Submission to the Global Commission
on HIV and the Law

Dear Global Commission on HIV and the Law,

Ten years have passed since the Doha Declaration established that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) "can and should be interpreted and implemented in a manner supportive of [World Trade Organization's] members' right to protect public health and, in particular, to promote access to medicines for all."

In that time, generic competition has fueled a revolution in global HIV/AIDS treatment, reducing costs of first-line HIV/AIDS medicines by 99 percent, from over $10,000 per person per year to under $100 per person per year today. This has helped six million people in low- and middle-income countries access lifesaving antiretroviral therapy. As costs have fallen, governments and global donors have exponentially increased their treatment programming.

But newer therapies, including second- and third-line medicines, are widely patented, aggressively monopolized and still very expensive. The high costs of patented HIV medicines compromise the finances of HIV/AIDS programs, including not only treatment but also prevention services.

Looking ten years further ahead, we can envision two radically different scenarios based on recent events.

In the first scenario, patent holder interests prevail in major trade agreements, at international organizations and in public debate. The US successfully isolates India through the Trans-Pacific Free Trade Agreement and inaugurates low patentability standards throughout the Asia-Pacific, limiting not only treatment access but generic production. As mergers in India and elsewhere eliminate viable global sources of generic supply, the economies of scale necessary to advance global generic competition prove unattainable. Treatment costs for newer medicines remain exceptionally high, making it more difficult to scale up treatment to meet global objectives including the Millennium Development Goals. Many people die needlessly, for lack of access to existing medicines.

In the second scenario, the access to medicines movement wins major concessions in trade agreements and at international organizations. Governments begin to use compulsory licensing and other competition measures with greater frequency, reducing costs and

improving countries' bargaining positions. This in turn increases the power and attraction of the voluntary Medicines Patent Pool – to which the United States could begin making significant contributions through government licensing rights to federally-sponsored research. Game-changing strategies like innovation inducement prizes and a global framework on research and development gain adherents. Taken together, a new "innovation plus access" framework emerges. Perhaps most importantly, more efficient research and development and lower treatment costs help inaugurate the era of global treatment as prevention.

A recent study has suggested antiretroviral therapy can, under the right conditions, reduce HIV transmission rates by 96%. This provides an unprecedented opportunity to cut transmission as we expand access to treatment – and possibly even effectively end AIDS in our time. The policies the international community establishes for innovation plus access can make the difference.

So, how can we guarantee sustainable & universal access to HIV/AIDS treatment in the future?

Two approaches must be pursued concurrently in our strategy to guarantee access to HIV/AIDS treatment in the future. One approach is to encourage and assist countries' use of TRIPS-flexibilities and to engage in other strategies within the current system to provide access. The second approach must focus on exploring and utilizing alternatives which deal with rising costs of treatment and scaling up of IP across the world.

Alternative models of innovation have been at the forefront of discussions on biomedical research and development. Most prominently, discussions are taking place at the WHO. In 2006, the WHO Commission on Intellectual Property, Innovation and Public Health asserted that "for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market."[1] Following this report, all countries, including EU Member States, agreed to a comprehensive 'Global Strategy and Plan of Action (GSPA) on Public Health, Innovation and Intellectual Property' at the World Health Assembly in May 2008. The strategy includes the promotion of measures to increase access to medicines and encourages member states to develop new models of biomedical innovation in order to ensure both access and innovation.

[1] WHO (2006) 'WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health', Geneva: WHO p.22

The GSPA calls on stakeholders to "explore and promote a range of incentive schemes for research and development including addressing the de-linking of the cost of R&D and the price of health products.'' This way it would not be the price of medicines that is used to retrieve the cost of the innovation, and broad access would be possible immediately after the product came on the market. A Consultative Working Group on Research and Development: Financing and Coordination (CEWG) has been established to analyze various proposals for innovative mechanisms.[2,3]

EU member states in the "EU Communication and Council Conclusions on Global Health," in May 2010, called for further exploration of innovation models that de-link the cost of R&D from the price of medicines.[4] Another important policy development regarding access and innovation is the "Innovation Union Communication," which is a flagship policy for the 2020 strategy, which states that EU innovation should be needs-driven, more efficient, cooperative, and inter alia calls for the creation of platforms for open innovation and citizen engagement, including through the awarding of prizes for research.[5] These EU-sponsored initiatives show that there is potential within developed countries to advance and support the exploration of new models on innovation.

Alternatives

Parallel to the intergovernmental policy discussions and international debates, various proposals and projects have been developed by governments, civil society, academics and industry. A number of these initiatives aim to ensure affordability of newly developed products, delinking the price of the product from the cost of the R&D and dismissing the exclusivity model. Other proposals seek to attract funding for research into neglected diseases, without including the aforementioned principles. Some are relevant for patients in developed countries, while others focus entirely on developing countries and/or neglected

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2 http://www.who.int/phi/news/phi_cewg_background_2011_en.pdf

3 WHO (2006) 'WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health', Geneva: WHO.

4 Particularly relevant elements of the Council Conclusions with regards to access and innovation are the 18 "c. *exploring models that dissociate the cost of research and development and the prices of medicines in relation to the GSPOA, including the opportunities for EU technology transfer to developing countries*,'' and "d. *ensuring that EU public investments in health research secure access to the knowledge and tools generated as a global public good and help generate socially essential medical products at affordable prices, to be used through rational use.*''

5 http://ec.europa.eu/research/innovation-union/index_en.cfm?section=competitiveness-report&year=2011

diseases. While a number of these initiatives have already been implemented, others still remain policy proposals. This section briefly describes some of the proposed mechanisms, some of which are currently being implemented.

Humanitarian or Equitable Licensing:

One of the proposals being considered is humanitarian or equitable licensing of IP rights, especially for R&D that has received public funding. The rationale behind equitable licensing is to generate the highest possible social benefit out of publicly-funded research. In a case where R&D results are licensed to a private company, the contract would include a set of conditions with the aim of achieving a low product price, high accessibility and, if possible, an access concept. For example, this access concept could be a differential pricing condition, ensuring affordable prices in developing countries.

The equitable or humanitarian licensing concept encourages open or non-exclusive licensing of patented technology. Non-exclusive licensing grants the right to use something, such as IP, on a non-exclusive basis. The same right can be granted to several licensees allowing more than one actor to make use of results stemming from (publicly-funded) R&D. The license can also be open, meaning anybody can use it. In the field of biomedical technology, non-exclusive licensing would generally allow for broader access to the technologies and health products, as it allows for more than one company to exploit the innovation, enabling generic competition, and in consequence, lower prices.

The first time the term equitable licensing was used was when Yale University renegotiated its license with Bristol-Myers Squibb (BMS) with regard to the HIV-medicine Stavudine (Zerit®) in 2001. Now, there are several institutionalised equitable licensing programs like the "Socially Responsible IP Management Program" at UC Berkeley.[6,7]

Equitable Licensing is now in use in the United States by several universities and by the National Institutes of Health,[8] and is promoted by GSK and the Gates Foundation in the area of certain neglected diseases.[9] UC Berkeley's Socially Responsible IP Management Program has collaborated with both companies on licensing agreements to ensure affordable

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6 http://ipira.berkeley.edu/socially-responsible-ip-management

7 Wagner, Equitable Licensing, Submission to the CEWG, 2011 http://www.who.int/phi/news/phi_21_cewg_med4all_en.pdf

8 http://www.biodevelopments.org/innovation/ist3.pdf

9 Ibid.

pricing in low-income countries for products stemming from university research. Projects with agreements under this program include TB vaccine research, malaria ACT research and research on a possible HIV treatment, among others.[10]

Voluntary licenses to the Medicines Patent Pool

Obtaining a licence for existing patents can be done on a case by case basis through voluntary or non-voluntary licensing. But, it is also possible to manage IP collectively through patent pooling. The Medicines Patent Pool (MPP) was established for the development and production of second-generation antiretroviral drugs (ARVs) and fixed-dose combinations (FDCs) used to treat adults and children with HIV/AIDS. The MPP is designed to reduce the price of existing medicines and speed up their availability. Here, any producer may pay royalties to patent owners in order to manufacture patented medicines and sell them in countries well before the expiration of the patent term.

Prizes For Innovation

Prizes are an incentive system to induce R&D for new essential medicines, and can be implemented in a manner that ensures competition, affordability and widespread access. In the open licensing approaches, cash prizes would be a substitute for exclusive rights to sell products and monopoly prices. Innovators would be awarded large monetary "prizes" based in part or in whole on the improvements to health outcomes over existing products. This would dramatically reduce incentives for the marketing and promotion of medicines that are used irrationally, or that are not better than the benchmarked alternatives. Prizes can also be designed to provide incentives to share materials, data, technology and access to knowledge.[11] While drawing up the prizes may seem difficult, in reality, this represents less of a challenge than determining the appropriate reimbursements for biomedical products.

There already exists a variety of prize schemes relevant to medicines development. In order to further advance discussions on prize fund models, government- and donor-backed research must be carried out to investigate the costs, benefits and feasibility of various implementation schemes.

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10 http://ipira.berkeley.edu/sites/default/files/shared/doc/SRLP_Highlights_100910.pdf

11 Love & Hubbard, The Big idea: Prizes To Stimulate R&D For New Medicines, Chicago-Kent Law Review, 2007.

The most ambitious prize fund approaches combine several different prize mechanisms. These include (1) end-product prizes that are awarded to the developers of products that are registered for sale and used by patients, (2) open source dividend prizes, which reward upstream open sharing of knowledge, data, materials and technology, and (3) prizes for earlier or interim development, such as achieving specific product development benchmarks or identifying biomarkers.

All of the issues in the design of prizes involve some controversy, including in particular the management of intellectual property rights, or the use of open source dividends. Some have argued that prize funds should not require open licenses on patents, and/or that prizes should only be used for achieving interim product development, and never be a substitute for the monopoly for the final product.[12] Within the pharmaceutical industry, some companies, like Gilead, J&J and Novartis have expressed support for exploring final product prizes for products like AIDS or TB medicines in developing countries, but oppose the use of prizes for products like cancer medicines, or AIDS and TB medicines in high-income countries.

An open source dividend for the prizes rewards researchers and organizations for sharing knowledge and information relating to product development. For example, in several of the WHO proposals being considered by the CEWG, 10% of the total final product prize would be reserved for entities making useful information contributions to the end product. To qualify for the open source payment, entrants must make their work freely available.[13]

The Donor Fund Prize

One specific proposal is the Donor Prize Proposal for HIV/AIDS treatment, which addresses the problem of the rising costs for antiretroviral drugs (ARVs) and the large number of people who still lack access to these treatments. Donor-funded treatment initiatives such as the Global Fund, UNITAID and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) depend upon generic competition, with more than 90% of donor-funded AIDS medications to developing countries supplied by Indian generic

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12 The Health Impact Funds seeks to modify the early prize fund models by eliminating open licensing of patents, and the X-Prize Foundation is opposed to linking prizes to open licensing of patents.

13 See for example, the definitions in S.1138, which would allocate 5 percent for the open source dividend.

manufacturers.[14] As generic competition is restrained and costs of treatment rise because patients are switching to more expensive second- and third-line treatment, donors such as the Global Fund may not be able to continue to finance treatment of 5.2 million PLHIV, not to mention the 9.7 million PLHIV in need who still lack access to treatment. Donors therefore urgently need to find a way to pay less for ARVs.

The donor prize proposal[15] presents a possible solution for reconciling innovation and access for certain markets where donors play an important role on the demand side. The donor prize fund would address the need for donors to have access to second- and third-generation HIV/AIDS medicines at competitive generic prices, while providing rewards to innovators. The prize proposal asks donors to place a fraction of their budget used for purchasing drug treatment (for example, 10%) into a funding pool that would be used to reward companies who license their patent to the MPP. Subsequently, generics suppliers would be able to easily obtain licences for these patents, in turn enabling donors to purchase generic medicines at marginal costs. Tying the prize fund reward to the need to licence patents to the MPP would create strong economic incentives for industry to adopt such a licensing practice, and to accept the scope of these licences would extend to developing and middle-income countries.

There is some controversy concerning the proposal to set aside a fraction of the budget currently used to purchase medicines for the prize fund rewards. Some fear this would interfere with current treatment programs. The rationale, however, is that the prize fund would effectively increase the donor's purchasing power. While it would be slightly more expensive to buy the cheap generic products, this would be offset by dramatic decreases in prices for the patented medicines now only available from originators. Furthermore, creating a market for generic products through open licensing would allow developing countries that

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14 Waning, Diedrichsen, Moon; A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries, The Journal of International AIDS society, Sept 2010, *available at*: http://www.jiasociety.org/content/13/1/35.

15 ***A Prize Fund to Support Innovation and Access for Donor Supported Markets*** *that would link rewards for innovation to the competitive supply of products for HIV-AIDS, TB, Malaria and other diseases for humanitarian uses. Presented in the European Parliament on November 18 2009 by James Love, KEI.* The proposal is based in a proposal presented by the governments of Bangladesh, Barbados, Bolivia, Barbados and Suriname to the World Health Organization in April 2009. http://www.who.int/phi/mspublichearing_rdf/en/index.html

do not benefit directly as grant recipients from the donor programs to benefit from the greater economies of scale and more efficient supply of low cost versions of medicines. [16]

The Prize Fund for HIV/AIDS

U.S. Senator Bernie Sanders introduced The Prize Fund for HIV/AIDS (S. 1138, 112th Congress) as an alternative innovation incentive system to exclusive marketing rights. "The proposed legislation would eliminate patent and other intellectual property barriers to the introduction of generic medicines for AIDS."[17] Rather than monopoly marketing rights (and the monopoly prices which come with them), innovation would be rewarded with a prize fund of more than $3 billion per year (.02% of U.S. GDP). The fund would be financed by the U.S. federal government and private health insurance programs. Though the $3 billion price tag is considerable, savings due to the increased competition between pharmaceutical manufacturers are expected to total more than $7 billion per year in the U.S. domestic market alone.

Three different programs would allocate the prize money:

- *End Product Prizes* would distribute prizes to "the first person who registers a, 'Qualifying Treatment for HIV/AIDS,' or a new manufacturing process for such a product." The size of these prizes would be based on the value of innovation measured in terms of the number of patients who benefit, the needs of special populations (e.g. paediatric HIV patients), the incremental therapeutic benefit of the drug or process and the improved efficiency of the manufacturing process.[18]
- *Open Source Dividend.* At least 5% of the prize fund would be devoted to rewarding "the open, non-discriminatory and royalty-free sharing of knowledge, data, materials and technology that has contributed to the development of the new medicines or manufacturing efficiencies that qualified for the end product prizes."[19]
- *The Donor Innovation Prize Fund* would be established by the Secretary of the Department of Health and Human Services. This fund would receive an amount

16 Ibid.

17 Love, The Prize Fund for HIV/AIDS - A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs for AIDS: De-Linking Markets for Products from Markets for Innovation, 26 May 2011.

18 Ibid.

19 Ibid.

equal to 10 percent of the cost of AIDS drugs in programs supported by PEPFAR and other federally funded HIV/AIDS treatment programs. Prizes from this fund would only be distributed as rewards for products which permit open competition in developing countries by[20],

- not patenting products,
- providing non-discriminatory royalty-free open licenses and other IP claims on at least a field of use for the treatment of HIV/AIDS in developing countries, or
- licensing to the Medicines Patent Pool.

Coordination and Funding: Essential Global Health and Biomedical R&D Treaty

A binding intergovernmental instrument regarding the coordination and financing of biomedical R&D is being considered at the WHO. This instrument would contain financial obligations for countries to contribute to R&D financing with incentives that deliver innovation and access. Since 2000, discussions on such an instrument have been taking place, and the need to coordinate and prioritize R&D has become increasingly obvious and pressing. Discussions at the WHO are becoming more concrete, most specifically in the establishment of the Consultative Expert Working Group on R&D Financing and Coordination, which is recommending for negotiations to start. Negotiations on such a binding intergovernmental instrument would take place under the auspices of the WHO.

The proposal to develop an Essential Global Health and Biomedical R&D Treaty would have a huge impact on public health as it would aim to create a new global framework for supporting priority medical research and development that is based upon the equitable sharing of the costs of research and development and incentives to invest in needs driven R&D. The treaty would provide the framework for ensuring that sufficient, regular, predictable and sustainable financing for R&D for type I, II and III diseases is secured and that mechanisms to facilitate health needs assessment, priority setting and the assessment of funding needs are developed and put into practice.

The Objectives of such a treaty would be to promote a sustainable system of medical innovation that would:

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20 Ibid.

1. Ensure adequate and predictable sources of finance for needs-driven medical R&D particularly relevant to diseases and conditions which disproportionately affect developing countries;
2. fairly allocate the costs of supporting needs-driven medical R&D, in particular, to meet the health needs of developing countries;
3. identify priority areas of needs-driven R&D;
4. explore and promote a range of incentive schemes for health-needs-driven R&D addressing the de-linkage of the costs of R&D and the price of health products;
5. encourage the broad dissemination of information, sharing of knowledge, and access to useful medical inventions, including the facilitation of access to publicly-funded research;
6. promote transparent and ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies;
7. enable medical researchers to build upon the work of others;
8. support diversity and competition;
9. utilize cost-effective incentives to invest in promising and successful research projects that address health care needs;
10. enhance the transfer and building of technological knowledge and R&D capacity to further social and economic welfare and development in developing countries and;
11. promote equitable access to new medical technologies, so that all share in the benefits of scientific advancement.

Recommendations:

<u>Explore and support these proposals by, among other things:</u>

- Engage in a feasibility study of the Donor Prize Fund.
- Encourage companies to license to the Medicines Patent Pool.
- Encourage the EU and the US to constructively engage in discussions around an Essential Health and Medical R&D treaty.
- Support the mandating of equitable licensing of publicly funded biomedical research.

Sincerely,

Submission to the Global Commission
on HIV and the Law

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