The Potential Impact of the Proposed East African Community (EAC) Anti-Counterfeiting Policy and Bill on Access to Essential Medicines

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Abstract

This discussion paper examines the potential impact of the proposed East African Community (EAC) Policy on Anti-Counterfeiting, Anti-Piracy and other Intellectual Property Rights Violations ("the EAC Anti-Counterfeiting Policy") and the EAC Anti-Counterfeit Bill, 2010 ("the EAC Anti-Counterfeiting Bill") on access to medicines in the East Africa region, including the potential impact on the region's efforts to develop regional pharmaceutical manufacturing and innovative capacities.

The paper argues that an intellectual property (IP) enforcement-based approach to public health and safety is unlikely to address any real health safety and product quality concerns. The grant of IP titles, such as patents and trademarks, and the acquisition of copyright over a particular work do not signify the quality and safety of any product. The safety of products, including products over which IP rights are conferred, can only be confirmed through quality testing and market surveillance. There is also no evidence that the policy, in its current form, would result in any of the expected economic, business or government revenue outcomes. Instead, such an approach has the potential to negatively affect both regional and national efforts in EAC Partner States to protect the right health and life as well as improve public health, regulatory standards and quality control and promote local production, industrial development and trade in generic medicines.

While the paper's focus is on the implications for access to medicines, it also makes the argument that the proposed Anti-Counterfeiting Policy and Bill are likely to have negative implications for other critical development sectors in the EAC including access to knowledge, agriculture, education and training, particularly higher education and professional training, as well as overall science and technology development.

In light of the above conclusion and the reasons thereof, the paper proposes that the EAC Partner States reconsider whether there is a need for such a policy and law, and if so, what its scope should be. This process of reconsideration should be done on the basis of better evidence and analysis and in the context of a better understanding of the relationship between IP enforcement and development.

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All opinions and any errors or omissions in the paper are, however, the sole responsibility of the author.

Abbreviations and Acronyms

ACE	Advisory Committee on Enforcement
ACTA	Anti-Counterfeiting Trade Agreement
APPG	All Party Parliamentary Group on AIDS
ARV	Antiretroviral
BASCAP	Business Action to Stop Counterfeiting and Piracy
BSA	Business Software Alliance
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
EAC	East African Community
EC	European Community
EDLs	Essential Drugs Lists
GATT	General Agreement on Tariffs and Trade
ICC	International Chamber of Commerce
ICF	Investment Facility for Africa
INTA	International Trademark Association
IP	Intellectual Property
LDCs	Least-developed Countries
NIHCM	National Institute of Health Care Management Research and Educational Foundation
OECD	Organization for Economic Development and Cooperation
PCT	Patent Cooperation Treaty
RIAA	Recording Industry Association of America
R&D	Research and Development
STG	Standard Treatment Guidelines
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
WCO	World Customs Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive Summary

Significant progress has been made in improving access to essential medicines for the populations of the East African Community (EAC) Partner States.[1] This progress has been the result of increased financing for medicines and investments in health systems as well an enlightened approach to intellectual property (IP) laws ensuring wide availability of generic medicines in the region.[2] Nevertheless, the state of health in the EAC Partner states remains precarious and much more work needs to be done to ensure access to essential medicines for all.

The burden for providing treatment in cases such as that of HIV/AIDS continues to grow. This is due to the positive development that the people who are currently on treatment are living longer, which is good news, but also due to continued high levels of new infections. It is reported that for every person put on treatment, there are two new infections.[3] According to the United Kingdom (UK) All-Party Parliamentary Group on AIDS (APPG), by 2030, an estimated 50 million people will need HIV/AIDS treatment compared to only 9 million who need the treatment today.[4]

Future projections aside, the situation of access to essential medicines in Africa, particularly HIV/AIDS treatments, calls for urgent action. This is because in 2008, the number of people living with HIV stood at 33.4 million with approximately 67% (22.4 million) living in Sub-Saharan Africa.[5] The implications, in terms of access to HIV/AIDS treatments are that notwithstanding the major efforts that have gone into improving access to medicines by governments, civil society, international organisations and agencies and the private sector we are still very far from achieving universal access. Indeed, except for Rwanda, the coverage of antiretroviral (ARV) therapy among people with advanced HIV infection remains below 40% in the EAC Partner States.[6] Beyond HIV/AIDS, the burden of disease in Africa, including in the EAC Partner States remains significant. For example, while Africa is home to only 11% of the world population it carries 25% of the world's disease burden.[7] Lack of access to medicines therefore continues to contribute to millions of deaths and untold suffering in the EAC Partner States.

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[1] Detailed information on the regional economic community, including health statistics can be found on its website at http://www.eac.int/.

[2] A study by UNCTAD for the EAC Secretariat shows that all the EAC Partner States have made efforts to use the flexibilities provided in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in order to improve access to essential medicines, including HIV/AIDS medicines, by facilitating the development of local manufacturing capacity and importation of high quality generic medicines from competitive markets such as India. See UNCTAD (2008) "Comparative Study of Provisions of EAC Partner States' Patent Laws Reflecting TRIPS Flexibilities Relevant for Access to Medicines", UNCTAD, Geneva.

[3] See Message of the Executive Director of UNAIDS, Michel Sidibe, on the occasion of World AIDS Day 2009 available at http://data.unaids.org/pub/SpeechEXD/2009/20091201_exd_wad_message_en.pdf.

[4] All Party Parliamentary Group on AIDS "The Treatment Timebomb" All Party Parliamentary Group on AIDS, London available at http://www.aidsportal.org/repos/APPGTimebomb091.pdf.

[5] UNAIDS and WHO (2009) *AIDS Epidemic Update 2009*, UNAIDS and WHO, Geneva.

[6] See WHO (2009) *World Health Statistics 2009,* WHO, Geneva, p.25. The coverage is: 23% in Burundi; 38% in Kenya; 71% in Rwanda; 31% in Tanzania; and 33% in Uganda.

[7] Berger, M., Murugi, J., Buch, E., IJsselmuiden, C., Kennedy, E., Moran, M., Guzman, J., Devlin, M., and B. Kubata (2009) *Strengthening Pharmaceutical Innovation in Africa,* COHRED and NEPAD, p. 13.

It is in the context of these statistics as well as other access to medicines indicators that the recent national and regional initiatives to "fight counterfeiting and piracy" have raised concerns regarding their impact on the availability and access to generic medicines in the region. In particular, there are growing concerns that the recently published "East African Community Policy on Anti-Counterfeiting, Anti-Piracy and Other Intellectual Property Rights Violations" (hereinafter 'EAC Anti-Counterfeiting Policy') and the East African Community Anti-Counterfeit Bill, 2010 (hereinafter "the EAC Anti-Counterfeit Bill) may significantly set back the region's efforts to improve healthcare in general and access to medicines, in particular.[8]

The EAC Anti-Counterfeiting Policy comes in the wake of the adoption of the Kenya Anti-Counterfeiting Act 2008[9], the 2008 Merchandise Marks Regulations in Tanzania[10] and the proposal for a Counterfeit Goods law in Uganda. The Kenyan law as well as the proposed law in Uganda have already generated significant public debate especially with respect to how these laws might affect access to generic medicines.[11] In the Kenyan case, the law has been challenged in the constitutional court on the grounds that it violates the right to life of persons living with HIV by threatening their access to essential medicines.[12] Similarly, the EAC Anti-Counterfeiting Policy, which takes a similar approach to the Kenyan law and the Tanzania Regulations, is raising questions regarding the impact on access to medicines, including the possible impact on efforts to enhance the local manufacture of medicines, vaccines and diagnostics, as well as regional trade in generic medicines more generally.[13]

At the broad level, the trend in the EAC with respect to IP enforcement through anti-counterfeiting laws runs counter to the growing recognition that questions around quality and standards are not only complex but need to be resolved on the basis of better evidence and with recognition of the needs and interests of the broad range of stakeholders.[14] These

[8] The analysis in this paper is based on a review of the drafts of the policy and Bill dated 14th December 2009.
[9] The law is available at http://www.kenyalaw.org/Downloads/Bills/2008/The_Anti-Counterfeit_Bill_2008.pdf.
[10] These regulations are purportedly made under Section 18A of the Merchandise Marks Act, Chapter 85 Laws of Tanzania.
[11] On the controversy surrounding the law in Kenya see e.g. Wadhams, Nicolas, "Kenya Pressured to Implement Anti-Counterfeit Law Despite Access Fears", Intellectual Property Watch, Geneva, 2 July 2009 available at http://www.ip-watch.org/weblog/2009/07/02/kenya-pressured-to-implement-anti-counterfeit-law-despite-access-fears/. With respect to the Uganda Bill see e.g. Wambi, Michael "Uganda Counterfeits Bill Threatens Access to Medicines", IPS. Available at http://ipsnews.net/news.asp?idnews=49163.
[12] Petition No. 409 of 2009. For reporting on the case see e.g., Wadhams, Nicolas "Kenya AIDS Patients Seek to Overturn Anti-Counterfeiting Law as Unconstitutional", Intellectual Property Watch, Geneva, 7 July 2009 available at http://www.ip-watch.org/weblog/2009/07/07/kenyan-aids-patients-seek-to-overturn-anti-counterfeiting-law-as-unconstitutional/.
[13] For example, the Report of the EAC Regional Meeting on EAC Policy and Protocol on Public-Health Related TRIPS Flexibilities and Pharmaceutical Manufacturing Plan held in Arusha from 3rd to 5th February 2010 notes "the material contradictions in the draft Anti-Counterfeit Bill and the draft Protocol on Public Health Related WTO-TRIPS Flexibilities and Access to Medicine". See EAC document EAC/TF/06/2010.
[14] For example, Recommendation 45 of the WIPO Development Agenda (available on the WIPO website at http://www.wipo.int/ip-development/en/agenda/recommendations.html) calls for IP enforcement to be approached "in the context of broader societal interests and especially development-oriented concerns, with a view that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

stakeholders and interests go much beyond the trade and investment interests that seem to drive most of the EAC efforts. In fact, the claims that issues such as sub-standard or fake medicines can be addressed through IP enforcement has led to a global debate that has drawn in governments, United Nations (UN) agencies and donors providing or funding the procurement of medicines for the poorest in East Africa and other parts of Africa as well as in other developing countries.

The evidence that the EAC Anti-Counterfeiting Policy and Bill ignore critical concerns, international trends and basic principles of IP enforcement abound. Consider, for example, that:

- The World Health Organization (WHO) makes it clear that "Both branded and generic products are subject to counterfeiting."[15] This means that IP rights are not necessarily the determining factor as to whether there is a "counterfeit" medicine or the main entry point for eliminating sub-standard or illicit medicines.
- In 2007, the 184 Members of World Intellectual Property Organization (WIPO), including all the EAC Partner States, adopted the WIPO Development Agenda and agreed that IP enforcement should be approached *"in the context of broader societal interests and especially development-oriented concerns..."* This approach, they considered, is the only way to ensure that the protection and enforcement of IP contributes to the promotion of technological innovation and to the transfer and dissemination of technology as contemplated in Article 7 of the TRIPS Agreement.
- The Policy fails to recognise or acknowledge that the international IP framework embodied in the WTO TRIPS Agreement is aimed not only at reducing distortions and impediments to international trade that might result from the failure to promote effective and adequate protection of IP rights but, crucially, that it is also intended to *ensure that measures and procedures to enforce IP rights do not themselves become barriers to legitimate trade.*[16] The Policy and Bill also do not demonstrate how the proposed measures and legal provisions comply with the mandatory general obligation of all WTO Members, including the EAC Partner States, under Article 41 of the TRIPS Agreement to ensure that IP enforcement procedures "*shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."*
- In letters to the Geneva Missions of EAC Partner States in September 2009, the UN Special Rapporteur on the Right to Health, Mr. Anand Grover, reports of complaints from civil society groups in the region and local generic manufacturers regarding the potential impact of EAC Anti-Counterfeiting Policy on access to medicines. In these letters the Special Rapporteur refers to concerns relating to the enjoyment of the right to health in the EAC region. There is no evidence that the EAC Partner States and/or the EAC Secretariat have convincingly responded to these concerns.
- The WIPO Director General recognising the potential to use IP rights in an uncompetitive manner notes, in his Report to the 2009 WIPO General Assembly, on the question of counterfeiting that "by counterfeiting, I mean the deliberate, large-scale imitation of brands, identity and trade dress. I certainly do not mean generic

[15] See the WHO website at http://www.who.int/medicines/services/counterfeit/en/.
[16] See the first recital in the Preamble of the TRIPS Agreement.

pharmaceutical products, which have their legitimate place within the competitive and regulated market for pharmaceuticals."[17]

- The European Community's (EC) Council Regulation 1383/2003[18] and national laws which apply IP enforcement procedures to goods in transit, including medicines, is the subject of a WTO dispute between India/Brazil and the EC and its Member States. These procedures have resulted in dangerous delays in the procurement of essential medicines to developing countries including shipments to Brazil, Colombia, Ecuador, Mexico, Nigeria and Peru. Many developing countries led by India and Brazil have asserted that the said EC Regulation does not only go against international efforts to improve access to medicines (such as the WTO Doha Declaration on the TRIPS Agreement and Public, the WHO Global Strategy on Public Health, Innovation and IP and the principles of WIPO Development Agenda) but also that it is contrary to the freedom of transit under Article V of the WTO's General Agreement on Tariffs and Trade (GATT 1994). The latter Article provides *inter alia* 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".[19] Consequently, contrary to the claim in the EAC Anti-Counterfeiting Policy (section 3.8.8.4) that the policy would be

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[17] The Report is available on the WIPO website at http://www.wipo.int/meetings/en/2009/a_47/a47_dg_speech.html.

[18] 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. The EAC Bill proposes similar powers and procedures for customs authorities.

[19] With respect to seizure of generic medicines by the Dutch Customs as counterfeits on the basis of alleged to infringement of IP, medicines that were in fact found to be legitimate and of high quality India has argued at the Council for TRIPS at the WTO that (See paras 140 and 141 of WTO document IP/C/M/59 – Minutes of the Council for TRIPS) that:

> "The action of the Dutch customs authorities to seize generic drugs, traded between developing countries in full conformity with international disciplines, ran counter to the spirit of the TRIPS Agreement and the resolution 2002/31 of the Commission on Human Rights on the right to enjoy the highest standard to physical and mental health. Measures of this nature had an adverse systemic impact on the legitimate trade of generic medicines, South-South commerce, national public health policies and the principle of universal access to medicines... In addition to going against the spirit of the rules-based trading system and impeding free trade, such acts represented a distorted use of the TRIPS Agreement and the international IP system, and reduced the flexibilities enshrined in TRIPS. Article 41.1 of the Agreement provided that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" and Article 41.2 provided that the procedures should be "fair and equitable".

On its part the Government of Brazil has been reported as observing as follows (See paras 149 and 150 of WTO document IP/C/M/59 – Minutes of the Council for TRIPS:

> "[E]xcessive and inappropriate interpretation of IP rights, granting extraterritorial effects, ran counter to the objectives and purposes of the TRIPS Agreement and effectively gutted the provisions granting TRIPS flexibilities to developing countries. Article 7 stated that the "enforcement of intellectual property rights" must be done "in a manner conducive to social and economic welfare". Article 8 upheld Members' rights to "protect public health and nutrition"...TRIPS flexibilities were so vital that the WTO Ministerial Conference had decided to strengthen them by adopting the Doha Declaration on the TRIPS Agreement and Public Health which had also paved the way to the Paragraph 6 System, a much needed and long awaited response to the specific situation of countries with insufficient or no manufacturing capacity in the pharmaceutical sector."

important for better international trade relations; such a policy is likely to lead to a deterioration of trade and diplomatic relations with key partners for the EAC.[20]

- A broad range of health groups and important donors, such as UNITAID, have condemned and/or expressed concern regarding the seizure of legitimate generic medicines destined for developing countries under the EC Regulation and/or implementing national legislations, such as the law in the Netherlands. For example, when UNITAID funded medicines were seized in Europe, the organisation had the following to say "UNITAID is worried more generally about the trend that seems to have taken hold in recent months where generic medicines are stopped or confiscated while transiting through the Netherlands."[21]
- The data and figures used with respect of the impact or the magnitude of trademark counterfeiting and copyright piracy and other IP infringements suffers from serious methodological problems and have come under criticism leading, for example, the WIPO Advisory Committee on Enforcement (ACE) to ask for a literature review of methodologies and gaps in the existing studies regarding counterfeiting as well as "analysis of various efforts, alternate models and other possible options... to address the counterfeiting and piracy challenges".[22] As IP and trade economist Carsten Fink has observed, a close inspection of the methodology used to arrive at the Organization of Economic Development and Cooperation (OECD) figures that are being used to justify anti-counterfeiting efforts such as those in the EAC show that "it is more an educated guess than a true estimate." On industry estimates he observes that "such estimates often rely on questionable assumptions about market demand."[23]
- Respected legal and economics scholars as well as judges such as Correa[24], Fink[25] and Supreme Court of Appeal Justice Harms of South Africa[26] have cautioned against a

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[20] Indeed, the Indian government and industry players have expressed concerns with the "anti-counterfeiting" initiatives in the EAC. See e.g., the report by Unnikrishan, C.H, titled "Indian Drug Makers Worried about East Africa's Legal Proposals" available at http://www.livemint.com/2010/02/15221607/Indian-drug-makers-worried-by.html.

[21] The full statement is available at http://www.unitaid.eu/index.php/en/NEWS/UNITAID-statement-on-Dutch-confiscation-of-medicines-shipment.html.

[22] See para 12 of the Conclusions of the Chair of the Fifth Session of the WIPO Advisory Committee on Enforcement, document WIPO/ACE/5/11 available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_5/wipo_ace_5_11-main1.pdf. For detailed discussion of the problems with the data and quantification see e.g., Fink, Carsten and Carlos Correa in "The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries", *Issue Paper 22,* ICTSD, Geneva, 2008 available at http://www.iprsonline.org/New%202009/fink-correa_feb2009.pdf; and Musungu, Sisule "The Contribution of, and Costs to, Right Holders in Enforcement, Taking into Account Recommendation 45 of the WIPO Development Agenda" available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_5/wipo_ace_5_10.pdf.

[23] See para 54 the paper presented by Fink at the Fifth Session of the WIPO Advisory Committee on Enforcement (ACE) in December 2009 titled "Enforcing Intellectual Property Rights: An Economic Perspective" available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_5/wipo_ace_5_6.pdf.

[24] Correa, Carlos in "The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries", *supra* note 21.

[25] Fink, Carsten in "The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries", *supra* note 21.

rush to criminalising IP infringement without understanding the socio-economic, cultural and industrial development consequences.

Taking into account existing evidence and literature and the various global developments referred to above, an overall analysis of the EAC Anti-Counterfeiting Policy and Bill shows, among other things, that:

1. The primary driving force of the proposed 'policy' is to improve the "business and investment" climate in the region for certain industrial players. This is probably to be expected as the work was funded by the Investment Climate Facility for Africa (ICF).[27] Consequently, while there are references to consumers, safety, health and related socio-economic concerns in the Policy, these appear not to be the fundamental considerations driving the elaboration of the Policy. Even considered on the narrow premises of business and investment climate, the Policy raises serious trade, competition, and innovation concerns. For example, if adopted and implemented, the policy and the Bill could deny the four East Africa Partner States that are LDCs, the opportunity to develop their technological capacity in the pharmaceuticals sector contrary to aims of Article 66.1 of the TRIPS Agreement.
2. The Policy does not take into consideration the tremendous efforts and initiatives in the EAC health and other sectors, such as education and training, aimed at improving the availability and quality of medicines, including the efforts to enhance local production of pharmaceuticals[28] pool procurement[29] and on medicines regulations and market surveillance[30]. There are also on-going efforts to develop a regional HIV law with an access to medicines component and a Protocol on the use of TRIPS flexibilities which are not taken into account by the Anti-Counterfeiting Policy.

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[26] See Harms, Louis "The Enforcement of Intellectual Property Rights by Means of Criminal Sanctions: An Assessment", WIPO document WIPO/ACE/4/3, p. 15 available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_4/wipo_ace_4_3.pdf.

[27] Information about ICF can be found on its website at http://www.icfafrica.org/.

[28] In 2005, the EAC Secretariat launched an initiative aimed at harmonising the partner states' policies, legislations and regulations on IP in order to facilitate regional manufacturing of medicines as well as importation and trade in essential medicines. In the context of this initiative, there has been on-going work, including studies on: regional essential medicines policy, legal, regulatory, procurement, distribution and management framework; legal and economic capacity of national and regional manufacturing capacity of generic essential medicines; and the use of TRIPS flexibilities to promote access to medicines in EAC. This initiative has led to the current work to develop an EAC Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation and an EAC Regional Protocol on Public Health Related WTO-TRIPS Flexibilities.

[29] The EAC Secretariat in partnership with the Partner States has been undertaking work, since 2007, towards establishing a regional pool procurement framework for medicines. With the assistance of the World Health Organization (WHO) and UNDP, the EAC has carried out a major studies aimed at: analysing the legal and regulatory framework on procurement and delivery of pharmaceutical products and other essential medical supplies in the public sector of the EAC Partner States; determining the feasibility of pooled procurement of medicines; recommending a specific model of pooled procurement and identify a potential target commodity list for bulk purchasing; developing guidelines and recommendations for the implementation of the recommended model.

[30] The EAC Secretariat, working with the WHO, among others, has been making efforts towards regional harmonisation of medicines regulation. These efforts continue. Ultimately, if a system of joint registration and market surveillance is attained or if a mutual recognition system is established the availability and access to medicines is likely to be improved due to increased efficiencies and cost savings.

3. The Policy and Bill takes little account of the extensive national legal regimes that deal with health and food standards, quality, market surveillavance and enforcement. The implicit suggestion that the EAC Partner States lack adequate laws to deal quality and safety problems or illicit trade in sub-standards goods should be re-assessed after a comprehensive review of the laws and policies of the EAC Partner States relating to public health, access to medicines, medicines and food quality, competition and market surveillance.
4. The approach and suggested solutions in the Policy and Bill:
    - Are based on general statements and, in many instances, statements that are unsupported by any credible evidence. These include most of the statement made in section 3 of the Policy.
    - Overlook the basics of IP and the tenets of IP enforcement laid out in Part III of the TRIPS Agreement regarding fair and equitable procedures and ensuring that enforcement efforts do not become barriers to legitimate trade; international developments on access to medicines; and, most importantly, the extensive economic, scientific and legal literature on the subject, literature that clearly suggests that a different approach, especially in a developing country and LDC context, would be preferable to address medicines quality problems and IP enforcement generally.
    - Are arrived at based on questionable and/or incomplete and contested figures regarding the magnitude and nature of the problem. These include the OECD figures given in paragraph 1.2.5 of the Policy document as well as the figures on claimed losses by various companies in EAC Partner States.
    - Are based on the opinions and views of a very narrow group of stakeholders who do not represent the broader developmental interests in the region. Other than some government officials most of the data and solutions are based on select industry views. The views and opinions of the health community in the region, for example, are not reflected.

What emerges from the summary above is that the proposed EAC Anti-Counterfeit Policy and Bill have been developed on the basis of insufficient evidence, incomplete analysis and without taking account of public health and access to medicines concerns as well as broader development consequences.

This discussion paper, in the following sections, elaborates on this conclusion and suggests an alternative approach that could assist the region and each Partner State to address any legitimate problems with sub-standard, poor quality and dangerous products or IP concerns without compromising efforts to improve access to essential medicines, including access to HIV/AIDS medicines, and other development efforts such as education.

1. Introduction

The enforcement of Intellectual property (IP) rights has recently been receiving unprecedented global attention.[31] This increased attention reflects a range of interests by different stakeholders; from IP rights holders to governments, consumers, researchers and academics through to the general public. Right holders and governments, justify this heightened attention to the issue IP enforcement by citing what they see as record levels of trademark counterfeiting and copyright piracy and other IP infringements. On the part of other governments, health groups, consumer groups and other stakeholders, there are concerns, among others, regarding the potential for abuse of IP rights enforcement procedures and the use of these procedures to prevent market entry by competitors, to erect barriers to legitimate trade, such as in generic medicines, and to compromise efforts to enhance transfer of technology, including in the pharmaceutical sector.

It is therefore critical, at the outset, to understand that the current political, diplomatic and substantive discussions on IP enforcement reflect important differences of opinions on a range of issues. Differences exist with respect to the scale of the problem of counterfeiting, copyright piracy and other IP infringements; on the methodologies used to quantify losses suffered by right holders, the trade and economic impact of trademark counterfeiting and copyright piracy, and the social implications of various IP enforcement policies and laws such as those that have been or are being proposed in the East Africa Community (EAC) and its Partner States and the possible solutions.

New policy proposals and laws on IP enforcement therefore have to be approached with circumspection. In particular policy proposal and laws which seek to address IP infringement through criminal sanctions should only be approved if such proposals are backed by good empirical evidence, a cost and benefit analysis and after consultation with a broad range of stakeholders. This discussion paper examines the potential impact of the proposed EAC Policy on Anti-Counterfeiting, Anti-Piracy and other Intellectual Property Rights Violations (hereinafter "EAC Anti-Counterfeiting Policy") and the EAC Anti Counterfeiting Bill, 2010

[31] In addition to hundreds, if not thousands, of national initiatives there are now many international initiatives and processes that seek to address IP enforcement. For a description and discussion of some these international initiatives and issues see e.g., WIPO Secretariat's report on "Activities of WIPO in the Field of Intellectual Property Enforcement including the Global Congress on Combating Counterfeiting and Piracy", WIPO document WIPO/ACE/5/2 available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_5/wipo_ace_5_2.pdf; The Dubai Declaration adopted at the end of the Fourth Global Congress on Combating Counterfeiting and Piracy available at http://www.ccapcongress.net/archives/Dubai/Files/Final%20Dubai%20Outcomes%20Declaration.pdf and the activities described under the International Chamber of Commerce's (ICC) Business Action to Stop Counterfeiting and Piracy (BASCAP) programme at http://www.iccwbo.org/bascap/id1127/index.html; The OECD Report on "The Economic Impact of Counterfeiting and Piracy" available at http://www.oecd.org/dataoecd/11/38/38704571.pdf; The Report of the G8 Intellectual Property Experts Group (IPEG) to the 2009 G8 Summit available at http://www.g8italia2009.it/static/G8_Allegato/ITALY%20G8%20IPEG%20Final%20Report,0.pdf; Sell, Susan (2008) "Global IP Upward Ratchet, Anticounterfeiting and Piracy Enforcement Efforts: The State of Play", *IQsensato Occasional Paper 1,* IQsensato, Geneva available at http://www.iqsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf; Fink and Correa (2008) *supra* note 22; and Biadgleng, Ermias and Viviana Munoz (2008) "The Changing Structure and Governance of Intellectual Property Enforcement", *Research Papers 15,* South Centre, Geneva available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1210622.

(hereinafter "EAC Anti-Counterfeiting Bill") on access to essential medicines in the region in the context of these parameters.

The analysis begins, in section 2, with an overview of the policy and legal framework for ensuring access to, and the quality of, essential medicines in the EAC. This is followed, in section 3, by an analysis of the potential impact of the proposed EAC Anti-Counterfeiting Policy and Bill on access to medicines, including with respect to innovation and the development of regional manufacturing capacities in the pharmaceutical sector. Finally, in section 4, the paper offers a set of recommendations regarding alternative approaches to addressing quality and standards as well as IP enforcement in the EAC.

2. The Policy and Legal Framework for Ensuring Access to, and Quality of, Essential Medicines in East Africa

The EAC as a community and each of the Partner States have highlighted health as a key priority area. The policy and legal framework at both levels cover a wide range of issues including quality standards, market surveillance, registration, health systems management and training.

2.1 Regional level policy and legal framework

Under Article 118 of the Treaty Establishing the EAC, the Partner States have made a number of important undertakings. Among others, the Partner States have committed themselves to:

- developing a common drug policy which would include establishing quality control capacities and good procurement practices;
- harmonising drug registration procedures so as to achieve good control of pharmaceutical standards *without impeding or obstructing the movement of pharmaceutical products within the community*[32]*;*
- cooperating in the development of specialised training, health research, reproductive health, the pharmaceutical products and preventive medicine; and
- Developing a common approach...for the control and eradication of the trafficking and consumption of illicit or banned drugs.

Through the Sectoral Council of Ministers of Health, the EAC has over the last ten years made significant strides in achieving the above goals.[33] Consequently, there are a number of on-going or new initiatives at the EAC level which are relevant to the quality, trade and access to essential medicines.

The main initiatives relate to matters of IP and patents, medicines regulations, including registration and market surveillance, procurement and regional pharmaceutical

[32] Emphasis added.

[33] The 4th EAC Community Health and Scientific Conference scheduled for Kigali, Rwanda from 31st March 2010 to 2nd April 2010 will examine the achievements and challenges of the last 10 years. Information about the conference is available at http://www.eac.int/health/. Among the key themes to be discussed are: maternal and child health; models of health financing; management of health services; ICT in health care; and quality of health care.

manufacturing. Some of the key initiatives and processes in this category include the initiative on: harmonisation of TRIPS flexibilities, in particular, to promote local manufacturing of medicines, including HIV/AIDS medicines; pool procurement of medicines; and harmonisation of standards and medicines regulatory systems.

2.1.1 Intellectual property management, innovation and access to medicines

The EAC Partner States have, under Article 103 of the Treaty Establishing the EAC, undertaken to promote cooperation in science and technology through a range of cooperative activities and initiatives. Among these is cooperation through the harmonisation of policies on commercialisation of technologies and promotion and protection of IP rights. In the main, the efforts on harmonisation of IP related matters in the EAC were intended to operate within the framework of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to which all the EAC Partner States are party.[34]

A key area of focus in the implementation of the TRIPS Agreement in developing countries, including in the EAC Partner States, has been the relationship between the protection of IP rights and access to essential medicines. There are three main reasons why this is the case.

The first reason is related to role of IP rights, particularly patent rights, in determining the price of essential medicines. High prices for medicines in countries such as those in the EAC seriously compromise the ability of communities, governments and other players in the health sector to effectively manage infectious and communicable diseases. In cases such as HIV/AIDS, high prices had virtually guaranteed that most of those who needed treatment in the region had little or no access to the best available treatments until a few years ago. High medicine prices also mean that governments have to spend a disproportionate amount of money on medical supplies affecting investments in infrastructure and training. It is for these reason that in 2001, at the Fourth WTO Ministerial Conference in Doha, trade ministers adopted a Declaration on the TRIPS Agreement and Public Health (hereinafter "the Doha Declaration") in which, among other things, the Ministers declared that *"the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.*" In addition, the Minsters affirmed *"the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose*."[35]

The Doha Declaration confirms that while WTO Member States are required to comply with minimum standards imposed by TRIPS, they can also take measures to adapt IP provisions to their access to medicines needs and shape their public health policy. The flexibility provided under the TRIPS Agreement enable WTO members, including the EAC Partner States to: interpret the three criteria of patentability (novelty, inventive step, and industrial application); issue compulsory licenses and government use orders; make use of the

[34] The Agreement Establishing the WTO (WTO Agreement) as well as the text of the TRIPS Agreement, which is Annex 1C to the WTO Agreement, is contained in WTO 1999, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations,* Cambridge University Press, Cambridge.

[35] Emphasis added. This statement is in paragraph 4 of the Doha Declaration. The Declaration is contained in WTO document WT/MIN(01)/DEC/W/2 and is available on the WTO website at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

international exhaustion of rights to parallel import; apply a number of general exceptions available under Article 30 of TRIPS such as the early working or *bolar* exception as well as the research exception; interpret the provisions related to the protection of pharmaceutical test data; and to make use of transitional arrangements.[36] Since the adoption of the Doha Declaration, a number of countries, including the EAC Partner States, have used these flexibilities with significant positive impacts on access to medicines.[37] Most case studies show significant price reductions achieved and significant improvements in the access levels in these countries.

The second reason for the focus on the impact of IP on innovation and access to medicines is that although the global protection of IP has expanded rapidly as developing countries implement their TRIPS obligations, the research and development (R&D) situation for diseases that predominantly affect developing countries remains worrying. Developed countries, which represent nearly 90% of the global pharmaceutical sales, represent only 10% of the 14 million plus global deaths that occur annually due to infectious diseases, while developing countries which represent 90% of the 14 million deaths represent only 10% of the global pharmaceutical sales.[38] Africa's capacity for R&D is among the lowest globally.[39]

The 10/90 gap can be interpreted to mean that the current system for providing incentives for innovation (IP being a key part of that system) in the pharmaceutical sector has failed to ensure that R&D priorities reflect the health needs of the poor. It is for this reason that the Wold Health Organization (WHO), with the active participation of the EAC Partner States, adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (hereinafter "the Global Strategy") with the aim of promoting new thinking on innovation and access to medicines and to provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven health R&D into diseases which predominantly affect the populations of developing countries and LDCs.[40]

Finally, there is the issue of the types of innovations being generated under the current IP system. In general, innovation in the pharmaceutical industry varies widely. It ranges from breakthrough discoveries to minor modifications of existing medicines. A 2002 study by the

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[36] For a detailed discussion on the use of TRIPS flexibilities see e.g., Musungu, Sisule and Cecilia Oh "The Use of Flexibilities by Developing Countries: Can they Promote Access to Medicines?" Study Commissioned by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) available at http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf.

[37] For detailed discussions of specific case studies see e.g., the APPG report, *supra* note 4; Musungu and Oh, *ibid*; Report of the WHO Mission to Thailand in February 2008 titled "Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities" available at http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf; and Médecins sans Frontières (MSF), "Untangling the Web of Antiretroviral Price Reductions" available at http://www.msfaccess.org/resources/key-publications/key-publication-detail/?tx_ttnews%5Btt_news%5D=1581&cHash=94b2ecf706.

[38] For a detailed analysis of the problems relating to research into diseases that disproportionately affect developing countries see CIPIH (2006) *Public Health, Innovation and Intellectual Property Rights,* WHO, Geneva and MSF Drugs for Neglected Diseases Working Group and the Campaign for Access to Essential Medicines (2001), *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases,* MSF, Geneva.

[39] Berger *et al, supra* note 7, p. 14.

[40] See para 13 of the Global Strategy which is available at http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

National Institute of Health Care Management Research and Educational Foundation (NIHCM) showed that in the United States, the market with the largest number of pharmaceutical patents, in the 12 year period from 1989 to 2000 of the 1,035 new medicines approved by the federal regulatory agency only 35 per cent of them contained a new active ingredient.[41] Highly innovative drugs –medicines which contain new active ingredients and at the same time provide significant clinical improvement- were found to be rare. During the 12 year period, only 15 per cent qualified as such medicines.[42] In the recent past, concerns regarding the rate of pharmaceutical innovation have led, for example, the European Union to undertake a pharmaceutical sector inquiry.[43] That inquiry revealed that widespread abuse of IP rights and enforcement procedures may be one of the factors retarding innovation in the pharmaceutical sector.

In 2005, the EAC Secretariat, taking into account the Doha Declaration and other WTO decisions in favour of using flexibilities in the TRIPS Agreement to promote access to medicines, launched an initiative aimed at harmonising the partner states' policies, legislations and regulations on IP in order to facilitate regional manufacturing of medicines as well as importation and trade in essential medicines. Through this initiative, a number of studies have been conducted. These include studies on:

- Regional essential medicines policy, legal, regulatory, procurement, distribution and management framework.
- Legal and economic capacity of national and regional manufacturing capacity of generic essential medicines.
- The use of TRIPS flexibilities to promote access to medicines in EAC.

These studies and other related work have led to the preparation of: A Draft EAC Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation; a Draft EAC Regional Protocol on Public Health Related WTO-TRIPS Flexibilities; and a Draft EAC Regional Pharmaceutical Manufacturing Plan of Action for 2010 – 2016.[44] The three documents are to be considered for adoption at the fifth EAC Sectoral Council of the Ministers of Health to be held in Kigali in March/April 2010.

2.1.2 Pharmaceutical supply management and pooled procurement

The EAC Secretariat, in partnership with the partner states, has been undertaking work, since 2007, towards establishing a regional pool procurement framework for medicines. With the assistance of the WHO and with contributions by UNDP, the EAC has carried out a major study aimed at:

[41] NIHCM (2002), *Changing Patterns of Pharmaceutical Innovation*, NIHCM, Washington, D.C., p. 3.
[42] *Id*.
[43] The report of the inquiry is available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf.
[44] The objective of the draft policy and protocol are to "guide the EAC Partner States on how their National Intellectual Property (IP) legislation should be adjusted in order to enable them to fully utilise the public health related WTO-TRIPS flexibilities for optimising the populations' access to health products and medical devices".

- Analysing the legal and regulatory framework on procurement and delivery of pharmaceutical products and other essential medical supplies in the public sector of the EAC Partner States.
- Determining the feasibility of pooled procurement of medicines.
- Recommending a specific model of pooled procurement and identifying a potential target commodity list for bulk purchasing.
- Developing guidelines and recommendations for the implementation of the recommended model.

The study recommended that the EAC adopt a group contracting model of pool procurement for essential medicines, including HIV/AIDS medicines.[45] Further work is on-going, including consideration for beginning to apply the model on a pilot basis.

Pooled procurement of medicines can offer distinct benefits to EAC Partner States with respect to accessibility and quality of medicines.[46] The most obvious reason is the potential for lowering medicines prices. The second benefit of pooled procurement relates to improved quality of medicines. This happens as a result of improved access to information about drug quality through exchanging information about supplier performance with respect to quality of drugs, coordinating technical aspects of quality assurance through a centralised quality assurance laboratory and coordinating and cost sharing GMP inspections. Third, pooled procurement also has the overall effect of improving availability. In particular, by sharing information EAC Partner States and/or their procurement agencies will be able to make better decisions on selection of suppliers. Procurement agencies will also be better able to access information on the state of the market and drug availability, including with respect to anticipated short-supply or difficult to obtain drugs. Finally, pooled procurement can help improve rational use of drugs in the EAC by increasing the incentive for coordinating drug selection and use, for example, of drug medical supply registration procedures, essential drugs lists (EDLs) and standard treatment guidelines (STG).

2.1.3 Regulatory standards and quality control

Regulatory approval processes for medicines, including HIV/AIDS medicines, raise a number of issues with respect to availability and improved access to essential medicines. At the national level in the EAC Partners States regulatory agencies face a range of challenges including resource constraints. These difficulties and constraints at the national level could be addressed in a regional context through coordination of registration and cross-recognition of medicines in other countries as well as cooperation on market surveillance. Such cooperation has become increasingly important with the implementation of the EAC Customs Union[47] and soon the EAC Common Market[48]. To be able to establish a coordinated

[45] Group contracting is a model where member countries jointly negotiate prices and select suppliers and agree to purchase from selected suppliers but each country conducts purchasing individually. Details on the study and its findings are available on the EAC website at http://www.eac.int/health/index.php?option=com_content&view=article&id=52&Itemid=117.

[46] See Management Sciences of Health (2003) Regional Pooled Procurement of Drugs in Sub-Saharan Africa", p. 1-2.

[47] The Protocol establishing the EAC Customs Union is available on the EAC website at http://www.eac.int/customs/index.php?option=com_content&view=article&id=2:customs-union-protocol&catid=3:key-documents&Itemid=141.

regional system of regulatory approval and or a system of cross-recognition of registrations, however, several actions will need to be taken by countries.[49]

These actions could include: the coordination of the current lists of drugs registered in each country; the creation of independent and transparent drug regulatory authorities; the coordination of national drug policies and guidelines related to rational drug use including the use of national essential medicines lists for drug selection; adherence to interagency guidelines on medicines donations; and, creation of mechanisms to deal with differences in resistance patterns and how to reflect these in drug lists.

The EAC Secretariat, working with the WHO, among others, has been making efforts towards these actions. These efforts continue. Ultimately, if a system of joint registration and market surveillance is attained availability and access to essential medicines is likely to be improved due to increased efficiencies and cost savings. Such a system will also be critical in addressing a range of quality concerns including dealing with trade in fake or sub-standard medicines.

2.2 National level policy and legal framework

In addition to the regional efforts to use TRIPS flexibilities, improve regulatory and quality control capacities and efficiencies in pharmaceutical management, each of the EAC Partner States has a range of policies and laws aimed at improving access to, and the quality of, essential medicines. These include IP specific policies and measures as well as other laws and policies.

2.2.1 The use of TRIPS flexibilities to improve access to medicines in the EAC Partner States

All EAC countries have taken measures to take advantage of TRIPS flexibilities to enhance access to essential medicines in their territories. While some improvements might still be required, as outlined in the recommendations of the Draft EAC Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, significant progress has been made. In summary, the situation with respect to the various flexibilities is as follows[50]:

- **Transition periods:** All the EAC LDCs (Burundi, Rwanda, Tanzania and Uganda) have taken measures to use the 2016 transition period. Essentially, the laws or draft laws exempt pharmaceutical products from patentability until at least 2016. It is important to note, however, that most of these laws have just been passed and are in early stages of implementation (Burundi, Rwanda[51] and Zanzibar[52]) or are in draft (Tanzania mainland and Uganda).

[48] The Protocol establishing the Common Market is on the EAC website at http://www.eac.int/advisory-opinions/cat_view/68-eac-common-market.html.
[49] See discussion in Musungu, Sisule., Villanueva, Susan., and Roxana Blasetti (2004) *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks,* South Centre, Geneva.
[50] This summary draws from the analysis in UNCTAD (2008) *supra* note 2.
[51] See the Rwanda Intellectual Property Code of 2009.
[52] See the Zanzibar Industrial Property Act of 2008 (Act No. 4 of 2008).

- **Patenting of pharmaceuticals including new use:** In Kenya, which does not enjoy the LDC transition period, the Industrial Property Act 2001 requires that patents be granted to all products and processes that meet the patentability criteria. The law also permits the patenting of new uses of pharmaceutical products. The law, however, takes full advantage of the freedom to exclude certain methods and subject matter from patentability as well as the policy space not to provide patent term extensions for any reason. In the current laws of Tanzania[53] and Uganda[54], which have not yet enacted their new laws to exclude pharmaceutical patenting under the 2016 transition period, the approach to patentability of pharmaceutical is similar to that taken as in Kenya.
- **Parallel importation:** Kenya, Uganda and Zanzibar have taken the route of international exhaustion meaning that medicines can be imported from anywhere in the world.[55] Rwanda, under the new IP Code, only allows parallel importation in exceptional circumstances. Note, however, that in light of the transition period, this provision does not apply to medicines in Rwanda. At the time of writing it remains unclear whether parallel importation is allowed or not in Burundi.
- **Compulsory licensing and government use:** All the EAC Partner States provide for compulsory licenses and government use, though the grounds upon which such licenses can be issued differ slightly. All the Partner States also generally provide for detailed rules taking into account the requirements of Article 31 of the TRIPS Agreement.
- **Early working (Bolar) and research exception:** All the EAC countries provide for an exception for experimental use of patents. However, only Rwanda, Uganda and Zanzibar have explicit provisions that allow for experimental use for commercial purposes. The law of Burundi has a formulation that is rather vague but the reference to experimental purposes could be taken to cover activities for both non-profit and commercial purposes.[56] In the case of Kenya and Tanzania, the laws do not address the question of whether the research exception covers experimentation for commercial purposes. With respect to the early working exception all the countries, except Tanzania, provide for the exception. The scope and wording, however, differ in each case.[57]
- **Pharmaceutical test data protection:** The exact status with respect to test data protection in EAC Partner States is unclear. The issue is not directly addressed in the patent or other laws in any of the countries. However, interviews carried out by UNCTAD with the EAC Partner States officials in 2008 revealed that there is no prohibition for drug regulatory authorities relying on data submitted by the originator to register generics.[58] The situation in Burundi and Zanzibar could not be ascertained.

[53] See the Tanzania Patent Act, 1987 (available at http://www.parliament.go.tz/Polis/PAMS/Docs/1-1987.pdf).
[54] See the Uganda Patent Statute No. 10 of 1991.
[55] UNCTAD (2008), *supra* note 2, p. 40.
[56] UNCTAD (2008), *supra* note 2, p 34.
[57] For detailed discussion see UNCTAD (2008), *supra* note 2, p. 37.
[58] See UNCTAD (2008); *supra* note 2, p. 61.

2.2.2 Other laws and policies relevant to access to medicines, quality control and market surveillance

While IP laws and policies have a significant impact on the availability and access to essential medicines, there are a number of other laws and policies in the EAC Partner States that contribute to this goal. In particular, there are a number of laws and policies that are critical in facilitating the use of the TRIPS flexibilities for access to medicines and ensuring quality control as well as providing a legal regime for market surveillance and tackling fake and sub-standard medicines.

The most relevant laws and policies that need to be taken into account with respect to developing an EAC laws or policies relating to IP, including IP enforcement, quality standards and market surveillance include the following[59]:

Kenya

The key laws and policies include:

- The Constitution which guarantees the right to life.
- The Children's Act of 2001.
- The Penal Code, Chapter 63 Laws of Kenya.
- The Dangerous Drugs Act, Chapter 245 Laws of Kenya.
- The Food, Drugs and Chemical Substances Act, Chapter 254 Laws of Kenya.
- The HIV and AIDS Prevention and Control Act No. 14 of 2006.
- The Kenya National HIV/AIDS Strategic Plan.
- Kenya Vision 2030.
- The National AIDS Control Policy of 2005.
- The National Hospital Insurance Fund Act No. 9 of 1998.
- The National Poverty Eradication Plan.
- The Public Health Act, Chapter 242 Laws of Kenya.
- The Pharmacy and Poisons Act, Chapter 244 Laws of Kenya.
- The Standards Act, Chapter 496 Laws of Kenya.
- The Restrictive Trade Practices, Monopolies and Price Control Act, Chapter 504A.

In addition to these laws, Kenya is also considering a Traditional Medicines Bill which, if enacted, would also be relevant to question of access to essential medicines.

Rwanda

The key laws and polices include:

- The Constitution of Rwanda which guarantees the right to life.
- National Strategic Plan on HIV and AIDS 2009-2012.

[59] This section is based, in part, on the analysis in Kazimbazi Emmanuel., Mulumba, Moses., and Rene Loewenson (2008) "A Review of Kenyan, Ugandan and Tanzania Public Health Law Relevant to Health Equity", *EQUINET Discussion Paper 63,*EQUINET, Harare. Please note that while additional information with respect to Rwanda could be found no sufficient information has yet been obtained with respect to the situation in Burundi.

- Law No. 12/99 on Pharmaceutical Art (O.G No. 23 of 1 December 1999).
- The Penal Code
- Rwanda Poverty Reduction Strategy Paper 2008.
- Rwanda Vision 2020.
- Standards Act, N° 43/2006 0f 05/10/2006.

Tanzania[60]

The key laws and policies include:

- The Constitution of Tanzania which guarantees the right to life.
- The HIV and AIDS (Prevention and Control) Bill 2007.
- The Infectious Diseases Act, Chapter 96 Laws of Tanzania.
- The Food, Drugs and Cosmetics Act No. 1 of 2003.
- The National Policy on HIV/AIDS.
- The National Health Policy.
- The National Strategy for Growth and Reduction of Poverty 2005.
- The Pharmaceutical and Poisons Act, Chapter 219 Laws of Tanzania.
- The Pharmacy Act No. 7 of 2002.
- The Penal Code, Chapter 16 Laws of Tanzania.
- Tanzania Bureau of Standards Act, Act No. 3 of 1975.
- Tanzania Development Vision 2025.
- The Traditional and Alternative Medicines Act No. 23 of 2002.

Uganda

The key laws and policies include:

- The Constitution of Uganda which guarantees both the right of access to health care and the right to life.
- The Food and Drugs Act, Chapter 278 Laws of Uganda.
- The Health Sector Strategic Plan.
- The National Health Policy.
- The National Drug Policy and Authority Act, Chapter 206 Laws of Uganda.
- The Penal Code, Chapter 120 Laws of Uganda.
- The Poverty Eradication Plan.
- The Pharmacy and Drugs Act, Chapter 280 Laws of Uganda.
- The Public Health Act, Chapter 281 Laws of Uganda.
- Uganda Bureau of Standards Act.
- Uganda Vision 2025.

Uganda, like Kenya, is also considering laws on traditional knowledge, including on traditional medicines.

[60] There are also additional laws that are specific to Zanzibar that need to be taken into account.

3. The Potential Impact of the Proposed EAC Anti-Counterfeiting Policy and Bill on Access to Essential Medicines in the Region

The overall objective EAC Anti-counterfeiting Policy is stated to be to "provide a Policy basis for a robust legal framework for the protection and enforcement of Intellectual Property Rights in the region with specific focus on combating counterfeits and pirated products".[61] In the name of achieving this overall policy objective, the EAC Anti-Counterfeiting Policy sets out eight specific objectives.[62] These range from the objective of defining and creating a sound EAC legal framework to combat counterfeiting, piracy and other IP rights violations to establishing a harmonised institutional framework through a dedicated lead agency and sub-agencies in each Partner State through to creating a conducive investment climate in the region. On its part, the EAC Anti-Counterfeit Bill aims to create an Act of the Community to prohibit trade in counterfeit goods, to establish national anti-counterfeit boards and for connected purposes. Simply described, the proposed EAC Anti-Counterfeiting Bill aims to create criminal offenses, procedures for prosecution and criminal sanctions with respect to IP infringements.

This section provides an analysis of the potential impact of the EAC Anti-Counterfeiting Policy and Bill. The analysis and the recommendation that follow in section 4 primarily focus on the proposed Policy since it provides the basis for the Bill. However, where relevant provisions of the Bill will be analysed or referenced. It is also important to note that while the paper focuses on access to medicines, many of the points made are equally applicable to other key development sectors such as agriculture.

3.1 Definitional problems

One of the main reasons why serious concerns have been raised with respect to the various anti-counterfeiting initiatives in the EAC and elsewhere relates to the definition of the term "counterfeit" or "counterfeiting". The key issue is that the term has both a technical IP meaning (as defined in the TRIPS Agreement) and a common usage as in fake.[63] As Correa has observed, the 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."[64]

The EAC Anti-Counterfeit Bill defines counterfeit goods as "goods that are the result of Counterfeiting (including goods generally known as pirated goods), and includes any means used for purposes of counterfeiting". Counterfeiting is defined in the Bill to mean:

> "(a) the manufacturing, producing or making, whether in the Community or elsewhere, of any goods whereby those protected goods are imitated in such

[61] See p. 16 of the Policy.
[62] See p. 16 – 17 of the Policy.
[63] The TRIPS Agreement only uses the term counterfeiting to refer to trademark infringement. Footnote 14, in particular, defines trademark counterfeiting as referring to "any 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."
[64] Correa, *supra* note 22.

manner and to such a degree that those other goods are substantially identical copies of the protected goods without the authority of the Owner of any Intellectual Property Right subsisting in the Community in respect of Protected Goods;

(b) the manufacturing, producing or making or applying to goods, whether in the Community or elsewhere, the subject matter of that Intellectual Property Right, 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 without the authority of the Owner of any Intellectual Property Right subsisting in any of the Partner States in respect of the Protected Goods."[65]

Interestingly, the EAC Customs Management Act, 2004, which is referred to in the Anti-Counterfeiting Policy, does not define the term counterfeiting but uses the term in various contexts including falsification of documents or with reference to "counterfeit" currency.[66]

IP right under the Bill is defined to mean either "the rights in respect of trademark conferred by trademarks laws of the relevant Partner State" or "the copyright in any work in terms of copyright laws of the relevant Partner State" or "any plant breeders' right conferred by the relevant legislation in the Partner State". This means that patent infringement is not covered. Because of this some may assume that there is no potential impact on access to medicines, particularly generic medicines. This is, however, an erroneous for a number of reasons.

The first and most important problem lies with the first part of the definition, which refers to the "manufacturing, producing or making...of any goods whereby those goods are imitated in such a manner and to such a degree that those goods are identical copies of the protected goods..." The key issue which has significant implications for access to generic medicines is that trademarks or copyright do not protect goods *per se* but rather signs (marks) or the expression of an idea. It is only patent protection that confers exclusivity to goods (products). In the specific case of trademarks, Article 15 of the TRIPS Agreement provides that "Any sign, or combination of signs, capable of distinguishing the goods or services of one undertaking from those of another undertaking, shall be capable of constituting a trademark." As a corollary, the right conferred by a trademark (see Article 16 of TRIPS) is the "exclusive right to prevent third parties not having the owner's consent *from using in the course of trade identical or similar signs* for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion."[67]

The implication of Article 15 and 16 of the TRIPS Agreement is that the manufacturing, producing or making a good which is substantially identical to another good cannot constitute a trademark violation. It is only the imitation of signs or a combination of signs (marks) affixed on goods that can constitute a trademark violation. Consequently, a generic company which manufactures, produces or makes a generic medicine, which for safety

[65] See Section 2 of the Bill.
[66] The Act is contained in the Gazette of East Africa No. 001 Vol. AT 1 of 1 January 2005.
[67] Emphasis added.

reason must be an identical copy in its chemical composition as the brand, may be found to have "counterfeited under the proposed EAC Bill even though such a generic company never imitated the trademark because the focus of the definition is on the similarity of goods as opposed to similarity of signs (marks).

Second, it is notable that the EAC Anti-Counterfeiting Policy does not contain a definition of counterfeiting, piracy or what constitutes IP rights violations. It should therefore not be assumed that the Bill cannot be broadened to cover patents in the process of enactment since no explanation is given for this omission. In addition, since the Policy is the overall framework, nothing would stop future measures that could cover patent rights in context of implementing the Policy.

Thirdly, it striking that a significant part of the justification for the proposed Policy, particularly, section 3, relies heavily on patent theories regarding innovation, investment and competition.

Finally, egregarious application of IP enforcement measures in the trademark and copyright area can also negatively affect access to essential medicines and the building of innovative capacities in the pharmaceutical sector. Consider, for example, the implications of copyright enforcement measures which impact on the limitations and exceptions to copyrights in the EAC Partner States.

Facilitating access to use of copyright protected works is essential for promoting creativity in general and for promoting key goals such as education and scientific research.[68] The fair use and fair dealing doctrines as well as other exceptions therefore permit certain unauthorised but socially beneficial uses of copyrighted works either because of transactions costs or because of the benefits to the public and for specific sectors such as the education sector.[69] Considering the enormous needs in education and training in the health sector in the EAC, the importance of copyright exceptions and limitations cannot therefore be gainsaid. As a corollary, any enforcement measures that negatively affect these exceptions and limitations have a direct impact on access to medicines by impeding science and technology development, R&D and innovation as well as the dissemination of critical health information.

3.2 IP Enforcement, access to medicines and the EAC Anti-Counterfeiting Policy and Bill

Enforcement of IP rights is an important part of the TRIPS framework. The purpose of the TRIPS framework and specific enforcement provisions is, however, multifaceted reflecting a range of economic, trade, social, cultural, scientific and innovation parameters. The TRIPS

[68] Okediji, Ruth (2006) "The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries in the Digital Environment", *Issue Paper No. 15,* ICTSD, Geneva, p. x. For a discussion of some of the practical implications of copyright on access to learning materials see e.g., Rens, Andrew., Prabhala, Achal., and Dick Kawooya (2006) "Intellectual Property, Education and Access to Knowledge in Southern Africa", ICTSD, UNCTAD and TRALAC, Geneva and the work of the African Copyright and Access to Knowledge (ACA2K) Project, which includes case studies on Kenya and Uganda. This work is available at http://www.aca2k.org/.

[69] UNCTAD and ICTSD (2005), *Resource Book on TRIPS and Development,* Cambridge University Press, New York, p. 187.

enforcement framework also recognises important human rights considerations. An understanding of these parameters is therefore critical in any meaningful discussion on IP enforcement and in addressing trademark counterfeiting and copyright piracy. In this context, the proposed EAC Anti-Counterfeiting Policy suffers from significant weaknesses because it is premised on an incomplete understanding of the TRIPS enforcement framework. Sections 1.3.3 through to 1.3.6 of the Policy fail to acknowledge or consider a number key parameters with the effect that the goal and objectives of the proposed Policy are not well grounded in the international system of IP.

In particular, the proposed Policy fails to acknowledge and/or fully consider that:

- The adoption of the TRIPS Agreement was informed by a desire, on the part of WTO Members, "to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade".[70] In other words, the purpose of the TRIPS Agreement and national IP systems, including those in the EAC, is not just to promote the protection and enforcement of IP but also to prevent anti-competitive behaviour by IP right holders and the abuse of IP rights and/or IP enforcement procedures. This is why the mandatory general obligations of WTO Members under Article 41 of the TRIPS Agreement include the requirement to ensure that IP enforcement measures are "*applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse*." (See Article 41.1) and that enforcement procedures "*shall be fair and equitable*" (Article 41.2). By failing to consider this fundamental principle and the attendant TRIPS obligations, the EAC Anti-Counterfeiting Policy and Bill have significant potential to reduce competition and erect barriers to legitimate trade contrary to the enormous efforts that have gone into opening up trade in the region, including trade in the pharmaceutical sector. It is also to be noted that no effort has been made to ensure that the proposed measures to enforce IP in the EAC are fair and equitable.
- IP rights are private rights.[71] As private rights any demand for state intervention to enforce IP rights must follow the dictates of common welfare. It for this reason that the use of criminal procedures and border measures are treated as special cases under the TRIPS Agreement as opposed to a general rule. It is also for this reason that Article 41.5 of TRIPS makes it clear that there is no obligation on any WTO Member State to create a special judicial structure for IP enforcement or to skew resource allocation towards IP enforcement. Once a state has put in place the measures required by TRIPS, which the Policy document acknowledges all EAC Partner States have done, any additional measures such as those proposed by the Anti-Counterfeiting Bill must be based on a compelling case. The use of tax resources drawn from a largely poor population for purposes of promoting TRIPS-plus measures in the EAC, including the creation of special judicial personnel (see Part V of the Bill), raises significant policy and political questions which the proposed Policy does not consider.

[70] See the first recital in the Preamble to the TRIPS Agreement.
[71] See the Preamble to the TRIPS Agreement, para 4.

- The structures to be put in place for IP enforcement must take "into account differences in national legal systems"[72] and recognise the right of each WTO Member "to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"[73]. The Policy and Bill seek to harmonise the legal framework for IP enforcement in a way that fails to recognise the clear differences between the economic and social circumstances of the EAC Partner States, circumstances that have been recognised by all WTO Member States and in the TRIPS Agreement itself. Of particular importance is the fact that except for Kenya, all EAC Partner States are LDCs, which under the TRIPS Agreement and by virtue of the decisions of the Council for TRIPS do not have to implement any TRIPS enforcement provisions at least until 1 July 2013.[74]
- The implementation and interpretation of the TRIPS Agreement is subject to the rules of the Vienna Convention on the Law of Treaties[75] one of which requires that treaty provisions (in this case the enforcement provisions of TRIPS) must be interpreted in light of the object and purpose of the treaty. The purpose and objective of TRIPS is not the protection of IP as an end in itself but rather to ensure that that the protection of IP rights contributes to technological innovation, the transfer and dissemination of technology and that there is a balance of benefits for producers (IP right holders) and consumers of knowledge and technology (general public, competitors etc.).[76] The implication is that the enforcement provisions should help ensure the achievement of these objectives by, among others, facilitating measures necessary to protect public health and nutrition and promote public interest in sectors of vital importance to the country and to prevent the abuse of IP by right holders as well as anti-competitive practices and measures that restrain legitimate trade.

The importance of the above considerations and parameters has been brought into sharp focus in the recent past particularly with respect to access to medicines. Two particular cases are discussed below to demonstrate the potential negative consequences of the proposed EAC Anti-Counterfeiting Policy and Bill.[77] The first case relates to border measures and international trade, in particular, the application of IP enforcement measures in a manner that interferes with the freedom of transit. The second case relates to the abuse of IP rights and enforcement procedures in the pharmaceutical sector.

[72] See para 2(c) of the Preamble to the TRIPS Agreement.
[73] Article 1.1 of the TRIPS Agreement.
[74] Article 66.1 of the TRIPS Agreement provides a longer transition period for LDCs and gives the Council for TRIPS the power to extend that transition period indefinitely in recognition of the fact that LDCs have economic, financial and administrative constraints, and that they need flexibility, including with respect to the application of enforcement provisions, to create a viable technological base. Subject to further extensions, the Council for TRIPS extended, in November 2005, the transition period for LDCs until 1 July 2013. The decision is contained in WTO document IP/C/40.
[75] See United Nations Treaty Series vol. 1155, p.331.
[76] See Article 7 of the TRIPS Agreement.
[77] The discussion in both cases are partially based on the analysis in Musungu, Sisule (2009) "The Contribution of, and Costs to, Right Holders in Enforcement, Taking into Account Recommendation 45 of the WIPO Development Agenda", WIPO document WIPO/ACE/5/10 available at http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_5/wipo_ace_5_10.pdf.

3.2.1 IP enforcement, freedom of transit and access to medicines

The idea of tackling trade in counterfeit goods while avoiding the use of IP to create barriers to legitimate international trade makes the application of IP rules and procedures at the border and in the general course of trade a particularly complex and sensitive matter. This is even more complex and controversial, when dealing with the application of such procedures to goods in transit. It should therefore be no surprise to see that much of the current discussion and debates on IP enforcement relate to border measures.[78]

The application of the European Community's (EC) Council Regulation 1383/2003 and European Customs Code, on which some of the EAC Anti-Counterfeiting Bill is modelled, to certain shipments of generic pharmaceutical has attracted special attention in recent months.[79] Similar, concerns have also been raised regarding laws such as the Kenya Anti-Counterfeiting Act of 2008, which gives customs authorities the power to seize IP infringing goods that are entering or leaving Kenya, including, ostensibly, goods in transit. At issue in cases of goods in transit is the interpretation and application of Article 51 of the TRIPS Agreement.

The question is whether the application of the provisions of this Article to goods in transit, such as in the case of the EC Regulation, constitutes a barrier to legitimate trade and a threat to development goals particularly access to medicines.[80] This question is particular important because the Draft EAC Bill, under Section 32, would give customs authorities powers "to seize and detain all goods... which are imported into or *enter the Partner State..."*[81] More specifically, the arguments turn on whether the application of Article 51 of TRIPS in the manner envisaged in EC Regulation 1383/2003 and provision such as those proposed in Section 32 of the proposed EAC Bill are contrary to the balancing safeguards under Article 41, which are meant to ensure that enforcement procedures do not create barriers to legitimate trade.

Broadly speaking there are two viewpoints on the legitimacy and balance in the application of measures such as those contained in the EC Regulation 1383/2003 to goods in transit. On

[78] Correa (2009) *supra* note 22, pp. 29- 80 at 48.

[79] 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 on the controversy regarding generic medicines see e.g., Seuba, Xavier (2009) "Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit", ICTSD, Geneva and Kumar, Shashank, "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,* forthcoming. Available on SSRN at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1383067. Also see the report by Mara, Kaitlin and William New, "Concerns Continue over Drug Seizures As Legality Debate Begins", Intellectual Property Watch, Geneva, 5 March 2009 available at http://www.ip-watch.org/weblog/2009/03/05/concerns-continue-over-generics-drug-seizures-as-legality-debates-begin/ as well as the debate and discussion on the International Economic Law and Policy Blog at http://worldtradelaw.typepad.com/ielpblog/2009/01/generic-pharmaceuticals-patent-infringement-and-freedom-of-transit-.html.

[80] Interestingly, Article 51 of the TRIPS Agreement was largely modelled on existing national laws. See UNCTAD and ICTSD; *supra* note 69, p. 609.

[81] Emphasis added.

the one hand, there are governments, such as that of Brazil and India, supported by a range of civil society organisations, industry players and commentators who argue that the application of Article 51 measures to goods in transit runs contrary to the objectives of the TRIPS Agreement. On the other hand is the EC, which argues that the application of Regulation 1383/2003 to goods in transit is consistent with TRIPS, including its objectives. This is because the TRIPS Agreement is part of the international efforts to fight counterfeit goods and the said Regulation contains the safeguards envisaged under Article 41 of TRIPS. This view of the Regulation finds support among some academics and other stakeholders.[82]

What is important in this debate for the EAC Partner States is not the differences of opinion on the implications and interpretation of the EC Regulation but the clear agreement by both sides that the application of IP enforcement measures should not negatively affect trade in legitimate goods such as generic medicines. Indeed, overall, the overriding importance of freedom of transit finds support in case law. A number of court decisions in the EC have found that IP rights subsisting in the country of transit do not apply to goods in transit. For example, in *Montex Holdings Ltd. v. Diesel SpA*[83] the European Court of Justice (ECJ) found that the provisions of the EC Directive on Trademarks (Directive 89/104/EEC) providing for the prohibition to the importation or export of goods under a trademark sign are to be:

> "[I]nterpreted as meaning that the proprietor of a trademark can prohibit the transit through a Member State in which that mark is protected of goods bearing the trademark 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 border measures similar to those contained in Regulation 1383/2003.[84] In *Eli Lilly & Company & Anor v. 8PM Chemist Ltd*[85] a three judge bench of the Court of Appeal for England and Wales, citing Montex and Class International, has recently 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."[86]

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[82] See e.g. the debate on the International Economic Law and Policy Blog, *supra* note 79.

[83] Case C-281/05. Judgment 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. There are other ECJ decisions which also address the question of the application of IP rights in the transit country to goods in transit with generally the same result including *Class International v. Colgate Palmolive,* C-405/03 [2005] ECR 1-8735.

[84] 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 intellectual property rights (OJ 1994 L 341).

[85] [2008] EWCA Civ. 24 (05 February 2008). The judgment is available at http://oami.europa.eu/pdf/natcourt/Lilly.pdf.

[86] See para 44 of the judgment.

The debate in the Council for TRIPS on EC Regulation 1383/2004 touches and/or raises similar issues as discussions in other international forums such as at the World Customs Organization (WCO)[87] and with respect to the negotiation on an Anti-Counterfeiting Trade Agreement (ACTA)[88]. At all levels, the debate reflects the inherent complexity in finding the right balance between the multiple objectives and interests recognised in the TRIPS Agreement and the challenges that national legislatures and courts face in interpreting and implementing this key TRIPS provision.

3.2.2 Abuse of IP rights, IP enforcement procedures and competition in the pharmaceutical sector

The abuse of IP enforcement procedures can result in significant negative consequences for competition, including consequences for promoting a competitive and price-efficient pharmaceutical sector. Indeed, there is already significant literature and case law that discusses the question of abuse of enforcement procedures in the context of competition or antitrust law. The United States' "Walker Process claims" is one of the most discussed concepts around abuse with respect to patent enforcement.[89] Essentially, Walker Process claims concern cases where a patentee who knowingly obtained a patent by fraud on the patent office seeks to enforce such a patent by threatening to sue a third party or the third party's customers or actually suing such a third party or their customers.[90] In the context of competition, such a patentee may be found in violation of section 2 of the Sherman Act, which prohibits monopolisation of trade or commerce.[91] This type of conduct is considered abuse and is frowned upon because it is driven by bad faith and does not promote the purposes of the patent law. A related area of abuse concerns what are called "Handgards claims" also developed in United States case law.[92] Here the issue relates to knowingly enforcing a patent that is invalid even if the patent was obtained properly and without fraud on the patent office.

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[87] See e.g., the work related to Standards Employed by Customs for Uniform Rights Enforcement (SECURE) at http://www.wcoomd.org/files/1.%20Public%20files/PDFandDocuments/Enforcement/SECURE_E.pdf.

[88] The background to ACTA and summary of the main issues under discussion as well as other information is available at http://www.ustr.gov/about-us/press-office/fact-sheets/2009/april/acta-summary-key-elements-under-discussion.

[89] The name 'Walker Process' originates from the 1965 Supreme Court decision in *Walker Process Equipment, Inc v. Food Machinery and Chemical Corp,* 382 U.S. 172 (1965) in which this doctrine was established.

[90] For a detailed discussion of the doctrine see e.g., Mathews Jr, Robert (2007) "A Primer on US Antitrust Claims Against Patentees under Walker Process", *Journal of Intellectual Property Law and Practice,* Oxford University Press. Accessible at DOI 10.1093/jiplp/jpm142. See also the discussion in Leslie, Christopher (2007) "The Role of Consumers in Walker Process Litigation", *Southwestern Journal of Law and Trade in the Americas,* Vol. 13 available on SSRN at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1070242; and in Correa, Carlos (2007) "Intellectual Property and Competition Law – Exploring Some Issues of Relevance to Developing Countries", *Issue Paper No. 21*, ICTSD, Geneva available at http://www.iprsonline.org/resources/docs/corea_Oct07.pdf.

[91] Section 2 provides that:

> "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court."

[92] The name here is derived from the case *Handgards, Inc v. Ethicon, Inc* 743, F.2d 1282 (9th. Cir. 1984).

In developing countries and LDCs, such as the EAC Partner States, the work of Prof. Correa on abuse of IP enforcement procedures and competition is particularly instructive.[93] Correa argues that there are many examples of abusive requests for interlocutory injunctions and threats to sue in Latin America which should incur antitrust liability. He cites cases in Chile, Argentina and Venezuela as examples. Without understanding and ascertaining the full magnitude of such problems, the move by the EAC Partner States to use criminal enforcement procedures should be carefully considered. It is also notable that the EAC competition framework does not provide the type of protections envisaged in the Walker Process and Handgards claims nor does the proposed EAC Anti-Counterfeiting Bill.

Beyond the situations and examples discussed above with respect to the United States and the cases that Correa cites in Latin America, the question of abuse of enforcement procedures and abuse of IP rights generally could involve quite complex strategies when examined from a competition perspective. The recent Report of the EC on the Pharmaceutical Sector Inquiry provides a particularly helpful example in this regard.[94] The Report is important because it addresses a range of issues starting with patent application stage through to litigation. Table 1 below summarises the key issues and the main relevant findings of the Report. The Report offers important insights which EAC Partner States should consider before moving forward with any Anti-Counterfeiting initiatives.

Table 1:

Summary of the Key Issues and Findings in the Report on the European Commission Pharmaceutical Sector Inquiry

Scope and key issues under the inquiry

In January 2008, concerned with the proper functioning of the pharmaceutical sector and with indications that competition in the sector might not be working well, the European Commission launched an EU-wide inquiry into the sector. The purpose of the inquiry was to examine the reasons for observed delays in the entry of generic medicines to the market and the apparent decline in innovation as measured by the number of new medicines coming to market. The inquiry concentrated on practices that may be used to block or delay generic competition as well as practices that could be used to block or delay the development of competing originator products. This means that the inquiry examined the competitive relationship between originator and generic companies as well as among originator companies. In terms of product scope, the focus was on prescriptions medicines for human use, while in terms of time, the inquiry covered the period from the year 2000 to 2007.

Main relevant findings

As already noted, the inquiry covered a range of issues from patent filing strategies through to litigation strategies. Some of the key findings relevant to the question of abuse of IP rights and/or IP enforcement procedures include the following:

- **Patent Filing Strategies:** There were clear cases where originator companies had strategies which aimed at extending the breadth and duration of their patents. Filing of numerous patents on one medicine to delay or block generic entry was a common practice. In this context, the inquiry found that some individual medicines could be protected by up to 100 product-specific patent families which could lead to up to 1,300 patents or pending applications in the EU.
- **Litigation:** There is evidence that originator companies, in some instances, considered IP litigation as

[93] Correa (2007), *supra* note 93, p.18.

[94] Sector inquiries are used in the EU to gather information in the context of applying the competition rules under Articles 81 and 82 of the EC Treaty. The text of the EC Treaty can be found at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:321E:0001:0331:EN:PDF.

signalling mechanism to deter generic entrants. In this regard, litigation strategies were found to be efficient means of creating obstacles for generic companies especially the smaller ones. It was also found that although most cases were commenced by originator companies, of the cases in which final judgement had been rendered generic companies won 62% of the times. The inquiry also notably found that in 46% of the cases where interim injunctions were entered against generic companies the final judgement or settlement went in favour of the generic companies. Finally, in cases of settlements, approximately half of the cases showed that the ability of the generic company to market was restricted.

- **Marketing authorisation:** There are cases where originator companies intervene in market authorisation procedures arguing that authorisation of generics could violate their patents. However, from the litigation reported originator companies claims were only upheld in 2% of the cases related to marketing authorisation. In terms of impact, the inquiry found that on average marketing authorisations were granted four months later in cases where there were interventions.

Source: Musungu (2009)

This case provides a reason for more dedicated discussions regarding the nature, extent and impact of abuse of IP enforcement procedures on competition and how such situation should impact on the structure of IP enforcement. The problem is not only a patent problem but also involves trademarks. For example, the combined impact and practices relating to patents and trademarks in the pharmaceutical sector can be far-reaching.

Overall, considering that existing civil and administrative enforcement procedures can be abused with such serious consequences as can be seen in the EC pharmaceutical sector, EAC Partner States need to pay close attention to the impact of the proposed policy and the Bill which would avail the IP rights holders state machinery for use in criminal cases. These countries, which have expressed a keen interest in developing regional manufacturing capacities in the pharmaceutical sector, may therefore, by adopting a law on counterfeiting as currently proposed, pose a serious threat to not only this industry but others such as in agricultural chemicals.

3.3 The evidence base for the EAC Anti-Counterfeiting Policy and Bill and the implications for access to medicines

IP rights issues relate to, and are described using numerous terminologies and concepts. The area covers many controversial issues that are linked to different disciplines, in science, technology, economics, law and other fields. The field is enriched by contributions from different jurisdictions and the practice or practices in industries. The concepts and main issues in the field are also approached from different perspectives and with different political and economic agendas, sometimes in a misleading context, and often, in imprecise manner. It is for this reason that critically examining the evidentiary basis and justification of any IP related policy initiatives, such as the EAC Anti-Counterfeiting Policy, is critical.

The EAC Anti-Counterfeiting Policy, and consequently the EAC Anti-Counterfeit Bill, are justified on the basis of a range of assumptions and statements enumerated in Section 3 of the Policy titled “The Impact of Counterfeiting, Piracy and other Violations”. As the analysis in this sub-section will demonstrate these assumptions and statements are not supported by strong evidence. The statements also fail to take into account and/or acknowledge the

complexity of the relationship between IP, development, access to medicines and a range of other sectors, including education and agriculture.

It is beyond the scope of this analysis to engage with each and every fallacious assumption or statement in the 60 plus page policy document. However, it is worth, briefly commenting on a number of these assumptions and statements to demonstrate why these constitute incomplete evidence on which to base a policy with extensive implications for the health of the populations of the EAC Partner States as well as the overall development of the region.

3.3.1 IP enforcement and health and safety

In sections 3.1 and 3.4.6 the EAC Anti-Counterfeiting Policy makes a range of claims regarding the public health and safety consequences of "counterfeit" products. In the context of the IP-based framing of the Policy, the suggestion is that the protection and enforcement of IP rights automatically ensures quality and safety. This suggestion is erroneous and dangerous.

First, the grant of IP titles, such as patents and trademarks and the acquisition of copyright over a particular work in no way signify the quality and safety of any product. Equally the bodies or authorities that deal with safety and quality of products are invariably different from those dealing with the grant and administration of IP. The safety of products, including products over which IP rights are conferred, can only be confirmed through quality testing and market surveillance. This is particularly important with respect to medicines since quality and safety problems with medicines may relate to fake products or sub-standard products.[95]

On the one hand, fake medicines or what are commonly referred to as counterfeit medicines, relate to what the WHO Secretariat considers to be "deliberately and fraudulently mislabelled with respect to identity and/or source".[96] As already noted, the WHO Secretariat makes it clear that this is a problem that affects both brand and generic medicines. On the other hand, are sub-standard medicines which, according to the WHO, are genuine products which do not meet quality specifications set for them. There are four important points that emerge when one distinguishes the differences between fake medicines (commonly referred to as counterfeit medicines) and sub-standard medicines. None of these points appear to have been considered in the Policy or taken into account in drafting the Bill.

The first key point is that there are different causes/reasons for fake and sub-standard medicines and there are different solutions for addressing the problem. The second point is that both fake and sub-standard medicines are a health hazard and require dedicated efforts to tackle. The third point as emphasised by WHO is that fake (counterfeit) medicines

[95] For a detailed discussion of the differences between fake and substandard products and the key causes of quality problems in developing countries and LDCs such as those in the EAC, see Caudron, J.M., Ford, N., Henkens, M., Mace, C., Kiddle-Monroe, R., and J Pinel (2008) "Substandard Medicines in Resource-Poor Settings: A Problem that can no Longer be Ignored", *Journal of Tropical Medicine and International Health,* Vol. 13, No. 8, pp. 1062 – 1072.

[96] See WHO Technical Series 937 on a model for quality assurance system for procurement agencies.

affect both brand (patented) and generic products suggesting that the determining factor is not whether an IP right exists over the product or not. Finally, because sub-standard products relate to what are considered "genuine" products, an IP enforcement-based approach to medicines quality is likely to result in totally ignoring this major problem. The latter point is particularly important in considering the approach taken in the EAC Anti-Counterfeiting Policy and Bill.

While the number of studies looking at fake and sub-standard medicines as distinct problems remains limited, the few that have done so have found that, except in a few cases such as Malaria medicines, the majority of the quality problems relate to the sub-standard question.[97] Consequently, an approach that fails to focus on the sub-standard problem does not reflect the reality of the needs on the ground. This approach is also dangerous to the health and safety of the EAC Partner States citizens as it is likely to divert resources that would have been used by health regulatory authorities to tackle a major problem to IP enforcement.

In the case of fake (counterfeit) medicines the failure by the drafters of the EAC Anti-Counterfeiting Policy and Bill to analyse the workings of the extensive regulatory framework (discussed in section 2 of this paper) at the regional level and in each of the EAC Partner States suggests that the policy conclusions and proposals regarding how to tackle fake medicines are uninformed.

3.3.2 IP enforcement, government revenue, economic growth and trade

The proposed Policy makes a number of claims relating to the relationship between 'counterfeiting' and government revenue (section 3.3.1), economic growth (section 3.4.1) and trade (section 3.4.4). The information and data used to support these claims essentially come from the International Chamber of Commerce (ICC). This is the data generated under the latter's lobbying programme "the Business Action to Stop Counterfeiting and Piracy" (BASCAP).[98] There are other industries initiatives which also generate lobbying data including the Business Software Alliance's (BSA) Global Anti-piracy Portal[99], the work of the International Trademark Association (INTA)[100] and the work of national groups such as the Recording Industry Association of America (RIAA).[101]

The overall assumption underlying the industry data, which is reflected in the EAC Anti-Counterfeiting Policy, is that the protection of IP and more enforcement automatically leads to economic growth, increased government revenue and trade. This assumptions, however, is contradicted by a number of expert studies and analyses. In a recent review of studies and methodologies used to generate data on counterfeiting and copyright piracy, Fink, for example, concludes, among other things, that the estimates by industry associations

[97] See e.g., Caudron *et al., supra* note 95.
[98] Information about BASCAP and its work is available at http://www.bascap.com/.
[99] Information available at http://www.bsa.org/Piracy%20Portal.aspx.
[100] Information available at http://www.inta.org/index.php.
[101] See website at http://www.riaa.com/.

representing the copyright holders rely on "questionable assumptions about market demand."[102] He also observes that:

> "[T]he economic effects of IPRs violations depend critically on the types of IPRs involved and the underlying market characteristics. In developing an IPRs enforcement strategy, policymakers would thus benefit from empirical guidance on how producer, consumer and economy-wide welfare will cope under alternative enforcement policies.

By relying on questionable assumptions and assuming, without any real evidence, causality between IP, economic growth and trade, the proposed EAC Anti-Counterfeiting Policy, if adopted, would likely deny the EAC Partner States the opportunity to make informed policy decisions. All in all, while some of the industry and other data on IP enforcement might provide important insights, it is highly problematic to unquestionably rely on such data to create an expensive legal system particularly in countries such as the EAC Partner States.

3.3.3 IP enforcement and innovation in the pharmaceutical sector

In general, since the early 1990s patenting has accelerated rapidly in most technology areas. The same is true with respect to trademarks. However, the use of the patent and trademark systems remains highly concentrated in developed countries. For example, the latest WIPO statistics show that while developing countries make up over 78% of the membership of the Patent Cooperation Treaty (PCT), they only accounted for 14% of the total number of patent filings in 2009 (with China and the Republic of Korea accounting for 10%).[103] And even among developing countries, though the overall number of patent filings by residents of these countries, has been increasing, the increase is also highly concentrated among a few emerging economies.[104]

In addition to the concentration of patent ownership, which virtually leaves out small countries such as those in the EAC, actual impact of patenting in sectors such as pharmaceutical varies significantly across countries. In developing countries and LDCs the role of IP in supporting innovation and R&D especially into diseases which mainly affect these countries has been found to be negligible. Indeed, as the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) has observed "where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market."[105] It is on the basis of this empirical finding and other studies that the 192 Member States of the WHO adopted, in 2008, the Global Strategy with the aim of promoting new thinking on innovation and access to medicines.

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[102] Fink, *supra* note 22, p. 13.

[103] See WIPO (2009) "International Patent Filings Dip in 2009 amid Global Economic Downturn" available at http://www.wipo.int/pressroom/en/articles/2010/article_0003.html.

[104] According to WIPO the largest number of international applications received from developing countries in 2009 came from the Republic of Korea (8,066) and China (7,946) followed by India (761), Singapore (594), Brazil (480), South Africa (389), Turkey (371), Malaysia, (218), Mexico (185) and Barbados (96).

[105] CIPIH (2006) *Public Health, Innovation and Intellectual Property Rights,* WHO, Geneva, p.22.

The above shows that the claims on innovation and competition in the proposed EAC Anti-Counterfeiting Policy (section 3.4.7) may not apply with respect to innovation in the pharmaceutical sector of the EAC Partner States and may also lead to measures which jeopardise the on-going efforts by the Sectoral Council of Ministers of Health to improve innovative capacities and local production of pharmaceuticals.

3.4 Cost-benefit analysis of the EAC Anti-Counterfeiting Policy and Bill

It is critical, before adopting any IP enforcement policies and laws, as would be the case with any other policy or law, that the potential costs and benefits be clearly understood. This is particularly the case for countries which have limited resources such as the EAC Partner States. This explains why the WIPO Development Agenda gives particular importance to the issue of cost-benefit analysis in the area of IP. In particular, WIPO Member States have agreed that norm-setting activities, such as the EAC Anti-Counterfeiting initiatives have to take into account "a balance between the costs and benefits."[106]

As already noted, the EAC Anti-Counterfeiting Policy and Bill seek to establish an extensive IP enforcement structure including the establishment of a regional and national enforcement agencies and special judicial officers. The costs for establishing this new framework will be in addition to the costs that EAC Partner States are already incurring in implementing their onerous obligations under the TRIPS Agreement. Apart from the costs incurred by government administrations, it is also important to remember that there will be important costs incurred by business and other sectors in terms of adjusting practices, training, litigation etc.

It is therefore obvious that although it is difficult to be definitive about the cost of implementing the proposed Policy and Bill, these costs are likely to be substantial. As is clear, from the preceding analysis, however, the benefits of the proposals are unproven. For health policymakers and other stakeholders in other development sectors there is therefore an important question regarding the implications of this proposed policy on resource allocation. The substantial cost requirements for implementing the proposed policy and Bill are likely to impact on the available resources for health and access to medicines as well as financing for education, including training for health workers and scientists for the pharmaceutical sector.

4. Policy Recommendations

The proposed EAC Anti-Counterfeiting Policy and Bill contain several potentially negative consequences for access to medicines in the EAC Partner States as well to the development of other vital sectors of the Partner States, such as food production. The potential for these negative consequences is particularly heighted because the proposed Policy and Bill have been developed on the basis of one sided evidentiary basis, shallow analysis and without taking into account important public health, access to medicines and other development concerns and implications. Equally, the policy proposals find limited support in studies on IP

[106] See Recommendation 15 of the WIPO Development Agenda. Available at http://www.wipo.int/ip-development/en/agenda/recommendations.html.

and development. The unavoidable conclusion is that the EAC Partner States should not adopt the proposed Anti-Counterfeiting Policy nor enact the Anti-Counterfeiting Bill as currently proposed.

Recognising that the EAC Partner States are committed to both ensuring quality products in the Common Market and to working towards effective IP protection consistent with their development levels and goals, it is recommended, before moving forward with any anti-counterfeiting initiative, that in order to ensure that any IP enforcement measures do not negatively affect access to medicines or comprise development in the region, the EAC Partner States should:

- Undertake more rigorous research, analysis and evidence gathering with respect to the problem of fake or sub-standard products and a complete review of the existing policy and legal framework for addressing these problems in different sectors so us to identify any gaps that need to be addressed. As shown in section 2 of this discussion paper there is an extensive legal and policy framework in the area of public health, including criminal enforcement measures, which was not considered at all in the proposed Policy.
- On the basis of better evidence, analysis and understanding of the existing legal framework, consider if a policy, such as the one currently proposed for the enforcement of IP rights, would address the core problems relating to the existence of fake and/or sub-standard products in the Common Market.
- On the basis of better evidence, analysis and understanding of the existing legal framework, undertake a cost-benefit analysis of the proposed anti-counterfeiting measures taking into account the objectives set out in Article 5 of the Treaty establishing the EAC particularly the objective to ensure equitable economic development within the Partner States and raise the standard of living and improve the quality of life.
- Enhance their understanding of the role of, and impact, of IP protection and enforcement in different sectors of the economy and society especially the importance of balanced and equitable enforcement taking into account international discussions and developments such as those outlined in the executive summary to this discussion paper.
- Consider more seriously the impact of the proposed measures on the various regional and national efforts to use TRIPS flexibilities to promote access to essential medicines as well as local innovation and production capacities in the pharmaceutical sector.
- Engage a broader group of stakeholders in consultations and evidence gathering beyond the narrow set of industry players whose views disproportionately shaped the current drafts of the Policy and Bill. The fundamental factors to consider also need to go beyond improving investment environment to include broader industrial policy, technology, science, health, food security and education parameters.