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'A proposal for change: Managing patents to ensure access to AIDS medicines for all'

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Ten years ago, the world prepared to gather in Durban, South Africa, for the first International AIDS Conference to be held on the continent most devastated by this terrible disease. At the time, the statistics were grim: only one in a thousand African people in need could get access to AIDS treatment, because the drugs were only available from originator companies who owned the patents on these medicines. They came with a paralysing price tag of US\$10,000 to US\$15,000 per patient per year.

Through an immense joint mobilization of people living with HIV/AIDS and their organisations, their doctors and nurses, civil society, dedicated ministries of health, donor governments, and pharmaceutical companies, we have achieved today what most delegates at Durban thought impossible: access to AIDS treatment for more than 4 million people in the developing world.

This achievement required some key essential ingredients: first of all the AIDS treatment movement that put the AIDS crisis on the political agenda, alongside courageous medical leaders willing to take risks, increased funding for HIV treatment, the availability of low-cost medicines.

While the achievements so far are enormous, there are huge challenges that still need to be overcome to ensure that current and future unmet needs are met.

The last ten years have shown how we can have a tremendous impact on reducing illness and death in developing countries through ARV treatment. But in this current climate of wavering support for achieving universal access to treatment – a promise only 5 years old - we must look ahead to see how we can have an even greater impact by making treatment more affordable so that the millions of people still waiting for treatment can be brought onboard and those already on treatment are ensured a chance at long-term survival.

In line with scientific consensus, the latest WHO treatment guidelines recommend that people should start treatment earlier, before they become very ill and weak. This is a critical step toward bringing treatment for people in developing countries in line with treatment in wealthy nations, and is expected to help prevent transmission of the virus. However, it also means that 14 million people are now in urgent need of treatment. But of these 14 million people, only 4 million receive treatment, leaving a further ten million waiting empty-handed .

I have been asked by the IAS to address today how intellectual property – or IP – rules and practices relate to access to medicines. I will look at where we have been and what we have learned over the last decade, before focusing on ways to ensure affordable treatment is available to people in developing countries in the future.

The AIDS crisis and all its actors have caused a radical change in how we approach intellectual property in the field of medicine. This is reflected in legislative and policy changes, and changes in pharmaceutical companies' business practices.

It started in 1996 when a group of health NGOs met in Bielefeld, a mid size, sleepy town in Germany – made famous by John le Carre's *The Constant Gardener* – to discuss 'Access to Medicines and the WTO GATT Agreement'.

The TRIPS Agreement had just come into force. The TRIPS Agreement, an annex to the WTO rule book, was intended to encourage trade among its members. The TRIPS Agreement sets out minimum standards for IP protection and enforcement. The negotiations leading to the agreement had been primarily driven by the trade and commercial interests of powerful nations. Public health was not their focus and civil society organisations had not been part of the process.

The new WTO rules globalised intellectual property standards that were the norm in highly industrialized Western countries, and made them enforceable through the WTO dispute settlement procedures. Before TRIPS, pharmaceutical patent policies and practices were diverse. For example, many countries did not consider patents on products such as medicines and food to be in the public interest and half of the

countries actively excluded pharmaceutical (product) patenting altogether. This included a number of European countries such as Spain and Norway.

The WTO rules put an end to this when it required all member countries to introduce 20 year patents on medicines. As part of the WTO package, it was not possible for countries to opt out of TRIPS while becoming a member of the WTO, and the following years saw a wave of IP reforms in most developing countries to meet the requirements of the TRIPS Agreement. The policy space countries once enjoyed to design IP systems in line with their own development needs and priorities was rapidly shrinking.

In the late nineties, the potential effect of the changing IP rules on access to medicines was little understood, and interest in IP issues among the public health community was still rare.

A couple of things changed that:

In 1998, 39 drug companies and their representative body sued the new democratic South African government over amendments to its Medicines Act, which aimed to make low cost medicines more readily available. The companies asserted it was both unconstitutional and not compliant with the TRIPS Agreement.

This was done against the backdrop of the growing AIDS treatment crisis in the developing world at a time when HAART had become available in Western countries. HAART had shown that treatment could turn a disease with a certain death sentence into a chronic illness.

Big Pharma vs. Nelson Mandela provided shock therapy. It was a call to action that pulled many different actors onto the stage.

In 1999 at the UN in Geneva, a group of NGOs and AIDS activists held a conference titled 'compulsory licensing of AIDS drugs.' A compulsory license – or CL – is a way to overcome a patent barrier, whereby a government grants a license to an entity other than the patent holder, allowing them to produce the given product in exchange for

“adequate remuneration”. It is allowed under the TRIPS Agreement under certain circumstances and has been used repeatedly in industrialized countries throughout history – including to purchase low cost medicines.

Today there is nothing revolutionary or newsworthy about holding meetings about compulsory licensing and access to medicines – this conference has seen a number of sessions related to the topic – but in 1999 that was quite different. Discussing CLs were the exclusive domain of a subset of specialized IP lawyers. Here was a gathering of NGOs and health officials discussing how flexibilities in IP law could be used to increase the availability of low cost AIDS treatment in the developing world. This caused a great deal of concern among the patent holders.

Thailand and Brazil were the first developing countries with AIDS treatment programmes that embraced the notion of universal access. They both heavily relied on the ability to produce low cost medicines in government facilities, illustrating the enormous cost reductions that could be achieved. (e.g., Thai fluconazole for 0.29 USD vs. 11 USD Guatemala negotiated price from originator, a 38-fold difference). But both countries experienced pressure from wealthy nations that were concerned that strategies to create alternative sources of low cost medicines would be detrimental to their pharmaceutical industries.

The growing discontent culminated at the WTO ministerial conference in Seattle in 1999 with a call to ‘humanize the trade agreements’ – the rallying cry of the NGOs campaigning for access to medicines - and allow measures such as compulsory licensing to accelerate the production and availability of low cost AIDS medicines without risk of trade retaliation. A strong coalition of NGOs and developing countries was forming. Some soothing statements on access to medicines were made, but this was primarily aimed at diverting more radical change.

At the time, an editorial in the *Pharmaceutical Executive* commented: “*Unlikely as it seems, the pharmaceutical industry may have reason to thank the demonstrators who brought Seattle and the ministerial meeting of the World Trade Organization (WTO) to a standstill. Had the demonstrators not disrupted the gathering, the forecast for global pharma might be much cloudier* (Gopal 2000).”

But those that thought that the collapse of the WTO talks in Seattle would mute the demands for change in IP rules were wrong.

The period between the failed Seattle WTO Ministerial conference in 1999 and the 2001 WTO meeting in Doha saw a number of developments that had a profound effect on access to medicines and intellectual property.

Both Brazil and Thailand began to experience the consequences of pharmaceutical patents on AIDS drugs. Patents significantly limited their ability to produce generics at much lower cost, resulting in a heavy burden on their public health budgets. In Brazil 3 (out of a total of 17 products) patented medicines ate up 75% of the AIDS programme's drug budget.

In May 2000, five pharmaceutical companies had announced the Accelerating Access Initiative (AAI) to improve access to more affordable HIV-related medicines and diagnostics for developing countries and those hardest hit by the epidemic.

However, the voluntary price discounts offered through this initiative paled in comparison to the prices offered by the low cost generic producers. The generic producers were not yet hampered by patents, and so could also offer products in fixed dose combinations – or FDCs – that combined three medicines into one pill, which brought us 'Triomune' a FDC that helped to ease treatment tremendously.

Generic production of ARVs in India was possible because the Indian Patents Act did not provide for patents for pharmaceutical products until it had to in 2005. In early 2001, the Indian generic medicines producer Cipla offered triple-therapy AIDS treatment for 350 USD per patient/year to NGOs and for 600 USD for governments of developing countries. Cipla's dramatic price reduction, which received widespread media attention, hammered the message home that many of the multinational drug companies were abusing their monopolistic position in the face of a catastrophic human disaster and drew attention to the effects of generic market competition in bringing drug prices down. India quickly was becoming the 'AIDS pharmacy of the developing world.'

The same year controversy had broken out over the cost of the drug stavudine (also known as d4T) which came to a head on the Yale University campus in March 2001. Stavudine was developed by researchers at Yale University, which held the patent on the drug. The price of the generic version of stavudine in South Africa was thirty-four times less than the price of the brand-name product, but the patent prevented its use in South Africa. Under pressure from researchers, students, and access advocates, Yale renegotiated its license with Bristol Myers Squibb to ensure the availability of generic versions of stavudine in developing countries.

In 2000, the G8 paid unprecedented attention to health and the need for action to increase access to medicines. In December of that year, a 3-day global summit in Okinawa on infectious diseases outlined an agenda to prevent the spread of AIDS, provide treatment and care for those affected, and to enhance R&D for international public goods, including new approaches to managing IP. Most importantly, the Okinawa summit was the birth place of the Global Fund.

Then, in April 2001 after a global and domestic public outcry under the leadership of the South African Treatment Action Campaign, the 39 drug companies dropped their case against the South African government. The landscape had dramatically changed.

Access to medicines and the need to revisit the patent rules that govern them had become part of a larger political agenda and was no longer the exclusive domain of trade negotiators.

In November 2001, governments at the WTO Ministerial Conference – in an unprecedented move – adopted the Doha Declaration on TRIPS and Public Health. The Doha Declaration made clear 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.”

This represented the first significant push back to the relentless march to strengthen private IP rights without regard for societal consequences in poor countries.

In 2003, the WTO adopted the August 30th decision in an attempt to find a remedy for legal barriers to exporting sufficient amounts of medicines produced under a compulsory license, and to ensure that countries that rely on import for their medicines supply could benefit from CLs. While the solution that was adopted is deeply flawed, the TRIPS 31*bis* amendment is the sole amendment agreed since 1994 not only to TRIPS itself, but also to the full set of WTO agreements. It was public health considerations and especially the AIDS crisis that moved this.

On 1 December 2003, WHO together with UNAIDS declared the lack of HIV/AIDS treatment to be a global public health emergency and announced the 3by5 campaign.

The 500-word Doha Declaration on TRIPS and Public Health has been essential in making low cost medicines available on a large scale. While Thailand and Brazil's compulsory licenses for ARVs in 2006 and 2007 (and more recently in Ecuador) have been widely publicized, it is a little known fact that low and middle income countries have enabled procurement of low cost medicines on a large scale using the flexibilities contained in the Doha Declaration. Sixteen low and middle-income developing countries have issued compulsory licenses or government use licenses to gain access to generic ARVs. Twenty-eight out of 32 LDC WTO members authorized importation of generic ARVs with reference to paragraph 7 of the Doha declaration, which gave them the right to delay granting or enforcing of medicines patents until 2016.

When India became compliant with TRIPS in 2005, it incorporated public health safeguards in its Patents Act, introducing strict patentability criteria and the possibility for anyone to oppose the granting of patents. PLWHA and the Indian Lawyers Collective used these new flexibilities successfully to oppose patents on AIDS medicines that did not fulfill the patentability criteria India had adopted. A challenge to these provisions by one drug company (Novartis) – whose patent application for its cancer drug (Glivec) was rejected.

We have also seen companies responding to the challenges to their patents by agreeing to voluntary licenses to their patents, for example in South Africa as part of a

settlement reached after people with AIDS and the Treatment Action Campaign had filed a successful complaint with the South African Competition Commission. Companies have also made voluntary licenses available in response to the threat of non voluntary measures such as CLs and patent grant oppositions.

The AIDS crisis has been an engine for change – not only in thinking about IP and Health -

- but also in the way health care is delivered through task shifting;
- in treatment literacy, which empowered PLWHA and made them central to their own treatments vs. systems controlled DOTs;
- in increased political attention for health well beyond AIDS;
- in the role of civil society in decision making in global health;
- in the establishment of access strategies by the pharmaceutical industry;
- in the establishment of the WHO Pre Qualification system which helped create the market for low cost generics;
- and in bringing about new financing mechanisms such as the Global Fund, PEPFAR and UNITAID whose beneficiaries go beyond AIDS. The AIDS crisis is also fuelling the Robin Hood tax movement.

Market competition for the early generation of generic ARVs resulted in prices per patient per year dropping by 99% over the past decade. Drugs that used to cost \$10,000 per year are now widely available for \$67 per year.

So, what is the problem?

First, the cost of treatment is increasing again because new AIDS medicines are likely to be patented in developing countries and thus more expensive. Even in India, the new ARVs are likely to be patentable. Without production sources, the countries that rely on importation will find it hard to source low cost medicines. New FDCs will not be available automatically because of patents on the individual compounds.

Second, increasing numbers of people will need access to new generation treatments. These treatments in general are more widely patented and more expensive.

Third, we still need to expand access to first line medicines to people that do not benefit from them today. For example, the prices of HIV treatment even in some of the Eastern European countries are out of reach of the people who need them. The current licensing practices of the patent-holding companies are too scattered and come with limitations that hamper the full effect of generic competition and the ability to develop FDCs.

Fourth, we need to be able to respond to new scientific knowledge and evidence; we need to find ways of making key products affordable and available on a wide scale. For example, we need to replace older treatments that have significant side effects with the newer, less-toxic medicines that are now recommended by the WHO. But the cost of doing so is a barrier.

Fifth, we are faced with a serious financial crisis that risks setting back the treatment achievements of the last 10 years.

At the same time we see provisions in bilateral or regional Free Trade Agreements that try to limit flexibilities in patent law well beyond what is required by the WTO.

In July 2009, the UK all Party Parliamentary Group on AIDS called this situation the ‘Treatment Timebomb’ and called for “political activism” to “ensure that the next generation of drugs is available to the world’s poorest in future”

We need to go further than where we are today. We need expanded use of the existing flexibilities in patent law and new models to address the second wave of the access crisis, because, without generic competition, prices for newer drugs will not come down the same way they did for the first generation of medicines.

UNITAID is a new financing mechanism based on a small solidarity tax on airline tickets supported by 29 countries, the Bill and Melinda Gates Foundation, NGOs, and communities. Our mission is to increase access to treatments for AIDS, TB and malaria by making markets work better for health. UNITAID has raised 1 billion US\$. It is innovative in the way it raises money, and also in how it is spent.

UNITAID, together with its implementing partner, the Clinton Health Access Initiative, created the market for pediatric fixed-dose combination ARVs, representing more than 99% of the market for these products in 2008 and 2009. These purchase arrangements also resulted in a two-thirds price-reduction for pediatric ARVs, allowing many more children to be treated with more acceptable formulations.

UNITAID stimulated the development of nine new second-line ARV formulations since 2007 and contributed to price reductions of up to 43% for some 2nd line ARVs.

UNITAID's support of the WHO Prequalification of Medicines Programme ensures that medicines purchased with donor funds are of assured quality. A total of 28 medicines have been WHO Prequalified since early 2007.

It is UNITAID's overarching principle to make markets work for health that made it a natural birthplace for the Medicines Patent Pool Initiative, which will go live in the weeks to come.

The idea for an AIDS Medicines Patent Pool was first launched at the 2002 AIDS conference in Barcelona by James Love from Knowledge Ecology International. He had studied the US airplane patent pool which was established in 1917 by the US government to overcome the patent barriers to the mass production of airplanes needed for the military. He suggested doing the same for AIDS drugs patents.

The patent pool is a response to the changed IP environment in which medicines are being more widely patented in developing countries. It is built on the proven way of bringing prices down, namely competition in the market. But we can only have robust competition if licenses are available.

This is how the Pool will work:

Patent holders make licenses available through the patent pool that will allow others to produce low cost generic versions of patented ARVs for developing countries. Generic companies will also be able to make and sell FDCs and develop adapted formulations e.g., for the treatment of children.

Those who take licenses from the pool will pay royalties on their sales to the patent holders. The Patent Pool will be a systematic and predictable way of making voluntary licenses available, which offers legal certainty to all involved.

It can function within the existing IP framework. No change in international or national law is required – what is required is a change in mindset from the patent holders without whose collaboration this initiative cannot succeed.

Voluntary is the key word here, which means that the Patent Pool will only work if the patent holders are willing to collaborate with the patent pool and make their IP available. The good news is that some have shown a keen interest and see the potential of the Pool. Others have told us this week that they already think they do enough. I disagree.

One warning: sorting out IP difficulties cannot be a proxy for financing. They have to go hand in hand. Without an assured market for even the lowest cost medicines, we cannot expect that anyone will be ready to develop and produce these products. We have a model that can work to address IP barriers to improved and scaled up treatment, but assured adequate funding remains a prerequisite.

The fight for access to medicines has been and will be a continuous fight, sometimes an uphill battle, and not always easy to win. But the lessons of the past ten years show what can be achieved if we mobilize.

We are at a crucial point in time - not only do we need to protect what has been achieved, we also need to be ambitious and go further. It is feasible that with better adapted, more affordable ARVs, we can double or triple the number of people on treatment without doubling or tripling the cost. We can also ensure that people have access to better and better-tolerated treatment.

I remember sitting next to Fred from Malawi, a village farmer living with HIV/AIDS who had left his village for the first time to come to the AIDS conference in

Barcelona in 2002. We were listening to a presentation by an economist on the ‘cost effectiveness of ARV treatment’. It had lots of graphs and was hard to follow but at some point Fred leaned over and asked me: ‘Are these people saying it costs too much to keep me alive?’ I will never forget that moment. That was indeed what was being said.

I would like to be able to say 'luckily those days are over, never to return.'

Cost considerations simply cannot be a ground for withholding lifesaving treatments from people. Access to lifesaving treatment is a fundamental human right. This puts the obligation on all of us to do all we can to make sure that it happens Right Here, Right Now.