Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future

Where We Stand Today

- Despite huge progress in some areas of global public health, access to medicines remains insufficient in many countries, in particular due to lack of financing, underperforming health systems and high medicines prices.
- The data shows that the gap in life expectancy between high and lower- middle-income countries is reducing, thanks to 50 years of technological and social advances.
- In view of their specific needs and the wide range of flexibilities available to them within the framework of the TRIPS Agreement, governments have used diverse measures to enhance access to pharmaceuticals. Compulsory and government use licenses and extended transition periods in least-developed countries have been the most discussed, but other options have also been implemented.
- Voluntary license agreements are also used increasingly; they have the potential for developing countries to improve access to medicines, while retaining the incentive to innovate.

TRIPS at 20

The World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) celebrated their 20th anniversary in 2015. To mark the event, the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and the WTO held the fifth in the series of trilateral symposia to discuss practical ways in which the twin challenges of innovation and access have been addressed. It looked at selected data on the complex relationship between trade in medical technologies, patents, innovation and access, including the role of TRIPS flexibilities and recent experiences with the use of compulsory licenses and voluntary license agreements. The aim was to assist governments and other interested parties in well-informed, evidence-based policy making.

“Trade and the multilateral trading system can help in creating a more favorable global environment for public health policies and the implementation of a balanced and effective intellectual property system” said Robert Azevêdo, Director-General of the WTO by way of opening the symposium. “[TRIPS] is a key tool for balancing the need of ensuring fair access to medicines, while also supporting the necessary innovation. In these 20 years, over 130 WTO members have notified IP laws and regulations under TRIPS — and they have shown considerable diversity in how they have applied the broad principles of the Agreement,” he added.

Margaret Chan, Director-General of the WHO, reminded the audience that patents are not only meant to promote technological innovation, but they should

also contribute to the dissemination of technology, to the mutual advantage of producers and users alike. She expressed concerns about poorer countries being exposed to a growing number of TRIPS-plus obligations that are embedded in new bilateral and regional trade agreements. “Innovations that result in better medicines, vaccines, and other medical products represent great potential benefits for health. But to realize these benefits, we must ensure access for those in greatest need. An affordable price is one of many determinants of access” she said. “When new bilateral and regional trade and investment agreements are negotiated, I ask WHO Member States to scrutinize their provisions very closely for any potential impact on access to affordable medical products.”

Francis Gurry, Director General of WIPO said that the underlying policy challenges around public health, intellectual property and trade remain essentially the same as 20 years ago, but the policy instruments available are now very different. “The intense wave of globalization in the last twenty years has contributed to the movement across borders of ideas, creating new complexity in policymaking. This requires enhanced cooperation between state and non-state actors, especially given the shift in power and resources to the private sector.”

The Importance of Data

Policymaking cannot occur in a vacuum. To be relevant, it needs to be informed by accurate and detailed data about the reality on the ground and how things are likely to evolve in the future.

According to the keynote address from Hans Rosling of the Gapminder Foundation, a lack of understanding of the data means that conventional wisdom around public health is fifty years out of date. The world is not driven by increasing social and health polarisation, as is popularly imagined; rather, the data shows that the gap in life expectancy between high and lower- and middle-income countries is reducing, thanks to 50 years of technological and social advances. 80% of the world’s people now have electricity at home, 80% of the world’s children are now vaccinated against measles, and more people are now living above the poverty line, even in the face of major population increases. The average life expectancy globally is now 71 years and the population will stop growing within 85 years. The data on income trends shows that the world is no longer divided into two distinct groups and thus the terms "developed" and "developing" countries appear to be outdated now.

The data gives cause for optimism: “In the old days, the human population was kept in balance by death – no drugs, no new vaccines. Now the population is controlled by drugs, technology and parental choices. This is an enormous positive change,” concluded Professor Rosling.

Ongoing Health Challenges and Policy Responses: What Does the Data Say?

The last twenty years have seen some notable successes around access to medicines, especially for anti-retroviral medicines (ARVs) to treat HIV, according to Kees de Joncheere, WHO Department of Essential Medicines. “Between 1995 and 2000, a mixture of advocacy, corporate responsiveness and market forces reduced prices of these drugs by around 95%. The major drivers of these price reductions were the commitment of large sums by donors for global procurement, creating new markets, plus the availability of good quality generics” he said. Problems remain, however, particularly for the middle-income countries in which a large proportion of the world’s poor live. “Middle-income countries do not generally benefit from international medicine financing and its attendant lower pricing, and this is where the major access problems currently are.”

Aside from access to ARVs and essential medicines, new challenges are emerging. Current prices paid by high-income countries for new medicines are unsustainably high even for both high-income and for middle-income countries, as they would require enormous increases in health budgets. “New medicines are being made available to lower and middle-income countries at lower prices but even these pose affordability problems. As the burden of non-communicable diseases (NCDs) is set to increase in coming years, the question of how to improve access to innovative drugs will become ever more pressing,” added Mr. de Joncheere.

One possibility for increasing access to patented pharmaceuticals is for countries to take advantage of flexibilities in the intellectual property system, particularly those clarified in the Doha Declaration on the TRIPS Agreement and Public Health. Many countries have been doing exactly that, according to research presented by Ellen t’Hoen of Medicines Law & Policy. Following a comprehensive review of legal and medical literature, the media, government publications, websites and the archives of procurement agencies, Ms t’Hoen was able to identify:

- 34 instances of compulsory licensing of patents by 24 countries
- 48 instances of “government use” of patents by 34 countries
- 32 instances of use of the pharma waiver (pursuant to paragraph 7 of the Doha Declaration) by 23 Least Developed Countries.

Use of these flexibilities peaked between 2004 and 2008, mainly for HIV medication. Crucially, the clarification of these flexibilities within the TRIPS Agreement is vital for procurement agencies, as it gives them the certainty they could supply generic medicines without fear of infringement.

A different perspective was provided by Reed Beall of the University of Ottawa, Canada, who presented comparative data around the prices paid for HIV medicines procured under compulsory licenses and from the international market with support from global funders such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. Both compulsory licensing and international procurement save money, but non-coercive strategies saved just as much or even more than compulsory licensing. “Compared to a notional pre-compulsory licensing price, compulsory licensing saved 71%, but international procurement saved 79%, on average. Furthermore, compulsory licensing for local manufacturing in lower or middle-income countries was always more expensive than international procurement” said Mr. Beall.

An often-overlooked dimension of the access to medicines debate is the need for transparent and up-to-date patent information data. “This data is necessary to ensure that policymakers are properly informed and procurement officials can buy generic products without fear of patent infringement. Unfortunately, there is no international medicine patent register, and disclosure of international patent holdings is not standard practice amongst rights-holders”, said Mr. Beall. Existing public and commercial patent databases have sparse and outdated information particularly for developing countries, and often do not contain accurate or updated information. There is, he argues, an urgent need for more transparency in this regard.

Twin Challenges of Innovation and Access: Leveraging IP to Achieve Both

Gregg Alton of Gilead Sciences presented examples of collaboration with generic pharmaceutical manufacturers. In September 2014, Gilead signed voluntary licensing agreements with seven Indian generics companies to manufacture its proprietary drugs for Hepatitis C (HCV) at a cheaper price for distribution in the developing world, in return for a nominal royalty. The developing countries covered in the agreements account for around 54% of the total global infected population: over 100 million people. The licenses involve complete transfer of technology, including the transfer of Gilead’s manufacturing know-how.

“We believe that IP can and does enable access,” says Mr. Alton. “We have shown that by fairly and appropriately pricing our products through dialogue with governments and others, and by licensing them to generic manufacturers to increase manufacturing capacity and further reduce prices, it is possible to expand access to affordable medicines.”

The potential for voluntary licenses to improve access to medicines while retaining the incentive to innovate was recognized by Subhanu Saxena of Cipla Ltd, India. Mr. Saxena acknowledged that compulsory licensing remains in some cases the only option available to governments that face high prices for medicines, but it has often proved cumbersome, difficult and politically costly.

By contrast, “the voluntary licensing approach taken by some companies represents a remarkable opportunity and a more favorable alternative for developing countries” says Mr Saxena. “Companies like Gilead, ViiV or Janssen have made innovative products available to generic manufacturers in specific territories, usually the lower income countries. The geographic scope of such licenses is often negotiated with vigor on both sides as we always prefer that the largest possible number of poor patients be included in the licensing zone.”

Although Cipla has signed more than a half-dozen voluntary license agreements, Mr. Saxena believes there is room for improvement. “Often, licenses do not cover middle-income countries although it is where the majority of the poor reside. Finding mechanisms that would allow competition and access for the poorest without hampering the market aspirations of the innovator is important”.

Egypt has been able to make great strides in tackling HCV, according to Manal El-Sayed of the Egyptian National Committee for Control of Viral Hepatitis. As a result of an agreement with the originator company, Egypt introduced the new directly acting antiretroviral for the treatment of HCV very early. Before 2006, Egypt had the highest HCV prevalence rate globally, with 40,000 deaths from liver disease per year. Thanks to a prevention program aiming among other things at a better infrastructure, blood safety and vaccination, and better access to new technologies and treatments, Egypt’s national HCV treatment and prevention plan is on track to achieve a 90% cure rate by 2030.

Trade Agreements: How to Measure Their Impact on Innovation and Access to Medicines

Antony Taubman from WTO observed that trade is a vital component of access to medicines, given that most countries rely on imports to meet their health needs. Good data around trade in pharmaceuticals is needed to allow better policymaking.

The session then heard about Peru’s experience in negotiating and implementing Free Trade Agreements (FTAs) (delivered by Javier Andrés Latorre Vaca from the Ministry of International Trade, Ecuador, on behalf of Laura Ceron Aragon from the Peruvian Ministry of Health). The US-Peru FTA in particular included a number of “TRIPS-Plus” IP provisions, including a period of exclusivity of five years regarding the protection of clinical data. Importantly, Peru was able to secure language in the FTA that would give it the necessary flexibility to protect public health.

Selected Key Issues

- Voluntary license agreements are increasingly used to improve access to medicines while preserving the incentive to innovate. More work needs to be done to ensure licenses also cover upper middle-income countries. The data suggests that partnerships and international procurement mechanisms improves access.
- More data on the impact of such tools is needed to better assess their efficacy. As most countries rely on imports to meet their health needs, sound data on trade in medicines is also needed in order to support better policymaking.
- Complementing each other in their respective areas of expertise, the WHO, WIPO and the WTO will continue to assist national policymakers in taking measures to improve public health, particularly by providing objective and reliable data on all relevant aspects of health, IP and trade.
- Complexity in policymaking requires government commitment, as well as enhanced cooperation among the different state and non-state actors.
- When countries negotiate Free Trade Agreements, it is vital for trade ministries to understand the access to medicines dimension of trade agreements.
- Other trade policy settings can have significant impact on timeliness and affordability of medicines, especially for more vulnerable countries particularly dependent on trade for their needs.

Among the lessons learnt was the importance of the involvement of health officials at the start of the FTA negotiations on chapters which may affect access to medicines, their careful preparation on those trade issues and their ability to assess the change in their own regulations taking into account the degree of economic development of their countries.

Health officials also need to “keep close to officials from the trade sector and persuade them to take into account the potential impact on population health when they are negotiating FTAs,” said Mr. Latorre Vaca.

These findings were echoed by Mboi Misati of the Kenyan Industrial Property Institute. In his overview of the Kenyan experience of negotiating trade agreements, he pointed to the need for developing countries to invest in human resources to improve their negotiating capacities. He also stressed the need for more and better data on the impact of trade agreements, which is often lacking.

According to Chutima Akaleephan of the Thai Ministry of Public Health, Thailand is a middle-income country making great progress towards Universal Health Coverage. However, the high cost of new medical technologies hinders access to healthcare. Thailand has issued seven Government Use Licenses (GULs) to promote access to low cost medicines between 2006 and 2008. According to her research, these GULs have saved Thailand USD338.8m on drug costs between 2010 and 2014 alone, and have contributed to increasing rates of access to medicines. Despite fears to the contrary, the data shows that these GULs have not had a negative impact on Foreign Direct Investment in Thailand.

Antony Taubman concluded by referring to a presentation on the symposium website that illustrated in more detail the significance of trade policy settings for access to medicines. There was a rough correlation between countries' needs and dependence on trade for access to medicines, and the trade challenges they faced. Pharmaceutical imports often have to travel a long way, the average distance exceeding, for example, 10,000km for one LDC, and 8,000 km for three others. Some LDCs were almost 10 times more dependent on a narrow range of suppliers than the global average. While tariffs on medicines and ingredients for medicines had fallen overall, there were some high tariffs that fed into higher costs of production and distribution of medicines. The regular delays and costs of exporting from low-cost producer countries, to countries in Sub-Saharan Africa were many times higher than for trade between OECD countries; recent WTO analysis showed that these costs and delays amounted to an effective 'tariff' that would materially affect timeliness and affordability of medicines for those countries in greatest need. Competition policy safeguards and building TRIPS flexibilities into trade patterns would also improve trade flows of affordable medicines and thus sustainable access.

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