**COMMENT ON UNITED STATES' PROPOSAL ON PATENTS AND HEALTH**
**SUBMISSION BY THIRD WORLD NETWORK**
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## Introduction

The Africa Group and the Development Agenda Group (DAG) presented a specific proposal on Patents and Public Health during the 16th session of the SCP (SCP/16/7). This proposal received significant support from a number of countries as well as non-governmental organizations. The Third World Network also made a submission supporting the proposal presented by the Africa Group and the DAG.[1]

In response to this proposal, the United States submitted its own proposal (SCP/17/11) during the 17th session. This proposal is disappointing as it makes a number of frivolous observations and attempts to trivialise the impact of patents on access to medicines. Further by raising issues such as substandard/unsafe medicines which are not relevant to the mandate of the SCP, the US is attempting to confuse matters and distract member states from discussing the linkages between patents and public health, and possible WIPO activities in this regard raised in the proposal put forward by the Africa Group and DAG.

## Comment on specific issues raised by the US

The US proposal argues that a number of factors affect the availability of medicines in developing countries. While this may be the case, it is also important to acknowledge that the "price" factor can singularly be determinative of life or death, where a deadly disease is treatable.[2] It can determine whether patients will have or will not have access to the treatment it requires.

Today the world has been above to scale-up HIV/AIDs treatment largely due to the fact that the price of ARVs dropped dramatically in the past decade from more than US$10,000 per person per year (pppy) in 2000 to less than $150 pppy today. This price reduction has made lifesaving drugs accessible to millions of people in developing countries. By the end of 2010, 6.6 million people in low- and middle-income countries – 47% of the total number eligible – had access to antiretroviral therapy, a dramatic increase from the 300 000 (2.7% of those eligible) on antiretroviral therapy in 2002[3].

This is very much the result of competition from suppliers of generic drugs principally from India. The transitional period in place in India allowed firms to produce affordable generic versions of ARVs and even more importantly to produce easier to administer combinations of antiretrovirals not already available from brand-name companies. This single example shows how the removal of patent barriers as well as the use of TRIPS flexibilities has had an enormous positive impact in improving access to medicines in developing countries.

To support its proposition that many other factors and not patents directly affect the availability of medicines, the US proposal relies on WHO's List of Essential Medicines, adding that only about 4% of the medicines are presently protected by patents. It is indeed

[1] See http://www.wipo.int/scp/en/meetings/session_17/health/twn.pdf
[2] WHO member states have agreed in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property adopted through WHA 61.21 in 2008 that "The price of medicines is one of the factors that can impede access to treatment" (para 11).
[3] DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf

disappointing that despite evidence of how patents on medicines affect access to affordable medicines, the US has chosen to insist that patents don't matter. It is a well-known fact that drugs for HIV/AIDS were only added to the EML after extensive campaigning by AIDS activists and that the WHO Model List is underinclusive because it excludes some expensive newer treatments that remain covered by patents such as in the case of cancer treatments.

In addition, just because other factors may affect access, this does not preclude the need to also address patent barriers. In fact, while US refers to WHO's EML, WHO Secretariat itself has recognized that patents can impact access to medicines and has issued/commissioned various publications on the matter that encourage the use of TRIPS flexibilities to overcome the patent barrier. See http://www.who.int/phi/publications/category_ip_trade/en/index.html for a full list of WHO publications on intellectual property and health.

It is also worth recalling that the Doha Declaration on TRIPS and Public Health itself recognizes "the concerns about its [TRIPS Agreement] effects on prices".

In recognition of the potential adverse effect of IP on public health, the Declaration states: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The Declaration also reaffirms the right of WTO member states to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, the right to determine what constitutes a national emergency or other circumstances of extreme urgency (mentioned in Article 31 of the TRIPS Agreement) and the freedom to determine its own regime of exhaustion of rights.

Moreover the simple fact that a number of governments have taken action to override the patent barriers through the use of public health relevant flexibilities (e.g. transitional period, strict interpretation and application of patentability criteria including prohibiting patenting of new uses of pharmaceuticals, parallel importation, exception to patent rights, compulsory license and government use orders) to improve access to medicines is evidence that patents can be a barrier to access to medicine in a particular country.

*Role of public health relevant TRIPS flexibilities in improving access to medicine*

The US proposal undermines the role of TRIPS flexibilities particularly compulsory licensing in improving access to affordable treatments. Clearly the US has deliberately chosen to ignore concrete evidence available today[4] on the positive impact of the use of public health relevant flexibilities on public health.

The example highlighted above provides solid evidence on how the use of transitional period in India facilitated the availability of generic medicines, which in turn enabled scaling up of HIV/AIDS treatment. Use of flexibilities such as pre-grant opposition and prohibition on patenting of new uses of existing pharmaceuticals available in India's Patent Act has also facilitated access. For instance, in March 2006, a coalition of public-interest groups filed an opposition against GlaxoSmithKline (GSK)'s application for a patent on Combivir (a FDC of zidovudine+lamivudine) arguing that the product is a combination of two drugs in one pill

[4] See for e.g. South Centre/WHO. The use of flexibilities in TRIPS by developing countries: can they promote access to medicines? Geneva: South Centre/WHO, 2006; DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

and thus not entitled to a patent under the Indian patent law. Following filing of the pre-grant opposition, GSK withdrew its pending patent applications in India as well as in other countries, thus enabling improved access to generic versions of Combivir.

A number of countries have also used compulsory licensing to overcome the patent barrier and improve access to medicines. This includes Malaysia, Zimbabwe, Brazil, Thailand, Indonesia, Ecuador and evidence available suggests that overall the compulsory licenses improved access to medicines in the country issuing the license by either allowing the production or importation of more affordable generic versions of medicines.[5]

For instance Malaysia's issuance of a government use order to import three ARVs including Combivir from India to supply public hospitals led to an average cost reduction of about 81% per month per patient for the Ministry of Health.[6] The number of patients that could be treated in government hospitals and clinics increased from 1,500 to 4,000. The government-use order also resulted in reduction of the prices of the originator companies. By 2004, GSK reduced its ARV prices by 53–80% compared with 2001 prices, and Bristol-Myers Squibb dropped the price of its product didanosine (100mg formulation) by 49% and the price of the 25mg formulation by 82%.

In 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs issued a notice declaring a period of emergency on HIV/AIDS for the purpose of enabling "The State or a person authorised in writing by the Minister to make or use any patented drug, including any antiretroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions." Following the emergency declaration, in April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwe-registered company, was granted authority to use relevant patents. Under the terms of this authorization, Varichem was to "produce antiretrovirals or HIV/AIDS-related drugs and supply three quarters of its produced drugs to state-owned health institutions".

At the start of production, Varichem reportedly agreed to supply the government with its generic version of Combivir at US$ 15 per patient per month and to meet 75% of the government needs for this drug. Two other companies later received authorization. Datlabs, a pharmaceutical manufacturer, was authorized to import antiretroviral medications from Ranbaxy in India, while Omahn, an agent for the Indian manufacturer Cipla, was authorized to import Cipla products.[7]

The Government of Brazil has used compulsory licensing strategically in price negotiations, and it has also issued licences when price negotiations failed. Using the threat of compulsory licensing, the Brazilian Government negotiated significant price reductions for efavirenz and nelfinavir in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006. It has been estimated that the Brazilian Government's policies, including the use of TRIPS flexibilities have saved the country about US$ 1.2 billion on antiretroviral purchasing costs between 2001 and 2005.[8]

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[5] Country Experiences in Using TRIPS Safeguards, WHO, 2008 available at http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf

[6] Chee Yoke Ling, "Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option", Third World Network, IPR Series 9, available at http://www.twnside.org.sg/title2/IPR/pdf/ipr09.pdf

[7] DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

[8] See http://www.who.int/phi/phi_trips_policybrief_en.pdf

In 2007 after protracted negotiations with the patent holder, Brazil issued a compulsory licence for efavirenz an important antiretroviral drug used by a third of Brazilians on treatment through the national programme. It is reported that after the licence was issued, the price dropped from US $1.60 per dose to US $0.45 per dose for the imported generic version of the drug.[9]

In late 2006 and early 2007 Thailand issued compulsory licences for a number of pharmaceutical products: efavirenz, lopinavir/ritonavir and clopidogrel (a drug used for heart disease). It is reported that by by early 2008 the number of patients using lopinavir/ritonavir had tripled. In early 2008 the Thai Government issued additional compulsory licences for letrozole (a breast cancer drug), docetaxel (a breast and lung cancer drug) and erlotinib (a drug used for treating lung, pancreatic and ovarian cancer).[10]

Compulsory licenses have not only benefitted developing countries but also developed countries. For instance Canada made extensive use of compulsory licensing to promote the production of generic pharmaceuticals, and this scheme reportedly produced some of the lowest consumer drug prices in the industrialized world. Between 1969 and 1992, there were 1 030 applications to import or manufacture medicines under such licences, of which 613 were granted.[11]

In March 2007, the Italian Competition Authority ordered Merck & Co. Inc. to provide free licences for the manufacture and sale in Italy of the active ingredient finasteride (used in the treatment of prostate hypertrophy) and related generic drugs.[12] In an earlier investigation in 2005, the Competition Authority had already obliged Merck to grant licenses for its antibiotic combination imipenem+cilastatin, in order to rectify alleged abuse of a dominant market position, while in February 2006 its investigations led GSK to license its migraine drug sumatriptan succinate.

The above examples clearly show that US's assertions about TRIPS flexibilities including compulsory license are baseless and that these flexibilities can be an effective mechanism for promoting access to medicines and boosting local production capacity. In fact while the US is discouraging the use of compulsory license, the US itself has issued several judicial compulsory licenses following the *eBay v. MercExchange*, 547 U.S. 388 (2006) decision, whereby in cases pertaining to patent infringement of medical devices or inventions, courts have denied injunctive relief and granted monetary damages and royalties instead.[13]

The adverse effect of IP on the entry of generic competition and prices as well as the value of using TRIPS flexibilities to promote access to medicines has also observed in international instruments as well as by various international organizations.[14]

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[9] See http://www.who.int/phi/phi_trips_policybrief_en.pdf
[10] See http://www.who.int/phi/phi_trips_policybrief_en.pdf
[11] ICTSD/UNCTAD, 2003. Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA available at http://www.iprsonline.org/resources/docs/Reichman%20-%20Non-voluntary%20Licensing%20-%20Blue%205.pdf
[12] See http://www.twnside.org.sg/title2/health.info/twninfohealth086.htm
[13] See James Love, The CoreValve compulsory license on patent to treat aortic stenosis, (Sept. 1, 2011), http://keionline.org/node/1218; Anne Mira Guha, The Johnson & Johnson Acuvue Compulsory License (Sept. 1, 2011), http://keionline.org/node/1219; Anne Mira Guha, U.S. Compulsory licensing of medical inventions as a limit on remdies under eBay v. MercExchange, (June 7, 2010), http://keionline.org/node/862.
[14] See DOHA+ 10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future; UNAIDS Technical Brief 2011 available at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

For instance the WHO Global Strategy and Plan of Action on public health, innovation and intellectual property (GSPOA) adopted by all WHO member states including the US in 2008 through resolution WHA 61.21 states in para 12 that: " International intellectual property agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries. However, developing countries may face obstacles in the use of these flexibilities. These countries may benefit, inter alia, from technical assistance."

This same instrument calls on for the provision of "technical support…to countries that intend to make use of the provisions contained in the Agreement on Trade- Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products." (see para 5.2 of GSPOA).

The UNGA Political Declaration on HIV/AIDs adopted in 2011[15] also states:
"Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care, including by amending national laws and regulations, as deemed appropriate by respective Governments, so as to optimize: (a) The use, to the full, of existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights Agreement specifically geared to promoting access to and trade of medicines…"

"Urge relevant international organizations, upon request and in accordance with their respective mandates, such as, where appropriate, the World Intellectual Property Organization, the United Nations Industrial Development Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the World Trade Organization and the World Health Organization, to provide national Governments of developing countries with technical and capacity-building assistance for the efforts of those Governments to increase access to HIV medicines and treatment, in accordance with the national strategies of each Government, consistent with, and including through the use of, existing flexibilities under the Trade-Related Aspects of Intellectual Property Rights Agreement, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health.."

The 2011 UNGA Political Declaration on the Prevention and Control of Non-communicable diseases also notes the link between access and use of flexibilities:

"45. Promote, establish or support and strengthen, by 2013, as appropriate, multisectoral national policies and plans for the prevention and control of non-communicable diseases, taking into account, as appropriate, the 2008-2013 WHO Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases, and the objectives contained therein and take steps to implement such policies and plans; (p) Promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of non-communicable diseases, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities".

In 2002, the Global Fund board, specifically adopted an approach designed to encourage countries to use TRIPS flexibilities to achieve the lowest possible price for products of assured quality.[16]

[15] http://daccess-dds-ny.un.org/doc/UNDOC/LTD/N11/367/84/PDF/N1136784.pdf?OpenElement

UNITAID, whose mission is to contribute to scaling up access to medicines for HIV/AIDS, tuberculosis and malaria in low-income countries also provides in its constitution that "Where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing or other flexibilities under the framework of the Doha declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) Agreement and Public Health, when applicable."[17]

*Comment on alternative approaches proposed*

The US argues that alternative approaches such as voluntary licensing and tier pricing are preferred to use of flexibilities in providing availability of medicines.

Voluntary licences are contract negotiations between private parties. Terms in a voluntary licence may set price ranges, or include other terms that maintain prices at or near the same level as those offered by the patent holder. Or, terms may limit how many patients or which categories of patients are eligible to benefit from the lower prices provided by the licensee. In short, voluntary licensing arrangements depend crucially on the terms of the licence.

For instance in the case of the voluntary licenses developed under the Medicines Patent Pool, there are certain restrictions attached to the licenses. This includes that licences to manufacture are granted only to Indian manufacturers and a number of developing countries with high HIV burdens are excluded from the scope of the licences. Also MPP acknowledges that "it is not in a position to dictate terms and conditions to licensors".[18] Further in the case of MPP, in Dec. of 2011, Johnson & Johnson refused to license its patents on the HIV drugs to the MPP.

In short in a voluntary licensing arrangement much depends on the terms of the license and this in turn depends on the willingness of the patent holder. It is also worth noting the observation made on voluntary licensing in a report of WHO mission i.e. that "Voluntary licensing arrangements, at the discretion of the patent holder, are usually made for strategic reasons (e.g. market entry) rather than as price gestures and they may, in certain cases, not entail any price reduction at all. In developing countries, due to the lack of negotiating capacity of the licensee, voluntary licensing does not always translate into price reductions."[19]

The US proposal also promotes "tier-pricing" as a solution. On this it is worth noting the observation made in the WHO Commission Report on Intellectual Property, Innovation and Public Health i.e.

"The differential pricing approach undertaken by pharmaceutical companies varies significantly in response to price elasticity and other factors. Where they exist, open market prices usually respond to local market conditions. Companies do generally set different prices that take account of market conditions, willingness to pay and local regulations. Companies may be concerned that lower priced drugs in low income nations may be channelled back, one way or the other, to higher income countries, undermining their profits there even if, as is currently the case in most of the developed world, patented products from elsewhere (known as parallel trade – see below) are generally not permitted to be imported. Even if there is no

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[16] See the Report of the Third Global Fund Board Meeting held in October 2002 available at http://www.theglobalfund.org/en/board/meetings/third/

[17] See Article 1.2 of the UNITAD Constitution. http://unitaid.eu/images/governance/en_constitution_rev6july2011.pdf.

[18] See http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Q-and-A-Gilead-Licences#14

[19] Improving Access to Medicines in Thailand: The use of TRIPS flexibilities, Report of a WHO Mission, 31 January-6 February 2008, available at http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf

physical leakage of product between different markets, they may be concerned that governments in developed countries, under pressure from drug purchasers, may use prices in low income countries as a reference point for their own price setting or purchasing decisions. Moreover, because incomes are very unequally distributed in most developing countries, companies may find it best for their profitability to concentrate only on high income segments in developing countries, in particular because it is more difficult to apply a differential pricing policy within developing countries than it is between them."[20]

This comment clearly shows that tier-pricing is an inadequate tool for resolving the access problems of a particular country.

*Intellectual Property, Public Health and Innovation*

The US also argues in its paper that "weakening the patent rights" "in certain markets not only removes or reduces the incentive to develop new medicines but also leads manufacturers to keep already developed medicines out of the market" adding that "a new drug is more likely to be launched in a country where patent protection is strong".

This argument has simply no basis. Firstly no data is presented to support the co-relation between the use of flexibilities and reduced incentive for development of new products. Secondly it is now acknowledged that the existing incentive system is unable to address the R&D needs of many people living in developing countries.

On this an expert WHO report has noted that: "Where there is no purchasing power – either on the part of the government or the patient – the market is not an adequate determinant of value. Thus too few resources are likely to be devoted to developing drugs, vaccines and diagnostics that address the needs of people living in developing countries, because they are inherently unprofitable, or the relationship between investment and risk, in relation to potential profit, is unattractive to the private sector. The market alone, and the incentives that propel it, such as patent protection, cannot by themselves address the health needs of developing countries. That is the principal reason why new initiatives have sprung up in recent years, such as public–private partnerships."[21]

Thirdly just having a new drug available makes little sense if it is unaffordable to the majority of the patients that need the drug. Thus to ensure that the needed pharmaceuticals are available to the majority of people in developing countries it is important to use all measures available to reduce the cost of the product and to make it affordable.

The US proposal also calls for a study to evaluate the role of patent protection in providing incentives for research and development and in fostering technology transfer necessary to make generic and patented medicines available in developing countries.

In 2003, the World Health Assembly created a Commission that undertook a thorough review of the linkages between intellectual property rights, innovation and public health and emerged with a detailed report on this matter in 2006.[22] This report is widely known as the CIPIH report. This report also led to the adoption in 2008 of a Global Strategy and Plan Of Action on public health, innovation and IP (GSPOA).[23]

On the relationship between patents and R&D in the context of developing countries, the CIPIH report notes:

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[20] See http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf, pg. 129
[21] See http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf
[22] See http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf
[23] http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

"Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. However, the fact that a patent can be obtained may contribute little or nothing to innovation if the market is too small or scientific and technological capability inadequate. Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding. Because the balance of costs and benefits of patents will vary between countries, according to their level of development and scientific and technological infrastructure, the TRIPS agreement allows countries some flexibility in finding a balance more appropriate to their circumstances."

Noting the extensive work done in WHO to investigate the linkages between IP, public health and innovation as well the adoption of the GSPOA, the SCP should build on this work as per it mandate rather than to duplicate it.

**Comment on Enforcement**

The US in its proposal raises the issue of falsified and other substandard medicines adding that the SCP work program should address to what extent the presence in a market of falsified medicines hinders the availability of genuine medicines, both generic and patented.

The issue of falsified and substandard medicines has absolutely NO connection whatsoever with patent issues and thus WIPO does not have the mandate to discuss this issue. A pharmaceutical product is granted a patent on the basis whether it fulfills the patentability criteria used nationally and not on the basis of quality and safety of medicines.

Further the topic of proliferation of poor quality medicines is the mandate of the World Health Organization. In the WHO there is already an ongoing intergovernmental process that is working on this matter.

US attempts to raise this issue in the SCP is devious as it is aimed at confusing issues, and to distract the attention of the SCP from the actual issues that the SCP should be working on.

US suggestion that WIPO analyse all factors that affect the availability of off-patent medicines is absolutely ludicrous. As noted by the US, these factors are "unrelated to patents" and thus definitely not within the mandate of the SCP or of WIPO. Accommodating US suggestion would basically expand the mandate of WIPO to all other health issues.

**Comment on US's specific Proposals**

First the US proposes that WHO be invited to make a presentation to the SCP on the availability of generic medicines in DC/LDCs, on the non-patent barriers to availability of safe and effective medicines that are encountered in many countries, and on the effect of falsified medicines, both generic and patented, on the availability of proper medicines. This is aimed at putting "in context the potential effect of patents, as compared to the effect of other factors, on the availability of medicines".

This proposal of the US makes little sense as US is proposing inviting WHO to present at the SCP on issues SCP has simply no mandate to work on while refusing to discuss patent issues that SCP has a mandate on. Clearly it is an attempt to trivialize the impact of patents and to avoid any discussion on the impact of patents on public health.

Second - The US proposal also calls for a study to evaluate the positive role of patent systems in providing lifesaving medicines to developing countries adding that the study would evaluate the role of patent protection in providing incentives for research and development and in fostering technology transfer necessary to make generic and patented medicines available in developing countries.

The study proposed by the US is one-sided as it focuses only on the positive role of the patent systems. Further it has been noted above that in 2003, the World Health Assembly created a Commission that undertook a thorough review of the linkages between intellectual property rights, innovation and public health and emerged with a detailed report on this matter in 2006.[24] This report is widely known as the CIPIH report. This report also led to the adoption in 2008 of the GSPOA mentioned above.

Noting the extensive work done in WHO to investigate the linkages between IP, public health and innovation as well the adoption of the GSPOA, the SCP should build on this work as per it mandate rather than to duplicate the work.

Third- The US proposes conducting a comprehensive study to examine the availability of lifesaving medicines that are not protected by patents, and the reasons for their lack of availability adding that an important factor to be reviewed is the effect of falsified medicines, which circumvent any regulatory and enforcement regime. In support of its proposal the US argues that the availability of safe and effective medicines is a multifaceted problem and that informed analysis on how the patent system may or may not affect the availability of medicines is only possible with an understanding of these additional factors that affect the problem.

As has been noted above, this proposal of the US goes beyond the mandate of the SCP and should not be accepted. The proposal is about examining issues that have nothing to do with the patent system. The US argues that "the SCP would not be expected to take action on these non-patent issues which are not within its mandate but would benefit from an understanding of where its action fits within the broader range of factors influencing access to medicines".

It has been mentioned above that just because other factors may affect access, this does not preclude the need to address issues that arise in the context of patents and public health. Thus it makes little sense to discuss issues that the SCP has no mandate to work and that has nothing to do with the patent system.

It is strange that the US only wants to examine availability of medicines not protected by patents. This approach is selective. It also suggests that if patients don't have access to affordable medicines due to patents, and die as a result, this is not an issue that concerns the US.

**Conclusion**

As noted above the US proposal is based on frivolous points aimed at trivialising the issue of the impact of patents on access to medicines. In addition, the proposals made by the US falls outside the mandate of the SCP and thus should not be accepted.

On the other hand, the proposals of the Africa Group and Development Agenda Group should be adopted.

In its earlier submission, the Third World Network had also made a number of observations on the proposal of the Africa Group and DAG and provided additional proposals for

[24] See http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

consideration. We reiterate those observations and proposals.

Below are some brief inputs on the joint proposal of the Africa Group and DAG:
(i) On Element 1 pertaining to Studies, we welcome the proposal for a framework study. However, to ensure that the experts are fully informed about the challenges and constraints faced in using the flexibilities, we would also urge that Member states ensure that the experts commissioned to undertake the framework study do obtain inputs from public interest civil society groups by way of a public hearing as well as written submissions through web-based hearings. Civil society participation from developing countries to attend the public hearing should be facilitated with funding support from WIPO.

(ii) On Element II pertaining to Information Exchange, we are supportive of proposals contained in paragraph 9 to 12. These proposals (e.g. on developing a database on the patent status in WIPO member states (see para 12) are indeed justified in view of the challenge of information asymmetry faced by developing countries.

(iii) On Element II on technical assistance, we welcome the call to develop targeted technical assistance program following from the outcomes of the studies and information exchange. However we should also stress on the need to avoid conflicts of interest and to have proper reporting, monitoring and evaluation of these technical assistance programmes to ensure that these programmes are indeed consistent with public health objectives of the countries participating in the programmes.

**Further proposals on Patents & Public Health**

In view of the issues raised above in the introductory section, we are of the view that the SCP should also consider the following activities as part of their work-programme:

(i) Establish a panel of experts on patents and development to review patent provisions in bilateral and plurilateral trade and investment agreements and its impact on public health. To facilitate the review, public hearings and/or other forms of consultations with Member states and civil society should be conducted.

(ii) Conduct a study on patenting strategies and practices employed by pharmaceutical companies to prevent or delay generic competition. To facilitate information gathering and the preparation of study, Member states and civil society should be given the opportunity to make written submissions.

(iii) Conduct a web-based hearing on patent examination practices to facilitate the grant good quality patents and prevent the grant of frivolous pharmaceutical patents. The hearing could be followed up with a discussion in the SCP.

(iv) Setup a database to facilitate prompt dissemination of information pertaining to pre-and post grant oppositions to patent applications and grants related to pharmaceutical products filed in WIPO member states. The database should be publicly accessible and contain information on the patent oppositions filed including the rationale for opposition, responses to the oppositions, appeals filed (if any) and the final decision made on the opposition.

(v) Compile information on the legislative implementation of the 30th August 2003 Decision by WIPO Member states and to convene a discussion panel at the next SCP on the operation and use of the 30th August 2003 decision of the World Trade Organization.