I-MAK initiative for medicines access & knowledge
ITPC Strengthening Community Responses to HIV Treatment & Prevention

Voluntary Licensing: Optimizing Global Efforts and Measuring Impact

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Introduction

For the past decade, pharmaceutical companies have increasingly used voluntary licenses to allow generic production of patented antiretroviral drugs (ARVs) for People Living with HIV/AIDS (PLHIV) in poor countries. However, these licenses have not been pursued optimally from a public health standpoint. For example, some originator companies allow only a limited number of licensees, thereby restricting generic competition and the potential for reduced drug prices. And all originators currently exclude some portion of low- and middle-income countries (LMICs) from being eligible to purchase these lower-cost generic medicines. As the next generation of ARVs are developed and patented, expanding access to treatment will increasingly rely on improving voluntary licensing practices within the pharmaceutical industry.

Recently, global health organizations have made efforts to advance the voluntary licensing agenda. Most notably, the UNITAID-funded Medicines Patent Pool (MPP) launched in 2010 to negotiate licenses with ARV patent-holders and act as a central hub for sub-licensing to generics. Compared with the traditional system of bilateral agreements, this approach seeks to streamline the licensing process, reduce transaction costs, and increase transparency.

Other global actors have more recently entered the fray by proposing licensing guidelines for originator companies. These include the newly-launched HIV Medicines Alliance (HMA), whose draft charter proposes general principles for intellectual property and licensing, and a combined effort from UNAIDS and the Clinton Health Access Initiative (CHAI), who have gone a step further by drafting a detailed set of standards for future licenses.

Though these latter projects have yet to come to fruition, it is critical to take a step back and evaluate the collective efforts of global actors to improve the state of voluntary licensing. The stakes are particularly high when it comes to creating normative standards, as pharmaceutical companies are unlikely to agree to terms more generous than those endorsed by agencies like UNAIDS, which is seen as representing the entire HIV community.

This paper will comment on the current efforts of these global health institutions and propose a path forward to ensure that voluntary licenses are pursued in a strategic, access-maximizing manner. Specifically, if these institutions are going to act on behalf of the global patient community, they must do so in a way that upholds the central tenet of universal access for *all* PLHIV; ensures that TRIPS flexibilities are protected and efforts to implement them are not undermined; and harnesses all available negotiating leverage to maximize the public health benefit of each license.

Standards for Geographic Coverage

As a global health community committed to universal access, we must remember our individual and collective mandate to work for PLHIV in all countries, particularly those in LMICs. The draft standards from both the HMA and UNAIDS/ CHAI endorse voluntary licenses that fall short of this standard – including only low-income, least-

developed and Sub-Saharan African countries in the case of HMA (~75%[1] of people needing antiretroviral therapy (ART)), and approving coverage of only 90% of PLHIV in the case of UNAIDS/CHAI.

Accepting access to affordable ARVs for some while endorsing the exclusion of others is an abdication of our collective responsibility to the global patient community. Understandably, concessions may be necessary to move a specific negotiation forward; however, to endorse a framework of exclusion is a breach of our community's mandate to promote universal access.

Furthermore, the proposed HMA and UNAIDS/CHAI standards implicitly endorse the status quo, thereby failing to move the access agenda forward. Most originator access programs already cover a vast majority of low-income, least developed, and Sub-Saharan African countries (three-fourths of all patients needing ART) as suggested by the HMA, and in the case of Gilead Sciences' licenses, geographic coverage includes nearly 90% of people needing ART[2]. The true value-add of global health institutions is to advocate for coverage of the middle-income countries that are being systematically left behind, particularly for second-line ARVs which are often priced out of reach. These countries account for one fourth of total patients needing ART (~3.5 million people) and a similar proportion of those needing and still not receiving treatment (~2 million out of 7.5 million total across LMICs).

There is a widespread assumption that the middle-income distinction indicates the ability of a country to fully fund ARV treatment. This erroneous assumption ignores the percentage of the population in poverty, the unique intellectual property barriers middle-income countries often face, and the fact that scarce government resources are insufficient to fund universal access at exorbitantly high branded prices. In these countries, the HIV epidemic is often concentrated in vulnerable communities plagued by stigma and discrimination and ignored by governments.

"Endorsing a framework of exclusion is a breach of our community's mandate to promote universal access"

It is these communities that struggle the most to access treatment and need the intervention of public health institutions to make access a reality.

Strengthening the Pool

Amongst the organizations discussed, the MPP is unique in that it aims to act as the lead negotiator for all future ARV voluntary licenses. In assuming this role, it is incumbent upon the MPP to develop strategies that seek to optimize the outcomes of their negotiations, particularly in terms of geographic coverage. To do this, the MPP should think more expansively about its role; streamlining process and reducing transaction costs only scratches the surface of what is achievable. To this end, we urge the following actions:

The MPP must find its leverage. To be a negotiating body without any meaningful leverage renders the MPP model virtually powerless in advancing the goals of universal access. To achieve the best possible license terms from originator companies, the MPP must use the only real source of negotiating leverage available to them: the right of developing countries to implement TRIPS flexibilities. There are numerous examples in which the use or threat of use of TRIPS flexibilities have driven originator companies to

[1] All statistics in this section were calculated using 2010 data for people needing ART according to WHO guidelines. This data was obtained from "The Progress Report 2011: Global HIV/AIDS Response," available at www.who.int/hiv/pub/progress_report2011/en/index.html.

[2] The 2011 Gilead-MPP license for TDF increased patient coverage by less than 1% from the original licenses Gilead signed in 2006, which covered 89% of people needing ART. See "A Consultation between Representatives from the Global South (ITPC/I-MAK/Lawyers Collective/Regional Representatives) and the Medicines Patent Pool/UNITAID," 2 October 2011, available at www.i-mak.org/presentations.

grant significant concessions in their access policies[3]. Drawing on UNITAID's support, the MPP should explore ways that it can harness this leverage, including direct involvement with governments on compulsory licensing, or indirect involvement with patent oppositions by making publicly available the findings of a patent quality review. Given that many countries have yet to consider using these flexibilities, this is an area ripe with need for greater and more coordinated intervention. And failing to move in this direction would be an enormous missed opportunity, as it is the only source of power to counter the otherwise full control of originators in limiting the reach of affordable, generic ARVs.

> ***"It is these vulnerable communities that struggle most to access treatment and need the intervention of public health institutions to make access a reality"***

The MPP should implement a process that meaningfully includes civil society. A central tenet of the PLHIV movement is that there can be no negotiating for drugs affecting our lives without full participation at every stage. In assuming its role as lawyer on behalf of the community, the MPP should create a truly inclusive, democratic process by which its key constituents are involved in creating baseline terms and conditions from which it operates, as well as approving licenses before they are signed. The ongoing, case-by-case involvement of civil society is necessary because of the unique considerations of each situation (e.g. current patent landscape and remaining patent life, benefit of drug versus alternatives, access concerns for specific populations).

The MPP should develop meaningful indicators to assess its impact. Such metrics should include global patient coverage in LMICs, global ARV cost savings resulting from licenses, and other qualitative indicators relating to the health of the marketplace (see *Voluntary License Scorecard* below for further detail). These indicators should be used not only to measure potential impact, but also to track the actual, ongoing impact of licenses in the market (e.g. countries supplied, prices paid in each country, time-to-market for new formulations, etc.). The number of licenses signed and media coverage[4] should play a diminished role in the MPP's definition of success.

The MPP should build upon its first major success: the ARV patent database. The database is a tremendous contribution to the global health community in providing increased transparency around ARV patenting. The MPP should now improve upon this database by providing relevant documentation for each patent and creating comprehensive patent landscapes on each drug, including claims analyses. In addition, the MPP should expand the database's functionality to include legislation tracking, including all pending and final patent legislation, rules, guidelines, and decisions across LMICs. This information can ultimately bring more transparency to the negotiation and implementation of licenses.

Conclusion

At their best, voluntary licenses can create robust generic competition that enables affordably-priced ARVs for all patients in LMICs. At their worst, they can be a tool of the pharmaceutical industry to manage competition, segment developing markets, and collect royalties even in the absence of patent rights. Working more strategically to optimize voluntary licensing should be a top priority for the MPP and other global health organizations if they are to truly accelerate access and achieve the UNAIDS goal of 15 million people on treatment by 2015.

[3] See pages 5-7 of UNAIDS Policy Brief, "Using TRIPS to improve Access," at www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

[4] For a complete list of indicators, see page 125 of UNITAID's Patent Pool Implementation Plan.

Voluntary License Scorecard

Licenses should be evaluated according to the extent to which they expand access, lower treatment costs, and create a robust, competitive generic market. To measure the impact of future licenses, we propose the following set of indicators for both structuring license terms & standards and monitoring their impact on an ongoing basis. This scorecard should be used for all public health institutions intervening in the licensing space.

Key indicators

1. **Global patient coverage:** The percent of people needing ART in LMICs that live in the geographic territories covered by the license. Patient coverage should be measured both:
    a. as an improvement from the status quo (i.e. the originator's current access policy, or where none exists, the average originator program's figure of 75%), including coverage of traditionally excluded middle-income territories, and
    b. against the goal of universal access (100% of all PLHIV needing ART).

2. **Financial impact:** The global savings expected/achieved from purchasing the drug at generic vs. branded prices, based on projected demand initially then actual purchase volumes and prices on an ongoing basis.

3. **Market impact:** The extent to which the license fosters a healthy and competitive marketplace, including the following elements:
    a. Competitive landscape – number of licensees
    b. Free competition – little to no restrictions on sourcing (e.g. of API) or other aspects of manufacturing and marketing to licensed territories; elimination of grant-back clauses[5]; independent and frequent review of licensed patents and patent applications[6]
    c. New product development – time to market of new formulations (e.g. pediatric and FDC formulations)
    d. Transparency – public disclosure of license terms and related IP information; technology transfer to licensees and its impact on generic time-to-market (as reported by licensees)

4. **Impact on TRIPS flexibilities,** including:
    a. Not undermining the use of public health safeguards in patent laws, e.g. the efficacy standard[7], and the uninhibited use of compulsory licensing by developing countries
    b. Ensuring that licenses and royalties are not enforced until a patent is granted in the relevant licensed territories, including non-enforcement if a patent application is refused and/or under appeal. *(Payment of royalties while patents are refused through examination or opposition renders such processes toothless.)*

Note: This list is meant as a starting point and not intended to be exhaustive.

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[5] Grant-back clauses run the risk of scrutiny under competition law when they require licensees to license back all technological developments to the licensor without royalties or protection, and allow open use by the licensor.

[6] An ongoing review of patents and patent applications licensed into the Pool is particularly important for the purpose of monitoring their scope and the Pool's impact on the shaping of market dynamics.

[7] In 2005, India introduced into its patent law a requirement that new forms of known compounds demonstrate efficacy, or therapeutic benefit, in order to be patentable. Other countries have adapted this standard into their laws and rules.