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Discussion Paper

Anti-counterfeit Laws and Public Health: What to Look Out for

United Nations Development Programme

HIV/AIDS

CONTENTS

EXECUTIVE SUMMARY

The purpose of the Discussion Paper is to facilitate the UNDP consultation on enforcement of intellectual property rights, in particular anti-counterfeit measures and access to HIV treatment and other essential medicines in sub-Saharan Africa. The Discussion Paper summarizes the developments in intellectual property rights enforcement in the world and in the region. It elaborates on the public health impact of anti-counterfeit laws and discusses whether they are an adequate solution to the legitimate concerns about the quality, safety and efficacy of medicines. The Discussion Paper explores the impact of such laws on the spread of substandard and falsified medicines compared to their impact on good-quality generic medicines, which are essential for the public health systems of most African countries.

The Discussion Paper explores model provisions for the definition of 'counterfeiting', criminal liability, powers of seizure and storage, goods in transit, rules on evidence and presumptions and liability for loss of or damage to goods. Discussions of the model provisions evolve around the public health priorities of African countries, and the need to avoid conflation between good-quality generics and substandard and falsified medicines.

The last part of the Discussion Paper elaborates on the need to develop public health alternatives to the attempts to regulate the quality, safety and efficacy of medicines through intellectual property enforcement. It explores initiatives that focus on educating and empowering national drug regulatory authorities and promoting local expertise, as well as regional and international cooperation.

This Discussion Paper is drafted for a broad audience of stakeholders, including legislators, policy makers, healthcare and trade officials and drug regulatory experts. It can also be useful for academics teaching intellectual property rights and public health. The Discussion Paper can be used by treatment activists, public health legislation advocates, as well as representatives of the media.

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral (medicines)
DRA	Drug regulatory authority
EAC	East African Community
EC	European Community
ECJ	European Court of Justice
ECOSOC	Economic and Social Council (United Nations)
GATT	General Agreement on Tariffs and Trade
GDP	Good Distribution Practices
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
HAI	Health Action International
HIV	Human Immunodeficiency Virus
INN	International Non-proprietary Name
IP	Intellectual Property
IPR	Intellectual Property Rights
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

INTRODUCTION

The global Intellectual Property enforcement agenda and its impact on access to medicines

Intellectual Property (IP) plays an important role in the economies of developed countries such as the United States (US)[1], Japan and some countries of the European Union (EU). Many of these developed countries are net IP exporters. As pointed out in the EU's Lisbon Strategy, its strategic goal in the next decade is "to become the most competitive and dynamic knowledge-based economy in the world."[2] Understandably, high standards of IP protection have become characteristic of the legal systems of these countries. The proposed Europe 2020 Strategy emphasizes the need to access IP protection as a priority and urges member states to improve IP enforcement.[3]

This has not always been the case. In the recent past, many now developed countries did not have strong IP protection systems. They were building their national industries and considered national development needs, including the need to develop their pharmaceutical industries, to be their priority.[4] Today, some low- and middle-income countries are at the same stage of development as developed countries were decades ago. However, the paradigm on IP has shifted – nowadays developing countries have significantly less flexibility to establish the priority of their technological and industrial development over IP rights. The economic interests of knowledge-based economies to protect IP rights have spread not only domestically but also internationally, including through furthering ever higher standards of IP enforcement. In 1994, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is part of the Law of the World Trade Organization (WTO), tied IP protection to global trade for the first time.[5]

The TRIPS Agreement contains numerous provisions, known as 'flexibilities', which can and have been used to secure priority of development needs over IP protection, particularly in access to medicines. The priority of public health over IP was reaffirmed with the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health.[6] However, proponents of stronger IP enforcement regimes continue to promote measures in excess of the TRIPS Agreement requirements (referred to as TRIPS-plus and TRIPS-plus-plus). Their efforts have gone beyond the typical fora for IP discussions, such as the World Intellectual Property Organization, and now include WTO, the World Customs Organization, Interpol, the Asia Pacific Economic Cooperation, and even the World Health Organization (WHO).[7] Bilateral and regional free trade agreements, investment treaties and economic partnership agreements are used to promote and impose IP protection standards that by far exceed TRIPS standards. More recent examples of this tendency can be found in the proposed Trans-Pacific Trade Agreement (TPPA)[8] as well as the proposed EU–India Free Trade Agreement.[9] Due to the economic incentives to access the large markets of the global North, developing countries often accept these TRIPS-plus or TRIPS-plus-plus requirements, without having the bargaining power to negotiate better terms. In many cases, TRIPS-plus deals have negative impacts on their national healthcare systems.

[1] United States Trade Representative, Strategic Plan 2007–2012, http://www.ustr.gov/sites/default/files/asset_upload_file726_14695.pdf.

[2] Presidency Conclusions, European Council, 23–24 March 2000, http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/00100-r1.en0.htm.

[3] European Commission, Europe 2020: a Strategy for smart, sustainable and inclusive growth (proposal), http://ec.europa.eu/commission_2010-2014/president/news/documents/pdf/20100303_1_en.pdf, 10, 15.

[4] Carlos Correa, *The Push for Stronger IPRs Enforcement Rules: Implications for Developing Countries, ICTSD,* Geneva, 2009, http://ictsd.org/i/publications/42762/?view=document.

[5] WTO, Annex 1C, Agreement on Trade-related Aspects of Intellectual Property Rights, http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[6] WTO, Declaration on the TRIPS Agreement and Public Health, adopted 14 November 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

[7] Susan K. Sell, 'The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play', *PIJIP Research Paper no. 15*, American University Washington College of Law, Washington, DC, 2010, http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1016&context=research.

[8] Congressional Letter to USTR on Preserving Access to Medicines in the Trans-Pacific FTA, 19 November 2011, www.citizen.org/access/Congressional-Letter-to-

Anti-counterfeit measures as part of the enforcement agenda

Anti-counterfeit measures also can be IP enforcement measures that exceed the requirements of the TRIPS Agreement. Typical examples are the measures envisioned in the Anti-counterfeit Trade Agreement (ACTA).[10] The initial drafts of ACTA, which were negotiated in secret, contained provisions about civil enforcement measures and criminal sanctions for patent infringement. The final text excluded patents from border measures and allowed countries to exempt patents from certain types of civil and criminal enforcement, but did not completely exclude patents as subject matter of the Agreement. At the time of finalizing this Discussion Paper, ACTA is subject to strong public criticism and debated with concern at the European Parliament and national parliaments of several EU Member States.[11]

Anti-counterfeit criminal sanctions are also included in the Council of Europe (CoE) Convention on the counterfeiting of medical products and similar crimes involving threats to public health (The Medicrime Convention), which is open for signature by non-CoE members as well.[12]

In general, anti-counterfeit legislation is proposed to address trademark infringing goods with safety concerns – such as spare airline parts – as well as brand name products or luxury goods where brands are believed to signal quality and/or status. However, a number of countries, including countries in Africa, have either passed or are considering broader anti-counterfeit laws, which, in addition to addressing the 'typical cases' of true trademark infringement mentioned above, emphasize IP enforcement measures as a way to address the trade in substandard and falsified medicines. This approach has engendered robust criticism, in particular concerning its overbroad definition of 'counterfeit'; its criminalization of all IP rights infringements, including patents; its granting broad powers to government agencies, especially customs officials, without judicial oversight; its providing for harsh criminal and other penalties; and its shifting presumptions on evidence. All of these features of typical anti-counterfeiting acts have the potential to negatively impact access to affordable generic medicines. At the same time, there is no convincing evidence that enacted anti-counterfeit measures have effectively prevented or reduced the spread of substandard and falsified medicines. This Discussion Paper debates whether anti-counterfeit measures are at all an adequate way to address the legitimate concern about the spread of substandard and falsified medicines.

USTR-on-Preserving-Access-to-Medicines-in-the-Trans-Pacific-FTA. See also: Public Citizen, *Briefing Memo: Leaks at Trans-Pacific Trade Talks Confirm Obama Administration Backtracking from Bush Era Access to Medicines Commitments*, 2011, www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacific_PCmemo.pdf. See also: Mike Palmedo, *Why the Trans-Pacific Partnership Should Not Include Pharmaceutical Pricing Provisions*, 2010, www.citizen.org/documents/PIJIPTPPandPharmaPricing.pdf.

[9] Médecins sans Frontières, http://www.msfaccess.org/hands-off-our-medicine-campaign. See also: ABIA, www.abiaids.org.br/noticias/destaqueView.aspx?lang=pt&seq=12796. See also: ICTSD, www.abiaids.org.br/noticias/destaqueView.aspx?lang=pt&seq=12796.

[10] Anti-Counterfeiting Trade Agreement, final text in English, http://register.consilium.europa.eu/pdf/en/11/st12/st12196.en11.pdf.

[11] BBC, *European Parliament Rapporteur Quits in ACTA Protest*, www.bbc.co.uk/news/technology-16757142. See also: ZDNet UK, *Czechs, Slovaks join Poland in pausing ACTA process*, www.zdnet.co.uk/blogs/communication-breakdown-10000030/czechs-slovaks-join-poland-in-pausing-acta-process-10025374/.

[12] Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health, www.coe.int/t/DGHL/StandardSetting/MediCrime/Medicrime-EdProv%20ENG.pdf. See also IP Watch, Medicrime: Another IP Enforcement Convention Emerges in Europe, 2010, www.ip-watch.org/2010/04/24/medicrime-another-anti-counterfeiting-convention-emerges-in-europe/.

‘Substandard and falsified medicines’ versus ‘counterfeits’ – why does it matter?

The need to ensure access to safe, efficacious and affordable medicines of assured quality in Africa and other parts of the global South is a core part of the efforts to achieve the health-related Millennium Development Goals (MDGs). In sub-Saharan Africa, home of 68 percent of the world HIV burden, this is an especially critical issue. Africans also have a growing need for newer and more affordable medicines to treat tuberculosis, hepatitis and malaria, neglected tropical diseases, and more recently chronic, non-communicable diseases. In the case of antiretroviral (ARV) medicines, due to the lifelong demand, the high costs of originator medicines and the continuing stigma around HIV, there are strong financial incentives for illegal production and trade in ‘cures’ that have no proven therapeutic effect[13] and in substandard and falsified ‘ARVs’. But just as there is lucrative trade in suspect ARVs that are relatively expensive, there is also a lucrative trade even in relatively low-cost substandard and falsified anti-malarials, where public-sector pharmacies are poorly stocked, patients need quick access to medicines, and unregistered anti-malarials are readily available from informal vendors. Where medicines registration regimes and pharmacovigilance activities are weak, where medicines distribution systems are porous and corruptible, and where the unsupervised sale of medicines can be an important source of income, the dangers of substandard and falsified medicines are more acute. It is in this context that there has recently been heightened concern regarding the supply of such medicines in Africa, a concern that threatens to become misdirected because of an ill-advised focus on IP-related, ‘counterfeit’ medicines rather than on public health-related substandard and falsified medicines.

There is no commonly accepted, everyday definition of what a ‘counterfeit medicine’ is, but as a technical term ‘counterfeiting’ applies to a very particular form of criminal trademark infringement on a commercial scale. Accordingly, to organize public policy and medicines safety concerns around the rubric of ‘counterfeit’ is to adopt the wrong tool – IP instead of medicines safety, efficacy and quality – which in turn leads to ill-advised policies. This Discussion Paper explores an alternative definition of problematic medicines, drawn from preliminary discussions at Chatham House[14] and a report from a WHO Working Group of Member States on substandard/spurious/falsely labeled/falsified/counterfeit medical products,[15] namely substandard and falsified medicines.

For the purpose of this Discussion Paper ‘substandard medicines’ are pharmaceutical products that do not meet their quality standards and specifications. Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing.[16] A substandard medicine, which can be either an originator or a generic product, is ordinarily below the specified safety, efficacy and quality because of failures of Good Manufacturing Practices (GMP)[17] and/or failures in Good Distribution Practices (GDP),[18] including expiry, resulting in contamination or degradation of the product. A ‘falsified medicine’ gives “a false