UNITAID'S CONTRADICTORY APPROACH TO INTELLECTUAL PROPERTY RIGHTS RISKS PROGRESS

Global health agency Unitaid has helped millions in low- and middle-income countries through its constructive and collaborative approach to intellectual property rights (IPRs). Its new, parallel strategy of attacking IPRs risks undermining this work.

» Unitaid and other global health organisations have demonstrated that access to medicines can be increased while respecting vital intellectual property rights.

» Nevertheless, Unitaid is encouraging middle-income countries to undermine and attack IP rights, by funding the lobbying activity of anti-IP NGOs.

» Unitaid risks undermining global health progress through its controversial approach to IPRs.

Founded in 2006 by the governments of France, the United Kingdom and others, Unitaid has carved out a niche in the crowded world of global health as a "market-shaper"[1] that aims to promote access to treatments and diagnostics for HIV (and its deadly co-infections such as Hepatitis C), tuberculosis and malaria.

Unitaid's most distinctive contribution is its Medicines Patent Pool, now approaching its tenth year of operation. By acting as a "one-stop shop" for patented medicines available for voluntary licensing in low- and middle-income countries, the MPP has demonstrated the power of cooperation and collaboration in improving access to medicines in poorer parts of the world.

Respecting existing intellectual property rights for new medicines is key to the success of the MPP, as it allows rights-holders of innovative medicines to distribute their medicines in lower-income markets without upsetting their franchises in wealthier parts of the world.

Despite demonstrating how intellectual property rights can be leveraged to promote access to medicines, Unitaid has also started to energetically pursue what it describes as a "complementary" strategy of encouraging middle-income countries to undermine and attack IP rights.

It does this mainly by funding civil society organisations to lobby for compulsory licenses and to campaign against IP rights for medicines in general; and by training

officials from developing countries in how to deploy compulsory licenses and other TRIPS flexibilities. The thinking is, that removing patent rights will promote access to medicines in countries that do not benefit from the voluntary licenses negotiated under its patent pool and elsewhere.[2]

Unitaid's board clearly views the organisation's schizophrenic attitude to intellectual property rights as justified to advance its public health objectives. However, promoting the erosion of IPRs and trust in the system is likely to do more harm than good in the long run, not least because its Medicines Patent Pool is proving so effective. It's time for a rethink of this counterproductive strategy.

UNITAID LOOKS BOTH WAYS ON IPRS

The global health landscape is crowded with NGOs, foundations, public-private partnerships and other governmental organisations working to promote innovation and access in the main disease areas covered by Unitaid. Many of these, such as the Global Fund, PEPFAR and the GAVI Alliance were founded in the early 2000s and were already well-established and prominent by the time Unitaid was established in 2006. As a smaller, newer organisation Unitaid has sought to differentiate itself by focusing on the "downstream" part of the global health value-chain by providing support for late-stage research and development for under-served needs; as well as attempting to shape the market and institutional conditions for the mass roll-out and adoption of new health technologies and medicines.

It is this attempt to position itself simultaneously as a champion of both innovation and access that has led to Unitaid being simultaneously for and against intellectual property rights.

Unitaid laid out its strategy on IPRs in a 2016 document presented to its Executive Board,[3] which argued that although IPRs are essential for innovation, they also block competition and therefore limit access to new technologies. To fulfil its mandate, the document argued, it must constructively manage IP through voluntary approaches to promote innovation and access, but it must also simultaneously promote coercive strategies to remove IP rights in order to achieve access at scale.

Unitaid
Innovation in Global Health

Unitaid simultaneously funds projects that work with and against intellectual property rights.

In practical terms, this has led to Unitaid financially supporting a blend of voluntary and coercive approaches to medicine-related intellectual property rights.

On the one hand, Unitaid manages and funds the increasingly successful and prominent Medicines Patent Pool, in which the developers of HIV, Hepatitis C, malaria and tuberculosis medicines voluntarily license their patents for low-cost manufacture and distribution in lower-income countries by reputable generic manufacturers.

On the other hand, Unitaid is ramping up funding to support organisations whose objective is to weaken or override medicine patents in lower and middle-income countries. To justify this, Unitaid cites internal calculations that this would save countries significant sums in medicine procurement costs.[4]

UNITAID'S ACTIVIST AGENDA

In 2015 a coalition of civil society groups lobbied Unitaid to fund their Hepatitis C activism because of their past role in "shaping the market" for ARV drugs in middle-and lower-income countries."[5] The document argued that "advocacy has sustained the largest gains in the ARV access movement by creating the enabling environment for generic drug access," citing previous work on promoting the use of TRIPS flexibilities such as compulsory licensing".[6]

Shortly after, Unitaid endorsed these lobbying efforts by agreeing to allocate funding support for projects that aim to weaken intellectual property rights via the use of compulsory licenses and other TRIPS flexibilities.[7] In 2017 it issued a call for proposals to "help countries use trade rules to increase access to drugs", eventually allocating grants in 2018 totalling $22m to a number of civil society groups including Third World Network, International Treatment Preparedness Coalition and the South Centre.[8]

All of these organisations are known for their longstanding hostility to intellectual property rights and represent a strand of opinion that sits outside the mainstream of the global dialogue on health and IP rights.

These grants will be used for a range of activities that aim to weaken patent rights, including lobbying governments to grant compulsory licenses for medicines. Examples of specific projects funded include:

- Grants to promote the use of TRIPS flexibilities to promote generic competition, including compulsory licensing;[9]
- Support for the "Make Medicines Affordable" campaign, which lobbies for compulsory licensing and weaker IP rights in the context of HIV medicines;[10]
- Making a specific call for a compulsory license of the HIV drug dolutegravir in twelve middle-income countries;[11]
- And lobbying for the exclusion of intellectual property provisions from Free Trade Agreements (despite evidence showing that such provisions have so far had no impact on the price of medicines).[12]

In 2018 Unitaid financially supported the "Global Summit on Intellectual Property and Access to Medicines" in Marrakech, in which participants adopted somewhat extreme positions against IPRs for medicines and the global trade rules that govern them. Intellectual Property Rights were denounced as "exploitation" and driven by "greed",[13] with advocacy around a "patent free future".

"The system is killing people, and will keep killing people unless we fight back," a delegate from ABIA Brazil told the conference. "It's time to accuse them of being criminals," he declared somewhat apocalyptically. "The end of impunity is coming," added a colleague.[14]

INTELLECTUAL PROPERTY RIGHTS WORK

Away from the bloodcurdling rhetoric of the Marrakech Summit, the reality is that intellectual property rights play a crucial role in promoting public health progress.

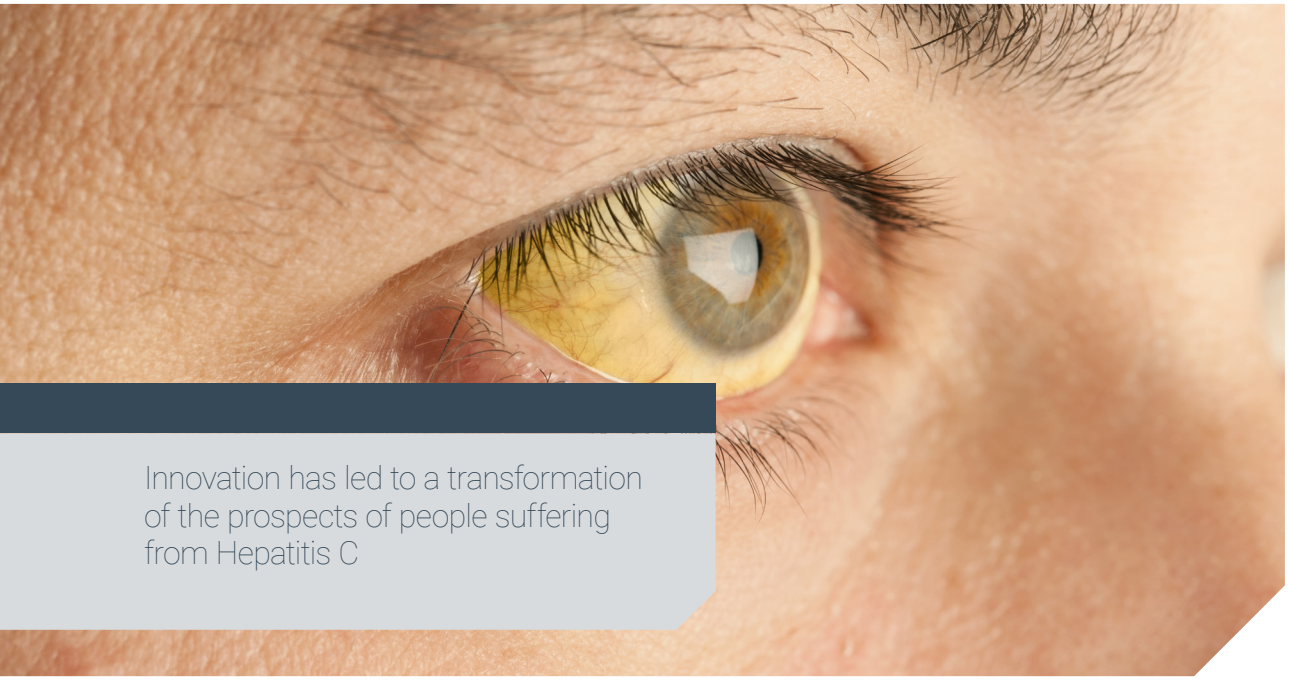
Most obviously, patent rights are responsible for the enormous strides in the efficacy of treatments and diagnostics for the diseases for diseases like HIV and Hepatitis C.

In the early 1980s, a HIV diagnosis was a certain death sentence. Now, thanks to a Copernican revolution in HIV medicine, a person diagnosed with HIV can expect to live a normal life well into old age. Over the last decade, hepatitis C has gone from having no effective treatment to having multiple cures available that treat almost every genotype of the disease, all manufactured by competing companies who have used the patent system.

"If you have to have Hepatitis C, now is the time to have it," Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York told the Financial Times. "We have these marvellous drugs we can treat you with right now, without side effects," he adds. "And this time next year, we'll have another round of drugs available."

Unitaid states in its IP policy document that "patents limit competition that could stabilize supply and/or reduce prices." Elsewhere, patents are routinely denounced as "monopolies" that are fundamentally incompatible with public health.[15]

One eminent scholar of patents, Prof. Edmund Kitch, labelled the application of the term "monopoly" to patents as one of the "elementary and persistent errors in the



Innovation has led to a transformation of the prospects of people suffering from Hepatitis C

economic analysis of Intellectual Property" in a well-known paper of the same title.[16]

While patents do provide exclusive rights, there are usually many substitutes and alternatives to a patented product that make market monopoly very rare. Markets for products covered by IP are often intensely competitive, because there are usually many substitutes and alternatives. This is particularly true of medicine.

For example, a patient needing a cholesterol drug has a host of statins from which to choose. Similarly, patients with osteoporosis can choose from Fosomax, Actonel, or Boniva.

There are no "monopolies" in the categories of medicine that fall under Unitaid's manate. Over the last decade, hepatitis C has gone from having no effective treatment to having around 14 FDA-approved cures available that treat almost every genotype of the disease.[17] The FDA has approved around 40 different antiretroviral drugs to treat HIV infection.[18] The 21st WHO Essential Medicines List includes 20 different medicines and combinations for the treatment and prevention of malaria, and 23 for tuberculosis.[19]

Occasionally, a medicine is launched that is so ground-breaking it creates a new category in which it is the only product (at least until other competitors catch-up). This was the case for a time for Sofosbuvir, a direct acting antiviral medication used as part of combination therapy to treat chronic Hepatitis C, approved by the FDA in late 2013. Whereas previously patients had to endure toxic, difficult to administer, poorly tolerated and often ineffective treatments, this new medicine was an easy to administer cure for the main genotypes of Hepatitis C.

> "The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries"
>
> **GEOFFREY DUSHEIKO & CHARLES GORE** IN THE LANCET

At the time, there was much pressure to compulsory license this product given its revolutionary potential to tackle the burden of Hepatitis C[20] – pressure that continues today. But it was important that the patent rights for this game-changing cure were respected despite its unique market position, to encourage other companies and the rights-holder itself to invest in competing, better treatments.

The financial potential of this new product category did indeed lead to multiple competing products entering the market in quick succession, in turn placing a downwards pressure on prices.[21] As Geoffrey Dusheiko and Charles Gore write in The Lancet: "The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries."[22]

There is some way to go before all those in need have access to Hepatitis C cures, not least because only 19% of the estimated 71 million people around the world infected with Hepatitis C are aware of their diagnosis.[23] Nevertheless, the rapid arrival of multiple, competing cures for this disease is a remarkable development that owes much to the incentives provided by intellectual property rights.

PRACTICAL SOLUTIONS

In most low- and middle-income countries, health insurance and other risk pooling mechanisms are minimal, meaning patients have to self-finance the vast majority of their care. For people on low incomes, even the cheapest generic medicines are unaffordable, let alone new innovative medicines.

A question that has therefore long exercised the global health community is how to widen access to medicines in low and middle-income countries while respecting innovation incentives such as intellectual property rights.

Over the last two decades, voluntary approaches have proven their worth. The Global Fund, the GAVI Alliance and the President's Emergency Plan for AIDS Relief have made major contributions to increasing access to medicines and vaccines, procuring and distributing both originator and generic medicines en masse while respecting intellectual property rights.

One solution that has been at the centre of these successes are voluntary licenses, in which patent holders license to generic manufacturers, on an exclusive or nonexclusive basis, the right to manufacture, import, and/or distribute a pharmaceutical product. The license usually sets quality requirements and limits the distribution of the product to specific markets. Royalties can either be foregone or set at a level appropriate to the economic status of the country in which the licensed product is to be distributed.

"Generic competition through public health licensing of patented products has been a game changer, especially for HIV", according to Philippe Francois, Head of Sourcing and Supply Chain at the Global Fund.[24] "With the help of partners like the MPP, the Global Fund has accelerated access to key new products in the countries it supports, putting 18.9 million people on antiretroviral therapy for HIV in 2018, and providing more than 83% of HIV-positive mothers with ARV therapy to keep them alive and prevent transmission of the virus to their babies, up from just 1% in 2000."

According to the 2018 Access to Medicine Index, a total of 18 compounds tackling HIV/AIDS are covered by voluntary licenses issued by AbbVie, Bristol-Myers Squibb, Gilead, GSK, Johnson & Johnson, and Merck.[25]

There are now five Hepatitis C compounds available for voluntary licensing to generic drug manufacturers for sale in lower- and middle-income countries. Voluntary licensing has increased the number of people treated by approximately 70 per thousand people diagnosed with hepatitis C, according to a study carried out in 2019 by researchers at

Imperial College, London.[26]

VOLUNTARY LICENSING ADVANTAGES

Voluntary licensing has numerous advantages over coercive approaches. Negotiations can be conducted swiftly without any time-consuming litigation or patent oppositions that would otherwise delay generic manufacture and launch. Further time and money can be saved by allowing the licensee to rely on the originator's clinical trials data already submitted and approved by regulatory agencies, meaning the generic manufacturer doesn't have to conduct its own clinical trials to gain marketing approval.

Because of their cooperative nature, voluntary licenses can involve the transfer of manufacturing technology and know-how. This not only speeds up the time in which generic versions can be manufactured and taken to market, but also helps build technological capacity in countries that do not have established pharmaceutical manufacturing industries.

If voluntary licenses are non-exclusive (as is the case of the MPP) they can encourage greater competition amongst license holders, which can result in further reduction of prices. Most importantly, voluntary licenses can speed up the launch of new medicines in less commercially attractive markets, as they can be served by generics companies who already have a presence, rather than the innovator itself.

Licenses can be structured in a way to ensure the quality of the drugs produced, essential for viral diseases like HIV and Hepatitis C where drug resistance is a constant threat. Crucially, voluntary licenses work with, rather than against intellectual property rights, preserving incentives to innovate while ensuring the broadest possible access.

Despite its ongoing campaign to promote the use of compulsory licenses, Unitaid understands the power of working with the IP system to achieve global health goals. It has been a pioneer of public health-oriented voluntary licenses, since 2010 using its Medicines Patent Pool to gather together in one place patents on HIV, malaria and tuberculosis drugs for licensing in developing countries.

Charles Gore, executive director of MPP explains. "Generally, where [pharmaceutical companies] make their money is in the developed world, so we work with them to give us licenses for the developing world … We then sublicense to generic manufacturers, which allows them to produce these cheap … yet quality-guaranteed medicines much earlier." This process ensures new drugs are made available at the same time worldwide, he adds.[27]

The MPP has already generated significant cost savings. A 2019 study estimated that direct savings generated by the MPP will be around USD 2.3 billion by 2028. In other words, for every USD1 spent on MPP, the global public health community saves USD 43. The saving of USD 2.3 billion is equivalent to more than 24 million People Living with HIV receiving first-line Anti-Retroviral Therapy in Low and Middle-Income Countries for one year at average prices today.[28]

Bryony Simmons, study author, Imperial College commented: "Voluntary licences appear to be a useful tool to lower costs and significantly reduce the time-scale for accessing patented medicines in poorer countries. Our results should be used to advocate for an expanded scope of licence agreements."

> “Taking an axe to IP rights in low and middle-income countries would in the long term, reduce access to medicines”

COOPERATION, NOT COERCION

Unitaid’s Medicines Patent Pool is a practical initiative that is demonstrably improving access to medicines without the uncertainty and conflict that arises from the abrogation of intellectual property rights.

Voluntary licensing as an approach stands in contrast to the use of compulsory licenses, which Unitaid is promoting by proxy via its grants to civil society groups. Compulsory licensing is a short-termist move that is unlikely to be sustainable in the long run.

Modern anti-viral drugs, biologic drugs and vaccines are complex to manufacture and require a high degree of know-how and technological capacity. More of these medicines come on to the market each year, with increasing numbers making their way onto the WHO’s Essential Medicine List, which provides a basis for selection into the MPP.

Although a compulsory license gives permission to an entity other than the patent owner to produce, import, sell, or use the patent-protected product, there is no obligation for patent owners to provide additional information. Therefore, manufacturing know-how is not necessarily obtained under a compulsory license.

Because of this, compulsory licenses may not be as cost-effective as voluntary methods of medical technologies procurement, particularly when licenses are issued for local production in lower-income countries.[29] In fact, manufacturers are likely to be disincentivized from sharing such information under these circumstances.

Evidence bears this out: one important study shows that for HIV drugs, international procurement through the Global Fund to Fight AIDS, tuberculosis, and malaria; UNICEF; and other international channels is able to achieve substantially lower prices than those medicines produced via compulsory licenses.[30]

Unitaid itself recognises the value of collaboration with regards to intellectual property rights through its Medicines Patent Pool: “The whole point of our model is it creates a win-win situation. Compulsory licensing is a threat to pharma companies, which is why we are not about that. We are a voluntary scheme and we are only talking about essential medications.”[31]

Counterintuitively, taking an axe to IP rights in low and middle-income countries would in the long term, reduce access to medicines. Evidence shows that countries with stronger patent protection typically enjoy access to new medicines several years before those with weaker protections.[32] [33]

This is because of the significant investments innovator companies make in order to launch a new medicine in a country: meeting regulatory requirements including local clinical trials, educating doctors and patients, building supply chains and distribution networks, and conducting post-launch surveillance and so on. IP rights are necessary to protect these investments, particularly for lower-income countries where market-size will limit potential returns.

These initial investments are also vital for subsequent competitive generic markets, as the investments required to establish an innovative product within a market will help the rapid and widespread uptake of generic equivalents upon patent expiry. Innovator launch of a medicine in a developing country "materially improves access to that medicine [by a factor of 7, on average] compared to instances or time periods when a generic provider" launches, according to one study of the impact of innovator drugs on subsequent generic markets in LMICs.[34]

CONCLUSION

Given the success and massive future potential of the MPP and its collaborative approach to the licensing of intellectual property, it is concerning that Unitaid is apparently waging a simultaneous proxy war on patent rights via its grants to third party organisations.

Ironically, these grant recipients are promoting anti-IP policies to which Unitaid's two biggest funders – France and the United Kingdom – normally strongly oppose at multilateral forums such as the WTO TRIPS Council. There is no logic there. Further, Unitaid's controversial IP strategy is likely standing in the way of its expansion to become a truly multilateral initiative, by making it very difficult for pro-innovation countries such as Switzerland, Germany, Japan and the United States to contribute. As it stands only six countries are on its board, limiting Unitaid's financial resources and its potential for political consensus.

Unitaid's expertise and not inconsiderable financial resources would be better directedat working to address gaps in healthcare delivery caused by weak health care systems, and supporting voluntary access programmes that work with rather than against intellectual property rights. Unitaid's Janus-faced approach to the intellectual property rights needs a re-think.

Unitaid's controversial IP strategy prevents it from becoming a truly multilateral initiative

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