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Resilient nations.*

# Discussion Paper

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

United Nations Development Programme

HIV/AIDS





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## 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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**DISCLAIMER:** The information contained in this Discussion Paper is to facilitate the UNDP consultation about enforcement of intellectual property rights and access to HIV treatment and other essential medicines. It does not necessarily reflect the official position of UNDP, its employees or board members. Please do not cite. Please submit questions and comments to: [tenu.avafia@undp.org](mailto:tenu.avafia@undp.org).

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## ACRONYMS AND ABBREVIATIONS

<b>AIDS</b>	Acquired Immune Deficiency Syndrome
<b>ART</b>	Antiretroviral therapy
<b>ARV</b>	Antiretroviral (medicines)
<b>DRA</b>	Drug regulatory authority
<b>EAC</b>	East African Community
<b>EC</b>	European Community
<b>ECJ</b>	European Court of Justice
<b>ECOSOC</b>	Economic and Social Council (United Nations)
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GDP</b>	Good Distribution Practices
<b>GFATM</b>	Global Fund to Fight AIDS, Tuberculosis and Malaria
<b>GMP</b>	Good Manufacturing Practices
<b>HAI</b>	Health Action International
<b>HIV</b>	Human Immunodeficiency Virus
<b>INN</b>	International Non-proprietary Name
<b>IP</b>	Intellectual Property
<b>IPR</b>	Intellectual Property Rights
<b>TRIPS</b>	Agreement on Trade-related Aspects of Intellectual Property Rights
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNDP</b>	United Nations Development Programme
<b>USAID</b>	United States Agency for International Development
<b>WHO</b>	World Health Organization
<b>WTO</b>	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)<sup>1</sup>, 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."<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup>

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.<sup>6</sup> 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).<sup>7</sup> 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)<sup>8</sup> as well as the proposed EU–India Free Trade Agreement.<sup>9</sup> 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.

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<sup>1</sup> United States Trade Representative, Strategic Plan 2007–2012, [http://www.ustr.gov/sites/default/files/asset\\_upload\\_file726\\_14695.pdf](http://www.ustr.gov/sites/default/files/asset_upload_file726_14695.pdf).

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

<sup>3</sup> 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](http://ec.europa.eu/commission_2010-2014/president/news/documents/pdf/20100303_1_en.pdf), 10, 15.

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

<sup>5</sup> WTO, Annex 1C, Agreement on Trade-related Aspects of Intellectual Property Rights, [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)

<sup>6</sup> 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](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf).

<sup>7</sup> 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>.

<sup>8</sup> Congressional Letter to USTR on Preserving Access to Medicines in the Trans-Pacific FTA, 19 November 2011, [www.citizen.org/access/Congressional-Letter-to-](http://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).<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup>

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.

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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](http://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/PIJIPTPandPharmaPricing.pdf](http://www.citizen.org/documents/PIJIPTPandPharmaPricing.pdf).

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

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

<sup>11</sup> BBC, *European Parliament Rapporteur Quits in ACTA Protest*, [www.bbc.co.uk/news/technology-16757142](http://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/](http://www.zdnet.co.uk/blogs/communication-breakdown-10000030/czechs-slovaks-join-poland-in-pausing-acta-process-10025374/).

<sup>12</sup> 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](http://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/](http://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<sup>13</sup> 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<sup>14</sup> and a report from a WHO Working Group of Member States on substandard/spurious/false labeled/falsified/counterfeit medical products,<sup>15</sup> 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.<sup>16</sup> 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)<sup>17</sup> and/or failures in Good Distribution Practices (GDP),<sup>18</sup> including expiry, resulting in contamination or degradation of the product. A ‘falsified medicine’ gives “a false

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<sup>13</sup> As pointed out by epidemiologist Joseph Amon, “the uncertainty and fear engendered by this incurable, stigmatizing and life-threatening disease can make people easy prey to promises of cures.” Joseph Amon, *Dangerous Medicines: Unproven AIDS Cures and Counterfeit Antiretroviral Drugs*, Globalization and Health, 2007, <http://www.globalizationandhealth.com/content/4/1/5>.

<sup>14</sup> Charles Clift, *Combatting, Counterfeit, Falsified and Substandard Medicines: Defining a Way Forward, Chatham House Briefing Paper*, Chatham House, London, 2010, [http://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/1110bp\\_counterfeit.pdf](http://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/1110bp_counterfeit.pdf). For an alternative discussion of the terminology, see K.M. Gopakumar & Sangeeta Shashikant, *Unpacking the Issue of Counterfeit Medicines*, Third World Network, Malaysia, 2010, 4–5.

<sup>15</sup> See WHO, *Report of Working Group of Member States on substandard/spurious/false labelled/falsified/counterfeit medical products*, A/SSFFC/WG5 (11 March 2011), Geneva, 2011, [http://apps.who.int/gb/ssffc/pdf\\_files/A\\_SSFFC\\_WG5-en.pdf](http://apps.who.int/gb/ssffc/pdf_files/A_SSFFC_WG5-en.pdf).

<sup>16</sup> Ibid. at 2 (relying on the current WHO definition developed by the 45th WHO Expert Committee on Specifications for Pharmaceutical Preparations.)

<sup>17</sup> According to the WHO, “Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production, which may broadly be categorized in two groups: cross contamination/mix-ups and false labelling.” [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/production/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/).



representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medical products.”<sup>19</sup> Falsified medicines ordinarily contain inaccurate information about contents, dosage, manufacturing date/site, expiration etc. and perhaps contain undisclosed and dangerous ingredients. Counterfeit medicines can be classified as a subset of falsified medicines because they unlawfully apply the registered trademark of another with intent to deceive.<sup>20</sup>

Using these definitions emphasizes the importance of registration of the medicines by an authorized national or regional drug regulatory authority where determinations of safety, efficacy and quality are made. Drug regulatory authorities are also ordinarily responsible for follow-up analyses of the safety of registered medicines, which can lead to products being withdrawn or to additional labelling requirements with respect to adverse side effects and safety problems that might arise when prescribed to more diverse patients over a longer period of time. In addition to registering medicines, drug regulatory authorities are also empowered to monitor the consistent quality, safety and efficacy of medicines throughout the supply chain by monitoring sample batches of medicines and adherence to proper storage, handling and distribution all the way to end users. Drug regulatory authorities are also tasked with regulating distributors, pharmacists and authorized vendors and with detecting and removing unregistered medicines from circulation. These post-registration safety activities are termed pharmacovigilance.<sup>21</sup>

Substandard and falsified medicines are a real and pressing problem that must be addressed. There is a critical need to find legislative and policy approaches that would reduce the spread of such illicit, unregistered and unsafe products without hindering access to good-quality, safe and efficacious medicines – particularly legitimate and affordable generics of assured quality. The most critical threshold issue for public health in any anti-counterfeit legislation is to limit the scope of criminalized activities and conduct what is prescribed by the TRIPS Agreement.

This Discussion Paper provides recommendations on the principles that should guide legislation in this area as well as recommended model provisions. Specific legislative language and model provisions are offered in eight key areas listed below. The rationale behind these suggestions is to prevent the adoption of overly broad anti-counterfeit provisions that are likely to have an adverse impact on access to medicines. In addition, the Paper discusses two very important aspects of the problematic medicines issue, namely the inappropriateness of anti-counterfeit measures as a policy measure for curtailing the spread of substandard and falsified medicines. An important discussion, the last section of this Paper, is the need to develop an alternative, positive, public health-driven agenda for improving access to safe and efficacious medicines of assured quality.

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<sup>18</sup> See WHO guideline for GDP by the 40th WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2005, WHO Technical Report Series, No. 937, Annex 5, Geneva, 2006, [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_937\\_eng.pdf#page=191](http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf#page=191).

<sup>19</sup> *Ibid.* Para. 9.

<sup>20</sup> TRIPS Article 51 fn. 14 reads:

For the purposes of this Agreement:

(a) “counterfeit trademark goods” shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation ... [emphasis added].

<sup>21</sup> See WHO, *Pharmacovigilance: ensuring the safe use of medicines*, Geneva, 2004, <http://apps.who.int/medicinedocs/pdf/s6164e/s6164e.pdf>; WHO, *The Safety of Medicines in Public Health Programmes: Pharmacovigilance an essential tool*, Geneva, 2006, [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/Pharmacovigilance\\_B.pdf](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf).

## Why is UNDP concerned?

As a founding co-sponsor of the Joint UN Programme on HIV/AIDS (UNAIDS), UNDP plays an important role in the global response to AIDS, leading the efforts to address HIV and development issues. Guided by the public health-related targets set out in MDG 6, “to halt and reverse the spread and HIV/AIDS, Malaria and other epidemics by 2015”, UNDP is mandated to provide technical and policy support to governments in their implementation of policies and programmes that protect the human rights of people affected by HIV and AIDS, including the human right to the highest attainable standards of health, which includes access to essential medicines. The UN Special Rapporteur on the Right to Health cautions against the possible adverse impact of IP considerations on the prices and availability of medicines, hampering countries’ efforts to comply with their obligations to protect the right to health.<sup>22</sup>

The Discussion Paper builds on the extensive work of UNDP on IP and access to medicines and particularly the outcomes of series of international meetings organized by UNDP in cooperation with government agencies and civil society partners.

These are:

- ‘The Expert Discussion on Uganda’s Counterfeit Goods Bill and the Draft EAC Anti-Counterfeit Policy’ held in Entebbe, Uganda, on 9–10 September 2009 (co-organized with the Open Society Foundations, Health Promotion and Social Development (HEPS)-Uganda, Health Action International (HAI)-Africa and Third World Network (TWN));
- the regional consultations ‘Proliferation of Anti-Counterfeiting Legislation in the East African Community (EAC): Addressing Public Health, Copyright and Development Concerns’ (co-organized with OSI and HAI-Africa, held in Arusha, Tanzania, on 25–26 March 2010; and
- the ‘EAC Regional Multi-sectorial Stakeholders Meeting on EAC, WTO, TRIPS and Pharmaceutical Sector Promotion’, held in Arusha on 5–8 December 2010 and organized in partnership with the German Society for International Cooperation (GIZ) and the EAC Secretariat.

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<sup>22</sup> Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, A/HRC/11/12, 31 March 2009, [www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12\\_en.pdf](http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf).

<sup>23</sup> WHO, *HIV treatment reaching 6.6 million people, but majority still in need*, Geneva, 2011, [www.who.int/mediacentre/news/releases/2011/hivtreatment\\_20110603/en/index.html](http://www.who.int/mediacentre/news/releases/2011/hivtreatment_20110603/en/index.html); see WHO, *New Progress and Guidance on HIV Treatment*, Geneva, 2010, [www.who.int/hiv/vienna2010/en/index.html](http://www.who.int/hiv/vienna2010/en/index.html).

<sup>24</sup> See Statement of Michel Sidibe, the Executive Director of UNAIDS on the occasion of World AIDS Day 2010, <http://unaids.org/?p=1739>.

<sup>25</sup> See the WHO website at <http://www.who.int/mediacentre/factsheets/fs314/en/index.html>.

<sup>26</sup> *Ibid.* WHO, *Antiretroviral Therapy for HIV Infection*.

## Do anti-counterfeit laws improve the safety, quality and efficacy of medicines?

### Recent success in scaling up HIV treatment; the role of affordable, quality generics

At the end of 2010, approximately 6.6 million people in low- and middle-income countries were receiving antiretroviral therapy (ART), a 16-fold increase since 2003,<sup>23</sup> undoubtedly a significant public health achievement. The impact of expanded treatment access is exemplified in Kenya, where it is estimated that AIDS-related deaths have fallen by 29 percent since 2002; globally, the number of new infections and AIDS-related deaths has fallen by nearly 20 percent.<sup>24</sup> Access to affordable and good-quality generic medicines has played a key role in this achievement. Increased financing for medicines and for treatment, new investments in health and community systems, human resources for health, as well as the use of TRIPS-compliant flexibilities in IP laws to ensure wide availability of affordable medicines, were all factors that positively influenced improvements in access to treatment.

### The persisting gap and the increasing need for treatment

However, the gap between need and access to medicines still persists. The burden of disease in Africa, especially for HIV and AIDS, remains disproportionately high, with 60 percent of those needing ART still untreated. According to the WHO, 72 percent of deaths in the region are due to communicable diseases compared to only 27 percent in all other WHO regions combined.<sup>25</sup> In its recently revised HIV treatment guidelines the WHO recommends starting ART at a higher CD4 cell count, which means that the number of people who require treatment reached approximately 16 million in 2010, which is another reason to predict an even greater increased need of affordable generic ARVs.<sup>26</sup> Beyond AIDS, deaths from non-communicable diseases are also on the rise throughout Africa. Therefore, much work remains to be done to ensure access to essential medicines for all in Africa and other regions of the global South.

### Cost and affordability of treatment: why substandard and falsified medicines exist

Increased demand for medicines unfortunately also leads to the production and circulation of substandard and falsified pharmaceuticals.<sup>27</sup> Some medicines, properly registered, are nonetheless substandard because of slippage from the GMP, improper storage and handling, and expiration. Other falsified products have the wrong active ingredients, insufficient or expired components or no active ingredients whatsoever, and there are also cases of these products including toxic ingredients. The result is no therapeutic effect and often grave harm to the lives and health of patients. The production and trade with such products is universally condemned by the UN and the international community and should not be tolerated.

Production and trade in substandard and falsified medicines is lucrative for criminals, due to the high profit generated by this illicit activity and the lack of sufficiently effective quality and safety control throughout the distribution system in many countries. No comprehensive regional research on the spread of substandard and falsified ARVs has been made, but there are indications that high volumes of such products are being produced and sold.<sup>28</sup> For example, data on anti-malarial medicines have been published by the United Nations Office on Drugs and Crime (UNODC), which estimates that the value of substandard and falsified anti-malarial medicines in West Africa alone is US\$438 million a year.<sup>29</sup> Various national investigations from the region have indicated that the problem of substandard and falsified medicines is indeed pressing.

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<sup>27</sup> Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom, *The Facts – Medicines*, <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm>.

<sup>28</sup> It is argued that there have been fewer major problems with substandard and falsified ARVs than, for instance, with anti-malaria medicines, because procurement and distribution are tightly monitored by the President's Emergency Plan for AIDS Relief (PEPFAR) and the GFATM and ARVs are often supplied with no costs or co-payments by the patient. This does not mean however, that the problem does not exist. WHO reports of several cases of substandard, spurious or falsified ARVs in several African countries revealed between 2001 and 2007. See WHO, *Survey of the Quality of Antiretroviral Medicines, Circulating in Select African Countries*, Geneva, 2007, [www.who.int/medicines/publications/ARV\\_survey.pdf](http://www.who.int/medicines/publications/ARV_survey.pdf).

<sup>29</sup> UNODC, *Transnational Trafficking and the Rule of Law in West Africa: a Threat Assessment*, Vienna, 2009, 33. Note that diverted, non-substandard medicines are also included in these statistics.

## The emergence of anti-counterfeit measures in Africa

In an attempt to address the problem of unregistered, unsafe and ineffective medicines, many countries in Africa have opted for enforcing IP-related anti-counterfeit measures. Arguments have been made that the use of anti-counterfeit laws and policies is an effective way to tackle substandard and falsified medicines and other problems of illicit trade because trademark infringing medicines are always unregistered (not granted marketing approval based on evidence of safety, efficacy and GMP) and because they often contain inactive, inaccurate or dangerous ingredients. This approach has captured the imagination of policy makers and large sections of the general public. As a result, a number of countries/regions have passed or are considering IP-related anti-counterfeit legislations. These laws or proposed laws include the EAC Anti-Counterfeit Bill of 2010; the Kenya Anti-Counterfeit Act of 2008;<sup>30</sup> Tanzania Merchandise Marks Regulations Act of 2008;<sup>31</sup> Zambia's proposed Anti-counterfeit Act of 2010; the proposed Uganda Anti-counterfeit Bill of 2011; and the Malawi Anti-counterfeit Bill of 2011.<sup>32</sup>

The basic characteristics of the IP-related anti-counterfeit approach to addressing quality, safety and efficacy are:

- use of the term 'counterfeiting' to cover all forms of IP infringement, including civil trademark infringement and patent infringement, as well as TRIPS-defined criminal trademark infringement;
- a focus on criminal IP enforcement and seizures/destruction not only for goods imported and exported but also those in transit;
- designation of customs officials as drug safety inspectors;
- designation of health and drug regulatory inspectors as IP-related 'anti-counterfeit inspectors';
- adoption of certain pro-IP presumptions regarding the IP basis of right holders' claims; and
- disproportionately severe penalties, including long prison terms for 'counterfeiters'.

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<sup>30</sup>The law is available at [http://www.kenyalaw.org/kenyalaw/klr\\_home/](http://www.kenyalaw.org/kenyalaw/klr_home/).

<sup>31</sup>These regulations are purportedly made under Section 18A of the Merchandise Marks Act, Chapter 85 Laws of Tanzania.

<sup>32</sup>Ruth Langa, *Zambia: Government Pushes Anti-Counterfeit Bill despite Health Danger* (30 April 2010), <http://allafrica.com/stories/201004300696.html>; see Claire Ngozo, *Malawi: Commotion about Anti-Counterfeit Bill Is Unnecessary*, IPSNews (19 May 2010), <http://ipsnews.net/news.asp?idnews=51494>; Suleiman Mbatiah, *Kenya: Court Victory against "Anti-Counterfeit" Agenda* (23 April 2010), <http://allafrica.com/stories/201004230734.html>; Pharmaceutical Insight, *Regional EAC Drug Anti-Counterfeit Bill Still Implicates Generics* (April 2010), [www.pharmaceuticalinsight.com/file/87758/regional-eac-drug-anti-counterfeit-bill-still-implicates-generics.html](http://www.pharmaceuticalinsight.com/file/87758/regional-eac-drug-anti-counterfeit-bill-still-implicates-generics.html).

<sup>33</sup>See Clift, *supra* note 14.

<sup>34</sup>WHO, *General Information on Counterfeit Medicines*, [www.who.int/medicines/services/counterfeit/overview/en/](http://www.who.int/medicines/services/counterfeit/overview/en/). For further discussion of the existing various definitions of anti-counterfeit medicines, see Gopakumar & Shashikant, *supra* note 14, 41–59.

## What is a counterfeit medicine? No common understanding

The anti-counterfeit approach, which emphasizes IP enforcement measures as the way to curtail the production and trade in substandard and falsified medicines, raises serious concerns. As previously discussed, referring to substandard and falsified medicines as ‘counterfeits’ is confusing because the term ‘counterfeit’ is an IP-related term, not a public health term. Except in the technical IP field, there is no common-sense understanding of what a ‘counterfeit medicine’ is and is not. Different sources provide different definitions,<sup>33</sup> and even the WHO definition has morphed over time. A counterfeit medicine was historically defined by WHO as:

[O]ne which is **deliberately** and **fraudulently** mislabeled with respect to **identity and/or source**. **Counterfeiting can apply to both branded and generic products** and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging [emphasis added].<sup>34</sup>

A more recent, tentative definition is longer, but still controversial.<sup>35</sup> The confusion about the term ‘counterfeit’ has resulted in the establishment of a working group at the WHO to examine the issue of medicine safety, efficacy and quality and to come up with a revised definition.<sup>36</sup>

TRIPS<sup>37</sup> uses the term ‘counterfeit’ more precisely and uses the related term ‘counterfeiting’ only in the context of criminal trademark infringements that are willful and on a commercial scale. Within the TRIPS framework, trademark counterfeit goods are “any goods, including packaging, bearing without authorization a *trademark which is identical to the trademark validly registered* in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question *under the law of the country of importation* [emphasis added].”<sup>38</sup> Such trademark counterfeits can arise from misuse of trade names and trade dress as well as other registered trademarks. The TRIPS term ‘counterfeiting’ is used only to designate willful counterfeits on a commercial scale, which, along with willful copyright piracy on a commercial scale, are the only IP violations for which criminal sanctions are required. **The terms ‘counterfeit’ and ‘counterfeiting’ are never used in TRIPS with respect to identical generics, which might violate a patent in a particular country, but do not in any sense intentionally deceive purchasers, prescribers or consumers by misbranding.**

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<sup>35</sup> See IMPACT, Draft Principles for National Legislation against Counterfeit Medical Products, WHO, Geneva, 2008, <http://www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf>, which included the following definition: A medical product is counterfeit when there is a false representation [5] in relation to its identity [6] and/or source. [7] This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components [8] or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging. Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches or quality defects or non-compliance with GMP/GDP in legitimate medical products must not be confused with counterfeiting. **5.** Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purpose of sanctions imposed. **6.** This includes any misleading statement with respect to name, composition, strength, or other elements. **7.** This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution. **8.** This refers to all components of a medical product.

<sup>36</sup> See Decision 63(10) at [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63-REC1/WHA63\\_REC1-P3-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-P3-en.pdf).

<sup>37</sup> Marrakesh Agreement Establishing the World Trade Organization, art. 8(1), annex 1C, 33 I.L.M. 81 (1994), [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

<sup>38</sup> *Id.* Art. 51, fn. 14(a).

## The Kenya Anti-Counterfeit Act court case

Recently national and regional laws and policies in Africa featured definitions of ‘counterfeits’ that ill-advisedly included generic medicines. Under Kenya’s Anti-Counterfeit Act’s<sup>40</sup> initial definition (2008), legitimate generic medicines, which are by definition ‘identical’ to the original product, were considered ‘counterfeit’ precisely because they were identical or substantially similar to the originator product.<sup>41</sup> Of course, the whole point of a ‘generic’ medicine is that it should be therapeutically identical to the original medicine, and thus ‘identity’ or twinship is a virtue, not a vice.<sup>42</sup>

Because of the imprecision and overbreadth of the definition and potential negative impact on access to medicines, Kenya’s Anti-Counterfeit Act of 2008 was challenged in court. Petition N 409 of 2009 was originally filed by three people living with, or affected by HIV. In March 2010, the AIDS Law Project, a Kenyan non-governmental organization (NGO), joined the petition as an interested party. In April 2010, the High Court granted a conservatory order, staying the application of Sections 2 (definition of counterfeiting), 32 (offences) and 34 (powers of seizure of goods suspected to be counterfeit) of the Act as far as it relates to importation of generic medicines. In 2011, the UN Special Rapporteur on the right to health, Anand Grover, was admitted as an *amicus curiae* – or friend of the court – and allowed to submit a brief.

On 20 April 2012, Justice Mumbi Ngugi of the High Court of Kenya delivered a judgment on the merits of the case, which is also referred to as *Patricia Asero Ochieng and 2 others v. the Attorney General & Another*.<sup>43</sup>

The High Court examined Sections 2, 32 and 34 of the Act from the perspective of their compliance with Articles 26 (1), 28 and 43 of the country’s Constitution, which guarantee the rights to life, human dignity and the highest attainable standards of health. The Judge specifically examined the definition of ‘counterfeits’ in Section 2 of the Act and agreed with the conclusions of the petitioners that the definition “is likely to be read as including generic medication”. The Judge further agreed with the *amicus* that the definition “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. 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.”

The Court cited the right to health standards set in international human rights instruments such as the International Covenant of Economic, Social and Cultural Rights, the Convention on the Elimination of All Forms of Discrimination against Women and the Convention on the Rights of the Child. It established that the state’s obligation regarding the right to health encompasses not only the positive duty to ensure that citizens have access to healthcare and medicines but “must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines. Any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state’s obligations under the Constitution.”

The Judge took the position that, while IP rights should be protected, where it is likely that their protection puts in jeopardy the right to life of others, “they must give way to the fundamental rights of citizens.”

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<sup>39</sup> *Id.* Art. 61.

<sup>40</sup> The Anti-counterfeit Bill of Kenya, 2008, Part I: “[C]ounterfeiting” means taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods: (a) *the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;* (b) *the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence;* (c) *the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author’s rights or related rights [emphasis added].* Available at [http://www.kenyalaw.org/Downloads/Bills/2008/The\\_Anti-Counterfeit\\_Bill\\_2008.pdf](http://www.kenyalaw.org/Downloads/Bills/2008/The_Anti-Counterfeit_Bill_2008.pdf)

<sup>41</sup> Since 90 percent of the medicines used in Kenya are generics, according to this definition this would have meant that they were counterfeit. See Health Action International Africa, [www.haiafrica.org/index.php?limitstart=40](http://www.haiafrica.org/index.php?limitstart=40).

<sup>42</sup> In June 2010, unnamed officials of Kenya’s Health Ministry conceded that the Act was promoted by Kenya’s Industry Ministry without public health considerations and substantial amendments are being considered to protect public health. See Economic Times of India, *Kenya Sees Cure in Indian Generics Now* (3 June 2010), <http://economictimes.indiatimes.com/articleshow/6005620.cms>.

The High Court ruled that Sections 2, 32 and 34 of the Anti-Counterfeit Act threaten to violate the right to health, dignity and life, as guaranteed by the Kenyan Constitution. The Court also declared that the fundamental rights to life, health and human dignity encompass access to affordable and essential medicines, including generics, that the Act severely limits or threatens to limit access to affordable and essential medicines, including for HIV and AIDS, and its enforcement would be a breach of the petitioners' rights to life, health and human dignity. The High Court concluded that it is incumbent on the state to reconsider the provisions of Section 2 of the Act and make appropriate amendments to ensure that the rights of the petitioners and others dependent on generics are not put in jeopardy.

After the conservatory order was issued in Kenya in 2010, Uganda revised its definition of counterfeits, which was originally very similar to Kenya's. The discussions around the Anti-Counterfeit Bill of Uganda are still ongoing, and by April 2012 the Bill has not been passed. The Draft East Africa Community Anti-Counterfeiting Act, which would bind all EAC Members, also included a definition of counterfeits as being goods that are 'identical' to IP-protected good, thus sweeping generics within its coverage. An international multi-stakeholder meeting, co-organized by UNDP on anti-counterfeit initiatives in East Africa in March 2010, concluded, among other things, that the EAC's anti-counterfeiting policy and Bill:

[F]ail to distinguish various IPR infringements, contain overbroad and imprecise definitions and do not consider the impact of the foreseen measures on access to knowledge, agriculture and public health. The ambiguity and poor quality of the drafts evidently require revisions, but the more important question is whether the policy and Bill are needed at all.<sup>44</sup>

In sum, anti-counterfeit measures to date tend to conflate the issues of quality, safety and efficacy of medicines with IP rights compliance, which is an alarming trend. The two subject matters require entirely different competencies of different government authorities. It is incorrect and dangerous to assume that compliance with IP requirements guarantees the safety, quality and efficacy of medicines. IP does not have the purpose of, and cannot address, these matters. A simple example is the case of defective or tainted medicines which can sometimes be manufactured by patent holders by mistake. Another example are medicines originally of good quality that degrade because of improper storage and handling or because of shelf-life expiry. Such medicines do not infringe the patents in an evident way, but they are certainly substandard and potentially dangerous and/or inefficacious. Recent examples show that such cases happen at both originator companies and generic producers,<sup>45</sup> and the only successful way to mitigate the negative effect from the release of such medicines is strict quality control, pharmacovigilance throughout the supply chain, immediate withdrawal of the substandard product, and transparency.

Conflating generic medicines with 'counterfeits' simply because they are identical to the originator product is another alarming characteristic of anti-counterfeit measures that must be redressed. As WHO points out, both generic and brand name pharmaceutical products are affected by the problem of substandard and falsified medicines.<sup>46</sup> Including genuine

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<sup>43</sup> Petition N 409 of 2009, Judgment (2012), [www.ip-watch.org/weblog/wp-content/uploads/2012/04/Kenya-Judgment-Petition-No-409-of-2009.pdf](http://www.ip-watch.org/weblog/wp-content/uploads/2012/04/Kenya-Judgment-Petition-No-409-of-2009.pdf).

<sup>44</sup> See the report of the International Meeting held in Arusha, Tanzania, on 25–26 March 2010 under the title 'Proliferation of Anti-Counterfeiting Legislation in the East African Community: Addressing Public Health, Copyright and Development Concerns'. The meeting, which was organized by the UNDP, the Open Society Institute (OSI) Public Health Program and Health Action International (HAI) Africa, was attended by officials of the EAC Secretariat, government officials, civil society, development partners and several international experts.

<sup>45</sup> GlaxoSmithKline was fined \$750 million for manufacturing defects in a Cidra, Puerto Rico, plant occurring over several years. Problems included cross-contamination between products through the air distribution system; contaminated water; pills of differing strength placed in the same container; unsterile conditions for intravenous cancer drugs; and use of rented vans for storage when the warehouse was over capacity. Gardiner Harris & Duff Wilson, 'Glaxo to pay \$750 million for sale of bad drugs', *New York Times* (26 October 2010). In 2007, originator pharmaceutical company Roche recalled protease inhibitor Viracept in Europe and other regions of the world due to impurity. See Roche media release, [www.roche.com/med-cor-2007-06-06b](http://www.roche.com/med-cor-2007-06-06b). Ranbaxy, a GMP-certified generic producer, had products recalled because of quality control issues at two of its plants. Lisa LaMotta, 'FDA: Ranbaxy Botched Manufacturing', *Forbes* (16 September 2008), [http://www.forbes.com/2008/09/16/ranbaxy-fda-generic-markets-equity-cx\\_la\\_0916markets39.html](http://www.forbes.com/2008/09/16/ranbaxy-fda-generic-markets-equity-cx_la_0916markets39.html), and a year earlier recalled the neuropathic drug Gabapentin in the USA. Reuters, *India's Ranbaxy Recalls gabapentin tablets in the U.S.* (17 November 2007), [www.reuters.com/article/idUSBOM996220071116](http://www.reuters.com/article/idUSBOM996220071116).

<sup>46</sup> WHO Factsheet, [www.who.int/mediacentre/factsheets/fs275/en/](http://www.who.int/mediacentre/factsheets/fs275/en/).

generics in the category of ‘counterfeits’ could have extremely serious consequences for people’s lives and health and for national public health systems. For example, in Kenya and Uganda most medicines are imported, and over 90 percent of them are generics. While there is no evidence that anti-counterfeit laws have effectively prevented the spread of substandard and falsified medicines, there is evidence that they have negatively affected access to generics. For instance, between 2008 and 2009, customs officials in the Netherlands and Germany seized approximately 20 in-transit shipments of legitimate, good-quality generic medicines lawfully manufactured in and exported primarily from India (and, in at least one case, China) and destined for lawful importation, sale and use in developing countries in Latin America and Africa, under the pretext that they were ‘counterfeit’. At least one of the shipments seized was of Indian ARVs, approved by the US Food and Drug Administration (FDA), purchased by UNITAID and destined for Nigeria.<sup>47</sup>

There is a real danger that the overly broad definition of the terms ‘counterfeit’ and ‘counterfeiting’, coupled with the criminalization of all IP rights infringements, including patent infringement; the granting of broad seizure powers to government agencies, including customs, without judicial oversight; and harsh penalties and evidentiary presumptions will negatively impact the availability of generic medicines.<sup>48</sup> In particular, there are important considerations regarding the potential for abuse of procedures for enforcing IP rights by right holders in transit countries and the use of such procedures to prevent trans-shipment and market entry by generics, thereby compromising efforts to enhance transfer of technology, including in the pharmaceutical sector.

Consequently, while recognizing the need to address the problem of substandard and falsified medicines, there is a critical need to find legislative approaches that would reduce the spread of such medicines without hindering access to good-quality, safe and efficacious medicines, particularly generics. This Discussion Paper provides recommendations on the principles that should guide legislation in this area as well as model provisions on some of the key issues addressed in IP-related anti-counterfeit legislation. The principles provide policy makers with considerations that should be taken into account when addressing issues around medicines and IP enforcement. The model provisions seek to provide legislators with specific language that prioritizes public health obligations with respect to access to medicines within an anti-counterfeit approach.

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<sup>47</sup> On seizures of medicines in transit, see International Center for Trade and Sustainable Development, <http://ictsd.org/i/news/bridgesweekly/39772/>; see also: <http://www.plusnews.org/report.aspx?ReportId=83459>; [http://www.mission-pharma.org/content/us/about\\_us/news/news\\_archive/seizure\\_of\\_generic\\_medicine\\_86-2009](http://www.mission-pharma.org/content/us/about_us/news/news_archive/seizure_of_generic_medicine_86-2009).

<sup>48</sup> For a detailed discussion, see, for example, S. Musungu, ‘The Potential Impact of the Proposed East African Community (EAC) Anti-Counterfeiting Policy and Bill on Access to Essential Medicines’. This paper was presented and discussed at the Arusha meeting referenced in note 44 above.



## Principles and model provisions for addressing public health concerns in anti-counterfeit laws

Ensuring that anti-counterfeit laws do not impede access to essential medicines, particularly generics, requires that policy makers be guided by certain public health-related principles and that key provisions in these laws be carefully crafted. The key areas where careful drafting is required to ensure that public health concerns are protected relate to:

- the definitions of counterfeits and counterfeiting;
- criminal liability for counterfeiting;
- seizures and storage of goods;
- treatment of goods in transit;
- presumptions relating to evidence; and
- liability for loss or damage suffered by wrongfully accused defendants/third persons.

These topics will be discussed in detail below.

### DEFINITION OF 'COUNTERFEITING'

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#### *Context: Avoid coverage of civil trademark violations and patent infringements*

There are three main concerns regarding the overly broad use of the terms 'counterfeit' and 'counterfeiting' in the context of efforts related to ensuring the quality, safety and efficacy of medicines. The first relates to the misuse of the terms to encompass all forms of IP infringement, as opposed to using the terms narrowly as defined in TRIPS. Apart from the TRIPS definitions, there are no other internationally agreed definitions, and differing sources provide a confusing array of definitions and interpretations.<sup>49</sup> In fact, because of the confusion and the differing definitions, the World Health Assembly at its 63rd Session in May 2010 decided to establish a Working Group on substandard/spurious/falsefully labelled/falsified/counterfeit medicinal products, which, among other things, will deal with the question of definition.<sup>50</sup>

The TRIPS Agreement only uses the term 'counterfeit' to refer to a **particular type of trademark infringement**. Article 51, Footnote 14(a), in particular, defines trademark counterfeiting as referring to:

[A]ny goods, including packaging, bearing without authorization a trademark which is identical to a trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

As described above, the definition of criminal 'counterfeiting' under TRIPS Article 61 is even narrower, focusing only on willful violations done on a commercial scale.

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<sup>49</sup> See, for example, Clift, note 14.

<sup>50</sup> See Decision 63(10), [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63-REC1/WHA63\\_REC1-P3-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-P3-en.pdf).

The extension of these terms beyond their technical meanings to include other forms of trademark infringement has serious implications for access to medicines. In normal circumstances, non-criminal trademark infringement occurs where use of an otherwise legitimate mark or packaging by one firm may create the likelihood of confusion in the market in relation to a pre-existing trademark. In such circumstances we are dealing with a civil infringement, which is normal in the ordinary course of business. Here, unlike in the case of criminal counterfeiting, the firm or individual does not willfully misuse another's trademark with intent to mislead and does not necessarily act on a commercial scale. Indeed brand confusion can and does occur between two validly registered, competing marks.

The distinction between trademark counterfeiting, which is a criminal action, and normal civil trademark infringement has special salience in the case of medicines.<sup>51</sup> In the pharmaceutical sector, it is fairly common for companies to name their products based in part on the active ingredient's international non-proprietary name (INN).<sup>52</sup> This means that a brand name product and generic medicine (which have the same active ingredient) may bear confusingly similar names. Similarly, the so-called 'trade dress' of generic medicines is often similar to that of branded originator products for two compelling public health reasons: because changing the shape, size and even colour of a medicine can affect bioequivalence, and because it is important to reduce consumer confusion over originator products and generics being equivalent, to encourage generic substitution adherence to treatment.<sup>53</sup>

The misuse of the term 'counterfeiting' with respect to patents also raises vexing problems. As Correa has observed, debates about counterfeiting, especially when relating to medicines, "are often obscured by inappropriate use of the concept of 'counterfeiting' or piracy to describe situations in which legitimate generic versions of medicines are introduced without the consent of the originator of the drug."<sup>54</sup> A generic company might produce and sell a generic version believing that the patent claim will be invalidated or that duplication might not even be challenged. Similarly, compulsory licences and parallel importation can result in the production, marketing and distribution of a medicine without the consent of the right holder.

Accordingly, applying border seizure and criminal sanctions in patent infringement disputes raises significant policy concerns. In a study for the World Intellectual Property Organization (WIPO), Justice Harms of South Africa identified at least seven reasons why criminalizing patent infringement could be bad policy.<sup>55</sup> These include the following:

- It is virtually impossible for law enforcement officers and border officials to determine whether any particular product is an infringing product.
- Criminal courts are, generally speaking, not qualified to deal with patent issues.
- Any given patent may cover many 'inventions'.
- The invalidity of the patent is the typical defence to infringement, and a significant percentage of patents are revoked in the course of patent litigation.
- The patentee's product may not be made in accordance with a process patent.
- The infringer's product may not be a copy of the patentee's product as marketed.

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<sup>51</sup> For a detailed discussion see, for example, the comments of Public Citizen to the European Commission (EC) with respect to EC Consultation, *Review of EU Legislation on Customs Enforcement of Intellectual Property Rights* (May 2010) <http://citizen.org/Page.aspx?pid=3458>.

<sup>52</sup> INNs facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. Detailed explanations and further information on INNs can be found on the WHO website at <http://www.who.int/medicines/services/inn/en/>.

<sup>53</sup> Some health officials are now arguing that it may be desirable to encourage generic equivalents to have the same appearance or trade dress (size, shape and colour of the medicine), to promote generic substitution and reduce prescription errors by pharmacists, to avoid patient confusion, and to enhance patient adherence. Jeremy A. Greene & Aaron S. Kesselheim, 'Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health', *New England Journal of Medicine*, 2011, 365, 83–89.

<sup>54</sup> Carlos Correa, 'The Push for Stronger Enforcement Rules: Implications for Developing Countries', in ICTSD Issue Paper No. 22 *The Global Debate On The Enforcement Of Intellectual Property Rights And Developing Countries*, 29–80, 48, ICTSD, Geneva, 2008.

<sup>55</sup> See L. Harms, *The Enforcement of Intellectual Property Rights by Means of Criminal Sanctions: An Assessment*, WIPO/ACE/4/3, 2007, p. 15, [http://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_4/wipo\\_ace\\_4\\_3.pdf](http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_4/wipo_ace_4_3.pdf).

This view is supported by a range of other commentators and organizations. For example, in its submission to the UK Gowers Review<sup>56</sup> the International Chamber of Commerce (ICC) UK argued that UK law should remain without criminal sanctions for patent infringement. The ICC UK justified this position on the basis of the potential anti-competitive effect of criminalizing patent infringement and the difficulties in assessing the validity and scope of a patent.<sup>57</sup> Even the newly negotiated plurilateral Anti-Counterfeiting Agreement has elected to exclude patents from border measures and criminal penalties.<sup>58</sup>

The second concern about attempts to stretch the meaning of the term ‘counterfeiting’ is that it may lead to the violation of human rights, particularly the rights to health and life. As discussed previously, on 20 April 2012, the Kenya High Court ruled that Sections 2, 32 and 34 of the Anti-Counterfeit Act threaten to violate the right to health, dignity and life, as guaranteed by the Kenyan Constitution.<sup>59</sup>

The third concern about the broad definition of the term ‘counterfeiting’ relates to serious scepticism about the real motives and intentions of IP enforcement advocates. The approach of certain multinational companies seems to put IP and monopoly rights – rather than health – at the core of the efforts to address medicines safety and efficacy. South African IP lawyer Marius Haman has also observed in the particular case of Africa, “Various stakeholders, including African governments, are often suspicious about whether big pharmaceutical companies conveniently use anti-counterfeiting laws to curb the flow of generic medicines, rather than ensuring public safety.”<sup>60</sup> Such skepticism creates a negative atmosphere, making it difficult to seriously tackle the real problem of substandard and falsified medicines in countries in Africa and other low- and middle-income countries.

### *Legislative principles*

To address concerns about the definitions of ‘counterfeits’ and ‘counterfeiting’, three important principles should guide policy makers and legislators when defining IP-related counterfeiting:

- The definition of ‘counterfeiting’ should be limited to willful criminal trademark counterfeiting on a commercial scale as defined in the TRIPS Agreement.
- If the law also covers copyright infringement, ‘piracy’ should be defined separately, also based on the TRIPS definition.
- Civil trademark infringement/confusion and patents infringement should not be included in the scope of any definition of ‘counterfeiting’.

### *Model definition of ‘counterfeiting’*

The above legislative principles can be achieved with the following language:

‘Counterfeiting’ means dealing, willfully and on a commercial scale, without the authority of the owner of a trademark in [insert name of country] with any goods bearing a trademark which is identical to a trademark validly registered in respect of such goods in [insert name of country] or which cannot be distinguished in its essential aspects from such a validly registered trademark.

<sup>56</sup> Information about the Gowers Review can be found on the UK IP Office website at <http://www.ipo.gov.uk/policy/policy-issues/policy-issues-gowers.htm>.

<sup>57</sup> See the ICC UK submission at [http://www.hm-treasury.gov.uk/d/international\\_chamber\\_of\\_commerce\\_462\\_91kb.pdf](http://www.hm-treasury.gov.uk/d/international_chamber_of_commerce_462_91kb.pdf).

<sup>58</sup> Anti-Counterfeiting Trade Agreement, 3 December 2010, <http://www.dfat.gov.au/trade/acta/Final-ACTA-text-following-legal-verification.pdf>. Pursuant to Art. 7 n.2, “A Party may exclude patents and protection of undisclosed information from the scope of this Section [emphasis added].” Likewise Art. 13 n.6 states, “the Parties agree that patents and protection of undisclosed information do not fall within the scope [of the Border Measures section [emphasis added]].”

<sup>59</sup> See Judgment, *supra* note 43.

<sup>60</sup> M. Haman, ‘Africa Rising to the Anti-Counterfeiting Challenge’, *Journal of Intellectual Property Law & Practice* 2010, 5, 344–349, 347.

## CRIMINAL LIABILITY FOR COUNTERFEITING (OFFENCES)

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### *Context*

The ‘anti-counterfeiting’ approach is based on the idea of seizing and destroying IP-infringing goods and criminalizing IP infringement by imposing ‘deterrent’ penalties for committing offences. It is argued that this ‘seek, destroy and prosecute’ strategy will reduce counterfeiting. However, applying criminal sanctions to ordinary IP infringement cases is cause for significant concern. Concerns range from economic matters,<sup>61</sup> to skepticism about using scarce public resources to protect private IP rights, to doubts about the deterrent effect of criminal sanctions, and finally to questions about the speed of proceedings and over-compensation for right holders.<sup>62</sup>

These concerns informed the crafting of Article 61 of the TRIPS Agreement, which addresses the question of criminal procedures for IP infringement:

Members shall provide for criminal procedures and penalties to be applied at least in cases of *willful trademark counterfeiting or copyright piracy* on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently *with the level of penalties applied for crimes of a corresponding gravity*. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular *where they are committed willfully and on a commercial scale* [emphasis added].”

There are three reasons why Article 61 is so carefully crafted in terms of what must be criminalized, the nature of penalties and where countries have wide discretion. The first reason relates to the question, discussed above, of criminalizing patent infringement and civil trademark infringement. Article 61 does not oblige members to adopt criminal sanctions beyond the cases of **willful** and trademark and copyright infringement **on a commercial scale**. It has been argued by some that the criminalization of patent infringement will have significant negative consequences for technological learning and transfer. Emulating is an important process through which societies can develop their technological capacity and move up the development ladder. As Dutfield and Suthersanen have pointed out:

There is ample historical evidence to indicate that freedom to imitate was an essential step towards learning how to innovate. In addition, numerous examples show that relatively unfettered access to goods, technologies and information from more advanced countries stimulated development in the less advanced ones. Support for both findings comes, as we saw, from the cases of Holland, Sweden, Japan, the United States and the Asian Tigers. It is difficult to see why they would not also be true for today’s developing countries.<sup>63</sup>

Criminalizing patent infringement may, therefore, have a serious chilling effect on innovation and technological learning in Africa, including in the pharmaceutical sector. Such an outcome would impede efforts, such as those in the EAC, to develop a regional generic pharmaceutical industry.

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<sup>61</sup> See, the discussions in C. Fink, ‘Enforcing Intellectual Property Rights: An Economic Perspective’, in *ICTSD Issue Paper 22*, *supra* note 54. He, for example, observes that although there are links that can be established between counterfeiting and piracy and organized crime, the evidence remains anecdotal. This means that it is important to establish more systemic evidence of the potential positive externalities from stronger enforcement action.

<sup>62</sup> See, for example, Correa *supra* note 54, p. 42.

<sup>63</sup> See G. Dutfield and U. Suthersanen, ‘Harmonisation or Differentiation in Intellectual Property Protection? Lessons from History’, *Occasional Paper 15*, QUNO, Geneva, 2005, 15, <http://www.quno.org/geneva/pdf/economic/Occasional/Harmonisation-or-Differentiation.pdf>.

The second reason for the careful crafting of Article 61 of the TRIPS Agreement was the need to ensure that not all forms of infringement are criminal – only those which are intended to confuse consumers and distort informed trade. It is for this reason that Article 61 requires that for both trademark counterfeiting and copyright piracy, as well as any other IP area where a country introduces criminal sanctions, such sanctions target **intentional acts on a commercial scale**. This is also the reason why Article 60 of the TRIPS Agreement contemplates that WTO Members may wish to exempt de minimis imports (small quantities of goods of non-commercial nature contained in travellers' personal luggage or sent in small consignments), even in civil cases. In other words, the TRIPS Agreement establishes willful infringement<sup>64</sup> and commercial scale<sup>65</sup> as the two triggers for establishing criminal liability in the area of IP enforcement.

The third reason for the careful crafting of Article 61 of TRIPS relates to ensuring proportionate and deterrent penalties. Article 61 provides that penalties in IP infringement cases “should correspond to the level of penalties applied for crimes of similar gravity under other laws.” However, Section 35 of the Kenya Anti-Counterfeiting Act 2008 provides for imprisonment of up to five years on a first conviction and up to 15 years for a second or subsequent conviction – penalties which are disproportionately high.

Article 41 of the TRIPS Agreement, particularly with respect to the question of abuse of enforcement procedures, is also relevant to the question of criminal liability in IP-related disputes. Article 41 provides, *inter alia*, that IP enforcement procedures shall be applied so as to provide safeguards against their abuse. Under paragraph 2 of the Article, it is required that such procedures be fair and equitable. In the context of criminal enforcement of IP, this calls for the creation of offences and deterrent penalties for any persons, including government officials, who abuse enforcement procedures. These offences and penalties should be in addition to the offences and penalties already contemplated with respect to prohibited disclosures of information and impersonation.

Strong measures are called for to ensure fairness and equity but also to protect the public interest. Consider, for example, a consignment of medicines to treat HIV seized at the borders without a valid and just cause. Such seizure could have life-threatening effects for those meant to benefit from such medicines. The same is true for food and other essential goods. In other words, someone who abuses ‘anti-counterfeiting’ procedures and deprives the public of legitimate essential products may be as dangerous as a counterfeiter.

### *Legislative principles*

A number of principles can be drawn from the discussion above. Three particular principles need to be kept in mind when developing legislative provisions on offences under ‘anti-counterfeiting’ laws:

- For criminal liability to attach to an act of trademark counterfeiting, such an act must be proven to be willful and on a commercial scale (as defined by the WTO panel in the USA–China case).
- The penalties imposed for counterfeiting must be proportional to the offence committed.
- Offences and penalties should be put in place to ensure that procedures under ‘anti-counterfeiting’ laws are not abused and that they are applied fairly, equitably and for the intended purpose.

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<sup>64</sup>The determination of what constitutes willful infringement should be based on the concept of intentional wrongdoing. This means that an act of IP infringement does not make persons criminally liable unless ‘their mind is guilty’.

<sup>65</sup>Regarding the scope of ‘commercial scale’, the WTO Panel in ‘China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights’ (hereinafter USA–China case) concluded that: [C]ounterfeiting or piracy ‘on a commercial scale’ refers to counterfeiting or piracy carried on at the magnitude or extent of typical or usual commercial activity with respect to a given product in a given market. The magnitude or extent of typical or usual commercial activity with respect to a given product in a given market forms a benchmark by which to assess the obligation in the first sentence of Article 61. It follows that what constitutes a commercial scale for counterfeiting or piracy of a particular product in a particular market will depend on the magnitude or extent that is typical or usual with respect to such a product in such a market, which may be small or large. The magnitude or extent of typical or usual commercial activity relates, in the longer term, to profitability. Para 7.577 of the Report of the Panel, WT/DS362/R (29 January 2009), [http://www.wto.org/english/tratop\\_e/dispu\\_e/362r\\_e.pdf](http://www.wto.org/english/tratop_e/dispu_e/362r_e.pdf).

### *Model provisions on criminal liability and offences related to counterfeiting*

The above principles can be implemented legislatively with the following model language:

#### *Offences relating to counterfeiting:*

It shall be an offence for any person to willfully and on a commercial scale:

- manufacture, produce or make any counterfeit goods;
- sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;
- expose or exhibit any counterfeit goods;
- distribute counterfeit goods; *or*
- import any counterfeit goods.

#### *Offences relating to abuse of procedures:*

It shall be an offence for any person to initiate procedures to detain or seize medicines alleged to be counterfeit or for a government official to enter any place, premises or vehicle to seize, detain or remove any goods suspected to be counterfeit, based on information he knows, or is reasonably expected to know, is false, or on expectation of unlawful personal or commercial gain, or so as to delay, interfere with or deter legitimate trade of non-counterfeit products. It shall also be an offence to continue an enforcement application or to continue the detention or to destroy seized goods after receiving credible information that such action is unwarranted.

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<sup>66</sup> See, for example, Section 23 of the Kenya law, *supra* note 30, Section 7 of the Uganda Bill and Section 19 of the EAC Bill.

<sup>67</sup> See Section 27 of the Kenyan Act, *supra* note 30.

<sup>68</sup> The Regulation, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF>, sets out the conditions under which customs authorities may intervene in cases where goods are suspected of infringing IP rights as well as the procedures to be followed. For a detailed discussion, see S. Kumar, 'Freedom of Transit and Trade in Generic Pharmaceuticals: An Analysis of EU Border Enforcement Law and Implications for the International Intellectual Property Law Regime', *European Intellectual Property Review* (2010) available on SSRN at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1383067](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1383067).

## POWERS OF SEIZURE AND STORAGE

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### Context

The 'anti-counterfeiting' laws, such as those in East Africa, give broad powers to government agencies and officials, among other things, to:<sup>66</sup>

- enter and inspect any place, premises and vehicles;
- take steps to terminate manufacturing, production or making of goods;
- seize, detain and remove goods;
- seize, detain and remove any manufacturing, production and packaging tools;
- question persons or procure documents; and
- seal or seal off any place, premises or vehicle.

In some cases, such as in Kenya, such powers are given and are meant to be exercised without a warrant or any judicial oversight. It is notable, however, that in other cases, such as of the Uganda Counterfeit Goods Bill 2010 and the draft EAC Anti-Counterfeit Bill, most of these powers can only be exercised on the authority of a court warrant.

There is a strong argument to be made that such broad and extensive powers, allowing government agencies and officials to interfere with goods which might be essential to health, nutrition etc., without judicial supervision, are in many instances unconstitutional. In addition, the exercise of such powers without judicial oversight may be incompatible with the proper principles of administration of justice in a free and democratic society. Further, granting and exercising such powers opens the door and provides extensive opportunities for harassment of business competitors and corruption of government officials. This risk is exacerbated because of limitations on personal liability for losses and damage (see below) for right holder complainants and government officials.

With respect to storage, the general approach in the anti-counterfeit laws is to require that seized goods are stored in safe custody at a counterfeit goods depot.<sup>67</sup> To a casual observer, this provision might look reasonable. However, it raises a number of important problems, especially in the context of medicines. The storage of medicines requires special facilities and conditions to avoid contamination and the effects of, for example, excess heat, cold or humidity. Poor storage of medicines by customs and other agencies may, therefore, pose serious safety problems. Inappropriately stored, legitimate medicines can end up being substandard. Anti-counterfeit actions which lead to defectiveness, contamination or other negative effects on medicines are, therefore, as dangerous as the actions which these laws purport to address.

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<sup>69</sup> John Miller & Geeta Anand, 'India Prepares EU Trade Complaint', *Wall Street Journal* (6 August 2009), [http://online.wsj.com/article/SB124949598103308449.html?mod=3Dgooglenews\\_ws](http://online.wsj.com/article/SB124949598103308449.html?mod=3Dgooglenews_ws).

<sup>70</sup> *Sosecal v. Sisvel*, District Court in The Hague (2008), [http://www.eplawpatentblog.com/PDF\\_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf](http://www.eplawpatentblog.com/PDF_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf); see Frederick J. Abbott, 'Seizures of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare', *W.I.P.O.J.*, 2009, 1, 43, 47); Frank Eijsvogels, 'Sisvel v. Sosecal: Acting Against Transit Goods Still Possible Under the Anti Piracy Regulation in the Netherlands', *IP Intelligence Europe* (Howrey LLP, Amsterdam, Netherlands), 2008, 10.

### *Legislative principles*

Legislative provisions in anti-counterfeit laws relating to seizures and storage of suspected goods, therefore, should be drafted based on the following five principles:

- In a free and democratic society, granting and exercising powers by governmental agencies with respect to private property must conform with human rights standards, proper administration of justice and constitutional safeguards.
- Powers to seize or otherwise interfere with private property must be conditioned upon judicial oversight. Hence powers to enter premises and to seize, detain, remove and eventually destroy goods should be exercised on the basis of a warrant or provisional measures or final orders issued by a court of law, although that law might provide for temporary detention (10 days) and notification both to the right holder and the holder of the goods with the right to be heard.
- The powers granted to government agencies and officials must not provide incentives or opportunities for corruption.
- These powers should be proportional and equipped with strong safeguards against their abuse.
- Goods seized under anti-counterfeit laws need to be stored in a manner that ensures that they are not contaminated and that their quality and safety are not otherwise compromised.

### *Public health-sensitive provisions on seizures and storage*

Taking into account the above principles, legislation should provide that:

Provisions allowing seizures of suspected counterfeit goods and stopping their manufacture and distribution by entry or otherwise should be temporary – no longer than 10 days – and thereafter conditioned upon notice and opportunity to be heard by the holder of the goods and the issue of a warrant and/or other provisional measures or final orders by a court of competent authority.

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<sup>71</sup> For examples of pharma letters seeking generic company acquiescence to seizure by border officials, see letter sent by Merck and Du Pont lawyers to Dr. Reddy on 24 December 2008 concerning Losartan en route from India to Brazil, <http://online.wsj.com/public/resources/documents/eudrugs2009letter1.pdf>; and the letter sent by Eli Lilly lawyers to Cipla on 9 December 2008 concerning Olanzapine en route from India to Peru, <http://online.wsj.com/public/resources/documents/eudrugs2009letter3.pdf>.

<sup>72</sup> 13 Bridges Weekly Trade News Digest, *European Generic Drug Seizures Take Centre Stage at TRIPS Council Meeting*, 10 June 2009, <http://online.wsj.com/public/resources/documents/eudrugs2009letter1.pdf>.

<sup>73</sup> See, for example, Henning Grosse Ruse-Khan & Thomas Jaeger, 'Policing Patents Worldwide? EC Border Measures against Transiting Generic Drugs under EC- and WTO Intellectual Property Regimes', *International Review of Intellectual Property & Comparative Law* 2009, 40, 502; cf. Xavier Seuba, *Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border*, International Centre for Trade & Sustainable Development, Geneva, 2010, [http://ictsd.org/downloads/2010/04/seuba\\_web\\_10.pdf](http://ictsd.org/downloads/2010/04/seuba_web_10.pdf).

<sup>74</sup> Ruse-Khan & Jaeger, *supra* note 73; Seuba, *supra* note 73. Ruse-Khan and Jaeger have been the most vociferous in arguing that Article 10 of BMR authorizing seizure goods in transit based on alleged IP infringement under the domestic law of the transit country may run counter to Article 52 of TRIPS, which requires that border measures be applied based on the "law of the country of importation".



## GOODS IN TRANSIT

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### Context

The protection and enforcement of IP under TRIPS is based on a number of international trade principles. In the Preamble of TRIPS it is recognized that provisions, including on enforcement, should support the desire and recognize the need of WTO Members to:

- reduce distortions and impediments to international trade;
- ensure that measures and procedures to enforce IP do not become barriers to legitimate trade;
- establish a multilateral framework for dealing with international trade in counterfeit goods; and
- reduce international trade tensions by providing effective and expeditious procedures for the multilateral prevention and settlement of trade disputes related to IP.

Addressing trade in counterfeit goods while avoiding the abuse of IP that creates barriers to legitimate international trade makes the application of IP rules and procedures to goods in transit particularly complex and sensitive. The debate on the application of border measures to goods in transit is particularly important.

In the last three years, the application of the EC's Council Regulation 1383/2003 and European Customs Code to certain shipments of generic pharmaceuticals has attracted special attention.<sup>68</sup> Between 2008 and 2009, Dutch and, on one occasion, German customs officials detained nearly 20 shipments of generic medicines<sup>69</sup> under the authority of the Regulation. When interpreting it, Dutch customs authorities applied the judicially created rule that the IP status of in-transit medicines should be judged under the fiction that the medicines had been manufactured in the Netherlands.<sup>70</sup> This interpretation was based at least in part on recital no. 8 of the Regulation, which reads "Proceedings initiated to determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights [emphasis added]." Although in some circumstances, customs officials acted ex officio to initiate temporary seizures based on suspicion of domestic patent law violation under the manufacturing fiction, they continued such seizures based on applications by pharmaceutical right holders, who requested impounding and delaying shipments of life-saving medicines bound from India, where they had been lawfully manufactured and exported, to countries in Africa and Latin America, where they would have been lawfully imported, marketed and consumed.<sup>71</sup> Most of the medicines were seized on the basis of fictional patent violations, but in at least one other instance, generic medicines were seized by over-zealous German customs officials on the premise that the generic medicine, 'amoxicillin', which as required bore the international non-proprietary name, had a 'brand' confusingly similar to GlaxoSmithKline's trademark-protected medicine Amoxil.<sup>72</sup> After these multiple seizures, customs authorities required that the suspect medicines be destroyed, returned to India or on occasion onward shipped on a delayed basis to their ultimate destination.

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<sup>75</sup> India's comprehensive WTO complaint cited violations of Paragraphs 2, 3, 4, 5 and 7 of Article V and Article X of the GATT 1994 (unreasonable and discriminatory interference of legitimate trade using routes most convenient for international transit); and Articles 2, 28, 31, 41 and 42 of the TRIPS Agreement, especially in reference to the Doha Declaration and the August 6 Decision (unreasonable interference with freedom of transit of generic medicines resulting in unnecessary burdens and unwarranted delays and frustrating export of medicines lawfully produced to countries where they could be lawfully consumed).

<sup>76</sup> WTO, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2 (20 Nov 2001), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm).

<sup>77</sup> WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (1 September 2004), [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>78</sup> Seuba, *supra* note 73, 16–17; Ruse-Khan & Jaeger, *supra* note 73; Abbott, *supra* note 70. The territoriality criticism is based on the premise that IP-related acts done outside a nation's territory do not violate the territorial rights in force within national borders and that medicines temporarily in transit do not involve any prohibited 'use' of the patent (making, using, offering for sale, selling or importing for these purposes) within a country's territorial market.

<sup>79</sup> Interestingly, Article 51 of the TRIPS Agreement was largely modelled on existing national laws. See UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, UNCTAD, ICTSD & Cambridge University Press, New York, 2005, 609.

Leading European scholars opined that it was unlawful under European Council law to apply EC Regulation 1383/2003 to truly in-transit medicines – medicines not destined for or likely to be diverted to European markets.<sup>73</sup> The application of fictional IP patent and trademark rights to medicines in transit was also roundly criticized by these same scholars<sup>74</sup> and by India<sup>75</sup> for violating core principles of the TRIPS Agreement, including Articles 2, 28, 31, 41, 42 and 52, Articles V and X of the General Agreement on Tariffs and Trade, the Doha Declaration on the TRIPS Agreement and Public Health,<sup>76</sup> and the Decision of August 30 on Paragraph 6 of the Doha Declaration.<sup>77</sup> At a more fundamental level, legal scholars criticized EC Regulation 1383/2003 and the EU's multiple seizures of generic medicines for violating core features of the international order including: the territoriality of IP rights; respect for the sovereign 'independence' of countries to adopt and implement TRIPS-compliant patent regimes as they consider appropriate; freedom of transit of goods moving through a country's transportation systems in the stream of international trade; and the human right to health and of access to essential medicines.<sup>78</sup>

As discussed above, similar concerns arise with the adopted or proposed anti-counterfeiting laws in Africa, some of which make it a criminal offence to transit through, trans-ship within or export 'counterfeit' goods. This is the case, for example, with Section 32(1) (f) of the Kenya Anti-Counterfeit Act 2008 and Section 12(1) (f) of the draft EAC Anti-Counterfeit Bill.

In cases of goods in transit the interpretation and application of Article V of GATT and Articles 41.1 and 51 of TRIPS are particularly important. Paragraph 2 of Article V of GATT 94 provides that:

There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.

Similarly, Article 41.1 of TRIPS requires that enforcement measures should "avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse". Likewise, Article 51 of the TRIPS Agreement provides that:

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right 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. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. *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* [emphasis added].

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<sup>80</sup> India has recently announced its suspension of its WTO request for consultation based on a tentative agreement with the EU. Press Release, *Government of India Ministry of Commerce and Industry, Indian EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit* (28 July 2011), <http://pib.nic.in/newsite/erelease.aspx?relid=73554>. Pursuant to the announced Understanding, the EU will no longer intercept in-transit generic medicines unless there is adequate evidence to satisfy customs authorities that there is a substantial likelihood of diversion of such medicines on to the EU market. In addition, the EU is to issue interim guideline advising member countries how to perform border enforcement. Finally, the EU has proposed a new Regulation (Proposed Border Regulation) to replace challenged Council Regulation (EC) No. 1383/2003, the so-called Border Measures Regulation (BMR 1383/2003). European Commission, *Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement Of Intellectual Property Rights*, COM (2011) 285, Brussels, 2011, [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/legislation/com285\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/com285_en.pdf). Although India does not completely endorse the phrasing of the draft proposal, it will convey its views on the proposal to the EU during the expected 12–18-month approval process. The Economic Times, *EU agrees to stop confiscation of India generic drugs* (29 July 2011), [http://articles.economicstimes.indiatimes.com/2011-07-29/news/29829346\\_1\\_customs-regulations-indian-generic-drugs-international-intellectual-property-agreement](http://articles.economicstimes.indiatimes.com/2011-07-29/news/29829346_1_customs-regulations-indian-generic-drugs-international-intellectual-property-agreement). There are reports that India does not consider the draft strong enough to satisfy its requirements. Matthias Williams, 'Update 2-India, EU health drugs seizures dispute with interim agreement', *Reuters* (28 July 2011), <http://www.reuters.com/article/2011/07/28/india-eu-drugs-idUSL3E7IS4WW20110728>.

The ultimate question is whether the application of the provisions of Article 51 read together with Article V of GATT to goods in transit, such as in the case of EC Regulation 1383/2003 and the Kenya Anti-Counterfeit Act 2008, constitutes a barrier to legitimate trade and a threat to development goals, particularly access to medicines.<sup>79</sup> Another issue is whether the application of Article 51 of TRIPS in the manner envisaged in EC Regulation 1383/2003 runs contrary to the balancing safeguards under Article 41.1, which are meant to ensure that enforcement procedures do not create barriers to legitimate trade where, by necessity, global trade requires temporary presence and trans-shipment through trade route countries. While the ultimate issue of the TRIPS compliance of seizing lawfully produced and marketed medicines in transit remains open at the WTO pending the outcome of two Dispute Settlement cases initiated against the EC by India and Brazil,<sup>80</sup> Europe is currently engaged in intensive efforts to amend EC Regulation 1383/2003<sup>81</sup> in an effort to satisfy access-to-medicines critics.

Europe's hand was pushed somewhat by a decision of the European Court of Justice (EJC) issued on 1 December 2011. The Court ruled that goods in suspensive procedures or in transit could not be detained unless it was proven that they were intended to be put on sale in the EU.<sup>82</sup> Satisfying this element requires showing that the goods had been sold to EU consumers or offered for sale or advertised, or that the documents or correspondence evidenced that diversion was envisaged. Unfortunately, under the Court's decision customs officials can still suspend the release of goods or temporarily detain them pending final substantive determination based upon lesser indications, including a lack of clarity about the intended destination of the goods, the manufacturer or the consignee, or a failure to cooperate with authorities. Nonetheless, this judgment should constitute the death knell for the manufacturing fiction at least in Europe, but this does not mean that the same error might not be used elsewhere.

This recent ECJ case is consistent with a number of earlier court decisions holding that IP rights subsisting in the country of transit do not apply to goods in transit unless they are virtually certain to be diverted to EU markets. For example, in *Montex Holdings Ltd. v. Diesel SpA*<sup>83</sup> the ECJ found that the provisions of the preceding EC Directive on Trademarks (Directive 89/104/EEC), providing for the prohibition of the importation or export of goods under a trademark sign, should be:

[I]nterpreted as meaning that the proprietor of a trade mark can prohibit the transit through a Member State in which that mark is protected of goods bearing the trade mark and placed under the external transit procedure, whose destination is another Member State where the mark is not so protected, only if he can prove that those goods are subject to the act of a third party while they are placed under the external transit procedure which necessarily entails their being put on the market in that Member State of transit.

(This case considered the implications of IP enforcement and border measures quite similar to those contained in Regulation 1383/2003.)<sup>84</sup>

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<sup>81</sup> See European Commission, Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement of Intellectual Property Rights, COM (2011) 285, Brussels, 2011 (hereinafter Proposed Border Regulation), [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/legislation/com285\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/com285_en.pdf); Internal Report of the European Parliament Committee on Internal Market and Consumer Protection on the proposal for a regulation of the European Parliament and of the Council concerning customs enforcement of intellectual property rights, A7-0046/2012.

<sup>82</sup> Case C-446/09, *Koninklijke Philips Electronic* (2010) OJ C 24/29 (relating to the old, superseded Customs Regulation No. 3295/94); and Case C-446/09, *Nokia Corporation* (2010) OJ C 37/22 (relating to BMR 1383/2003). Judgment available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=115783&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=2701>.

<sup>83</sup> Case C-281/05 available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62005J0281:EN:HTML>. In this case, Montex sold jeans in Ireland where the mark Diesel was not protected. The jeans were made by the manufacture of parts in Ireland, which were then exported to Poland under Custom seal where they were made up and returned as final products to Ireland. A consignment of the jeans was seized in transit by German customs, and the question was whether this was lawful.

<sup>84</sup> The applicable legislation at the time was Council Regulation No. 3295/94 of 22 December 1994 which laid down measures concerning the entry into the Community and the export and re-export from the Community of goods infringing certain IP rights (OJ 1994 L 341).

Likewise, in *Eli Lilly & Company & Anor vs. 8PM Chemist Ltd*<sup>85</sup> a three-judge bench of the Court of Appeal for England and Wales held that the question to be determined in cases relating to IP infringement by goods in transit is “whether or not there is an interference with the right of first marketing in the EU. The genuine goods of trademark owner which never become community goods do not interfere with that right.”<sup>86</sup> There are other ECJ decisions which also addressed the question of the application of IP rights in the transit country to goods in transit, with generally the same result, including *Class International vs. Colgate Palmolive*.<sup>87</sup>

Despite this precedent, the seizures of in-transit medicines in Europe in 2008–2009 were premised on the so-called ‘manufacturing fiction’ whereby the patent status of goods in transit was to be assessed according to the domestic-law fiction that the medicines had been manufactured domestically and were intended for the domestic market. This directly violates the TRIPS Agreement, which requires that the IP status of suspect goods be assessed based on the IP status of the goods in the destination (import) country rather than the transit country.<sup>88</sup>

### *Legislative principles*

There are at least two key principles which should guide legislative drafting with respect to goods in transit. These are:

- Anti-counterfeit procedures and measures should not become barriers to legitimate international trade. As such, these procedures should only be applied to goods which are virtually certain to be put on the market in the country in question.
- Anti-counterfeit procedures and measures should conform with the obligations of the country under WTO rules, including the GATT rules on freedom of transit.

### *Model provisions on goods in transit*

The above principles call for the introduction of special provisions on how to deal with goods in transit. These provisions should include a provision on the definition of goods in transit based on the GATT definition and a provision excluding the application of the procedures under the ‘anti-counterfeiting’ law to goods in transit.

DEFINITION: ‘Goods in transit’ means any goods, including baggage, vessels and other means of transport, whose passage across the country, with or without trans-shipment, warehousing, breaking bulk or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the borders of the country

EXCLUSION: The provisions of this Act/Law shall not apply to goods in transit.

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<sup>85</sup> [2008] EWCA Civ. 24 (5 February 2008), <http://oami.europa.eu/pdf/natcourt/Lilly.pdf>.

<sup>86</sup> See para 44 of the Judgment.

<sup>87</sup> C-405/03 [2005] ECR I-8735.

<sup>88</sup> TRIPS, *supra* note 6, Art. 52.

## RULES of EVIDENCE AND PRESUMPTIONS

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### *Context*

Anti-counterfeit laws establish a range of rules and presumptions regarding evidence in proceedings of alleged counterfeiting. A key part of these provisions relates to the presumption regarding ownership of IP. In particular, these laws provide that the complainant shall be presumed to be the owner of an IP right or an interest in such right until the contrary is proved. This reverses the usual rule of evidence which requires that a person who alleges interference with their right must first prove that they own such right or are entitled to it. There is no reason why IP rights should be any different, except in the special case of process patents, where the TRIPS Agreement reverses the burden of proof in civil cases.<sup>89</sup> Indeed, there are special reasons why such reversal of the burden of proof is detrimental to legitimate trade and can endanger a defendant's rights.

To start with, as recognized by the TRIPS Agreement, the reversal of the burden of proof even in cases of process patents can endanger the legitimate interests of defendants in protecting their manufacturing and business secrets.<sup>90</sup> At the second level, particularly in the case of trademarks, which require renewal, demonstrating that one was granted a trademark is not sufficient to prove current ownership. Proof of renewal must be provided in appropriate cases. Consequently, requiring defendants to invest money and effort in investigating the ownership of the IP rights in issue in counterfeiting cases goes against TRIPS principles of fairness and equity. Finally, requiring defendants, in a criminal law context, to prove the contrary on the presumption of ownership of rights may also lead to forcing such persons to incriminate themselves contrary to well-established human rights and constitutional principles.

### *Legislative principles*

The provisions in anti-counterfeit legislations regarding evidence and presumptions need to be guided by a key principle. With respect to the presumptions on ownership of IP rights, the overriding principles should be that a person who alleges interference with their right must first prove that they own or are entitled to such right. This principle is critical in ensuring fairness and equity and also safeguarding defendants' IP rights.

### *Model provisions on evidence and presumptions*

The following provisions on the presumptions regarding ownership of IP rights would sufficiently capture the above principle:

Where the existence of an intellectual property right in respect of suspected counterfeit goods or the title or interest in intellectual property is in issue, the complainant shall be required to prove ownership or entitlement in accordance with the relevant provisions of any intellectual property legislation for the time being in force.

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<sup>89</sup> See *id.* Article 34.

<sup>90</sup> See *id.* Article 34(3).

## LIABILITY FOR UNWARRANTED DETENTION, LOSS OF OR DAMAGE TO GOODS

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### *Context*

It has already been noted that a person who abuses procedures under 'anti-counterfeiting laws' deprives the public of legitimate essential products and endangers public health and safety. Similarly, any person, especially public officers, who through negligence, carelessness, corruption or bad faith allows the loss or damage to goods seized or detained by them under 'anti-counterfeiting' laws deprives the public of legitimate essential goods. In case of medicines, such person endangers and puts at risks the lives of many patients. It is, therefore, essential that the 'anti-counterfeiting' laws include adequate provisions to guard against this possibility.

In general, the laws or proposed laws in Africa contemplate compensation for owners or holders of goods who suffer damage or loss caused by wrongful seizure, removal or detention of goods only if the complaint was false, negligent or in bad faith.<sup>91</sup> The laws go further to provide that government officials in charge of a counterfeit goods depot can only be liable for loss or damage to goods if they are grossly negligent or are shown to have acted in bad faith. This approach means that millions of dollars worth of essential medicines or other goods can be delayed, damaged or lost and the owner of such legitimate and non-counterfeit goods would have little or no compensation or recourse whatsoever. Likewise, purchasers and consumers/patients are without remedies for the harm they suffer as a result of wrongful or unsuccessful anti-counterfeit enforcement activities. This not only goes against the TRIPS Agreement principles of equity and fairness but also other TRIPS Agreement requirements such as Article 56 which requires that "Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods."

The burden of proof and responsibility for ensuring the safe custody and storage of goods should, therefore, be strictly borne by the government or its officials and by the right holder who initiates wrongful or unsuccessful IP enforcement applications and procedures.

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<sup>91</sup> See, for example, Section 16 of the Kenyan Act and Section 5 of the Uganda Bill.

### *Legislative principles*

A number of principles should guide legislative drafting in this area. Two particularly important principles are that:

- any owner or holder of goods who suffers loss due to the wrongful seizure, removal or detention of their legitimate goods should be compensated; and
- consumers should not be deprived access to legitimate essential goods, such as medicines, for any reason, and should be compensated for harm proximately caused by wrongful or ultimately unsuccessful IP enforcement activities.

### *Model provisions on liability for loss of and damage to goods*

To safeguard the legitimate interests of defendants and the need to ensure that good-quality products reach the consumers and are not unnecessarily lost or damaged while in the hands of government officials or other persons acting for them, the following language can be used:

Any person, including both owners and holders of the goods and any purchaser or intended consumer, who suffers proximate damage or loss caused by wrongful seizure, detention, removal and/or destruction of goods alleged to be counterfeit, pursuant to an application or complaint under this Act, shall be entitled to a claim for monetary compensation for the damage or loss suffered by him against the perpetrator of the wrongful or ultimately unsuccessful seizure, detention, removal and/or destruction.

## The need to develop a positive public health agenda

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The authoritative General Comment 14 (2000) of the UN Economic and Social Council (ECOSOC) interprets the right to health to include the right to access to essential medicines and applies the principles of accessibility, availability, appropriateness and assured quality to this right.<sup>92</sup> In 2009, the UN Human Rights Council adopted a Resolution, stressing the responsibility of States to “ensure access to all, without discrimination, of medicines, in particular essential medicines, that are affordable, safe, effective and of good quality”. The Resolution also recognizes the concerns about the effects of IP protection on prices of medicines and encourages States to avoid creating barriers to the legitimate trade of medicines while applying measures and procedures for IP enforcement, as well as to provide safeguards against the abuse of such measures and procedures.<sup>93</sup> There is no doubt that fulfilment of the right to access to medicines is a global responsibility that calls for focus on access, innovation and technology transfer and strong emphasis on quality, safety and efficacy.

While IP can be an important but imperfect incentive to stimulate innovation, the assumption that national enforcement apparatuses are competent and apt to decide the quality, safety and efficacy of medicines is questionable. Anti-counterfeit measures and IP enforcement do not adequately address the problem of substandard and falsified medicines. They tend to conflate the public health concern over medicines’ quality with private right holders’ desire for monopoly IP protections. There are a number of indications that anti-counterfeit measures are driven by proprietary interests rather than true public health perspectives. Such measures tend to divert scarce public resources toward the enforcement of these private interests, and, more importantly, there is no evidence that IP-related anti-counterfeiting measures actually effectively prevent the spread of substandard medicines. As pointed out by Oxfam, developed countries do not rely on anti-counterfeit measures to assure the safety and quality of medicines from registration to end-use but have well-developed, well-funded and empowered drug regulatory authorities (DRAs) that authorize the use of medicines based on their demonstrated safety, quality and efficacy, and monitor the compliance with these requirements thereafter.<sup>94</sup> WHO, which in the past did not rely on IP considerations in its efforts to combat substandard and falsified medicines, now again seems to reiterate the importance of regional and national DRAs in this process.<sup>95</sup> In May 2012, the World Health Assembly adopted Resolution EB130/2012/REC/1, which envisions establishing a new mechanism for international collaboration among WHO Member States regarding ‘substandard/spurious/falsely labelled/falsified/counterfeit medical products’ from a public health perspective, excluding trade and IP considerations. Instead, the Resolution focuses on the need to strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries and to ensure supply chain integrity.<sup>96</sup>

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<sup>92</sup> UN ECOSOC, *General Comment N 14/2000*, <http://www.unhcr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En>; see also WHO, *Access to Essential Medicines as Part of the Right to Health*, [http://www.who.int/medicines/areas/human\\_rights/en/index.html](http://www.who.int/medicines/areas/human_rights/en/index.html).

<sup>93</sup> UN Human Rights Council, *Access to Medicine in the Context of the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Resolution adopted by the Human Rights Council, 12/24, 2009, <http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G09/167/45/PDF/G0916745.pdf?OpenElement>.

<sup>94</sup> Oxfam, *Eye on the Ball: Medicine regulation – not IP Enforcement – Can Best Deliver Quality Medicines*, Briefing Paper, Oxfam, Oxford, 2011, 143, <http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf>.

<sup>95</sup> WHO, *Guidelines for Measures for the Control of Counterfeit Drugs*, Geneva, 1999, [http://whqlibdoc.who.int/hq/1999/WHO\\_EDM\\_QSM\\_99.1.pdf](http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf).

<sup>96</sup> WHO, *Substandard/Spurious/Falsely labelled/Falsified/Counterfeit Medical Products*, EB130/2012/REC/1, Geneva, 2012, [http://apps.who.int/gb/ebwha/pdf\\_files/EB130/B130\\_R13-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_R13-en.pdf). See also: WHO, 65th World Health Assembly Closes with New Global Health Measures, Geneva, 2012, [www.who.int/mediacentre/news/releases/2012/wha65\\_closes\\_20120526/en/index.html](http://www.who.int/mediacentre/news/releases/2012/wha65_closes_20120526/en/index.html).



Determining medicines' quality requires expert knowledge and rigorous testing throughout the supply chain. The issues of quality, safety and efficacy of medicines should remain within the competencies of national DRAs and must be addressed by them through rigorous registration standards, GMP inspections, and enforcement of GDP as well. Shifting resources and competencies in IP and medicines' quality towards the border and towards IP enforcement only could have a negative impact on people's lives and public healthcare systems. This is especially true in the context of high levels of HIV prevalence, access-to-treatment challenges and dependence on generics – which is certainly the case in many countries of sub-Saharan Africa. From a public health policy perspective it is much more reasonable for countries to allocate resources to promote access to affordable, good-quality medicines and towards strengthening pharmacovigilance, rather than towards fighting major pharmaceutical companies' IP battles through anti-counterfeiting measures.

DRAs play a critical role in a more constructive and proactive approach for promoting safe and efficient medicines. Oxfam points out that in low- and middle-income countries these agencies either do not exist or are typically chronically underfunded, often with inadequate equipment and a shortage of human resources.<sup>97</sup> DRAs should be established in countries where they do not exist, and their capacity should be strengthened in all low- and middle-income countries – including through regional and international support and cooperation. DRAs should not focus only on pharmacovigilance but on promoting access to medicines more broadly, including by ensuring the supply of more affordable generic equivalents of assured quality. DRAs could also support the efficient procurement and rational use of medicines, which are other important components of the constructive approach. Good practices in this field already exist – for example in Brazil, which created and developed its National Health Surveillance Agency, ANVISA, in the late 1990s.<sup>98</sup> Investing in the quality of work of drug registration and control authorities is much more likely to curtail the spread of substandard medicines than is a narrow, border-based focus on trademark counterfeits. It also enables broader quality control, including over products where IP rights are not disputed.

There are a number of ongoing initiatives in the African regional economic communities such as the Southern African Development Community (SADC) and the East African Community (EAC) to improve access to affordable medicines and technology in Africa. Within the framework of the New Partnership for Africa's Development (NEPAD), African leaders adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 to strengthen Africa's ability to locally manufacture and supply essential drugs and commodities, including essential medicines to treat the three major pandemics: AIDS, tuberculosis and malaria. Having robust and sufficiently funded DRAs in place is also extremely important for developing and strengthening the local and regional pharmaceutical capacity; therefore, initiatives at the EAC and SADC levels to develop the capacity of DRAs are laudable and should be encouraged.<sup>99</sup>

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<sup>97</sup> For instance, Lesotho has only 21 trained pharmacists, with just three working in the public sector. Belize has only one inspector of medicines and no formal registration system. *Id.*, 17.

<sup>98</sup> *Id.*, 18; see also [www.anvisa.gov.br/eng/index.htm](http://www.anvisa.gov.br/eng/index.htm).

<sup>99</sup> Thulani Matsebula, Jane Goudge, Lucy Gilson, 'Regulating the Pharmaceutical Sector: Coping with Low Capacity While Maintaining Regulatory Independence', *Health Economics and Financing Programme (HEFP) working paper 01/05*, LSHTM, London, 2005, [www.dfid.gov.uk/R4D/PDF/Outputs/HealthEcFin\\_KP/WP01\\_05.pdf](http://www.dfid.gov.uk/R4D/PDF/Outputs/HealthEcFin_KP/WP01_05.pdf).

Multi-stakeholder initiatives can also play an important role in ensuring the safety, quality and efficacy of medicines. One such example is the WHO Prequalification Programme, which aims to ensure that diagnostics, vaccines and medicines for high-burden diseases are safe, efficacious and of good quality. The WHO list of prequalified medicines is used by international procurement agencies such as the United Nations Children’s Fund (UNICEF), GFATM and UNITAID and has gradually expanded from covering only HIV diagnostics and medicines to including more than 240 medicines for high-burden diseases. Other multi-stakeholder initiatives such as the Medicines Transparency Alliance (MeTA) pilot project have turned out to be promising. There are concrete efforts to harmonize registration standards in the EAC and in the African Union more broadly<sup>100</sup> and to coordinate pharmacovigilance at regional and national levels. On a bilateral level, the Promoting the Quality of Medicines (PQM) Program, implemented by the US Pharmacopeia and supported by the US development agency, USAID, assists countries in Africa, Asia and Latin America in ensuring the quality, safety and efficacy of medicines.<sup>101</sup>

These conclusions come in the context of the need to develop an overall constructive approach that effectively fosters the quality, safety and efficacy of medicines. It is evident that this positive agenda should focus on public health rather than on enforcing private proprietary interests. Low- and middle-income countries should rather prioritize the development and capacity-building of DRAs then pursue TRIPS-plus IP enforcement measures. Public and private funds should be invested in regulation and quality control over producers, importers and sellers of pharmaceuticals in these countries. Prices significantly affect access to medicines – even more so in low-income countries, where most medicines are paid for out of pocket. Inability to afford the quality product is one of the key reasons for the spread of substandard and falsified medicines. Therefore, promoting generic competition in national healthcare policies, including through the implementation of the TRIPS public health flexibilities, is extremely important for both increasing access to medicines and curtailing the spread of ‘counterfeits’.

High-income countries should support the development of regional drug regulatory cooperation and capacity and the strengthening of DRAs in low-income countries through donor support or bilateral or multilateral projects. It is important to point out that these projects must focus on quality, safety and efficacy, rather than ‘anti-counterfeiting’ initiatives or any other TRIPS-plus IP enforcement measures. Implementation of the constructive agenda should be a comprehensive process that includes all social sectors, including civil society. This approach would ensure broader awareness of the problem and engage all stakeholders in adequately addressing it, to secure affordable and accessible, safe and efficient medicines of good quality.

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<sup>100</sup> See Launch of the EAC Medicines Registration Harmonization (MRH) Project scheduled on 30 March 2012, Arusha, Tanzania, <http://www.amrh.org/newsroom/news.php>.

<sup>101</sup> See Oxfam, *supra* note 94, 19–20; see also <http://apps.who.int/prequal/>; [www.medicinestransparency.org/](http://www.medicinestransparency.org/); [www.usaid.gov/press/releases/2009/pr091026\\_1.html](http://www.usaid.gov/press/releases/2009/pr091026_1.html). Particularly in tropical climates, the problem of good distribution and storage standards of medicines and their control, at all levels of the distribution chain, is critical and very costly. There is, therefore, a need also to develop costed national distribution and control plans that address this issue, to improve the quality, safety and

ISSUE & REASONING	RECOMMENDATION	PROPOSED DEFINITION
<p><b>Definition</b></p> <p>Limiting the scope of the term 'counterfeit' may prevent actions against legitimate generic versions of medicines, which could amount to violating the human rights to life and health.</p>	<p>The definition of 'counterfeiting' should be limited to willful criminal trademark counterfeiting on a commercial scale (refer to Art. 51, Footnote 14(a) TRIPS Agreement).</p> <p>If the law also covers copyright infringement, 'piracy' should be defined separately (refer to Art.51, Footnote 14(b) TRIPS Agreement).</p> <p>Civil trademark infringement/confusion and patent infringement should not be included in the scope of any definition of 'counterfeiting'.</p>	<p>'Counterfeiting' means dealing, willfully and on a commercial scale, without the authority of the owner of a trademark in (insert name of country) with any goods bearing a trademark which is identical to a trademark validly registered in respect of such goods in (insert name of country) or which cannot be distinguished in its essential aspects from such a validly registered trademark.</p>
<p><b>Criminal Liability</b></p> <p>Criminalization of patent infringement may have significant negative consequences for technological learning and transfer, which is needed to develop technological capacity, for instance of regional pharmaceutical industries, and to move up the development ladder.</p>	<p>For criminal liability to attach to an act of trademark counterfeiting such act must be proven to be willful and on a commercial scale (refer to Para 7.577 in the Report of the Panel in WT/DS362/R 2009).</p> <p>The penalties imposed for 'counterfeiting' must be proportional to the offence committed.</p> <p>Offences and penalties should be put in place to ensure that procedures under 'anti-counterfeiting' laws are not abused and that they are applied fairly, equitably and for the intended purpose.</p>	<p><b>Offences relating to counterfeiting:</b> It shall be an offence for any person to willfully and on a commercial scale:</p> <ul style="list-style-type: none"> <li>- manufacture, produce or make any counterfeit goods;</li> <li>- sell, hire out, barter or exchange or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;</li> <li>- distribute counterfeit goods; <i>or</i></li> <li>- import any counterfeit goods.</li> </ul> <p><b>Offences relating to abuse of procedures:</b> It shall be an offence for any person to initiate procedures to detain or seize medicines alleged to be counterfeit or for a government official to enter any place, premises or vehicle to seize, detain or remove any goods suspected to be counterfeit, based on information he knows, or is reasonably expected to know, is false, or on expectation of unlawful personal or commercial gain, or so as to delay, interfere with or deter legitimate trade of non-counterfeit products. It shall also be an offence to continue an enforcement application or to continue the detention or to destroy seized goods after receiving credible information that such action is unwarranted.</p>
<p><b>Seizure &amp; Storage</b></p> <p>Broad and extensive powers to government agencies and officials to interfere with goods which might be essential to health, nutrition etc. without judicial supervision should be prevented.</p>	<p>In a free and democratic society, granting and exercising powers by governmental agencies with respect to private property must conform with human rights standards, proper administration of justice and constitutional safeguards.</p> <p>Powers to seize or otherwise interfere with private property must be conditioned upon judicial oversight. Hence powers to enter premises and powers to seize, detain, remove and eventually destroy goods should be exercised on the basis of a warrant or provisional measures or final orders issued by a court of law, although that law might provide for temporary detention (10 days) and notification both to the right holder and the holder of the goods with the right to be heard.</p> <p>The powers granted to government agencies and officials must not provide incentives or opportunities for corruption, but should be proportional and equipped with strong safeguards against their abuse.</p> <p>Goods seized under anti-counterfeit laws need to be stored in a manner that ensures that they are not contaminated or their quality and safety otherwise compromised.</p>	<p>Provisions that allow seizures of suspected counterfeit goods and stop their manufacture and distribution by entry or otherwise should be temporary – no longer than 10 days – and thereafter conditioned upon notice and opportunity to be heard by the holder of the goods and the issue of a warrant and/or other provisional measures or final orders by a court of competent authority.</p>
<p><b>Goods in Transit</b></p> <p>Enforcement of IP protection in transit countries can impose further unnecessary restrictions on goods in transit, possibly leading to the destruction of legitimate generic medicines.</p>	<p>Anti-counterfeit procedures and measures should not become barriers to legitimate international trade. As such, these procedures should only be applied to goods which are virtually certain to be put on the market in the country in question.</p> <p>Anti-counterfeit procedures and measures should conform with the obligations of the country under WTO rules, including the GATT rules on freedom of transit.</p>	<p>Definition of goods in transit: any goods, including baggage, vessels and other means of transport, whose passage across the country, with or without trans-shipment, warehousing, breaking bulk or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the borders of the country.</p> <p>Exclusion: The provisions of this Act/Law shall not apply to goods in transit.</p>
<p><b>Evidence &amp; Presumptions</b></p> <p>Fairness and equality in proceedings of alleged counterfeiting should be ensured and the IP rights of defendants safeguarded.</p>	<p>The provisions in anti-counterfeit legislations regarding evidence and presumptions need to be guided by a key principle: a person who alleges interference with their right must first prove that they own or are entitled to such right.</p>	<p>Where the existence of an IP right in respect of suspected counterfeit goods or the title or interest in IP is in issue, the complainant shall be required to prove ownership or entitlement in accordance with the relevant provisions of any IP legislation for the time being in force.</p>
<p><b>Liability</b></p> <p>The loss or damage of goods through negligence, carelessness, corruption or bad faith, which deprives the public of legitimate essential goods and endangers the lives of many patients, should be prevented.</p>	<p>Any owner or holder of goods who suffers loss due to the wrongful seizure, removal or detention of their legitimate goods should be compensated.</p> <p>Consumers should not be deprived access to legitimate essential goods, such as medicines, for any reason, and should be compensated for harm proximately caused by wrongful or ultimately unsuccessful IP enforcement activities.</p>	<p>Any person, including both owners and holders of the goods and any purchaser or intended consumer, who suffers proximate damage or loss caused by wrongful seizure, detention, removal and/or destruction of goods alleged to be counterfeit, pursuant to an application or complaint under this Act, shall be entitled to a claim for monetary compensation for the damage or loss suffered by him against the perpetrator of the wrongful or ultimately unsuccessful seizure, detention, removal and/or destruction.</p>

Substandard and falsified medicines are a real and pressing problem that must be addressed. There is a critical need to find legislative and policy approaches that would reduce the spread of such illicit, unregistered and unsafe products without hindering access to good-quality, safe and efficacious medicines – particularly legitimate and affordable generics of assured quality. The most critical threshold issue for public health in any anti-counterfeit legislation is to limit the scope of criminalized activities and conduct what is prescribed by the WTO TRIPS Agreement.

This Discussion Paper provides recommendations on the principles that should guide legislation in this area as well as recommended model provisions. Specific legislative language and model provisions are offered in eight key areas. The rationale behind these suggestions is to prevent the adoption of overly broad anti-counterfeit provisions that are likely to have an adverse impact on access to medicines.

The Paper also discusses two very important aspects of the problematic medicines issue, namely the inappropriateness of anti-counterfeit measures as a policy measure for curtailing the spread of substandard and falsified medicines and the need to develop an alternative, positive, public health-driven agenda for improving access to safe and efficacious medicines of assured quality.