



Access to Drugs at Risk: Securing Access to Medicines for Least Developed Countries

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Abstract

Is access to medicines at risk despite the Doha Declaration? What are the alternative mechanisms that should be instituted to guarantee continued access to life saving drugs for many in the least developed countries (LDCs)? The Doha Declaration affirmed that patent rules should be interpreted and implemented to protect public health. Since Doha, access to drugs has dramatically increased to reach more than five billion people in developing countries. The Doha declaration also gave WTO members that are among the least-developed countries, an extended transition period, until 1 January 2016, with regard to pharmaceutical patents and test data protection for pharmaceutical products. The transition period extension in favour of least developed countries is to allow additional access to generic medicines. Post the transition period, efforts are needed to protect what has been achieved. This is necessary because of the stifled research and development for new drugs on neglected tropical diseases and the current trend of the abuse of intellectual property enforcement measures provided for in the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs). Finding the right balance between health, trade and Intellectual Property policies to sustain innovation and ensure widespread access to life-saving technologies is one of the primary public policy challenges of our time.

Résumé

L'accès aux médicaments est-il menacé malgré la Déclaration de Doha ? Quels mécanismes de substitution faudrait-il établir pour garantir l'accès continu aux médicaments qui sauvent la vie à un grand nombre de personnes dans les pays les moins avancés ? La Déclaration de Doha stipule que les règles sur les brevets devraient être interprétées et mises en œuvre de manière à protéger la santé publique. Depuis Doha, l'accès aux médicaments a considérablement augmenté pour atteindre plus de cinq milliards de personnes dans les pays en

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développement. La Déclaration de Doha a également accordé aux pays les moins avancés membres de l'OMC une période de transition prolongée, jusqu'au 1er janvier 2016, concernant les brevets pharmaceutiques et la protection des données d'essais pour les produits pharmaceutiques. La prolongation de la période de transition en faveur des pays les moins avancés a pour objectif de permettre l'accès supplémentaire aux médicaments génériques. Après la période de transition, des efforts seront nécessaires pour protéger les acquis, à cause de l'étouffement de la recherche et développement de nouveaux médicaments pour les maladies tropicales négligées, et de la tendance actuelle à l'usage abusif des mesures d'application de la propriété intellectuelle prévues dans l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (Accord sur les ADPIC). Trouver le juste équilibre entre la santé, le commerce et les politiques en matière de propriété intellectuelle pour soutenir l'innovation et assurer l'accès généralisé aux technologies permettant de sauver des vies constitue l'un des principaux défis de politique publique de notre époque.

Introduction

The Doha Declaration affirmed that patent rules should be interpreted and implemented to protect public health and to promote access to medicines for all. Since Doha, more than sixty low and middle income countries have procured lower cost generic versions of patented medicines. Post the transition period, efforts are needed to protect what has been achieved. This is because of indications of the shrinking space of access to medicines, like the stifled research and development for neglected tropical diseases and the current trend of the abuse of intellectual property enforcement measures provided for in the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement. Finding the right balance between health, trade and Intellectual Property policies to sustain innovation and ensure widespread access to life-saving technologies is one of the primary public policy challenges of our time.

The recent court case ruling on the Anti-counterfeit law in Kenya that nullified some provisions of the law as a violation of access to medicines is an indication that access to medicines in developing countries depends on the ability of countries to produce, export and import generic medicines. Restrictions on generics impede competition leading to increased prices, and prevent people with limited resources from accessing the medicines that they need. Flexibility in generic drug manufacturing also stifles research and development for drugs, thus there is a need to strike a balance between supply and demand of these drugs.

Access to essential medicines as part of the right to the highest attainable standard of health ('the right to health') is well founded in international law.¹ The right to health first emerged as a social right in the World Health

Organization (WHO) Constitution (1946) and in the Universal Declaration of Human Rights (1948).² The binding International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966 details the progressive realization of the right to health through four concrete steps, including access to health facilities, goods and services.

The goal of this article is to contribute to the discussions about access to medicines and risks for least developed countries and provide mechanisms that should be instituted to guarantee continued access to life-saving drugs for many in the least developed countries.

Background

In order to understand the gains made under the Doha Declaration with regard to access to drugs for least developed countries, there is need to review the circumstances that led to the Doha Declaration and its objectives and aim. This will enable appreciation of how the Doha Declaration was a tool to promote public health. The Doha Declaration led to an increase in access to generic drugs for the least developed countries. It is thus necessary to maintain the gains under the Doha Declaration.

The Road to Doha

TRIPs were created in response to concerns over international patent protection and came into effect in 1995.³ The growth of global trade led to concerns over inconsistencies in patent laws.⁴ WTO Members negotiated TRIPs to facilitate innovation and ensure protection for domestic suppliers through establishing a minimum level of patent protection.⁵ The adoption of TRIPs did not come without significant opposition, particularly from developing countries.⁶ Fewer than twenty developing countries were involved in the negotiations, a rather unrepresentative group, given that as of 2009 there were 106 developing countries bound by the treaty.⁷ Indeed, many developing countries had a poor understanding of the scope and implications of signing up.⁸ Furthermore, through TRIPs, developing countries agreed to increased standards for Intellectual Property rights protection, while receiving few or no concessions from developed countries to ensure the availability of necessary goods, such as essential medicines.⁹ Thus it came as no surprise that conflict quickly arose over the implementation of TRIPs. This conflict was particularly heated in the area of public health. The rise and spread of diseases such as AIDS, tuberculosis and malaria caused many countries to look for a way in which they could protect access to medications, whether through compulsory patent licences, allowing the production of generic forms

of medication, or by declaring a national health emergency.¹⁰ This led other countries, particularly those with developed pharmaceutical industries, to argue that TRIPS protected their own domestic patents.¹¹ Generic medication producers and suppliers in poor countries justified their production by arguing that TRIPS allows for justified infringement of patents for the purpose of protecting public health.¹² However, the extent to which the agreement was supportive of public health became highly controversial, particularly around the time when most of the substantive obligations of the agreement for developing countries came into force in 2000.¹³

This controversy was further compounded in a landmark legal action, whereby a pharmaceutical industry association and thirty-nine of its affiliate companies filed complaints at the Pretoria High Court, alleging, among other things, that South Africa's law on medicines allowed for parallel importation of HIV/AIDS medicines and was inconsistent with the TRIPS agreement.¹⁴ The lawsuit triggered an active campaign led by NGOs and AIDS activists. During the court procedure, it was revealed that the South African law was based on a WIPO model law. In the end, many governments and others were convinced that the relationship between the TRIPS Agreement and public health needed to be clarified.¹⁵

The dispute over generic medication production grew to the point that most members felt an international solution was needed.¹⁶ This solution came in 2001, at the WTO Ministerial Conference in Doha.¹⁷ The WTO members adopted a ministerial declaration, known as the Doha Declaration, which stated that TRIPS should be interpreted 'in a manner supportive of public health'.¹⁸ Additionally, the Doha Declaration reaffirmed a country's freedom to designate which public health emergencies justified an infringement of the patent.¹⁹ The Doha Declaration also provided a boost to least developed countries by extending the amount of time they had to implement domestic patent protections.²⁰ Initially, TRIPS called for each country to implement legislation that would ensure other countries' patents were protected by 2006. The Doha Declaration extended this deadline for Least Developed Countries (LDCs) to 2016.²¹ This extension specifically targeted public health related patents, providing additional relief to LDCs that had not been able to enact the proper regulatory regimes.²² Perhaps more importantly, the Doha Declaration was enhanced by a General Council decision made in August 2003, which laid out a process to ensure the availability of medications to LDCs. The adoption of the Doha Declaration gave generic medication producers additional flexibility to address public health concerns.²³ This decision created a process by which LDCs could import generic medications from other countries under TRIPS. The Doha Declaration recognized that some countries were unable to develop

their own medications, and so it directed members to find a solution to this problem.²⁴ The General Council decision solved this issue by holding that a country could use compulsory licensing solely for exporting to LDCs if it notified the WTO and the medications were produced for a country unable to produce them on their own.²⁵

The essence of the Doha Declaration²⁶ is to protect public health and in particular to promote access to medicines for all.²⁷ The Declaration strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. In other words, the declaration does not open new avenues within TRIPS but confirms the legitimacy of measures seeking to use to the largest extent possible the built-in flexibility found in TRIPS.

At the national level therefore, LDCs may for the moment maintain their existing legal standards of protection and enforcement without having to comply with the patent and test data protection obligations specified in the TRIPS Agreement with respect to pharmaceutical products. However, if LDCs wished to lower their standards of patent protection for pharmaceutical products, which would be permitted under the above extension decision, they would normally still need to take action to incorporate these changes into their national laws. For example, in Rwanda in 2009 a new law on the protection of intellectual property was adopted. It excludes from patentability pharmaceutical products, for the purposes of international conventions to which Rwanda is party.²⁸ Under Rwanda's previous patent legislation, pharmaceutical products were patentable subject matter.²⁹ Alternatively, LDCs may leave their laws unchanged and simply declare that until the end of the transition period, they will not enforce legal provisions relating to test data protection or patents in the area of pharmaceuticals.³⁰ For any of these measures, the LDCs concerned would, in any event, also need to check the conformity of the intended action with their own legal system and with the legal obligations that result from their membership of regional organizations or from bilateral trade agreements or other treaties to which they are a party.

The Doha Declaration and the Transition Period

The TRIPS Agreement provides for a number of transition periods so that countries can engage in a phased implementation of their TRIPS obligations. Some of these transition periods specifically target the patenting of pharmaceutical products. While these transition periods have now expired for developed and developing country WTO members, LDCs, based on the Doha Declaration and subsequent TRIPS Council Decision, benefit from an extended transition period. The WTO General Council also approved

a waiver for LDCs from the obligation under Article 70.9 of the TRIPS Agreement and this also extended the transition period to 1 January 2016.³¹ As the transition period came to a close, LDCs requested that the TRIPS Council extend a waiver allowing them to abstain from enforcing IP rights on pharmaceutical products.³³ The countries are asking that the waiver apply until a country graduates from LDC status. The TRIPS Agreement states the waiver renewal shall be automatic upon request.³³ This 2002–16 transition period was specifically without prejudice to the right of LDCs to seek and obtain further extensions.³⁴ Although some 46 percent of LDC populations live below the poverty line (of US\$1.25 a day), about 50 percent of health expenditure in LDCs is out of pocket.³⁵ LDCs face growing burdens of neglected, infectious, and chronic non-infectious diseases and because of market failure in the patent-based innovation system, diseases that mainly affect poor people in lower income countries – so-called neglected diseases, including Ebola – still do not have many treatment options.³⁶ At the end of 2013, over 60 percent of the 10.7 million people living with HIV in LDCs ‘do not have access to antiretroviral therapy. The extension of the transition period, therefore, is critical to enable LDCs to be able to import affordable generic medicines as well as to strengthen local production capacity’.³⁹

The transition period potentially offers opportunities for these countries to attract investment for the local production of generic pharmaceutical products.³⁷ The transition period extension³⁸ in favour of LDCs allows additional access to generic medicines. During the transition period members are free to increase their own capacity to manufacture generic drugs, and export and import those drugs among themselves, without contravening the TRIPs Agreement. A number of LDCs, such as Uganda, Cambodia and Rwanda have made use of existing extended transition periods to develop legislation and the subsequent manufacturing of HIV-related medicines. These successes provide useful examples of what is achievable in the absence of full TRIPS compliance.³⁹

The Post-transition Period: Access to Generic Drugs Through Compulsory Licence

The Doha Declaration reaffirmed several terms of TRIPS as important measures in protecting public health. Chief among these was the ability to grant compulsory licences, a substantial tool for generic pharmaceutical producers.⁴⁰ Compulsory licensing gives government bodies the broad authority to ‘license the use of a patented invention to a third party or government agency without the consent of the patent-holder’.⁴¹ A compulsory licence is a way to remedy problems caused by a patent whereby a government

body, such as a Ministry, court or a statutory tribunal grants a licence to an entity other than a patent holder, allowing them to produce the patented product in exchange for adequate remuneration. While there are some restrictions on compulsory licensing, these restrictions are fairly flexible and can be waived at the country's choosing.⁴² During the post transition period, affordable access to patent medicines in developing countries will become increasingly dependent on compulsory licensing.⁴³ These compulsory licences have been used to produce generic drugs and enable developing countries to have access to drugs.

Access to Medicines at Risk

Despite the clarity the Doha Declaration brought to TRIPS for issues of public health, many problems still remain. Many countries claim TRIPS is still not an adequate solution to public health issues.⁴⁴ This is not far from the truth considering the recent acts that suggest that access to essential medicines is at risk. These include enforcement of intellectual property rights under the TRIPs agreement, seizure of generic drugs via transit, broad anti-counterfeit laws and too much flexibility given to generic manufacturers that stifles innovation and creativity.⁴⁵ This thus has a risk of limiting access to essential medicines for neglected, infectious, and chronic non-infectious diseases that affect LDCs.

Negative Side-effects of Enforcement of Intellectual Property Rights under the TRIPs Agreement

The TRIPS Agreement sets out the only comprehensive multilateral framework to enforce intellectual property rights. It contains a set of minimum standards that protect intellectual property rights while avoiding barriers to legitimate trade.⁴⁶ These standards include civil court procedures and remedies that should be made available, such as injunctions, damages and orders for the disposal of goods that are infringing trademarks.⁴⁷ These remedies must be available for all the intellectual property rights covered by the TRIPS Agreement, including patents, test data protection, trademarks and copyright.⁴⁸ Administrative procedures, such as actions before administrative authorities, are optional and have to conform to the principles applicable to civil procedures.⁴⁹ A wider range of procedures, including customs measures and criminal procedures, must be available for counterfeit trademark goods, as defined in the TRIPS Agreement, including medical products, and for pirated copyright goods.⁵⁰ The TRIPS Agreement also includes certain general obligations or performance standards which provide that WTO members must ensure that these specific enforcement procedures

permit effective action, including expeditious remedies to prevent and deter infringement.⁵¹ The TRIPS Agreement clarified that WTO members are not under any obligation with respect to the distribution of resources between the enforcement of intellectual property rights and general law enforcement.⁵² The TRIPS Agreement also gives members powers to adopt procedures to enable a rights holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent administrative or judicial authorities for the suspension by the customs authorities of the release into free circulation of such goods.⁵³ Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories. It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the rights holder, or to goods in transit.

The TRIPS Agreement defines 'counterfeit' in relation to trademarks in a general manner, not specific to the public health sector, and thus subject to abuse,⁵⁴ and further provides members with powers to enable a rights holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Such provision in the TRIPS Agreement has been a basis for abuse⁵⁵ by patent holders.⁵⁶

The fact that these enforcement provisions are minimal and general means they are subject to abuse and misinterpretation by member states who will use their resources to block generic drugs from moving to developing countries. This has enabled member states such as those in the East African Community to go higher than the TRIPS Agreement by drafting anti-counterfeit laws similar to the Anti-counterfeit Trade Agreement which is normally designed to tackle counterfeit drugs; but the term is defined in a way that includes patent violation shrinking the policy space to produce or import generic versions of patented medicines. Similar issues have been raised, among others, with respect to Uganda's draft Anti-counterfeit Bill and Tanzania's 2008 Merchandise Marks Regulations.⁵⁷ As a result, intellectual property enforcement measures can have positive side-effects, potentially supporting efforts to keep dangerous products out of the market but also negative side-effects as a result of abuse of these enforcement measures.

Despite these gaps, the TRIPS Agreement provides that the application of these procedures must avoid the creation of barriers to legitimate trade and

must provide for safeguards against their abuse. It is therefore necessary that the TRIPS Agreement goes a step further and provides safe guards against the abuse of the enforcement provisions.

Seizure of Generic Drugs in Transit

WTO (under article V) has recognized the principle of freedom from transit for goods moving through ports and airports in international trade. This fundamental principle has been so widely and consistently implemented that there has been virtually no controversy about it despite the fact that goods are constantly moving in transit through its member states. It is simply a given in international trade law that the customs authorities of a country do not seize or detain goods passing through their ports and airports enroute to foreign destinations without a good reason. The TRIPS Agreement also however allows members to adopt measures to prevent importation of goods infringing other forms of intellectual property. At the time the TRIPS Agreement was negotiated, the practice of seizing goods in transit based on allegations of patent infringement was unknown; so members would not have contemplated such a practice as an option when drafting the relevant provision. There have been a substantial number of recent cases in which EU customs authorities have acted to seize pharmaceutical products in transit between developing countries where there are no patents in force.⁵⁸ These seizures have been based on patents in force in the 'transit' EU member states.

This was clearly seen when the Dutch authorities seized various shipments of generic pharmaceuticals produced in India and Brazil and destined for developing countries.⁵⁹ Presumably the manufacture of these medicines in India or Brazil and their commercialization in their intended markets would not violate any relevant patent rights in those respective territories.⁶⁰ Patent rights arise on a national basis and are confined to national territory. However upon entry of these generic medicines into any national territory such as the Netherlands, where patent rights originate, those rights become applicable.⁶¹ The controversial Dutch seizures involved instances of trans-shipments where the presence of the offending products within the national territory was temporary and often happenstance.⁶² These cases do not involve the making, use or sale of products subject to the Dutch patent within the Netherlands though admittedly they do involve the import of such products.⁶³ Formally, the Dutch authorities appear to be within their rights. Given the territorial nature of the patent system, a Dutch patent owner should be able to take action against infringing goods imported into the Dutch national territory. But exercising these rights, in instances of trans-shipments (where no patent rights are violated in either the country of origin or destination), seems mean spirited,

at least in instances where the trade is sheltered by the new understandings within TRIPS.⁶⁴

The EU amended its border control regulations in 2003 in a way that allegedly signaled permission to EU patent holders to demand the seizure of goods in transit through EU ports and airports.⁶⁵ Implementation of this regulation represents a challenge to fundamental ideas about the way the international intellectual property system operates. The Paris Convention on the protection of industrial property incorporates independence of patents as a core principle.⁶⁶ The principle is framed in terms of protecting national institutions and decision-making against intrusive determinations by foreign authorities. The EU bases its exercise of jurisdiction over pharmaceutical products moving in transit through EU airports on its right as a sovereign body to control activity taking place within EU (and member states') territory and seeking to further the legitimate public policy goal of preventing the circulation of counterfeit drugs.⁶⁷ Yet a corollary of the axiom of sovereign control over activities within the national territory is that states have the right to cede elements of exclusive control through international agreement and custom.⁶⁸ It is neither the responsibility nor the right of WTO members outside a country that has not granted patent protection to 'cure' that situation in favour of a local patent holder by disregarding the decisions taken by authorities in the country that has not provided protection. The EU has elected to disregard the sovereign rights of foreign WTO members by refusing to give effect to their decisions as to patent status by the use of force – the seizure and detention by customs authorities of goods in transit.⁶⁹ The allegations of infringement are purely for the convenience of a patent holder that happens to have chosen a particular transit country as a place to obtain a patent.⁷⁰ The negative consequence of the EU policy with respect to the seizure of generic pharmaceuticals in transit is the breach of the understanding reached at the WTO regarding access to medicines as embodied in the Doha Declaration on the TRIPS Agreement and Public Health.⁷¹ Seizure of generic drugs moving legitimately in transit is a frontal assault by the EU on the object and purpose of the Doha Declaration. It is an effort to prevent developing countries from relying on the security of supply from Indian generic manufacturers and to put them out of business. Remarkably, the drugs seized had been purchased on behalf of UNITAID⁷² and Dutch customs authorities were interfering with a French-supported programme to supply generic antiretroviral medicines to Africa.⁷³ The flexibility in the TRIPS Agreement on the enforcement of patent rights is subject to abuse and manipulation by patent holders.

On 11 May 2010 India commenced a dispute settlement process in Geneva with respect to the WTO compatibility of these seizures,⁷⁴ followed

on 12 May 2010 by a similar complaint in Brazil.⁷⁵ In the end, both India and Brazil appear to have abandoned these complaints, and the commitment extracted from the EU and the Netherlands has not been revealed.⁷⁶ Thus the WTO-compatibility of the seizures remains unresolved.⁷⁷ There is thus need to provide protection to legitimate generic drugs in transit and put measures in place to avoid such seizures because developing countries rely on generic drugs that are much cheaper.

Flexibility to Generic Manufacturers Stifles Innovation and Creativity

Insufficient innovation and a lack of access to affordable medicines are major barriers to achieving the right to health in low and middle income countries. The lack of a vaccine or treatment for the deadly Ebola virus highlights the need for new ideas about how to finance pharmaceutical research and development (R&D). According to an MSF study, only eighteen of the 1,556 new drugs developed between 1975 and 2004 were for tropical diseases – and eight of those were for malaria.⁷⁸ The WHO estimates that nearly US \$150 billion is needed over the next six years for R&D on neglected diseases.⁷⁹

That investment is needed to protect or treat the billion people susceptible to these conditions. Although this estimate of the resources needed may be high—and some of the diseases on the list might not be neglected diseases according to different criteria – the current level of R&D investment in neglected diseases is inadequate by any standards. Notwithstanding the recent spending increases by the National Institutes of Health (NIH), the William Jefferson Clinton Foundation, and the Bill & Melinda Gates Foundation,⁸⁰ a recent survey found that less than US \$500 million is going in R&D annually to neglected diseases.⁸¹ The survey also found that nearly all of the funding was from public sources. The private sector was providing less than 10 percent. The United Kingdom, for example, spends approximately 6 percent of its biomedical R&D budget on neglected diseases.⁸² International aid agencies such as the WHO, the United Nations Children's Fund (UNICEF), the U.S. Agency for International Development (USAID) and the World Bank focus primarily on getting vaccines, drugs and biologics to the people who need them, but not on sponsoring pre-clinical research.⁸³

One sector that could provide greater investment in neglected diseases is the pharmaceutical and biotech industry. A review by Michael Kremer concluded that 'pharmaceutical R&D on health problems specific to poor countries is woefully inadequate'.⁸⁴ The current level of R&D investment most likely reflects the low sales volume in countries with high rates of neglected diseases.⁸⁵ In 2006, sales to all of the countries in Africa, Central and South America, and Asia and the Pacific (aside from Japan, New Zealand and

Australia) represented only 1 percent of sales by members of Pharmaceutical Research and Manufacturers of America (PhRMA).⁸⁶ Given the high cost of conducting research and developing new drugs, it is not surprising that for-profit drug and biotech companies go where the markets are. Pharmaceutical companies also have concerns about intellectual property protection and the tendency of low-income countries to force prices down once the R&D funds have been spent.⁸⁷ The TRIPS flexibilities, which allow LDCs to abstain from enforcing IP rights on pharmaceutical products, promote the production of low cost generic drugs that are not favourable for pharmaceutical companies. Patented drugs can command a premium price because patents legally entitle their owner to exclude all others from making or selling the patented invention during the patent term. In contrast, a generic drug has an abbreviated path to market for a small fraction of the time and cost. The time and expenses for generic companies are substantially abbreviated not only because they do not need to invest in research. In addition, brand companies note that while they must incur marketing costs, generics do no marketing and simply copy commercially successful drugs, for which the brand companies have already created a market. It is widely recognized that the pharmaceutical industry is unique among most industries in that patents are considered essential. Patents are critical to the success of a pharmaceutical company.⁸⁸ While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated.⁸⁹ Just as the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access. As noted in the WHO's Framework for Access to Medicines, access to medicines is rarely dependent on a single factor; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems, among other factors. In addition, patented drugs are also different from most patented products in that they are expensive and time consuming to develop, but easy to copy. The fact that generic drugs are less costly is not an incentive for pharmaceutical companies to invest in research and development (R&D) into drugs for neglected tropical diseases that affect LDCs.

International trade is critical to enabling access to medicines, particularly for smaller countries with no domestic manufacturing capacity. Trade stimulates competition and improves economies of scale, which in turn reduce prices and spawn a wider range of suppliers, improving stability of supply.⁹⁰ Trade policy also has an important bearing on efforts to build domestic production capacity in medical products and can directly affect accessibility to pharmaceutical ingredients and medical technologies.⁹¹ It is therefore necessary to strike a balance and identify solutions of promoting

R&D while promoting the production of generic drugs. There is an urgent need for a complementary system to drive and fund innovation for people in LDCs.

Filling the Gaps in Access to Medicines for LDCs

Access to essential medicines has gradually come to be recognized as part of the human right to health, enforceable under both international and national laws.⁹² Access is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population.⁹³ The UN Committee on Economic, Social and Cultural Rights (CESCR), authoritatively recognized access to medicines as a means of fulfilling the right to health in General Comment 14. Paragraph 43 of General Comment 14 stated clearly, for the first time, that state parties are obliged 'to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs' and 'to ensure equitable distribution of all health facilities, goods and services'. The explicit discussion of access to medicines in General Comment 14 should be understood against the historical background of the late 1990s. During that period, a number of actors began to advocate for the importance of access to medicines, particularly in relation to the HIV/AIDS pandemic and the expected negative impact of the WTO 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the availability of low-cost generic medicines.⁹⁴ Over the course of the next decade, a relatively strong and stable norm emerged regarding access to medicines in developing countries, particularly (but not only) regarding access to drugs for HIV/AIDS.⁹⁵

The pharmaceutical industry, particularly research-based, patent-holding multinational firms, has been both a major target and an influential shaper of this emerging norm. Civil society organizations, experts, governments, and intergovernmental organizations regularly call on the industry to adopt certain access policies or practices. The industry is explicitly named in the 8th Millennium Development Goal, which includes as a key target: 'In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.' Indeed, often in response to public pressure or expectations, most of the twenty largest multinational firms and a handful of the large generic firms have adopted a wide array of 'access policies'.⁹⁶

The United Nations Human Rights Council adopted a resolution on access to medicines on 14 June.⁹⁷ The resolution was adopted by thirty-one in favour, none against, and sixteen abstentions, and follows Special Rapporteur An and Grover's May 27 report analysing existing international challenges

toward realizing access to medicines within a right to health framework. The report detailed key international and national determinants of access, calling for increased focus on 'local production of medicines, price regulations, medicines lists, procurement, distribution, rational and appropriate use and quality of medicines'. It demanded a shift from 'the dominant market-oriented paradigm', reinstating access to medications as essential to the enjoyment of the right to health.

In short, over the past decade, the norm that access to medicines forms an integral part of the right to health became widely accepted, including – at least in part – by the multinational pharmaceutical industry. However, whether such firms had specific human rights obligations or responsibilities with respect to access to medicines remained a murky question. This thus means that there is a need to find alternative mechanisms that should be instituted to guaranteed continued access to life-saving drugs for many in LDCs.

Kenya Anti-counterfeit Ruling Paves the Way for the Protection of Access to Generic Drugs: The Patricia Osero Ochieng Case

This case is an indication that measures have to be put in place to protect generic drugs. Kenya enacted the Anti-counterfeit Act No.13 of 2008 to combat counterfeit trade.⁹⁸ The Act came into effect in 2009 and also established the Kenyan Anti-counterfeiting Agency, which came into operation in 2010.⁹⁹ The Act, which is aimed at deterring the illegal trade, established what constitutes counterfeiting offences and lists their penalties.¹⁰⁰ A petition was then filed in the Kenyan High Court challenging provisions of this Act.¹⁰¹ The petitioners in their case made it clear that they support the fight against counterfeiting in Kenya however they argued about the ambiguity in the definition of counterfeiting under the law.¹⁰² They argued that it provides sufficient room for abuse by both overzealous intellectual property rights owners and enforcement officers exercising their statutory powers to restrict access to essential and affordable medicines including generics.¹⁰³ Similarly the law created counterfeit offences, potentially criminalizing generic manufacturing and importation.¹⁰⁴ They further argued that these provisions would violate the right to life, dignity and health because they affect access to affordable and essential drugs and medications, particularly generic drugs.¹⁰⁵ The High Court held that the definition of counterfeit drugs would encompass generic medicines produced in Kenya and elsewhere and thus is likely to adversely affect the manufacture, sale and distribution of generic equivalents of patented drugs.¹⁰⁶ This would affect the availability of the generic drugs and thus pose a real threat to the petitioners' right to life, dignity and health under the Constitution.¹⁰⁷

The Court ruling is therefore an indicator that the TRIPS Agreement has to be clear and specific on the issue of defining counterfeit because of confusion surrounding exactly what is meant by the term which will thereby affect access to generic drugs in developing countries. The TRIPS Agreement also has to go further in providing clear steps that need to be taken to prevent importation of goods infringing other forms of intellectual property so as to avoid further seizures of generic drugs.

Research and Development Treaty

The problem with the current system of R&D is that it is incentivized by the potential profits a new medical product could generate through sales under a monopoly created by the granting of a patent. The reward of innovation is one of the basic tenets of a capitalist society and has, for the most part, generated progress and efficiency in the pharmaceutical industry.¹⁰⁸ However, predictably, this system does not always cater for the most vulnerable in society.¹⁰⁹ A regional treaty on R&D could both protect and even enhance pharmaceutical innovation and address the market failures of the current patent system. By creating a binding Convention on health R&D, countries would agree to a sustainable system of medical innovation with adequate and predictable financing, to deliver products that are focused on the priority health needs of developing countries.¹¹⁰ The Convention would create norms to ensure that the fruits of innovation and new medical products are accessible and affordable.

Today's system of medical innovation is one that is predominantly dependent on patent-protected monopolies, and the promise of high prices these bring, to steer R&D.¹¹¹ That products are then unaffordable for developing countries is very much an afterthought, leading to repeated battles pitching patents against patients.¹¹² Initiatives based on the principle of de-linking or separating the cost of R&D from the price of the resulting product are needed so that the cost of R&D is paid for up-front through grants or rewarded by a prize and does not need to be recouped through a high product price.¹¹³ The R&D Convention could set norms to facilitate access to the fruits of innovation and affordability of the final products.¹¹⁴

Conclusion

Health is a fundamental human right; indispensable for the exercise of many other rights, in particular the right to development, and necessary for living a life in dignity.¹¹⁵ The realization of the right to health is also a fundamental goal of state policies and programmes, regardless of their economic, social,

cultural, religious or political background.¹¹⁶ Nevertheless, for millions of people around the world, the full enjoyment of the right to health remains an illusive goal, which is partly due to the obstacles in accessing affordable medicines of good quality, and in a timely fashion, mostly in the LDCs. This constitutes a challenge to human dignity, the basis of all human rights, including the rights to life, health and development of all persons. From a human rights perspective, access to medicines is intrinsically linked with the principles of equality and non-discrimination, transparency, participation and accountability.¹¹⁷ It is therefore important that gains under Doha Declaration are maintained and not lost. This is only possible if the issue of access to medicines at risk is addressed. Addressing this means that the TRIPS Agreement goes a step further and provides safeguards against the abuse of the enforcement provisions. The WHO also needs to play a stronger role and create a regional treaty for LDCs that will promote research and development of neglected tropical diseases that affect LDCs. This will strike a balance between the production of low cost generic drugs and the promotion of research and development of neglected tropical diseases for LDCs thus leading to their securing access to medicines.

Notes

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10. The Doha Declaration on the TRIPS Agreement and Public Health, WTO, http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html, accessed 20 October 2015.
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15. *ibid.*
16. *ibid.*

17. *ibid.*
18. *ibid.*
19. *ibid.*
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22. *ibid.*
23. WTO Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540.
24. *ibid.*
25. *ibid.*
26. Ministerial conference, fourth session, Doha, 9–14 November 2001, WT/MIN(01) DEC/2, 20 NOVEMBER 2001.
27. Paragraph 4 of the Doha Declaration, ‘We agree that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS agreement, we affirm that the Agreement can and should be implemented in a manner supportive of WTO members right to protect public health and in particular to promote access to medicines for all.’
28. Article 18(8) Law No.31/2009 of 26/10/2009 on the protection of intellectual property.
29. *ibid.*
30. *ibid.*
31. WTO document WT/L/478.
32. IPW, WTO/TRIPS, 8 June 2015.
33. *ibid.*
34. *ibid.*
35. *ibid.*
36. *ibid.*
37. Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade 53–80 (2012).
38. ‘We reaffirm the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country Members pursuant to Article 66.2. We also agree that the least developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 of Part II of the TRIPS agreement or to enforce the rights provided for under these sections until 1st January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS agreement.’
39. Policy brief: Using TRIPS flexibilities to improve access to HIV treatment UNAIDS, WHO and UNDP.
40. *ibid.*
41. *Ibid.*
42. Article 31 of TRIPS laid out several conditions that countries were required to fulfil before issuing a compulsory licence, such as demonstrating unsuccessful negotiations

- with the patent owner and payment to the patent owner. The country could also waive these requirements by claiming a public health emergency. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization.
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 54. TRIPS Agreement.
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 56. Article 51(2) of the TRIPS Agreement.
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 67. *ibid.*
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