

THE IMPACT OF PHARMACEUTICAL PATENTS ON HEALTH  
EXPENDITURES IN LEAST-DEVELOPED COUNTRIES

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*The article critiques the Access to Essential Medicines campaign concerning the negative impact of pharmaceutical patents on health expenditures and drug prices in Least-Developed Countries (LDCs). The article adheres to the 1999 revision of the Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property, 1977 [Hereinafter, the Bangui Agreement]. The agreement done at Bangui, Republic of Central Africa on March 2, 1977 and revised in 1999, came into effect on 28 February 2002 binding seventeen western and central French-speaking countries known as Francophone Africa.*

*The 1999 revision of the Bangui agreement was made in response to the establishment of the World Trade Organization (WTO) and the signing of the Pax American 1994 Trade Related Aspects of Intellectual Property Rights (TRIPS). In acquiescence, the revised Bangui agreement strengthens the rights of patent holders. By so doing, LDCs adhering to the Bangui agreement effectively waived their right for a transition period defined in Article 66.1 to the TRIPS agreement. The transition period otherwise delays certain obligations with respect to pharmaceutical products until 1 January 2016.*

*As a consequence, the article analyzes the impact of strong pharmaceutical patent protection over LDCs adhering to the Bangui agreement in comparison with two other LDC country groups. These are LDCs which do not adhere to the agreement in Africa (non-Bangui African) and in Asia, central America and the Middle East (non-Bangui non-African).*

*The article then makes three assertions for the time series of 1995-2011. At a start, Total health expenditure (THE) rates in Bangui LDCs remain constant in comparison with non-Bangui LDCs between 1995-2011 and indifferent to pharmaceutical patents after 2002. A second conclusion follows. Bangui LDCs show similar time slope patterns over health expenditure rates in comparison with non-Bangui LDCs after 2002 in the main four expenditure sub-categories. Last of all, Bangui LDCs show similar ratio of means of health expenditure rates in comparison with non-Bangui LDCs between 1995, 2002 (the year when the Bangui Agreement came into effect) and 2011.*

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INTRODUCTION

Over the years, the role that intellectual property play in the development of and access to medicine has be examined extensively. The importance of patents to pharmaceutical innovation has been demonstrated by numerous economists and policymakers. The usual explanation of why patents are more important to pharmaceutical firms in appropriating benefit from innovation directly flows from the characteristics of the pharmaceutical R&D process. It is often said, as is asserted by Duke University economist Henry Grabowski<sup>1</sup>, that it takes several hundred million dollars to discover, develop, and gain regulatory approval for a

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<sup>1</sup>Henry Grabowski, Patents, Innovation, and Access to New Pharmaceuticals, Journal of International Economic Law (2002) pp849 – 860, <http://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/6707/Record5.pdf?sequence=1>

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new medicine. Absent patent protection, or some other form of protection, imitation could free-ride on the innovator's regulatory approval and duplicate the compound for a small fraction of the originator's costs. It is said that imitation costs in the pharmaceutical industry are extremely low relative to those incurred by the innovator to discover, develop, and gain regulatory approval. On his part, Grabowski considered the role that intellectual property plays in the development of and access to new pharmaceuticals. He concludes that there is a strong association between patents and R&D investment, and that patents offer a significant incentive for innovation of new drugs. He notes that the patent system has played a critical role in incentivizing R&D investments for global diseases such as HIV/AIDS.

Nonetheless, the impact of patents and other forms of IPRs on access to pharmaceuticals, especially drugs, has been a subject of much debate. The traditional and dominant view on this subject is that pharmaceutical patents, indeed strong protection of pharmaceutical patents, negatively affects access to medicines in the poorest parts of Africa, Caribbean and Asia. In the same regard, conventional wisdom has assumed that drugs patented in Europe or North America must also be patented in developing and LDC countries, or that a lack of generic competition and high retail prices (sometimes in excess of those charged in developed countries) in these countries are prima facie evidence of patents. For Grabowski, patented drugs have a comparatively higher prices which can serve as an additional barrier to many individuals in poor countries from gaining access to new medicine. But, he observes that more than 90% of the drugs on the World Health Organization's List of Essential Medicines are not patent protected, and are sold at comparatively low prices.<sup>2</sup>

On his part, Georgetown University professor Jayashree Watal<sup>3</sup> considered the price differences of medicine on account of patents. He notes that there are few reliable estimates of differences in prices of medicines in developing countries, on account of patents alone. He observes that a simple and appealing methodology often used is inter-country comparisons of drugs of similar composition and presentation. As he explains, such comparisons are clearly faulty as without more information one cannot attribute the differences to the presence or absence of patents alone. Even price comparisons between countries at similar levels of economic development only give a partial picture. On the other hand, he asserts that the more meaningful study would be of the effects of generic entry on drugs coming off patent, for which of course, data is not yet available in these countries. Through a simulation study for the Indian pharmaceutical market, he shows that, controlling for substitutes - considerably significant and rapid price decreases with generic entry upon patent expiry. The price increase on account of product patents alone could be as high as about 250% under certain assumptions. The indication is that where generic drugs are blocked from entry into a market, through patents for

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<sup>2</sup>Grabowski, supra, p856.

<sup>3</sup>Jayashree Watal, Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?, Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA, [http://www.iatp.org/files/Access\\_to\\_Essential\\_Medicines\\_in\\_Developing\\_Co.pdf](http://www.iatp.org/files/Access_to_Essential_Medicines_in_Developing_Co.pdf).

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instance, drug prices will remain high with negative implications on access to drugs among the poor.

This traditional view is possibly best captured in the work of the preceding director of the Médecins sans Frontières Ellen Hoen,<sup>4</sup> which interrogated the link between patents, high drug prices, and access to medicine in developing countries. She noted that the reasons for the lack of access to essential medicines are manifold. Unavailability can be caused by logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices. Yet as Hoen explains, in many cases, the high prices of drugs remains the major barrier to needed treatments. Crucially, prohibitive drug prices are often the result of strong intellectual property protection. Hoen authored her work during the early days of the implementation of the TRIPS Agreement in developing countries. In this regard, she opines that the expected result of the implementation of TRIPS is a further upward effect on drug prices, thus negatively affecting access to medicine in these countries. Within this context, she notes that Médecins sans Frontières together with other non-governmental organizations formulated several concerns related to TRIPS, among which are that: (i) increased patent protection leads to higher drug prices; (ii) the number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices. As a result, the access gap between developed and developing countries will widen; and (iii) enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend.<sup>5</sup> It is apparent that the question remains whether these concerns have been realized, considering that its now almost two decades since the TRIPS Agreement came into force.

Within the same context, the impact of the TRIPS Agreement on access to medicine in poor countries has received a lot of attention among academic experts, policy makers, and non-governmental organizations. So much so, at the cutting edge of the global campaigning and debates that have accompanied the globalization of intellectual property-related trade. The recurring theme is that the TRIPS Agreement, in providing for strong protection of patents and other IPRs, will make medicine inaccessible among the poor. Noticeably, Scheler and Watal<sup>6</sup> explore the tension between granting patent protection under the TRIPS Agreements and the availability of medicines at affordable prices to developing countries. They note that the best multinational drug pricing strategy combines equity with coverage of R&D costs. They note that this strategy is a variant of Ramsey pricing, under which prices are much lower in nations with low ability to

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<sup>4</sup>Ellen F. M. 't Hoen, TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond.

Economics of AIDS and Access to Health Care, <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf>

<sup>5</sup>Ibid, p p42.

<sup>6</sup>F. M. Scherer & Jayashree Watal, Post-TRIPS Options for Access to Patented Medicines in Developing Nations, *Journal of International Economic Law* Volume 5, Issue 4, Pp. 913-939, available on <http://jiel.oxfordjournals.org/content/5/4/913.short>

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pay and/or high price elasticities of demand than in wealthy nations. Based on statistical evidence on the prices of 15 AIDS drugs in 18 low- and medium-income nations, they show that tendencies toward Ramsey pricing of drugs were at best weak. The indication is that flexibilities under TRIPS, especially compulsory licensing, have not enhanced the supply of drugs in low income nations. The indication is further that parallel importation under TRIPS discourages Ramsey pricing, with a negative effect on the supply of drugs in poor countries. Thus, they suggest that, in fact, parallel imports under TRIPS should be barred from low income countries in order to encourage the Ramsey pricing so as to increase accessibility of drugs in these countries.

On TRIPS, Executive Director of the Geneva-based Drugs for Neglected Diseases initiative (DNDi) Bernard Pécoul and others,<sup>7</sup> examined the potential negative consequences of TRIPS on the availability of old and new drugs in poor countries. They note that, besides antiretrovirals for treatments of people with AIDS, there are many examples of existing drugs that are simply not affordable, largely because they are still patent protected. They further note that the enforcement of TRIPS with regard to the pharmaceutical sector raises certain doubts and concerns. It is argued that perhaps the most important provisions in TRIPS for pharmaceutical products in developing countries are: (a) those whose purpose is to put an end to protectionist measures; and (b) those which define as mandatory the protection of patents on drugs and their respective manufacturing processes. In this context, they argue that enforcing TRIPS will remove a source of affordable copies of innovative quality drugs upon which the poorest countries depend.

Based on the strength of results from his simulation study on the Indian market, Watal<sup>8</sup> makes an observation that TRIPS requires the availability of product and process patents for pharmaceuticals virtually from 1995, dramatically changing patent laws in developing countries that earlier allowed such exclusions. He then makes an argument that this change will, almost certainly, lead to higher prices up to about 200-300% for patented medicines, including for important diseases such as HIV/AIDS, in countries where such patents are valid. Thus, he suggests that there are policy instruments available under TRIPS such as compulsory licenses or government use, parallel imports and price controls that could attenuate such adverse effects on the affordable access to medicines considered essential. The suggestion is that where the intellectual property regime of a country blocks usage of these policy instruments, the supposed adverse effects of TRIPS, in limiting access to medicine, will be fully felt.

With all of that said, the view that patents hinder access to medicines has not gone unchallenged. Over time, several studies have suggested that patents are not the reason for lack of access to medicine among the poor in developing. One of the major works that offered this challenging view was done by Canadian law professor

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<sup>7</sup>Bernard Pécoul (et al), Access to Essential Drugs in Poor Countries A Lost Battle?, The Journal of American Medical Association, January 27, 1999, Vol 281, No. 4, <http://www.msfaccess.org/content/access-essential-drugs-poor-countries-lost-battle>

<sup>8</sup>Watal, supra, p5

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Amir Attaran.<sup>9</sup> He empirically examined the link between patents in developing countries and access to medicines for 319 medicines and medical products from the WHO's list of essential medicines. In this study, he shows that in developing countries, patent protection exists for less than 2% of these products and does not hinder access to these medicines in these countries.

In another provocative study,<sup>10</sup> Attaran and Gillespie-White considered the role of intellectual property law - specifically, patents - in the creation of monopolies that keep drugs inaccessible or unaffordable. They examined the current relationship between patents and antiretroviral drug access. They tested the hypothesis that patents are a leading barrier to widespread AIDS treatment in Africa by considering data on whether patents for antiretroviral drugs exist on the continent. In this study, they screened a total of 15 antiretroviral drugs patented by 8 pharmaceutical companies for patent status in 53 African countries. This study demonstrates that patent protection for antiretroviral drugs in Africa is not extensive. The study considered the question why there are not more antiretroviral drug patents in Africa. It contends that it is not simply because the option to patent has been lacking. Although the laws of some African countries do not permit pharmaceutical patents, or did not when applications to patent these antiretroviral drugs were filed, most have allowed pharmaceutical patents for years. The 15 member countries of the African Intellectual Property Organization (Organisation Africaine de la Propriété Intellectuelle (OAPI)) have offered a system of pharmaceutical product and process patents since the Bangui Agreement of 1977.

Similarly, pharmaceutical patent protection has been available in most of the 15 Anglophone countries of ARIPO since at least 1984. It is the contention of the study that it is doubtful that patents are to blame for the lack of access to antiretroviral drug treatment in most African countries. Though conventional wisdom has spuriously assumed that drugs patented in Europe or North America must also be patented in Africa, or that a lack of generic competition and high retail prices (sometimes in excess of those charged in developed countries) are prima facie evidence of patents, the study shows that they are not. The conclusion is that there is no apparent correlation between access to antiretroviral treatment, which is uniformly poor across Africa, and patent status, which varies extensively by country and drug.

The observations made in the study by Attaran and Gillespie-White have been challenged among those who are convinced that patents are a barrier to access to medicine among the poor in LDCs and other developing countries. For instance, the study by professor Jillian Clare Cohen-Kohler et al<sup>11</sup> considers TRIPS as

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<sup>9</sup>Attaran, How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries? 23(3), Health Affairs, 155 (2004)

<sup>10</sup> A. Attaran & L Gillespie-White, Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? J. Am. Med. Assoc. 286(15) 1886 (2001) (few African countries patented the reviewed 15 antiretroviral drugs among 53 African countries)

<sup>11</sup>Jillian Clare Cohen Kohler, et al., Addressing Legal And Political Barriers To Global Pharmaceutical Access: Options For Remediating The Impact Of The Agreement On Trade-Related Aspects Of Intellectual Property Rights (TRIPS) And The Imposition Of TRIPS-Plus Standards, [http://journals.cambridge.org/download.php?file=%2F852\\_9FBEB89045595A4CD987C4282D9EE014\\_journals\\_\\_HEP\\_HEP3\\_03\\_S1744133108004477a.pdf&cover=Y&code=8476d89545f3db221e3a1a9fe14560df](http://journals.cambridge.org/download.php?file=%2F852_9FBEB89045595A4CD987C4282D9EE014_journals__HEP_HEP3_03_S1744133108004477a.pdf&cover=Y&code=8476d89545f3db221e3a1a9fe14560df)

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representing a major legal and political constraint preventing implementation of coordinated global policy solutions to the problem of the global drug gap. The study maintains that the TRIPS agreement effectively creates extended barriers to market entry for generics, both through the requirement of 20-year patents, as well as its provisions on exclusive marketing rights and data protection. The conclusion is that this has negative consequences for drug costs, given the proven impact of generic competition on price. The study maintains that pharmaceutical product prices fall sharply when generic entry occurs following the expiration of patents. In making such a conclusion, the study faults Attaran's argument and states that Attaran's study fails to account for the disproportionate patenting of medicines in South Africa, where 13 of 15 ARV had been patented. It is observed that in South Africa, patents are a barrier to ARV access. It is maintained that this anomaly is not insignificant, since South Africa is a relatively wealthy middle income developing country with a developed generic industry, capable of supplying many African countries where patents have not been taken out.<sup>12</sup> Patents in potential supplier countries can allow the patentee to prevent supplies from being exported to poorer neighbors (i.e., those without domestic manufacturing capacity), particularly through controls on distribution channels. Drug pricing (sustained by patents in key producing and exporting countries) can be a considerable constraint on access in poor countries.

The fault in Attaran's argument has also been a subject of comment in a study by medical coordinator of Médecins Sans Frontières Eric Goemaere and others<sup>13</sup>. This study asserts that the study by Attaran & Gillespie-White is erroneous, for the reason that all countries are not equal. It is observed that drug companies tend not to patent in countries that lack market potential or manufacturing capacity. It is maintained that it is not surprisingly, in South Africa, which has manufacturing potential for domestic use and regional export, more than 95 percent of antiretrovirals (ARVs) are patented. The conclusion is that it only takes patents in a few key markets for patents to be a problem everywhere. It is further observed that all medicines are not equal. Just a few expensive patented medicines can skew entire treatment budgets.

The abovementioned anti-patent dialectics has been systematically funneled by ample policy concerning aimed at combating archetypical inequitable access to essential medicine. As part of this effort to ensure access to medicine, the World Health Organization (WHO) created a Model List of Essential Drugs. This model list provides a limited range of carefully selected essential medicines for purposes of better health care, better drug management, and lower costs. Several studies have considered the patent status of drugs on this list, as part of the analysis on whether patents have a positive impact on the cost of (essential) drugs. According to a study carried out by Richard Laing,<sup>14</sup> Many countries especially, LDCs, have no evidence of patent activity for medicines added to the essential medicines list. Besides, for

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<sup>12</sup>Jillian Clare Cohen Kohler, *supra*, p232.

<sup>13</sup>Eric Goemaere (et al), Patent Status Matters, Health Affairs, <http://content.healthaffairs.org/content/23/5/279.2.full>

<sup>14</sup>Richard Laing, The Patent Status Of Medicines On The WHO Model List Of Essential Medicines, WHO/WTO/WIPO Technical Symposium February 2011, [http://www.wto.org/english/tratop\\_e/trips\\_e/techsymp\\_feb11\\_e/laing\\_18.2.11\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/techsymp_feb11_e/laing_18.2.11_e.pdf)

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those countries where patents have been identified, these may not be valid, may be expired, and may not be relevant. The study concludes that at present, patents do not appear to be a major barrier to access to essential medicines on the WHO Model List in Low and Middle Income Countries.

Furthermore, the changes in the WHO Essential Medicines List to find out if the list has grown, or whether it now includes new clinical entities, have been a subject of analysis. A study by Laing<sup>15</sup> considered new clinical entities on the list. The study established that an analysis of the six lists produced between 1977 and 1990 shows an increase in the number of items from 205 to 268. It found out that 120 drugs have been added and 57 deleted. Crucially, it established that only 16 of the additional drugs can be considered new clinical entities or to have new indications. This clearly indicates that the list contains both old and new medicines. Considering that patent status is not one of the criteria for selecting medicines onto that list, but that the criteria include comparative cost-effectiveness, Laing's study would indicate that patents are not the reason for lack of access to medicine in LDCs and other developing countries.

It is notable that most of the literature on this subject proceed based on a theoretical, not empirical, analysis. Most of this literature does not provide empirical evidence linking patents to lack of access to medicine in poor countries. Though Attaran's study has been subject of criticism, it is apparent that the thesis is largely valid. It suffices to note that the study proceeds on an empirical analysis. Arguably, this is an opportune time to re-assess Attaran's thesis within the context of the extensions for LDCs under TRIPS' Article 66.1 in order to find out if patents have negatively affected access to medicine in those LDCs under the Bangui Agreement which have been prevented from enjoying those extensions. More importantly, Attaran's study cautions that it would be wrong to cite it as proof that patents never affect access to medicines - that conclusion, it is suggested, would require research well beyond antiretrovirals in Africa. It is apparent that Attaran is critiqued for a claim he scarcely made. His claim is limited to the role of patents in access to antiretroviral drugs in Africa, not all drugs in all LDCs everywhere. This provides an opportunity for an empirical research to find out if patents do in fact affect access to medicines in LDCs, beyond antiretrovirals in Africa as such.

What is also notable about most of the literature reviewed is that it focuses on the impact of patents on access to medicine in general terms. The focus is not on the effect of patents on health expenditure (especially on the amount of money spent on procuring drugs) in LDCs. Observably, access to medicine is a wide concept capable of having several meanings. It could mean 'physical availability', or 'affordability'. For the WHO, access to treatment is heavily dependent on the availability of affordable medicines.<sup>16</sup> As such, it is pertinent to specifically focus on the effect of patent on the cost of medicine. It is for this reason that this study proceeds to empirically research on the question whether patent affect health expenditure as an indicator of determining whether patents affect affordability of medicine.

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<sup>15</sup>Howard & Laing, Changes in the World health Organization Essential Drug List, Lancet 338 (1991) (16 out of 238 essential drugs (6.7%) are New Clinical Entities (NCEs))

<sup>16</sup>WHO, Access to Medicines, <http://www.who.int/trade/glossary/story002/en/>



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## I. THE STATUTORY FRAMEWORK

### A) *Of Least-Developed Countries (LDCs)*

Within the system of the World Trade Organization (WTO), countries are recognised as Least-Developed Countries (LDCs) if they have been listed as such by the UN.<sup>17</sup> Accordingly, the WTO system currently recognises 49 countries as LDCs as listed by the UN. Out of these 49 countries, 34 have become members of the WTO to date. Nine more LDCs are negotiating to join the WTO. These are: Afghanistan, Bhutan, Comoros, Equatorial Guinea, Ethiopia, Liberia, Sao Tomé & Príncipe, Sudan and Yemen. Notably, some LDCs (such as Senegal) were already WTO members before they were recognised as LDC under the UN. But, the majority of LDCs were already recognised as such by the UN before they became WTO members.<sup>18</sup>

It is notable that the UN generally created a norm of special treatment of LDCs.<sup>19</sup> This norm has spread to other agencies, especially the WTO where its institutionalization is particularly evident in the TRIPS Agreement. The TRIPS Agreement recognises the particular concerns and needs of LDCs when it comes to the IP system. In particular, TRIPS' Article 66.1 granted LDC Members a renewable ten-year transition period from most obligations under the TRIPS Agreement in view of their special needs and requirements, including their economic, financial and administrative constraints and their need for flexibility to create a viable technological base. This LDC transition period was originally set to expire on 31 December 2005. However, a TRIPS Council decision of 27 June 2002<sup>20</sup> extended the 2005 transition period until 1 January 2016 in relation to pharmaceutical patents. A separate 8 July 2002 General Council's decision<sup>21</sup> suspended the obligation of LDC Members under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products until 1 January 2016. Without prejudice to this pharmaceutical related extension, the TRIPS Council<sup>22</sup> further extended the general TRIPS compliance transition period for LDC Members for all obligations under the TRIPS Agreement, other than Articles 3, 4 and 5, until 1 July 2013 or until such date on which a Member ceases to be an LDC, whichever date is

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<sup>17</sup>[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm)

<sup>18</sup> See Appendix A, *infra*.

<sup>19</sup>Helen Hawthorne, *Least Developed Countries and the WTO: Special Treatment in Trade*, (Palgrave Macmillan, 2013), available [http://books.google.co.il/books?id=GaPHPvhi6ssC&pg=PA69&lpg=PA69&dq=LDCs,+WHO&source=bl&ots=2q\\_QZwkVAA&sig=mJOxaTivXKKWU1JKN9DOXWScVAs&hl=en&sa=X&ei=jgu4Uu\\_OGYmbtQbavIHQDg&](http://books.google.co.il/books?id=GaPHPvhi6ssC&pg=PA69&lpg=PA69&dq=LDCs,+WHO&source=bl&ots=2q_QZwkVAA&sig=mJOxaTivXKKWU1JKN9DOXWScVAs&hl=en&sa=X&ei=jgu4Uu_OGYmbtQbavIHQDg&)

<sup>20</sup>WTO TRIPS Council, "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products", 1 July 2002, IP/C/25, available on [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).

<sup>21</sup>WTO General Council, "Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products", Decision of 8 July 2002, WT/L/478, available on [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm)

<sup>22</sup>WTO Council for Trips, "Extension Of The Transition Period Under Article 66.1 For Least-Developed Country Members", 30 November 2005, IP/C/40, available on [http://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/7\\_1\\_ipc40\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf)

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earlier. In March 2013, the transition period was further extended to 2021.<sup>23</sup> Looking at the literature, it is apparent that the expectation is that the suspension of obligations of LDCs under these transitions with respect to protection of IP, especially in relation to pharmaceutical patents, will translate into an increased access to medicine, or reduced expenditure on health, in LDCs.

Theoretically, all WTO LDC members are entitled to enjoy the supposed benefits of the extensions (and the rights under the Doha Declaration). It is apparent, however, that LDCs in Francophone Africa are excluded from enjoying those benefits as a result of the effects of the Bangui Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property (Bangui, Central African Republic, March 2, 1977),<sup>24</sup> widely referred to as the Bangui Agreement. Adopted on 2<sup>nd</sup> March 1977, the Bangui Agreement established OAPI as the organization that ensures the protection of IPRs in the member countries. Currently, OAPI consists of 17 member states.<sup>25</sup> According to the TRIPS' classification, our of these countries belong to the group of 'developing countries',<sup>26</sup> and thirteen to that of LDCs.<sup>27</sup> The OAPI is responsible for the application in the member states of joint administrative procedures resulting from a uniform regime of intellectual property protection. In particular, it is responsible for the granting of patents which, through regional extension, automatically take effect in all member states. Principally, the Bangui Agreement acts as a common code of IPRs as the principles and provisions of the Agreement have the force of national laws in each Member State.<sup>28</sup> One of the key feature of the Agreement was the provision for a centralised procedure at the level of OAPI for the registration of patents (and other forms of IPRs). Notably, the Bangui Agreement of 1977 implicitly recognised patents on pharmaceutical products, as no distinction was made between patents on drugs and those on other products.<sup>29</sup>

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<sup>23</sup>

<sup>24</sup>[www.wipo.int/wipolex/en/.../details.jsp?...id](http://www.wipo.int/wipolex/en/.../details.jsp?...id), accessed on 20/02/2014.

<sup>25</sup>These are: Cameroon, Comoros, Gabon, Senegal, Ivory Coast, Mali, Equatorial Guinea, Chad, Burkina Faso, Mauritania, Guinea, Congo, Tongo, Niger, Guinea Bissau, Benin, Central African Republic

<sup>26</sup>These include: Cameroon, Congo, Gabon, and Ivory Coast. This classification is by the United Nations' Department of Economic and Social Affairs, available at [http://www.un.org/en/development/desa/policy/cdp/ldc\\_info.shtml](http://www.un.org/en/development/desa/policy/cdp/ldc_info.shtml)

<sup>27</sup>Comoros, Senegal, Mali, Equatorial Guinea, Chad, Burkina Faso, Mauritania, Guinea, Tongo, Niger, Guinea Bissau, Benin, and Central African Republic.

<sup>28</sup>Agreement Revising the Bangui Agreement, *supra* note 2, Articles 4§1 and 4§2; See <http://www.wipo.int/wipolex/en/outline/oapi.html>, accessed 14/12/2013.

<sup>29</sup>Fabbiene Orsi et al, "AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries", in B Andersen (ed), *Intellectual Property Rights: Institution, Governance and Institutional Environment*, (Massachusetts: Edward Edgar Publishing Inc., 2006 ), p78, available on [http://www.google.co.il/books?hl=en&lr=&id=ydV68o\\_oMHEC&oi=fnd&pg=PA70&dq=oapi%2Btrips+plus&ots=4FkDJi-2SP&sig=TsPOjZKPg6eRjeZCA7ZWqmQNxIg&redir\\_esc=y#v=onepage&q=oapi%2Btrips%20plus&f=false](http://www.google.co.il/books?hl=en&lr=&id=ydV68o_oMHEC&oi=fnd&pg=PA70&dq=oapi%2Btrips+plus&ots=4FkDJi-2SP&sig=TsPOjZKPg6eRjeZCA7ZWqmQNxIg&redir_esc=y#v=onepage&q=oapi%2Btrips%20plus&f=false)

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*B) The Revised Bangui and Pharmaceutical Patents*

As members of the World Trade Organisation (WTO), and pursuant to Article 69 of TRIPS, the OAPI member states were under an obligation to revise their joint intellectual property law to bring it into compliance with TRIPS. This revision of the Bangui Agreement was obligatory for all members of the OAPI, regardless of the LDC status of some member countries. It has been noted that although Article 65 of the TRIPS Agreement provided for an additional transition period for OAPI's four developing countries (the deadline being 2006), this period, under TRIPS' Article 65.4, was applicable only to countries that had to extend their patent laws to cover objects hitherto excluded from protection.<sup>30</sup> With respect to the OAPI member countries, the Bangui Agreement of 1977 extended protection to drug patents. The effects of this was that developing countries under the OAPI were not, in view of TRIPS' Article 65.4, entitled to an extended transition period. Now, the transition of these OAPI's four developing countries meant the transition of all OAPI member countries owing to the principle of 'common procedure' which lies at the heart of this organisation, which was introduced to strengthen local cooperation and reduce exchange costs with a view to constituting a unified zone that would be in a better position to face up to international competition.<sup>31</sup> The revision resulted into the Revised Bangui Agreement of 1999 (the Revised Agreement) binding on all member states.

The Revised Agreement has two parts: (a) the general agreement that sets out the terms and obligations of its members; and (b) 10 Annexes, each of which specifies substantive obligations on specific areas of IP - for instance Annex 1 is on patents. In accordance with its Article 43, the Revised Agreement, together with Annexes I to IX, entered into force on 28<sup>th</sup> February 2002, two months after the deposit of instruments of ratification by at least two-thirds of the Member States.<sup>32</sup> Notably, a member state is not required to take any further steps to implement the Agreement. Like the 1977 Bangui Agreement, the Revised Agreement applies automatically as national law in each of the OAPI member countries that ratifies the agreement. The issue of a (patent) title by the OAPI Secretariat automatically gives rise to rights valid in all its members.

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<sup>30</sup>Fabbiene Orsi et al, "AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries", in B Andersen (ed), Intellectual Property Rights: Institution, Governance and Institutional Environment ( ), p82.

<http://www.google.co.il/books?hl=en&lr=&id=ydV6>

<sup>31</sup>Fabbiene Orsi et al, "AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries", in B Andersen (ed), Intellectual Property Rights: Institution, Governance and Institutional Environment ( ), p82.

<http://www.google.co.il/books?hl=en&lr=&id=ydV6>

<sup>32</sup>See <http://www.wipo.int/wipolex/en/outline/oapi.html>, accessed 14/12/2013.

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Table 1: showing dates on which OAPI Member States ratified the Revised Agreement, as of December 2013

Country	Date of ratification
1. Cameroon	9 July 1999
2. Gabon	27 December 1999
3. Senegal	9 March 2000
4. Ivory Coast	24 May 2000
5. Mali	19 June 2000
6. Equatorial Guinea	23 November 2000
7. Chad	24 November 2000
8. Burkina Faso	8 June 2001
9. Mauritania	5 July 2001
10. Guinea	13 July 2001
11. Congo	19 October 2001
12. Togo	29 November 2001
13. Niger	28 May 2002
14. Guinea Bissau	14 August 2003
15. Benin	18 December 2003
16. Central African Republic	24 April 2004

Note: Equatorial Guinea also joined on the same date of the ratification.

Perhaps more importantly, the Revised Bangui Agreement is noted to have strengthened IPRs, especially patent rights. In this regard, the Revised Bangui Agreement, arguably, serves as a good case to study the impact of strong protection of IPRs on access to medicine and other essential needs in developing countries and in LDC. It is widely acknowledged that the Revised Agreement, especially with respect to patents, contains provisions which are more constraining than those which are under the TRIPS Agreement, such that its critics have labelled it TRIPS-Plus. Others have noted that it contradicts the letter and spirit of the rights of countries acquired in the 2001 Doha Declaration on TRIPS and Public Health.<sup>33</sup> Two provisions in the Revised Agreement have been noted as being more constraining than under TRIPS. These are those relating to compulsory licences and to parallel imports.

With respect to the provisions in this Agreement on the use of compulsory licenses by third parties (described in the Agreement as ‘non voluntary licenses’) or by governments (ex officio licenses), the general understanding is that they impose more stringent conditions than is provided under TRIPS. It is said, for example, that the Agreement requires a judicial procedure in national courts before licenses to third parties can be issued.<sup>34</sup> Also, the Agreement omits several of the possible grounds for compulsory licenses, such as the existence of import monopolies. Further, the Agreement as revised counts importation of patented products as one method of ‘working’ a patent. Before the revision (under the Bangui Agreement of 1977), a ‘non voluntary’ license could be issued if imports of the patented product prevented or

<sup>33</sup>Orsi, “AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries”, p78.

<sup>34</sup>Deere, *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, p257.

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hindered ‘working’ of a patent. Pre-TRIPS, this legal strategy of limiting rights of an IP-holder in the absence of ‘domestic working’ was used by many countries as a tool of promoting national industrial and scientific capacity. But, under the Revised Agreement the option of compulsory licensing is eliminated where demand of a patented product is met through imports.<sup>35</sup> Indeed, the Revised Agreement cancelled the possibility of resorting to compulsory licenses in the event of non-exploitation of the patent locally by the patentee, as well as the abolition of the specific regime of the ‘ex-officio’ licences enabling them to be used for imports. The Revised Agreement makes no distinction between ‘ex-officio’ and compulsory licenses. Under 56a of the Revised Agreement, ‘ex-officio’ licenses are subject to the same conditions as non-voluntary licenses. As a result, recourse to ex-officio licenses, so it has been argued, is no longer possible, as is the case with compulsory licenses, except under certain conditions, including prior negotiation with the patentee and ‘only after the expiry of four years from the date of registration of the patent request or three years from the date of the granting of the patent.

On parallel imports, TRIPS’ Article 6 grants WTO members the flexibility to determine the point at which IP rights have been exhausted. It has been argued that the choice of an IP exhaustion regime has a direct bearing on a country’s options with respect to parallel imports. Under TRIPS, countries may establish whichever exhaustion regime best fits their domestic policy objectives. Besides, there is an affirmation in the Doha Declaration that WTO members have the freedom to establish their own regime for such exhaustion without challenge, subject to issues of ‘most favoured nation’ and national treatment as stated in TRIPS’ Article 3 and 4. Countries have three options with respect of exhaustion of intellectual property rights on a product or work. These are: (i) a national regime where IP rights are said to be exhausted when the protected product or work has been put on the market with the consent of, or by, the right holder in the country where the right was issued; (ii) a regional system that extends the principle of national exhaustion to other countries within the region; and (iii) an international regime where rights of a protected work or product are exhausted in respect of those works or products put on the market anywhere in the world. Observably, if a country chooses a national or regional exhaustion regime, IP right holders can take action against parallel imports from outside those borders. Under an international exhaustion regime, they cannot take such an action.<sup>36</sup> Perhaps more importantly, OAPI members adopted a regional exhaustion system under the Revised Agreement. In this regard, the Revised Agreement makes it impossible to resort to compulsory licenses for imports outside the OAPI zone. It has been argued that this decision to retain a regional approach to exhaustion means that parallel imports are only possible from among the OAPI Members States, despite the fact that medicines can often be found at lower prices outside the OAPI region.<sup>37</sup> In practical terms, given that drug production capabilities of in the countries in this zone are limited or wholly non-existent, the regional

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<sup>35</sup>Orsi, “AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries, p84.

<sup>36</sup>Deere, *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, p84.

<sup>37</sup> *Ibid*, p75&p258.

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exhaustion regime blocks all access to generic drugs, often supplied at very low prices by foreign producers such as India and Brazil.<sup>38</sup>

Other constraining provisions in the Revised Agreement relate to the period of protection of patents. It has been noted that Article 9 of the Revised Agreement (relating to the duration of patent protection) extended protection to a period of 20 years, on the sole condition that the patentee pays the taxes required to maintain the patent in force.<sup>39</sup> Observably, this provision is in marked contrast to a comparable provision before the revisions (under the Bangui Agreement of 1977), under which the period for patent protection was split into three periods (10+5+5) and subjected it to conditions of local exploitation of the patented invention. Under Article 6 of the 1977 Bangui Agreement, a patent was to be granted for a period of ten years counting from the registration date, with the possibility of extending this initial period by two further periods of five years each upon request by the patentee. However, the protection thus granted was subjected to conditions of local exploitation of the patented invention. In this regard, if there was no local exploitation of the patent within five years following the grant of the patent, the local production and import of this invention without the authorisation of the patentee could not be regarded as infringement of the exclusive right of the patentee. As such, it is argued that this provision was essential in the specific cases of access to drugs, as it implicitly authorised not only the production of generic drugs before legal expiry of the patent but also the import of these drugs in the form of generic copies produced abroad.<sup>40</sup> Thus, one of the tools that governments under OAPI might have used to build production capacity and expand affordable access to medicines in the region was eliminated. Consequently, and in accordance with the terms of the Revised Agreement, any import of a patented invention or its local production by a third party without the consent of the patentee is liable to a claim of infringement, even if the patent is not exploited locally.<sup>41</sup>

Additionally, the Revised Agreement is regarded as having constraining provisions in relation to the protection of second use patents (which is not required by TRIPS) and data submitted for purposes of regulatory approval. It has been argued that this provisions can serve, respectively, to extend the length of patent protection and slow the marketing of generic of products such as medicine. While TRIPS' Article 39.3 does call for countries to provide some form of data protection, the Revised Agreement provides stronger standards than those necessary to meet the vaguely stated minimum standards under TRIPS. Additionally, the patent provisions of the Revised Agreement do not provide for any exceptions for experimental or research purposes. Finally, by extending the new twenty year protection to patents claimed under the priority regime, the Revised Agreement also deprives member states of the possibility to exploit patents that would otherwise have fallen into the public domain after ten years.<sup>42</sup>

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<sup>38</sup>Fabbiene Orsi, "AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries", p78

<sup>39</sup>Ibid, p 83.

<sup>40</sup>Orsi, "AIDS, TRIPS And TRIPS Plus: The Case For Developing And Less Developed Countries", p80.

<sup>41</sup> Ibid, p83.

<sup>42</sup>Deere, supra, p258.

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*C) The Impact of the Revised Bangui Agreement on Health*

The impact of the Revised Bangui Agreement on affordability of medicine in the OAPI Member States has been widely debated among scholars, health activists, and some advocacy groups. This debate was particularly sharp in the early years of the Revised Agreement, especially with regard to access to ARVs for HIV/AIDS patients. To critics, the cumulative effect of the Revised Agreement is to reinforce the monopoly given to patent-holders beyond existing requirements in international trade rules and that it will cause a major obstacle to access to medicines. It is also contended that it discourages the transfer of technology necessary for the development of the regional pharmaceutical industry and threatens to increase dependence on imports of medicines.<sup>43</sup>

The dominant theme in this debate is that the enhanced protection of patents under the Revised Agreement will result in an increased price of drugs, and that this will make healthcare unaffordable to people, especially among the poor, and produce negative health outcomes in the region. The point is perhaps best captured by views expressed by Bernard Pécoul, director of the MSF Access to Essential Medicines Campaign MSF. "Doctors in Africa", so he asserted, "are increasingly faced with a lack of life-saving medicines--either because they are too expensive, or because they do not exist. The revised Bangui Agreement means Francophone countries in Africa will no longer be able to shop around for the cheapest medicines, nor will they be able to produce drugs locally. The new rules mean the price of medicines will be 10 to 20 times more than they would be if they were generic. For people suffering from AIDS or other serious infections such as meningitis or pneumonia, this is basically a death sentence."

Increasingly, advocacy groups have claimed that the Revised Agreement affords Member States less leverage to access cheap pharmaceuticals within their own IP legal frameworks than was the case before the revision. It is contended that certain provisions in the Bangui Agreement before the revision could be used as legal basis to facilitate access to drugs, in the event that existing patents represented an obstacle to this access. Perhaps, the Revised Agreement is criticized mostly because of stringent conditions on compulsory licenses and the adoption of 'regional exhaustion'. On regional exhaustion, critics contend that it excludes the possibility of importing generic drugs from outside OAPI member states.<sup>44</sup> It has been noted that in 2002, for instance, one tablet of Glaxo's Combivir, a one pill combination of two antiretroviral, cost \$1.96 in Togo and \$0.94 in Senegal (the lowest price within the OAPI region), but only \$0.65 in India. If OAPI members had chosen

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<sup>43</sup>New Agreement on Patents for Medicines in Francophone Africa Threatens Health of Populations: MSF Calls Upon the Francophone Countries of Africa Not to Sign the New Patent Agreements (Bangui 99)

See <http://www.doctorswithoutborders.org/press/release.cfm?id=597&cat=press-release>.

<sup>44</sup>"HIS Global Insights," Revised Bangui Agreement Slammed For Over-Restrictive Patent Laws", March 08, 2002.

<http://academic.lexisnexis.co.il/>

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international exhaustion, Togo could have imported Combivir from India instead. Instead, Togo imported Combivir from Senegal at a price that was 45% higher.<sup>45</sup>

Within this context, it has widely argued that LDCs in the OAPI, though theoretically entitled as other WTO LDC members to enjoy the benefits of the extensions (and the rights under the Doha Declaration), were prevented by the revisions of the Bangui Agreement from enjoying the supposed benefits of the extension under TRIPS' Article 66.1. This raises the question whether the Revised Agreement resulted in increased expenditure on health in the OAPI LDCs increased compared to other LDCs in Africa and beyond. Suffice to note that it was widely feared that the Bangui Agreement will create an extremely dangerous situation in the countries concerned, even more deleterious in some respects than what would have resulted from the full application of TRIPS. It has been claimed that the constraints imposed by the Revised Bangui Agreement will particularly affect both the supply of medicine in the OAPI, especially ARVs, and that, in consequence, local public health outcomes will be adversely affected in these countries.<sup>46</sup> Though that may be the case, it merits pointing out that the effects of the Revised Agreement on the affordability of drugs and health outcomes in the OAPI countries remain largely unclear. Most of the available literature on the topic are theoretical, and less based on empirical evidence. This article offers an empirical contribution to this discussion.

At this point, the paper notes that the effects that the extension of the transition under TRIPS' Article 66.1 has had on WTO LDCs, especially on their public healthcare, remains unclear. Implicit in the available anecdotal literature, especially those that called for the extension, is an expectation that the extension would have a positive impact on access to medicine and health outcomes in WTO LDCs.<sup>47</sup> If this is the case, WTO LDCs in the OAPI will be expected to be in a worse off situation, compared to other LDCs, because of the constraints in the Revised Bangui Agreement. It is the aim of this paper to assess whether the Revised Bangui Agreement has made WTO LDCs in the OAPI experience increased expenditure on health, constrained access to medicine, and negative health outcomes more than the other WTO LDCs. Besides, the paper will assess if LDC Members of the WTO are worse off than non-members in how they access medicine. In some respect, the analysis in this paper will focus on any differences that may be there between LDCs which are members of the WTO, and those that are not

## II. THE MODEL

*A) Overview*

*B) Methodology*

[To be completed]

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<sup>45</sup>Deere, *The Implementation Game: the TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, p258.

<sup>46</sup>*ibid*, p71.

<sup>47</sup>See Third World Network , 'NGOs Call on LDCs to Request Extension of Transition Period', TWN Info Service on Intellectual Property Issues (Oct12/03) 16 October 2012, available on [http://www.twncside.org.sg/title2/intellectual\\_property/info.service/2012/ipr.info.121003.htm](http://www.twncside.org.sg/title2/intellectual_property/info.service/2012/ipr.info.121003.htm)

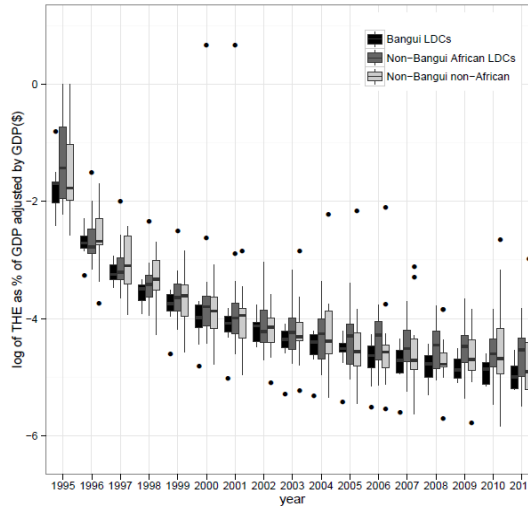


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C) Findings

1) The Null Hypothesis ( $H_0$ ): Total health expenditure (THE) rates in Bangui LDCs remain constant in comparison with non-Bangui LDCs

Fig. 1: Test for country group X time interactions over Total Health Expenditure as % of GDP (1995-2011) (adjusted by GDP)



The results show that the pattern of groups differences over total health expenditure (THE) remained constant in all three country groups before and after 2002 (the Bangui agreement). Accordingly, neither before 2002 nor after 2002 the time X group was interaction significant ( $F(2,651)=0.11$ , NS) and ( $F(2,651)=0.18$ , NS) correspondently.

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2) *The First Hypothesis (H<sub>1</sub>): Bangui LDCs show similar time slope patterns over health expenditure rates in comparison with non-Bangui LDCs after 2002*

Fig. 2: Test for country group X time interactions over General Government Expenditure on Health as % of Total Health Expenditure (1995-2011) (adjusted by GDP)

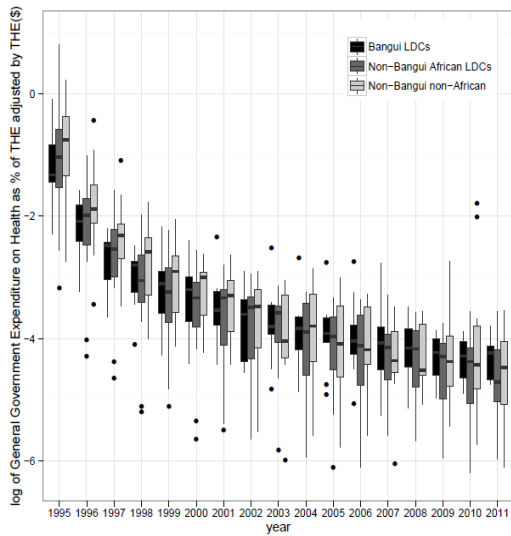


Fig. 3: Test for country group X time interactions over Private Expenditure on Health as % of Total Health Expenditure (1995-2011) (adjusted by GDP)

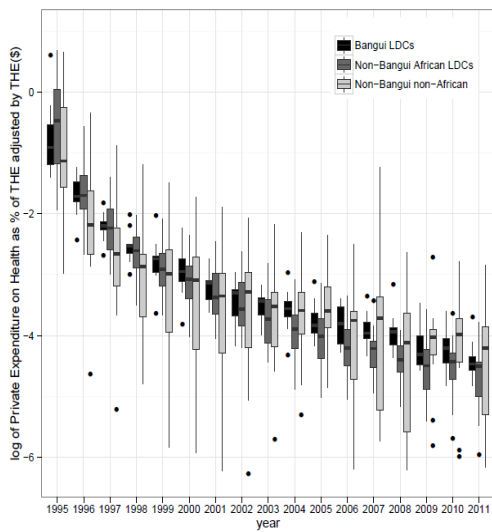


Fig. 4: Test for country group X time interactions over External Resources on Health as % of Total Health Expenditure (1995-2011) (adjusted by GDP)

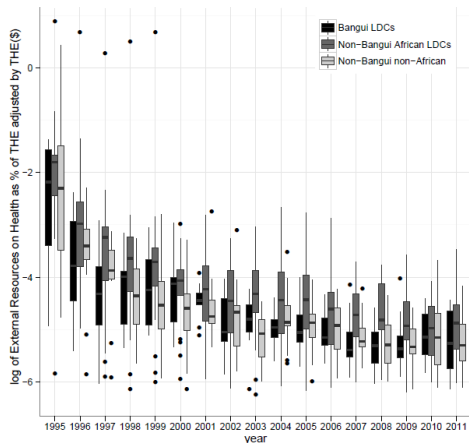
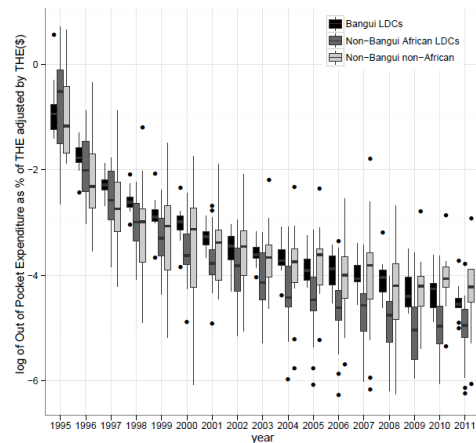


Fig. 5: Test for country group X time interactions over Out of Pocket Expenditure as % of Total Health Expenditure (1995-2011) (adjusted by GDP)



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Summary of results:

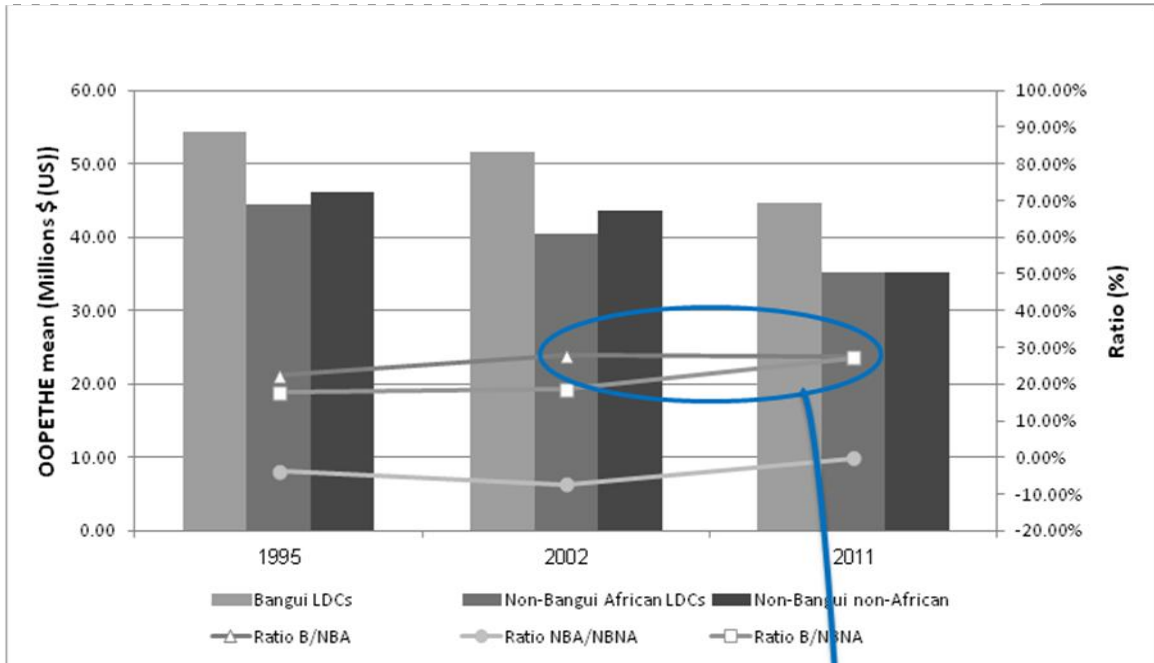
<b>Measure</b>	<b>F value before 2002</b>	<b>F value after 2002</b>
Total Health Expenditure as % of GDP	0.11, NS	0.18, NS
General Government Expenditure on Health as % of Total Health Expenditure	0.15, NS	1.01, NS
Private Expenditure on Health as % of Total Health Expenditure	0.39, NS	0.38, NS
External Resources on Health as % of Total Health Expenditure	0.19, NS	0.35, NS
Out of Pocket Expenditure as % of Total Health Expenditure	0.09, NS	0.25, NS

In conclusion, there is no significant interactions were found neither before 2002 nor after. The pattern of groups differences remained constant after the Bangui agreement.

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3) *The Second Hypothesis (H<sub>2</sub>): Bangui LDCs show similar ratio of means of health expenditure rates in comparison with non-Bangui LDCs*

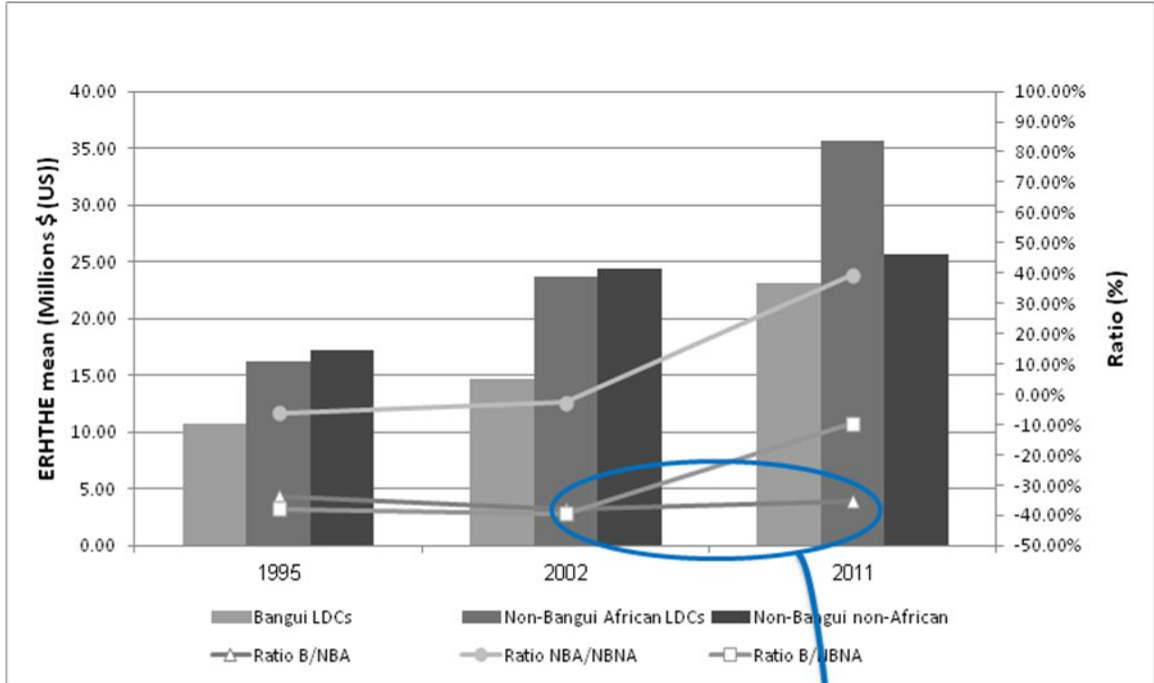
**Fig. 6: Ratio of mean value of Out of Pocket Expenditure as % of Total Health Expenditure (with confidence interval 95%)**



Year	Bangui LDCs	Non-Bangui African LDCs	Non-Bangui non-African	Ratio B/NBA	Ratio NBA/NBNA	Ratio B/NBNA
1995	54.33	44.45	46.18	22.23%	-4%	17.65%
2002	51.67	40.45	43.62	27.73%	-7%	18.46%
2011	44.75	35.15	35.21	27.31%	0%	27.08%

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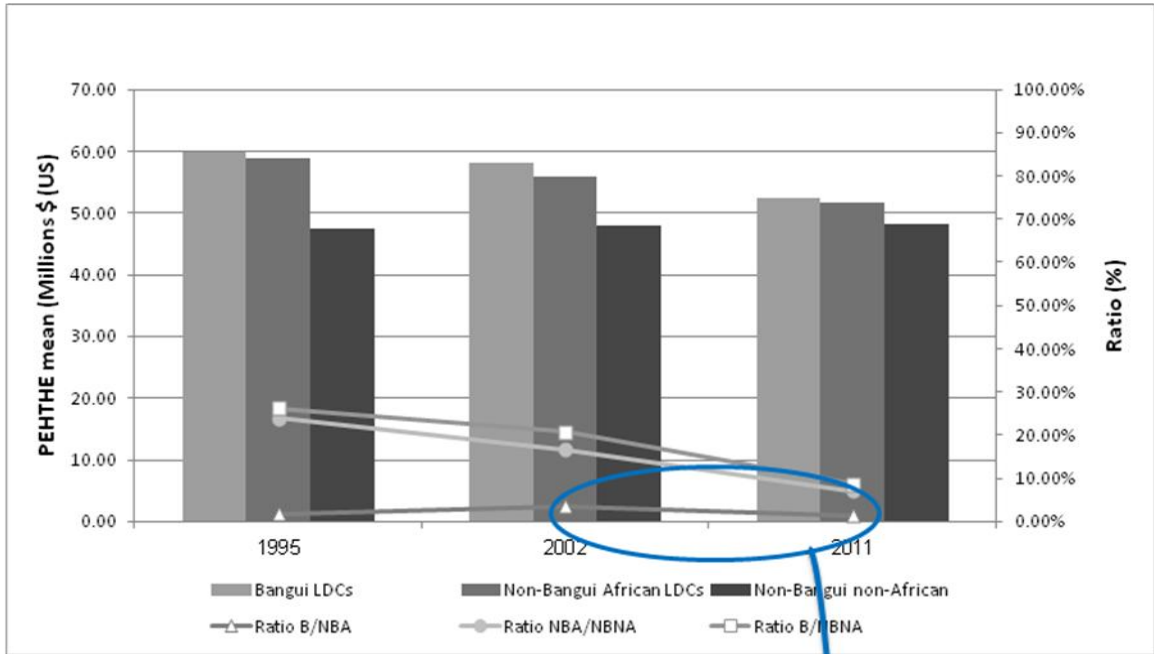
Fig. 7: Ratio of mean value of External Resources on Health as % of Total Health Expenditure (with confidence interval 95%)



Year	Bangui LDCs	Non-Bangui African LDCs	Non-Bangui non-African	Ratio B/NBA	Ratio NBA/NBNA	Ratio B/NBNA
1995	10.75	16.21	17.27	-33.69%	-6%	-37.76%
2002	14.75	23.7	24.33	-37.76%	-3%	-39.38%
2011	23.17	35.7	25.62	-35.11%	39%	-9.56%

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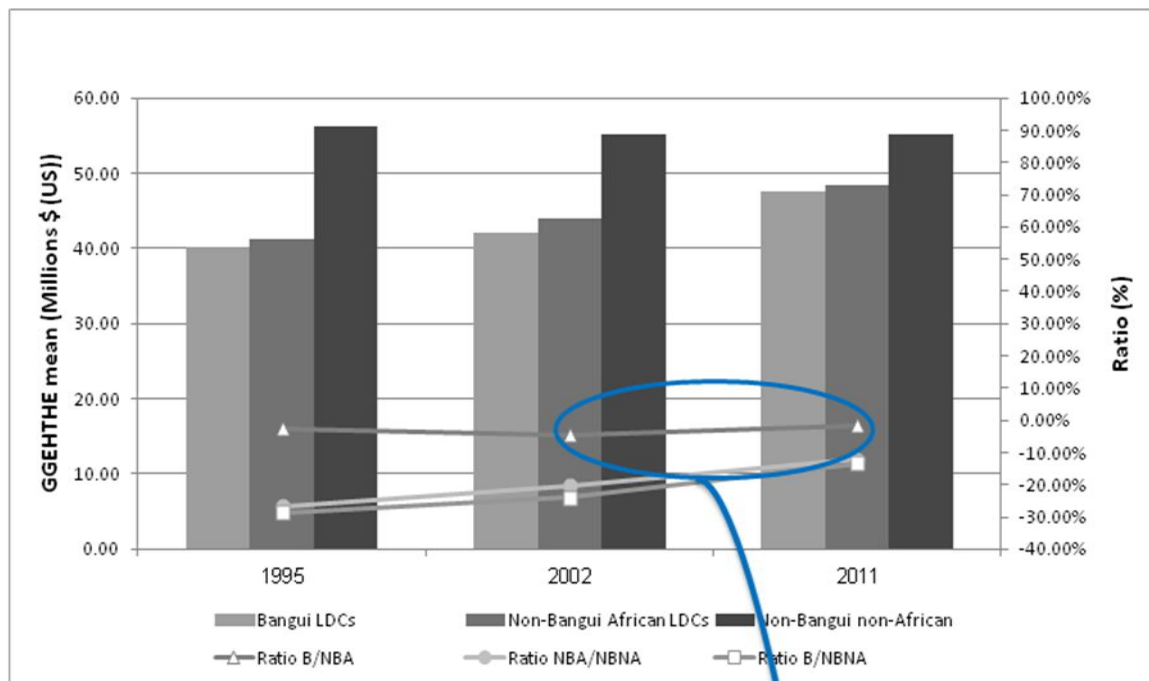
**Fig. 8: Ratio of mean value of Private Expenditure on Health as % of Total Health Expenditure (with confidence interval 95%)**



Year	Bangui LDCs	Non-Bangui African LDCs	Non-Bangui non-African	Ratio B/NBA	Ratio NBA/NBNA	Ratio B/NBNA
1995	59.83	58.75	47.42	1.84%	24%	26%
2002	58.00	56.00	48.00	3.57%	17%	21%
2011	52.33	51.55	48.14	1.52%	7%	9%

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Fig. 9: Ratio of mean value of General Government Expenditure on Health as % of Total Health Expenditure (with confidence interval 95%)



Year	Bangui LDCs	Non-Bangui African LDCs	Non-Bangui non-African	Ratio B/NBA	Ratio NBA/NBNA	Ratio B/NBNA
1995	40.17	41.25	56.23	-2.63%	-27%	-29%
2002	42.00	44.00	55.20	-4.55%	-20%	-24%
2011	47.67	48.45	55.07	-1.62%	-12%	-13%

[To be completed]

**III) THEORETICAL RAMIFICATIONS: OF NON-PATENT BARRIERS TO ESSENTIAL MEDICINES**

Various empirical studies have suggested that that lack of or limited access to essential medicines in low and middle income countries, especially in LDCs, is scarcely due to patents. These studies have variously observed that there are other barriers or constraints, other than patents, that limit access to essential medicines in these countries. The results in this study would seem to confirm the same observation. This observation necessarily begs the question: If it is not chiefly due to patents, what then is responsible for the lack of access to medicines in these countries?

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Some studies, Hanson et al<sup>48</sup> for instance, have attempted to categorise these non-patent constraints into the following levels: (i) community and household; (ii) health services delivery; (iii) health sector policy and strategic management; (iv) public policies; (v) and environmental characteristics. Evidently, the first two categories are factors that operate at the level of the community and the system that delivers the communities' health services. Constraints in the other three levels are more centrally about governance and institutional performance, and less about money per se. At the community and household level, there is a lack of demand of effective interventions.

This is further compounded by the presence of physical, social and financial barriers to the use of effective interventions. With regard to issues of health service delivery, there is a shortage of appropriately qualified staff and the distribution of the staff is problematic, weak technical guidance, program management and supervision, inadequate supplies of drugs and medical supplies, lack of equipment and infrastructure (including labs and communications) and poor accessibility of health services. With respect to health sector policy and strategic management, there are weak, overly centralized systems for planning and management; weak drug policies and supply systems; inadequate regulation of pharmaceutical and private sector and improper industry practices; lack of inter-sectarian action and partnership for health between government and civil society; weak incentives to use inputs efficiently and respond to user needs and preferences; reliance on donor funding that reduces flexibility and ownership; and donor practices that damage country policies. At the level of government policy, the barrier is in the form of government bureaucracy, and poor availability of communication and transport infrastructure. On environmental characteristics, it has been noted that there are, on one hand, issues of governance and the overall failings of policy. These include Corruption, weak government, weak rule of law and enforceability of contracts; political instability and insecurity; low priority attached to social sectors; weak structure for public accountability, and lack of free press. On the other hand, there are issues of the physical environment. This involves climatic and geographic predisposition to disease; and the availability of a physical environment which is unfavourable to service delivery.

Whereas lack of management capacity is a problem at all levels, some aspects can be more quickly and simply addressed at the local level, and thus are an immediate priority, whereas reforming and strengthening central government systems requires a long-term and sustained effort.

According to a study by Report of the Commission on Macroeconomics and Health<sup>49</sup>, the most severely constrained countries, making up the lowest quartile, include Angola, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of Congo, Eritrea, Guinea-Bissau, Haiti, Liberia, Mauritania, Niger, Nigeria, Somalia, and Yemen. Most of these countries are in sub-Saharan Africa, and many are in conflict (internally or externally) or have recently been in conflict. Many have grievous governance shortfalls. It is notable that some of these countries, especially Nigeria, do not belong to the LDC group. These most-constrained countries represent

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<sup>48</sup>Quoted in a Report of the Commission on Macroeconomics and Health Chaired by J. Sachs, "Macro-economics and health: investing in health for economic development", World Health Organisation, 2001, p71

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the hardest cases for intervention. They have health indicators significantly worse than those for low-income countries as a whole: they have only a third of the number of nurses per capita, almost twice the infant mortality, and more than twice the maternal mortality. The proportion of their population living on less than \$1 a day is twice that in other low-income countries.

Observably, short-term macroeconomic crises can gravely damage access to health services and upset the process of scaling up those services, unless the sector is well insulated from short-term shocks. Donor agencies and multilateral institutions, in concert with country officials, need to give special attention to protecting essential health interventions from budgetary austerity that might accompany a short-run macroeconomic crisis. Donor support can be a critical tool in that task of sustaining essential health services during economic downturns. Pre-emptive efforts to formulate social safety net schemes are equally critical to protect the poor in such situations; if households are thrown into poverty, simply maintaining the level of essential health services that existed before the economic downturn cannot prevent adverse health effects.<sup>50</sup>

Finally, non-patent barriers take the form of unreliable health care and supply systems. Besides, health systems may fail to use limited resources to purchase generic Essential Medicines; Trade agreements including TRIPS Plus measures related to data exclusivity and patent linkage creates regulatory and other barriers.

Be that as it may, it is now increasingly being agreed that the constraints to access to essential medicines in these countries are due to: (i) irrational use of drugs; (ii) unaffordable drug prices, (iii) unsustainable and inadequate financing, and (iv) unreliable health care and supply systems. For some, the constraints come about because of logistical supply and storage problems; substandard drug quality; inappropriate selection of drugs; wasteful prescription and inappropriate use; inadequate production, and prohibitive prices.

### *i) Rational selection and use of drugs*

The twin problems of irrational selection and use of drugs, especially in LDCs is long known. As aptly put by WHO, no health system in the world offers unlimited access to all medicines. It is for such reason that rational selection of essential medicines is advocated for as a core principle of a national drug policy. The concept of rational selection of drugs, so stated WHO, focuses therapeutic decisions, professional training, public information, financing, supply and quality assurance efforts on those medicines which will have the greatest impact in a given health care setting. It is a global concept which can be applied in any country, in both public and private sectors and at different levels of the health care system. For the WHO, rational selection and use can be pursued through various tools.<sup>51</sup> In defining rational use of medicines, the WHO states that it is a condition whereby patients receive medications appropriate to their clinical needs, in doses that meet their own individual

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<sup>50</sup> Ibid, p71.

<sup>51</sup>WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action - Policy Perspectives on Medicines", no. 008, March 2004, available on [apps.who.int/mecinedocs/en/d/Js4962e](http://apps.who.int/mecinedocs/en/d/Js4962e), accessed on 21/04/2014.

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requirements, for an adequate period of time, and at the lowest cost to them and their community.”<sup>52</sup> It is asserted that rational use of essential medicines is one of the core activities of health workers and patients. Trained and motivated health staff, and the necessary diagnostic equipment, are needed to ensure safe and effective treatments, minimizing the risks and waste linked to irrational prescribing and use of medicines. Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use as defined above. It has been observed that, worldwide, more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly. Moreover, about one-third of the world’s population lacks access to essential medicines. Common types of irrational medicine use are: (i) the use of too many medicines per patient (polypharmacy); (ii) inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; (iii) over-use of injections when oral formulations would be more appropriate; (iv) failure to prescribe in accordance with clinical guidelines; and (v) inappropriate self-medication, often of prescription-only medicines. Inappropriate use and over-use of medicines waste resources – often out-of-pocket payments by patients – and result in significant patient harm in terms of poor patient outcomes and adverse drug reactions. Furthermore, irrational over-use of medicines can stimulate inappropriate patient demand, and lead to reduced access and attendance rates due to medicine stock-outs and loss of patient confidence in the health system.<sup>53</sup>

### 1. Rational selection and use of essential medicines

Recognising that irrational selection and use of medicine are a problem that limits access to medicine, especially in LDCs, is not enough on its own. There is need for more action to address the problem. It is for this reason that there is advocacy for governments to employ interventions such as adopting national treatment guidelines. National treatment guidelines, as defined by WHO, are systematically developed evidence-based statements which assist providers, patients and other stakeholders to make informed decisions about appropriate health interventions.<sup>54</sup> Within the same framework, national lists of essential medicines should be developed for different levels of care and on the basis of standard treatment guidelines for common diseases and conditions that should be treated at each level. Careful selection of essential medicines is the first step in ensuring access.

### *ii) Affordable prices*

On the problem of high prices of drugs, views differ among academics, policy makers and other concerned parties. With the potential cost of providing a full range of treatments for prevailing common diseases, medicine prices and financing are inescapable factors in access to essential medicines. It is notable that the argument in fashion is that high prices of medicines are due to patents. But as the results of this study may indicate, patent may not be the cause of such prices. Indeed, comments by

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<sup>52</sup>WHO Policy Perspectives On Medicines - Promoting Rational Use Of Medicines: Core Components, September 2002 World Health Organization, Geneva, p 1.

<sup>53</sup>*Id.*

<sup>54</sup>WHO, “Equitable Access to Essential Medicines: A Framework for Collective Action - Policy Perspectives on Medicines”, no. 008, March 2004, available on [apps.who.int/mecinedocs/en/d/Js4962e](http://apps.who.int/mecinedocs/en/d/Js4962e), accessed on 21/04/2014.

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Laing<sup>55</sup> suggest that such high prices are scarcely a result of patents. He asserts that they are a result of duties, taxes, mark-ups and sometimes manufacturer costs.

It is evident that the task for governments is to pursue affordable prices of medicines. On their part, affordable prices of medicines can be pursued through the following mechanisms. Foremost, price information is fundamental in obtaining the best price. Several international and regional price information services are made available for Member States. Price information helps in price negotiations, in locating new supply sources, and in assessing the efficiency of local procurement. Additionally, price competition through tendering of generic products and therapeutic competition are powerful price-reduction tools, as evidenced by experiences from large producing countries such as Brazil and India. Through generic competition, price reductions of 75% to 95% were achieved over the initial brand prices.<sup>56</sup>

In addition, price reductions were also obtained through therapeutic competition - between several branded products belonging to the same therapeutic class. It is also widely acknowledged that bulk buying can reduce the cost of medicine. Bulk procurement encompasses that medicine orders are pooled together, that the focus is on a list of priority medicines and that duplication within therapeutic categories is avoided as much as possible. It is understood that this results in larger procurement volumes and will increase purchasing power. Or, bulk procurement can be through cooperation of facilities in a country. But, positive experience has also been reported from arrangements between states. Crucially, there is need for LDCs to have effective policies on generic drugs. Generics policies are effective instruments when a patent expires. In the United States of America the average wholesale price falls to 60% of the price of the branded medicine when one generic competitor enters the market, and to 29% with 10 competitors. To introduce and expand the use of generic medicine products, it is important, so contends the WHO, that: i) supportive regulations exist; ii) reliable quality assurance is in place; iii) professional and public acceptance is obtained; and iv) financial incentives are in place.

With respect to the cost of newer drugs, the widely held view is that these countries should advocate for equitable pricing. In fact, the WHO asserts that equitable pricing is especially important for newer essential medicines that are still protected by patents or other instruments that provide market exclusivity. As explained by the WHO, equitable pricing is the adaptation of prices which are charged by the manufacturer or seller to countries with different purchasing power. For the WHO, widespread equitable pricing is economically feasible provided that low-priced medicines do not leak back to high-income countries.

Perhaps more importantly, LDCs should be working towards the reduction or elimination of duties and taxes for both for both generic and patented essential medicines. The WHO states that in developing countries, the final price of a medicine may be two to five times the producer or importer price. To a greater extent, such price reflect high taxes. In some countries, there are taxes of over 20% on medicines, and pharmaceutical import duties of up to 65%. The prices also include high

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<sup>55</sup>Richard Laing, "The Patent Status Of Medicines On The WHO Model List Of Essential Medicines", WHO/WTO/WIPO Technical Symposium February 2011, p 9.

<sup>56</sup>WHO, "Equitable Access to Essential Medicines: A Framework for Collective Action - Policy Perspectives on Medicines", no. 008, March 2004, available on [apps.who.int/mecinedocs/en/d/Js4962e](http://apps.who.int/mecinedocs/en/d/Js4962e), accessed on 21/04/2014

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distribution costs, and pharmacy and drug seller charges. Seemingly, high prices of medicines are, to some extent, reflective of the effects of multiple middlemen. It is evident, therefore, that such a reduction or elimination of duties and taxes can contribute to price reduction on medicines.

In this pursuit of lower prices of medicines, a school of thought has emerged which posits that LDCs should be especially focusing on local production of medicines. The view is that local production of assured quality, when economically feasible and where it follows good manufacturing practices (GMP), can result in lower medicine prices. This can be facilitated by transfer of technology, GMP inspections, and other arrangements. Generic companies in India, Brazil and Thailand have offered their help to low- and middle-income countries to produce antiretrovirals locally through technology transfer through South-South collaboration.

The WTO/TRIPS Agreement defines minimum requirements for intellectual property rights that are applicable to all WTO members. Studies predict significantly higher medicine prices with full implementation of TRIPS requirements in low- and middle-income countries. National patent and related legislation should include standards of patentability that take health into account, promote generic competition, incorporate provisions for TRIPS compatible safeguards such as compulsory licensing and parallel import.

*iii) Unsustainable and inadequate funding*

The problem of high drug prices is inextricably linked to the problem of unsustainable and inadequate financing. Here, Laing suggests that the lack of, or limited access to medicines, is due to poverty and financing methods.<sup>57</sup> In particular, sustainable financing for essential medicines must be viewed in the context of overall health care financing. As noted by the WHO, most low- and middle-income countries rely on a diverse set of health and drug financing mechanisms which can contribute in the payment of medicines. Nevertheless there are still opportunities in many low- and middle-income countries for both better and more public spending on health and essential medicines. It has been noted that:

*“The inequities are striking. In developed countries, a course of antibiotics to cure pneumonia can be bought for the equivalent of 2 or 3 hours’ wages. One-year’s treatment for HIV infection consumes the equivalent of four to six months’ salary. And the majority of drug costs are reimbursed. In developing countries, a full course of antibiotics to cure a common pneumonia may cost one months’ wages. In many countries one-year’s HIV treatment - if it were purchased - would consume 30 years’ income. And the majority of households must buy their medicines with money from their own pockets.”*<sup>58</sup>

Within this context, it is suggested that LDCs should be aiming at increasing public funding for health. Indeed, increased public funding for health and medicines is

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<sup>57</sup>Richard Laing, “The Patent Status Of Medicines On The WHO Model List Of Essential Medicines”, WHO/WTO/WIPO Technical Symposium February 2011, p 9.

<sup>58</sup>WHO Press Release WHA/13, 22 May 1999

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important for high public health impact and strong potential for equity and solidarity, and for support to the disadvantaged. It does not mean that, , so argues the WHO, low- and middle-income countries should reallocate funds from prevention or other health priorities - but that additional new public funding should be brought to the health sector. An example is given of the Global Fund to fight AIDS, Tuberculosis and Malaria that offers an opportunity of additional new public funding to those countries where public funding is increasing very slowly or not at all.

Additionally, the inequalities in terms of out-of-pocket payments in LDCs as observed in this study is indicative of the failure of governments in these countries to spend on health. It is argued by the WHO that out-of-pocket spending is a result of failure by the government to allocate sufficient financial resources for medicine supplies essential for treating prevailing diseases for the majority of the population. Patients therefore have to buy all medicines they need from the private sector. For this reason, the suggestion is that governments in these countries should be aiming at increasing public spending on health, to reduce out-of-pocket payments. Further to this, the suggestion is that cost sharing with patients should be seen only as a transitional measure towards long-term aims, such as universal health insurance. It is understood that user charges or co-payments for medicines in public health services do not always lead to increased supply of medicines and can result in decreased utilization of public health services. In addition they can further impoverish already disadvantaged populations. User charges should complement rather than replace government allocations for curative health services and essential medicines provision. Other financing arrangements may be explored, such as donor assistance. Donor funding for and donations of medicines can have an impact on health progress in low- and middle-income countries in the short-term. In the medium-term these donations should be targeted at specific diseases and planned as additional supplies integrated into the national medicine supply system. But in the long-term, self-sufficiency is the only viable means to tackle increasing disease burdens. But, while donor assistance and development loans, such as bilateral aid and development loans/grants from development banks, continue to provide for many countries sources of health sector financing, which can include funding for essential medicines, such as HIV/AIDS-related therapies and combination treatments for medicine resistant malaria, it is open to debate whether development loans should be used for consumables, such as medicines. Other financing mechanisms which should be pursued include targeted use of debt relief funds, tax incentives in high-income countries, in-kind funding in the form of medicine donations, and solidarity funds.

### *iv) Reliable health and supply systems*

Finally, non-patent barriers take the form of unreliable health care and supply systems. Besides, health systems may fail to use limited resources to purchase, for instance, essential generic medicines. Within this context, it has been suggested that LDCs should continually carry out rapid assessment of health care and supply systems. Such assessment may be essential for identifying the major weaknesses and initiating corrective actions. For the WHO, those most important elements of an effective health care system, in supporting access to essential medicines, include: (i) health sector development; and (ii) public-private-NGO mix approaches.

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With regard to health sector development, the view is that it is a vital government obligation. In a national health system, proper use of well-known and newer essential medicines for priority health problems depends on a certain minimal level of medical and pharmaceutical services. This includes inexpensive diagnostic tests to confirm diagnosis, and well-informed trained clinicians, pharmacists, nurses and other health staff to help patients, especially those with chronic illnesses, to adhere to their treatments. Thus, an overall capacity strengthening of the health and supply systems is, for LDCs, a prerequisite to respond adequately to the increased medical and pharmaceutical needs of populations.

On public-private-NGO mix approaches, the understanding is that these are currently being pursued in some countries to ensure timely availability of medicine supplies of assured quality in the health care system. The use of these approaches in LDCs may vary considerably depending on the role of the government, the role of the private sector (non-profit and for-profit), and the incentives for efficiency in a particular country. Many countries struggle with the unfortunate combination of an inefficient public medicines supply system meant for the entire country and various private supply systems serving mostly urban areas. Increasingly, an effective medicines supply system is seen to depend on an appropriate mix of public, private, and NGO procurement, storage and distribution services.

It is noted that effective medicines regulation is a public service necessary to ensure the quality of pharmaceutical products, that producers fully implement good manufacturing practices to combat counterfeit and substandard medicines, and to contain drug resistance resulting from uncontrolled supply and use of antibiotics and other essential medicines in both public and private sectors. For this reason, the suggestion is that LDCs should be considering adopting shared regulatory control on medicines. Shared regulatory control entails that control is a shared responsibility of the national regulatory authorities, pharmaceutical producers, distributors, and other actors active in medicines management.

Additionally, it is suggested that LDCs should be considering procurement co-operatives, for these increase efficiency. Regional and sub-regional procurement schemes can become a credible option for ensuring reliable medicine supplies. An example is given of the Gulf Cooperation Council (GCC) and the Organization of Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS) which successfully organizes pooled procurement for six and eight countries respectively. Finally, LDCs should be considering increased use of traditional and complimentary medicines. Here, the understanding is that traditional and complementary medicines are increasingly used in many parts of the world and play a major role in the health care system. In many low- and middle-income countries, greater accessibility to and confidence in traditional medicine practitioners, especially in rural and remote areas, may explain why most patients consult them. Traditional practitioners can therefore play a considerable role in the health care system for some aspects of health care.

### CONCLUSION

[To be completed]

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Appendix A:

Year of joining WTO LDC	LDC
1995	Bangladesh, Burkina Faso, Burundi, Central African Republic, Djibouti, Guinea, Guinea-Bissau, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Senegal, Sierra Leone, Tanzania, Togo, Uganda & Zambia.
1996	Angola, Benin, Chad, Gambia, Haiti, Niger, Rwanda & Solomon Islands
1997	Democratic Republic of Congo
2004	Cambodia & Nepal
2012	Samoa & Vanuatu
2013	Lao People Democratic Republic

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