The cry that fuelled the flames already burning

ON 3 June 2015, the murder of Chiara Páez, a pregnant teenager from Santa Fe, at the hands of her boyfriend, sparked one of the most powerful mobilisations in recent Argentine history. Under the slogan #NiUnaMenos (Not One Less), a crowd took to the streets to say 'Enough is enough' to femicide and all forms of gender-based violence.

That day marked a turning point in the feminist organising process that had been unfolding since the return of democracy in communities, unions, health and educational institutions, both within and outside the state. It was a massive gathering that kicked off a cycle of feminist social mobilisation against neoliberalism, which soon spread throughout Latin America.

Since then, Ni Una Menos has ceased to be just a phrase. It has become a cross-cutting, intergenerational and continental slogan. In the squares of Buenos Aires, Lima, Santiago, Montevideo and Mexico City, thousands of women and dissidents began to organise. Assemblies, support networks, artistic collectives, feminist strikes, and campaigns for the legalisation of abortion where it did not yet exist emerged. This created the conditions for the reemergence of a political subject that had had a strong presence since the mid-1970s and throughout the following decade: Latin American popular feminism, which turned pain into organisation and anger into a transformative force.

## 'We are all workers': Between gender violence and economic violence

From its inception, the Ni Una Menos movement made it clear that sexist violence cannot be understood in isolation: it is deeply connected to economic inequality, job insecurity, indebtedness, and the multiple forms of exploitation that particularly affect women and dissidents. But it also forged a scene of rearticulation of feminist energy in every sphere of social, organisational and political life.

Through international women's strikes – promoted since 2016 by an assembly energised by feminist collectives, social movements, unions, political parties, gender diversity groups, anti-racist networks and migrant groups – the slogan was amplified: 'If our lives are worthless, produce without us.' The feminist strike challenged the economic system from a radical perspective. It highlighted that care work, which is mostly unpaid and feminised, sustains the functioning of capitalism. It demanded that *we are all workers*, not only in formal employment, but in every space where life is produced and reproduced.

In addition, Ni Una Menos incorporated the denunciation of debt as a form of subjugation: many women are forced into debt in order to survive or to cover what the state does not guarantee. This economic violence is also gender violence. Thus, feminism proposed a new framework for thinking about social justice: there can be no emancipation without redistribution, nor freedom without economic autonomy.

## It is not freedom, it is neoliberalism: The war against social justice

Ten years after the first 3J (3 June, the date of the movement's first mobilisation, which started it all), feminism faces not only its historic struggles but also a global conservative offensive that seeks to delegitimise transfeminisms and all forms of popular mobilisation of the last decade, as part of an ideological reinforcement of the radicalised right in the rearmament of financial neoliberalism in its most extreme and neo-colonial phase.

In 2024, Javier Milei's government in Argentina took office with the promise of carrying out 'the world's biggest adjustment'. Of the total spending cuts in 2024, contributory pensions and retirement benefits accounted for 24%, real direct investment in public works for 15%, transfers to provinces for 16%, energy subsidies for 10%, social programmes for 11%, and wages for 8%.

Under the rhetoric of individual 'freedom', fiscal austerity and the 'chainsaw' lies

a policy of state destruction and structural adjustment that hits the most vulnerable sectors: retirees whose pensions have lost up to 35% of their value due to inflation, coupled with cuts to essential free medications and a 29% increase in poverty. The reaction includes budget cuts in gender policies, the criminalisation of feminist activism, and the amplification of social and street violence against gender and sexual minorities. There is an attempt to return to the discourse of the traditional family, to question comprehensive sex education, and to erase inclusive language.

This conservative onslaught is also supported by the discrediting of achievements such as legal abortion, gender identity laws, and job quotas for transgender people. In the name of fiscal 'order', the popular economy is also being dismantled with the elimination of policies supporting cooperatives and informal workers, pushing thousands into poverty.

At the same time, memory, truth and justice are being persecuted: human rights policies are being dismantled, historical institutions are being delegitimised, and state terrorism is being denied. And state personnel in care sectors, including health and education, are being defunded and suffocated with wage cuts. These sectors are considered an expense, as are those specifically dedicated to promoting scientific and technical knowledge in the country.

These actions do not represent real freedom, but rather a neoliberal offensive that turns rights into privileges, redistributes power and resources to concentrated sectors of power, empties the role of the state, and attacks the very heart of social justice won through decades of struggle.

Faced with this scenario, the feminist movement is at a new crossroads: how to sustain its gains, protect its spaces, and respond to hatred with greater organisation and more street action. The networks built over the past 10 years will be key to resistance. But it is also necessary to renew strategies, add new voices and strengthen coordination with other social movements.

## Unifying struggles against the advance of neo-fascism

Feminism is not just a struggle for women's rights. Today, more than ever, it is a trench against all forms of authoritarianism and exclusion. In a global context where neo-fascist political projects – xenophobic, anti-feminist and anti-rights – are advancing, the challenge is clear: to build a broad, plural and combative unity that confronts hatred from below.

Ten years after Ni Una Menos, in a difficult scenario for street strategy, feminist organisations called for the unification of struggles in defence of pensioners – who for months have been mobilising and facing weekly repression by the libertarian government – but also of all those affected by this political project aimed at restoring class power to the concentrated sectors of power, mainly the financial sector.

On 4 June 2025, a large and diverse crowd mobilised in front of the Argentine Congress to protest budget cuts promoted by President Milei. The march brought together retirees, teachers, scientists, doctors, people with disabilities, social activists and feminists, unifying demands that had previously been expressed separately.

The feminist experience of this decade has shown that it is possible to change the rules of the game. But it has also shown an extraordinary sensitivity to the conflicts besetting society in the face of the dispossession of rights and destruction of the living conditions of the popular majority.

On the last 4J, called by Ni Una Menos, the streets once again became a territory of resistance. It was perhaps the most plebeian of all in the last 10 years on this date, sustained especially by the economic and political networks deployed in working-class neighbourhoods. Despite the goal of libertarian neoliberalism to break all the bonds of community solidarity and discourage all forms of political and social participation, there they were, alongside their comrades, embracing the women workers of Garrahan – Argentina's main high-complexity paediatric care centre – in struggle, the families of people with disabilities who have been the target of attacks by government officials, and women workers who mobilised with their unions.

The square was also filled with feminist comrades from the ecumenical roundtable that systematically accompanies the mobilisation of retirees, and the transvestite-trans community was also present, which since 2014 has been organising to demand reparations for the systematic persecution and institutional violence they have historically suffered.

It was also a square that reminded us that, in the face of fear and the feeling of vulnerability and unease, there is a more powerful force: solidarity, empathy, resistance and grassroots organisation. Because united, reorganised and with memory, we continue to shout: *Not one less, we want to live, free and debt-free.* ◆

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# African music festivals and the politics of reclamation

If they can navigate questions of ownership, authenticity and exploitation, African music festivals hold promise of becoming genuine platforms for both celebrating contemporary continental artistry as well as honouring cultural heritage and memory.

**Achille Tenkiang**

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**Attendees at the Afrochella festival in Ghana. African music festivals have become platforms for imagining new cultural, economic and political possibilities.**

THE energy at Afrochella in 2018 was palpable, electric, a heady mix of sound and movement that seemed to rise from the ground at Accra's El Wak Stadium. It wasn't just a music festival; it was a homecoming, a reunion of the African diaspora that stretched from Accra to Atlanta, Lagos to London. As the sun dipped below the horizon, the air filled with laughter, conversation and music that vibrated deep in my chest. One felt proud, not just in being African but in being part of something larger: a story that had always been ours but was now reclaiming its rightful place on the world stage.

That night, as Daddy Lumba's and King Promise's voices soared over the crowd and Stonebwoy delivered anthems of solidarity, I personally began to see African music festivals for what they truly are: not just gatherings but stages of cultural negotiation. In their exuberance lies a deep political project – to reclaim narratives, bridge diasporic divides and challenge the global commodification of African identity. Yet beneath the pride and possibility, these festivals also raise difficult questions. Who benefits from their growing global prominence? Are they amplifying authentic African voices or merely repackaging them for export? And what happens when a festival like Afrochella, a symbol of diasporic pride, becomes embroiled in disputes over intellectual property rights, as it did in its name debacle with the US-based Coachella festival in 2022?

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In 1977, Lagos hosted the Second World Festival of Black Arts and Culture (FESTAC), one of the largest cultural gatherings in African history. With over 17,000 participants from 56 nations, FESTAC was both an artistic celebration and a bold assertion of African agency in a postcolonial world. The festival's slogan, 'Rebirth and Rediscovery', underscored its dual mission: to reclaim African heritage and project its creativity onto a global stage.

Scholar Sylvia Wynter has argued that events like FESTAC challenged colonial epistemologies by foregrounding African art as a source of knowledge and power. The festival's diverse performances – from traditional drumming to experimental jazz – redefined African culture as dynamic, countering Western stereotypes of Africa as static or primitive. Materially, FESTAC bolstered Nigeria's position as a cultural leader in postcolonial Africa, but it also highlighted disparities in how resources for such events were allocated, sparking debates about the economic priorities of newly independent states. Nigeria in 1977 was under military rule, grappling with its identity as a nation-state composed of multiple ethnic groups. FESTAC's Pan-African ethos was an attempt to unify these identities under a broader cultural banner, even as internal tensions persisted.

The Pan-African Festival in Algiers in 1969 exemplified the revolutionary potential of art.

Hosted by a newly independent Algeria, the festival brought together artists, musicians and freedom fighters from across the continent. Frantz Fanon's belief that culture could catalyse political change was palpable. Performers like Miriam Makeba and poets like Aimé Césaire used their art to articulate visions of freedom and resistance. The festival not only celebrated African liberation movements but also cemented Algeria's role as a hub for revolutionary solidarity during a period marked by anticolonial struggles across the continent.

Algeria in 1969, having recently emerged from a brutal war of independence against France, was eager to position itself as a beacon of postcolonial hope. The festival's emphasis on liberation and solidarity echoed the nation's broader political agenda, combining cultural expression with the strategic goal of uniting African and diaspora communities against neocolonial forces.

The 21st century has seen African music festivals evolve into global phenomena, fuelled by the rise of Afrobeats and the increasing connectivity of the African diaspora. Afrochella, launched in Ghana in 2017, has become synonymous with Detty December, the annual holiday season when diasporic Africans return to the continent. The festival positions itself as a diasporic bridge, showcasing Ghanaian culture while appealing to international audiences. Similarly, Afro Nation, which debuted in Portugal, expanded to Ghana, drawing thousands to see stars like Wizkid, Burna Boy and Tiwa Savage. However, Afrochella's rebranding as AfroFuture – prompted by a lawsuit from Coachella's parent company – revealed ongoing tensions about cultural ownership and narrative control. Critics saw the lawsuit as Western cultural gatekeeping, but the festival's new name, AfroFuture, emphasises a vision embracing African culture's past, present and future.

Corporate sponsorships from companies like Heineken and MTN bring financial stability but also shape festival branding. UNESCO warns that such partnerships can risk diluting local authenticity in favour of a more globalised aesthetic. Festivals must navigate this tension carefully, balancing the financial support of global sponsors with the imperative to centre local narratives and participants.

Nyege Nyege, Uganda's avant-garde festival, exemplifies how festivals can navigate – and challenge – these tensions. By embracing experimental sounds like East African techno and gqom, Nyege Nyege redefines African authenticity as dynamic and evolving rather than fixed. Cofounder Derek Debru describes it as a space for 'freedom – to create, to experiment, to connect'. However, the festival's openness to queerness and unconventional performances has sparked backlash from Ugandan officials, with critics invoking colonial-era morality laws to denounce it. These laws, legacies of British colonial rule, highlight the contradictions of modernity: The very frameworks used to police identity are colonial impositions.

The 2018 controversy where Uganda's minister of ethics and integrity, Simon Lokodo, sought to ban Nyege Nyege, underscored the festival's role as a space of resistance. Critics of the ban noted the irony of invoking 'Africanness' to enforce colonial-era values, while the festival's programming resisted essentialist views of African culture. As *RA Magazine* observes, Nyege Nyege's blend of electronic innovation and traditional rhythms exemplifies Africa's pluralistic cultural landscape, offering a model of authenticity grounded in creativity and diversity.

From bustling urban centres like Accra during Detty December to the serene natural settings of Uganda's Nyege Nyege, these music festivals have turned cities into stages for cultural dialogue and celebration. Yet their impact is often fraught with contradictions, revealing the tensions between their lofty intentions and the realities of their execution.

Accra, for example, transforms into a cultural capital during December, drawing diasporic tourists who inject energy and economic activity into the city. Streets bustle with pop-up markets, Afrobeat sound systems and vibrant displays of local artistry. But many reports highlight that much of the revenue generated by these festivals flows to external organisers and upscale venues, often leaving small-scale vendors and local artists marginalised. Events like Detty December contribute to the gentrification of neighbourhoods, driving up rents and displacing local residents. This raises questions about who truly benefits from these events, especially as the commercialisation of cultural spaces often prioritises global consumption over local empowerment.

The case of Lagos's Nativeland festival further exposes the fragility of such events when profits overshadow the well-being of participants. The collapse of its stage in 2024, narrowly avoiding catastrophe, was emblematic of broader systemic neglect. What if a globally recognised artist like Wizkid had been injured during the incident? Such a scenario would likely have provoked greater scrutiny and more compassionate responses from organisers. Instead, the festival's tepid acknowledgment of the event underscored a lack of accountability and the risks faced by local communities when safety takes a backseat to commercial gain. Nativeland's logistical failures and profit-driven motives reflect a broader shift away from the grassroots ethos that once defined these gatherings. When cultural spaces are reduced to commodities, they risk losing their transformative potential.

Historically, festivals like

FESTAC in 1977 offered an alternative model. These events were grounded in collaboration between state actors and local communities, fostering cultural pride and solidarity. Unlike contemporary festivals that often rely on elite sponsorships, FESTAC prioritised community participation and state-led support, creating spaces where culture intersected with political empowerment.

Despite challenges, festivals retain the capacity to democratise cultural production and foster meaningful connections. By revisiting the collaborative ethos of their predecessors, contemporary festivals can bridge the gap between commerce and community. Investing in infrastructure, centring local stakeholders and fostering equitable participation could ensure these vibrant cultural events remain true to their promise – platforms for African creativity that honour the communities they represent.

Indeed, not all is bleak. Flytime Fest in Lagos offers a different narrative. As Africa's longest-running concert series, Flytime has consistently celebrated Nigerian music and culture since 2004. Its 2024 edition, headlined by Olamide, Davido and Ayra Starr at the Eko Convention Centre, marked 20 years of breaking barriers. By organising Nigeria's first-ever multi-day music festival and serving as a launchpad for both local and international acts, Flytime has set a standard for live entertainment in Africa. Similarly, festivals like WeLoveEya in Benin provide meaningful platforms for francophone artists, while East Africa's Blankets and Wine continues to be a staple of regional cultural expression. FEMUA in Côte d'Ivoire's use of proceeds to fund educational initiatives exemplifies how festivals can create lasting change. These examples highlight how festivals can combine commercial success with cultural celebration, fostering pride while creating opportunities for artists and audiences alike.

African music festivals have become platforms for imagining new cultural, economic and political possibilities. At their best, these festivals could be reimagined as spaces where local communities are not only included but centred as the most vital stakeholders. This means moving beyond the mere commodification of culture for a global or diasporic audience and instead fostering partnerships that empower the artisans, performers and vendors who give these festivals life. Locals must not only benefit economically but also shape the narratives and values that these events promote. For instance, infrastructure investments should prioritise safety and sustainability, addressing both the immediate risks to attendees and the broader need for long-term cultural preservation.

These festivals also have the potential to set a global standard for cultural integrity and inclusivity, challenging exploitative practices while celebrating Africa's dynamic, multifaceted creativity. By redistributing power and profits towards those who form the backbone of these events, African music festivals could evolve into truly transformative institutions – spaces that celebrate both the innovation of contemporary African artistry and the enduring importance of collective memory and cultural heritage.

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As the final notes of Afrochella 2018 faded into the warm Accra night, I stood there, awash in pride and possibility. That night, I realised that African music festivals are not just events; they are movements. They tell the world that Africa's cultural and artistic expressions are as diverse as its people, resonating with creativity and complexity.

These festivals are spaces where Africa negotiates its past, asserts its present and imagines its future. They remind us that music is more than entertainment – it is identity, history and power. Reflecting on festivals like FESTAC and the Pan-African Festival of Algiers, it becomes clear that these gatherings were never just about music or art but about articulating a vision of African identity and sovereignty in a postcolonial world. They sought to reposition Africa as a cultural and intellectual leader, challenging global perceptions rooted in colonialism and celebrating the continent's creativity as a force for solidarity and liberation.

Today, African culture occupies a more prominent place in the global imagination, but this visibility comes with new tensions. While artists like Rema, Tems and Tyla dominate international stages, and festivals like AfroFuture captivate diasporic audiences, questions of ownership, authenticity and exploitation persist.

This reflection is also a critique of myself. Over the past nine years, I've spent eight Christmases and New Years on the continent, immersing myself in these festivals. I've revelled in their joy and creativity, but I've also taken up space. In demanding accountability from organisers, I must also examine my own participation. How can I demand more equitable practices while ensuring my presence contributes meaningfully rather than detracting from local communities? The challenge now is ensuring that these platforms remain faithful to their origins as spaces of reclamation and resistance. As they evolve, their organisers, audiences and stakeholders must remain vigilant, ensuring that these soundscapes of identity remain movements that uplift and empower rather than exploit and commodify. ◆

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