Editorial

Pooling ARV Drug Patents: A Pro-Access Fitting Strategy?

BACKGROUND

Unaffordable prices still obstruct access to brand antiretroviral (ARV) treatments for HIV infection in the income-constrained countries, while being the challenges complicated by obstacles bound up with enforcement of World Trade Organization-WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) [1].

Definitely, patent protection, by eliminating generic competition, has skyrocketed the brand drug prices, while TRIPS-plus measures (such as exacerbated data exclusivity) do hamper the development of any new generic ARV formulation containing drugs with exclusive status.

As newer antiretroviral medicines (ARVs) are crucial once first line formulations fail, this is a worrisome situation despite that TRIPS rules encompass flexibilities (including voluntary and compulsory licensing) to help poor populations equitably access low-priced ARVs.

These constraints are further affected by the recent economic crisis.

These constraints, again, substantially suffer from the fact that, coherently with enforced national patent law and WTO obligations, many of the newer ARVs will be patentable in India (as already are raltegravir, maraviroc or etravirine): this means that Indian industries are barred from manufacturing and rolling out generic cheap copies as they used to do in the past [2].

THE ONGOING GAP

Based on the health spending is still less than US$ 10 per person per year in most African countries, these obstacles play as enormous barriers in preventing poor people from getting the care they need.

In low- and middle-income countries, more than 4 million people were receiving ARVs at the end of 2008 (while 5 million are still in need), with approximately 277 000 children (38% of those in need) benefiting from paediatric ARV treatments. Sub-Saharan Africa accounts for three quarters of these figures [3].

Intriguingly, the market for paediatric ARVs in the USA and Europe is very small compared with the developing world: so, there are no incentives for brand name corporations to develop new or more appropriate ARV formulations for children because they aren't a lucrative market. Difficulties are enhanced by the fact that treating children implies much higher costs than adults [4].

So compounded, the inequity still strikes children in resource-constrained countries does underscore the matter how to let adult and underage worst-off fairly access appropriate and affordable ARVs on ongoing basis. Regrettably, one-third of ARVs are not yet available in paediatric formulations; and some key first- and second-line triple fixed-dose combination (FDC) ARVs simply do not exist or enough suppliers are lacking.

In such a perspective, would a sustainable strategy attuning together the interests of all counterparts (end-users, generic and brand-name corporations, United Nations and governments in wealthy and under-served markets) be conceivable?

This strategy should 1) be up to securing the worst-off most expanded access to as fairly as possible low-priced and appropriate ARVs; 2) be equipped to equitably affect regulatory practices, while meeting the interests of generic and brand name manufacturers and, at the same time, favouring for-equity dynamics with trading policies of concerned countries (mainly China, India, European Union, United States, Brazil, South Africa and Thailand); 3) be suitable for helping generic plants for ARVs, including home plants in Sub-Saharan Africa, take off and undertake R&D partnerships encompassing innovation, technological catch-up, exploitation of TRIPS flexibilities, as well as raised marketing power and domestic employment increase.

TOWARDS A PATENT POOL FOR ARVs?

Aiming to help solve these problems, UNITAID (International facility to provide long-term funding to increase access to drugs and diagnostics for HIV/AIDS, malaria and TB) recently launched an initiative for the management of intellectual property (IP) rights – a patent pool for HIV medicines [5]. As remarked by Jorge Bermudez and Ellen 'tHoen in this issue ".... The idea behind a patent pool is that patent holders - firms, governments, researchers or universities - offer, under certain conditions, the IP related to their inventions to the patent pool. Any company that wants to use the IP to produce or develop medicines can seek a license from the pool against the payment of royalties, and may then produce the medicines for use in developing countries (conditional upon meeting agreed quality standards). The patent pool will be a voluntary mechanism, meaning its success will largely depend on the willingness of pharmaceutical companies to participate and commit their IP to the pool...".

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Patent pools are part of May 2008-adopted World Health Organization-WHO's Global Strategy on Public Health, Innovation and Intellectual Property to help increase access to medicines [6]. As far as ARV treatments are concerned, quantified benefits are expected to include, through skyrocketed market competition, substantially lower prices for second and third-line new FDC ARV formulations resulting from the pools.

Patent pools for ARVs should not be given up or delayed: indeed, full availability of appropriate and affordable FDC ARVs, including second and third-lines, is top priority for the worst-off in the developing countries [2]. Attaining this goal would effectively counter bitter reality witnessing that ARVs are primarily developed for wealthy country markets, while trials are focused on coping with registration requirements in these countries and key research matters for resource-constrained populations are often only tackled long after drug registration and rolling-out in the Europe and USA [7].

Pooling ARV drug patents would carry out WHO's calls on appropriately needed new FDC ARVs [8, 9]. These may include adding heat-stable protease inhibitor (PI) ritonavir (RTV) to each atazanavir (ATV), darunavir (DRV), or saquinavir (SQV) PIs, or variously combining raltegravir (or other integrase inhibitors) with either newer heat-stable RTV-boosted PIs (also unboosted in the case of ATV) or the non-nucleoside reverse-transcriptase inhibitor (NNRTI) etravirine (pending results from raltegravir-novel NNRTI rilpivirine interaction studies). For paediatric purposes, combinations including heat-stable 35 mg emtricitabine tablets should be taken into account.

CRITICAL POINTS

Unfortunately, multinational originator companies still seem to perceive patent pooling for ARVs as a minefield that would offer the generic competitors lots of deeply exploitable opportunities, to the detriment of patent owner's rights. Additionally, a number of other critical points have emerged and are discussed in this issue. Amongst them:.

- As remarked by Victor Rodriguez, ".... Patent pools do not correct all problems associated with patent thickets. In this respect, patent pools might not stop the outsider problem from striking pools. Moreover, patent pools could be expensive to negotiate, could exclude patent holders with smaller numbers of patents or enable a group of major players to form a cartel that excludes new competitors. For all the above reasons, patent pools are subject to regulatory clearance because they could result in a monopoly...".
- Moreover, as per Stavros Nicolaou's words ".... affordability through reduced pricing is only one part of enhancing access to treatment in Public Health emergencies: supply security and the guarantee of supply consistency is the other. To the extent that patent pooling is able to create Regional African Manufacturing capability, Africans will support the concept. However, to the extent that it further decentralises manufacture away from the continent and increases Africa's dependence on imports, patent pooling can potentially weaken supply security and will continue to relegate Africa a Continent of dependency, rather than one that invests in its own capability....".
- Again, as raised by Eric Noehrenberg, ".... Another important question is what are the implications of patent pools on innovation for creating new and improved ARVs. Indeed, given the continuing mutation of HIV and growing resistance to existing treatments, continued innovation in ARV development is vital for addressing these challenges. Would patent pools be a hindrance or rather a stimulus for further innovation?...".
- Furthermore, as underscored by Michelle Childs, "..... A patent pool must not be implemented at any costs, but answer medical needs, be based on economic realities and meet the access needs of the developing world, including middle-income countries....".

Dilemmas and conflicts bound up with patent pools for ARVs may explain why Antony Taubman's contribution plays as opening article here. Echoing the Author "....This paper seeks to set the practical discipline of public interest intellectual property (IP) management in public health into its broader policy context..and.... offers a tentative framework for a richer typology of those [related] choices, to give a sense of practical options available and the factors that might guide their application, but without advocating any particular approach..... This article therefore develops the concept of public-interest or public-sector IP management, concentrating on the management of IP directly to leverage public health outcomes.....".

So compounded, this paper fits as a comprehensively overarching perspective up to attuning together the overall challenges analysed in the special issue.

This Open AIDS Journal special issue tackles the questions and conflictual feelings bound up with patent pools for ARVs through broad range, invited contributions by acknowledged leaders and Institutions worldwide. Each contribution substantially adds to the matter, while allowing the readers to be aware and learn from the overall article collection. Again, synoptic comparison among visions, strategies and requirements featured by each contribution is expected to enhance the solution chances.

As a whole, overall insights in this special issue look for a model up to a free, non-discriminatory and equitable world market, while asserting the primacy of health over for-profit policies, and aligning with the 61st WHO's Assembly recommendations and G7, G8 and World Trade Organisation's warnings and pledges against trade protectionism.

So featured, there is room for hope that contents in this issue will be taken into consideration by the Expert Working Group (EWG) recently established by WHO (http://www.who.int/phi/ewg/en/index.html) to examine innovative sources of funding to stimulate R&D and long-term access related to diseases disproportionately affecting the developing world.

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