**Scoping a Compulsory Licensing Strategy for Countries Excluded from Gilead's Long-Acting Lenacapavir Voluntary Licenses**

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## I. Introduction

This paper presents a preliminary analysis of compulsory licensing opportunities available for middle-income countries that will want access to Gilead's breakthrough long-acting lenacapavir (LEN-LA) for both pre-exposure prophylaxis (PrEP) – once approved – and treatment, but that are excluded from Gilead's bilateral voluntary licenses. LEN-LA has been used successfully as a salvage therapy in high-income countries and recent clinical trials have found astonishing efficacy for PrEP in at-risk groups including young women in Africa (Purpose 1 - 100% efficacy) and cisgender men, transgender men, transgender women, and gender non-binary individuals who have sex with men (Purpose 2 - 96% efficacy) to be much higher than currently available PrEP options. Clinical trials are also underway for people who use drugs (Purpose 4). LEN-LA is considered to be a potential gamechanger in the campaign to greatly reduce new HIV infections, but only if it is affordable and introduced ambitiously to reach all relevant populations in need. Gilead's LEN-LA, astronomically priced at over $40,000 a year in the U.S. can be produced, with a profit, for only $40 per-person-per-year when produced at scale. Only with affordable prices can HIV programmes sustain ambitious scale up globally. And only with ambitious scale up will the benefit of LEN-LA be realized for communities

As discussed further below, the 26 countries and territories excluded from the Gilead license will not be able to source from Gilead's licensees under any circumstances due to the voluntary license terms and thus will need to find alternative generic producers who can supply them to overcome Gilead's onerous tiered-pricing and supply terms. Fortunately, there is growing interest in the use of compulsory and government use licenses (for example, the recent CL on dolutegravir in Colombia), CL on dolutegravir in Colombia and this paper analyzes potential supplier countries, patent landscapes, and practical compulsory licensing approaches that can be used to individually and collectively for excluded countries to access the active pharmaceutical ingredient for local production and the finished formulation of LEN-LA. Potential supplier countries include Bangladesh (where there is no blocking patent), India (where a product patent has not been granted, oppositions have been filed, potential suppliers have already quietly expressed interest, and there is an effective production-for-export mechanism), China (given its strong manufacturing capacity), and at least nine other middle-income countries that have producers who already produce quality assured antiretrovirals. The lenacapavir patent landscape indicates that fifteen excluded countries face barriers from filed or granted patents, but nine excluded countries face no such barriers. For both producer and importing countries with patent barriers there are several compulsory licensing routes to LEN-LA pursuant to TRIPS-compliant flexibilities found in Articles 31 and 31bis (though a more thorough examination of national CL provisions may still be needed). The most promising strategy requires collaboration between excluded countries and key manufacturing countries to coordinate their use of CLs to aggregate a market that will be attractive to one or more generic supplier. Available evidence shows that sourcing from CL-licensed generics can result in substantial costs savings and security of supply (for example Colombia's CL on dolutegravir may achieve a 26-fold reduction price). Even the plausible threat of CLs has been successful in strengthening countries' ability to negotiate better supply and price terms from patent holders such as Gilead.

This analysis leads to several, immediately operable recommendations:

- Excluded countries can issue expressions of interest in generic companies willing to be CL licensees; joint statements would be even better.
- Excluded countries without sufficient manufacturing capacity or markets too small for efficient and sustainable domestic supply should notify the World Trade Organization of their intent to import LEN-LA under Article 31bis procedures; joint notification would be preferable.
- Excluded countries should immediately take steps to determine the best CL or government use mechanism in their national law that would allow either sustainable local production or importation.
- Qualified producers for both API and finished LEN-LA should be identified with a focus on regional suppliers and/or suppliers facing no or easily traversed patent barriers.
- Excluded countries should cooperate and coordinate to aggregate their markets via TRIPS-compliant CLs as required and should further establish pooled procurement mechanisms as a further positive market-entry signal for generic licensees.
- Excluded countries should explore means for expediting regulatory approval or licensed LEN-LA.
- Key manufacturing countries should be encouraged to implement their CL-for-export mechanisms.
- WHO, UNAIDS, Unitaid, and others should signal support for excluded countries' use of TRIPS-compliant CLs and offer political, technical, and financial support for the same.
- Resources should be made available to civil society campaigners who can push globally, regionally, and nationally for patent oppositions and CLs in excluded countries, for community engagement and health literacy regarding the promise of LEN-LA, and for the rapid introduction and scale-up of LEN-LA and other PrEP programming.

## II. Gilead's Restrictive Voluntary License and its Challenges

As widely reported, Gilead issued bilateral voluntary licenses to six generic companies allowing them to manufacture lenacapavir active pharmaceutical ingredient and final formulation for sale and use in 120 countries and territories, mostly low- and lower-middle-income countries. Gilead's licenses, which are published, included extremely restrictive provision preventing sale and use in countries outside the listed territory with strict anti-diversion, reporting and termination provisions for unauthorized sales by licensees or their distributors and buyers. In particular, Gilead included a provision that prevents supply by a licensee to an excluded country even if no granted or pending patent would be infringed and even if compulsory licenses were to be granted to a licensee in a country of production, export, use, or import. This exclusion contrasts sharply with voluntary licenses negotiated by the Medicines Patent Pool, and past Gilead licenses, which routinely allows generic licensees to supply license-excluded countries that issue CLs or where no blocking patent rights are in force.

Although Gilead has promised to directly supply lenacapavir to the 26 middle-income countries and territories excluded from its voluntary licenses, it will do so pursuant to its commercial interests and on its own terms via tiered pricing, which will be negotiated, presumably confidentially, country-by-country. Historical experience suggests that Gilead will clad those price negotiations in secrecy via non-disclosure agreements and that the eventual tiered prices will be "predatory" in the sense that prices may be set at levels neither governments, insurers, nor individuals can truly afford, and will lead to rationing of LEN-LA for PrEP. History further predicts that Gilead can and will further pursue its commercial interests in the timing and scope of regulatory filings, with smaller and poorer countries left behind. The predictable outcome will be delayed and small-scale rollout, rationing, and a stark failure to reach HIV prevention and treatment goals that might otherwise be achieved.

Gilead's restrictive policy was widely condemned by access-to-medicines advocates, AIDS activists, the International AIDS Society, and researchers with demands that it expand its license to include the excluded middle-income countries. Such efforts should and will continue with additional pressure added by other global health actors including UNAIDS and Unitaid that have already urged license expansion. However, activists have also advocated for use of compulsory licenses (CLs) to overcome Gilead's monopoly control over supply, price, and distribution to excluded countries. Even countries that are included in the licenser may find that Gilead's restrictive licensing terms – for example limiting uses of long-acting lenacapavir for treatment and preventing co-formulation with other long-acting ARVs – to be unsatisfactory and therefore consider compulsory licensing. However, in all such cases, countries will need to look beyond Gilead's six licensees for supply of the active pharmaceutical ingredient (API) and finished product.

Countries excluded from Gilead's voluntary licenses will face a number of challenges in accessing more affordable generic lenacapavir including:

- Countries will have to identify one or more qualified producers that have existing antiretroviral (ARV) manufacturing capacity, that can meet national and perhaps global Good Manufacturing Practice (GMP) standards, and that are willing to invest in expensive product development, bioequivalence studies, and regulatory filings.
- Those manufacturers could face infringement and other law suits from Gilead and therefore should be willing to use CLs to overcome patent barriers in the country of production to allow domestic use and/or manufacture for export.

  - A regular compulsory or government-use license issued in line with TRIPS Agreement Article 31 requirements can be used to meet domestic demand; such licenses would also allow export of non-predominate quantities to other countries with no patents on lenacapavir or where patent barriers have been removed via a compulsory license to allow importation from the relevant manufacturer.
  - However, if the manufacturer seeks to export quantities in excess of what is provided domestically, it will need to meet special CL procedures mandated by Article 31bis of the TRIPS Agreement; in such instances, the manufacturer can only supply countries with no or insufficient manufacturing capacity to produce lenacapavir domestically; the Art. 31bis CL-authorized producer will also need to specify quantities to be exported to particular countries and meet notification and product differentiation standards.
- Excluded (and other) countries that wish to import non-Gilead-licensed generics from a qualified producer will not have to issue a compulsory license if they have no blocking lenacapavir patents; but, if they do have such patents, they will need to override them.
  - Importing countries with blocking patents can issue an Art. 31 import license to a qualified foreign producer with freedom to operate and export in order to import non-predominate quantities.
  - If countries have to import pursuant to Art. 31bis because of restrictions on quantities that can be export, the importing country will have to both notify the WTO that they have insufficient domestic manufacturing capacity and comply with the notification requirement specified in Art. 31bis.
  - (Note: Countries that have some domestic pharmaceutical manufacturing for ARVs (or possibly other small molecule medicines) but that lack sufficient domestic demand for commercially viable domestic-only production, may still be able to rely on Art. 31bis procedures by arguing that the term “insufficient” covers their circumstances.)
- Compulsory licenses are most often granted with respect to granted patents, but in several excluded countries, lenacapavir patents are still pending; in such cases, depending on domestic law, CLs might still be granted on conditional basis pending final patent decision.
- Exporting and importing countries might also consider recognizing and using an Art. 30 exception to the predominately-for-domestic-use requirement of Art. 31(f), but few countries have such a provision in their national legislation.
- In all instances, manufacturers and countries will have to follow domestic CL rules as well as TRIPS standards to avoid the risk of national, TRIPS, and investor-state-dispute-settlement claims by Gilead or TRIPS Member States; in some instances, bilateral and regional free trade agreement provisions might also need to be taken into account.
- Manufacturers and countries will also need to identify all relevant patents in advance, with the exception of no need to do so for government use licenses.

## III. Identifying quality assured MIC producers

In order to source timely, affordable, and sufficient supplies of lenacapavir to meet urgent need, excluded countries will need to attract and incentivize qualified producers (other than those licensed by Gilead).  Some excluded countries, like China, Argentina, and Brazil, certainly have robust manufacturing capacity and may have sufficient domestic demand for lenacapavir that local production could be viable.  This subset of countries could rely on national regulatory approval as they have done in the past with efforts to ensure that the API supplier meets WHO good manufacturing practice (GMP) standards.  However, if they wish to export non-predominate quantities to other countries where patent barriers do not exist or have been overridden by means of a CL allowing importation, meeting quality assurance standards, such as those endorsed by the Global Fund, may be required (see list of Global Fund approved LMIC producers of ARVs in Table 1 below).

**Table 1: Global Fund Eligible ARV Producer LMICs 2022**

| |
|---|
| Bangladesh |
| China |
| India (by far the largest number of qualified producers and ARVs produced) |
| Kenya |
| South Africa |
| Thailand |
| Uganda |
| Vietnam |

Additional generic producers that achieve regulatory approval from **WHO Level 3 or 4 Regulatory Authorities** (Dec. 2024: Ghana, Nigeria, Rwanda, Senegal, Serbia, Turkey, United Republic of Tanzania, Zimbabwe) may be able to supply countries excluded from the Gilead license.  According to **US Pharmacopeia** there are a total 20 ARV producers in 8 African countries – Egypt, Ghana, Kenya, Mozambique, Nigeria, South Africa, Uganda, and Zimbabwe. Two (sic: should be 3) are WHO PQ'ed and 6 have approvals from ML3 regulators. However, "[a]mong ARV producers in Africa, most distribute exclusively within their home country or export to just one country.  Only 2 manufacturers have registered their products in more than one country."

Even though they have not formally reached global GMP standards, there are qualified producers in Brazil, Argentina, and Mexico that are likely to be capable of producing lenacapavir. Brazil's public manufacturing Bio-Manguinhos/Fiocruz can only supply domestic public-sector demand, though there are also private-sector pharmaceutical companies in Brazil that are capable manufacturers.  By far the largest number of qualified ARV producers are in India and there are reports that several companies that have already started developing capacity to produce lenacapavir API and finished product that were not licensed by Gilead and may be interested in a CL.

Any manufacturer identified will have to find it commercially viable to invest in lenacapavir product development, bioequivalence studies, and pursuit of marketing approval in countries in might eventually supply.  As discussed further below, any such manufacturer will also need to identify all patent barriers and succeed in overcoming them, possibly in both countries of production and countries of import/use.  Overcoming patent barriers via CLs will, of course, require cooperation and action by the countries where they are needed.

## IV. Overcoming Patent Barriers via Compulsory Licenses

As shown in Table 2 below, there are nine countries with no lenacapavir patents filed.  These countries are theoretically free to manufacture for themselves and/or each other; but in each instance the domestic lenacapavir market is probably too small for economically viable production. Even joint procurement by all nine would probably be too small for viable production given their small populations and low HIV prevalence rates.

**Table 2:  Lenacapavir Patent Landscape in Excluded Countries Territories**

| LEN patents filed/granted in 15 excluded countries | No LEN patents in 9 countries |
|---|---|
| Albania, Argentina, Bosnia & Herzegovina, Brazil, China, Colombia, Costa Rica, Guatemala, Malaysia, Mexico, Montenegro, North Macedonia, Peru, Serbia, Turkey | Algeria, Ecuador, El Salvador, Iran, Iraq, Kosovo, Paraguay, Venezuela, Lebanon (L-MIC)<br><br>Note:  West Bank and Gaza are two additional excluded lower-middle-income territories for which there is no separate patent info. |

The fifteen excluded countries with pending or granted lenacapavir patents will certainly need to overcome patent barriers domestically and simultaneously secure government cooperation in the country of production (and probable export).  In some instances, countries may be able to do so by means of patent oppositions, such as those filed broadly in India, Thailand, Vietnam, and Argentina. However, opposition procedures are not available in all the excluded countries and even where they are opposition efforts will take time and must successfully address all blocking patents.  A more widely available strategy for overcoming patent barriers in both the countries of production and possible export and the countries of importation/use focuses on compulsory licensing as permitted by Articles 31 and 31bis of the TRIPS Agreement and authorized by national legislation.

However, the use of such CLs is complicated by limitations on or special rules with respect to export of medicines produced pursuant to Article 31.  The principal impediment is Art. 31(f) which restricts export of quantities greater than what is used domestically (supply must be predominately for domestic use), unless the CL is issued on Art. 31(k) competition grounds.

Accordingly, if a company wishes or needs to export the majority of its lenacapavir to other countries, including those with insufficient manufacturing capacity, it must rely on procedures mandated by Art. 31bis and Art. 31(k) and authorized by national legislation and convince the relevant countries to issue such CLs in all exporting and importing countries where blocking lenacapavir patents are filed or granted. (For a basic summary of CL access options, see Table 3 below.)

**Table 3: Compulsory Licenses for Export/Import**

| Exporting Country's Right to Export | Importing Country's Right to Import |
|---|---|
| **No patent(s) on file**<br><br>No CL required and no quantity limits:<br>● off-patent medicine;<br>● no patents filed or patents found to be invalid.<br><br>If there are patents in the importing country, CLs for importation may be necessary there (see right column, row below) | **No patent(s) on file**<br><br>No restrictions when importing from a no-patent country;<br><br>If there are patents in the exporting country, CLs for exportation may be necessary there (see left column, row below) |
| **Patent(s) on file**<br>Art. 31 Compulsory and government use licenses:<br>● Issued predominantly for domestic use, Art. 31(f), (at least 49% can be exported);<br>● Issued for abuse of patent, Art. 31(k), (unlimited export)<br>Prior negotiation for a voluntary license required except for government use, emergency/urgent circumstances, competition-based license.<br><br>Art. 31bis CL with all attendant notifications and limitations (identified quantities only).<br><br>Limited exception CL to permit export to a no-patent market or to effectuate a CL in a non-producing importing country, Art. 30 (of questionable practicality/utility because of developed country antipathy to a broad construction of limited exceptions). | **Patent(s) on file**<br>Regular compulsory license for import, Art. 31 (import allowed pursuant to Art. 27 because of its prohibition against discriminating against imports)<br>• Unlimited quantities from a no- patent exporter;<br>• Limited, non-predominant quantities from an "ordinary" compulsory license exporter;<br>• Unlimited quantities from a compulsory license exporter to redress anti-competitive practices; and<br>• Unlimited quantities imported pursuant to an Art. 30 limited exception in the exporting country (questionable legal authority).<br>Art. 31bis compulsory license for import with all attendant notifications and limitations. |

## V. Achieving Economies-of-Scale for Commercially Viable and Affordable Production

For one or more generic producer to be incentivized to manufacture and sell lenacapavir and reach economies-of-scale, producers must be able to supply commercially viable markets. A few excluded countries with granted lenacapavir patents, including Brazil and China, probably have domestic demand for lenacapavir that could be economically sustainable and commercially attractive for a domestic producer. In those cases, only one domestic compulsory license would be needed in either country. Existing rules, if properly invoked, would still allow them to export non-predominate quantities to other countries with no blocking patents or that have issued the appropriate import license.

But most of the excluded countries do not have sufficient lenacapavir demand to attract and sustain a local producer. Accordingly, if excluded countries want to reap the affordability and supply benefits of compulsory licenses, they may need to coordinate with other countries to support licenses that permit export of aggregated quantities pursuant to Art. 31 or Art. 31bis. An additional step that excluded countries can take to incentivize generic entry is to adopt or use pooled procurement mechanisms.

## VI. Completing the Supply Puzzle: Which LMICs are Best Positioned to Supply Generic Lenacapavir

Table 4 below identifies LMIC producer countries with quality assured ARV production capacity that might potentially supply the countries excluded from Gilead's lenacapavir license.

**Table 4: Patent Status in Potential LMIC ARV Producer Countries**

| LEN patents filed/granted | No LEN Patents |
|---|---|
| ***License-Excluded Country:***<br>Argentina, Brazil, China, Mexico<br><br>***License-Included MICs:***<br>Egypt, Indonesia, India, South Africa, Thailand, Uganda, Kenya, Vietnam | Bangladesh |

Obviously, companies in Bangladesh, where no blocking patent has been filed, have the most freedom to produce and export, though the exporter would have to be granted an import licensee in countries where there are blocking lenacapavir patents.

Producer countries that are excluded for the Gilead licenses and that have blocking patents have the most incentive to issue a compulsory license at least for domestic use. Regrettably, Brazil is reportedly seeking a voluntary license from Gilead pursuant to its long-standing industrial policy objectives, and it is doubtful that any such license would maximally lower prices or allow export to countries excluded from the original Gilead license. Therefore, country advocates are still pushing Brazil to consider a compulsory licensing approach, hopefully one that could support supply for both domestic use and excluded-country demand. Argentina, with a smaller population, might actually need export markets for viable production, so it might be more willing to issue production and/or export compulsory licenses, though the political intentions of the current conservative government might be more focused on preserving trade relations with the U.S.  China has ample generic capacity and a viable system for issuing compulsory licenses but has not done so historically.  Gilead might try to preempt Chinese CL activity by granting a voluntary license for domestic use only, as it is reportedly doing in Brazil.

For producer countries that are included in Gilead's existing license, there is unfortunately less incentive to issue a compulsory license that would primarily benefit other countries. Nonetheless, producers, for example in Africa, might do so to consolidate their manufacturing capacity, and African countries might support local producers to enable greater self-sufficiency. African producers and their supporters including Africa countries and the AU CDC are reportedly miffed that no African companies (except one in Egypt) were selected as Gilead licensees, so there might be a congruence of political will to support a local producer with CL.  Paradoxically, that producer might find it hard to service African buyers because of the need from CLs in the vast majority of African countries that have granted patents on lenacapavir.

The most promising supplier might well be India, even though it has recently eschewed issuing compulsory licenses since the one license it granted on a Bayer cancer medicine.  This is so because India has a "production for export provision" in its Patent Act, Sec. 92A, that requires a compulsory license be issued for export to supply countries with insufficient manufacturing capacity:

> Section 92A
> Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances
> (1) Compulsory licence ***shall be available*** for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.
> (2) The Controller ***shall***, on receipt of an application in the prescribed manner, ***grant a compulsory licence*** solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him. (Emphases added.)

Although two applications for export licenses have previously been filed in India, they were both withdrawn, presumably because of procedural errors, and pressure on the companies applying for the export CLs.  The provision that that the Patent Controller "shall … grant a compulsory license" on its face is obligatory.  This would obviously permit a Sec. 92A India licensee to supply countries with insufficient (or commercially impracticable?) manufacturing capacity to import, though it might not be able to export to Argentina, Brazil, or China, thus significantly diluting the overall size of the export market.

## VII. Immediate Recommendations

This analysis leads to several, immediately practical recommendations that excluded countries and their allies can take to help start a coordinated CL campaign for LEN-LA:

- Excluded countries can issue expressions of interest to generic companies that might be willing to be CL licensees; joint statements would be even better. Expressions of interest already being pursued by CL campaigners in Latin America will signal to potential generic companies that countries are looking for suppliers other than Gilead and that they are willing to use CL mechanisms. This will encourage potential suppliers to proceed with product development, to map regulatory pathways, and to estimate potential demand.
- Excluded countries without sufficient manufacturing capacity or markets too small for efficient and sustainable domestic supply should notify the World Trade Organization of their intent to import LEN-LA under Article 31bis procedures; joint notification would be preferrable. Article 31bis of the TRIPS Agreement allows countries with insufficient domestic manufacturing capacity to effectively utilize a domestic product CL to notify the WTO of their intent to import a pharmaceutical product under Article 31bis compliant procedures. Countries' assessment of their production capacity is not subject to much second-guessing and countries can submit such notifications jointly. Such notification is an additional signal to potential generic licensees that excluded countries are serious about seeking alternative sources of supply.
- Excluded countries should immediately take steps to determine the best CL or government use mechanism in their national law that would allow either sustainable local production or importation. This analysis has focused on TRIPS-compliant CLs, but has not analyzed countries' national legislation. Governments (and campaigners) should immediately assess national CL legislation for CL procedures that could best meet their needs.
- Qualified producers for both API and finished LEN-LA should be identified with a focus on regional supplier and/or supplier facing no or easily traversed patent barriers. This paper analyzes the countries where there are qualified producers, but not the producers themselves.
- Excluded countries should cooperate and coordinate to aggregate their markets via TRIPS-compliant CLs as required and should further establish pooled procurement mechanisms as a further positive market-entry signal for generic licensees. If all excluded countries could coordinate together, that would probably produce optimal results, but good results can also be achieved on a regional level, e.g., excluded MICs in the PAHO region working together. Pooled procurement sends a strong signal to potential generic licenses about potential and sustainable demand and is often cost-saving for both producers and buyers. Regional workshops and country-to-country consultations should be organized as soon as possible.
- Excluded countries should explore means for expediting regulatory approval or licensed LEN-LA. This paper has focused on overcoming IP barriers, but we know that regulatory barriers also exist including lack of access to samples for conducting bioequivalence studies. Gilead has only promised to focus regulatory approval in 18 licensed countries and has not directly stated its intentions or timelines for excluded MICs. Hopefully, Gilead will seek WHO-Prequalification and will allow recourse to the WHO Collaborative Registration system, which could accelerate national regulatory approval. Licensed

generic producers should be supported in the preparation of regulatory dossiers and regulatory review should be as expeditious as possible.  Unitaid could be a funder to support licensees' regulatory activities, as it is already planning to do for Gilead's voluntary licensees.
- Key manufacturing countries should be encouraged to implement their CL-for-export mechanisms, whether non-predominate quantities as allowed by Art. 31(f), unlimited quantities as allowed by Art. 31(k), or specified quantities to countries with insufficient manufacturing capacity as allowed by Art. 31bis.  In each case, requirements of domestic law will also need to be followed.
- WHO, UNAIDS, Unitaid, and others should signal support for excluded countries' use of TRIPS-compliant CLs and offer political, technical and financial support for the same. Multilateral and multistakeholder global health entities have stated their support for expanded generic supply to LEN-LA.  They should overcome any timidity about directly supporting the issuance of TRIPS-complaint compulsory and government-use licenses. Acceptance of CLs has reached new highs in international diplomacy, in the state practice of the US contracting government-use indemnification during covid, and in the EU proposal for a regional emergency CL mechanism.
- Resources should be made available to civil society campaigners who can push globally, regionally, and nationally for challenging pending patents and CLs in excluded countries, for community engagement and health literacy regarding the promise of LEN-LA, and for the rapid introduction and scale-up of LEN-LA and other PrEP programming. Campaigner could start immediately to urge countries to signal their interest/intent to issue CLs and their desire to do so on a coordinated basis with other excluded countries. This could put pressure on Gilead to expand its license, as it has done previously with respect to its hepatitis C antivirals.  Equally important will be campaigns to accelerate countries' commitment to use of long-acting lenacapavir and promoting community engagement and long-acting PrEP literacy among at-risk populations.

## VIII. Conclusion

This paper begins a more concrete analysis of steps needed to effectuate compulsory licenses that would allow supply of generic lenacapavir to countries excluded from the Gilead voluntary licenses. There is complexity to be sure and the need to organize support among viable and qualified MIC producers, producer countries, and the countries excluded from the license. Further analysis is needed, including on national law CL mechanisms, and the identification of quality assured producers.  Hopefully this paper can inform countries and activists and help spark a robust campaign for a coordinated compulsory licensing of LEN-LA.