

BROADER IMPACT ON ACCESS TO MEDICINES AND GENERIC INDUSTRY

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Anand Grover

Director, Lawyers Collective HIV/AIDS Unit

IMPACT ON ACCESS TO MEDICINES

- Competition has been key to lower prices of medicines to facilitate access to medicines.
- The MPP license allows Gilead to control API supply in India and other developing countries, both included and excluded.
- Control of API supply facilitates Gilead's agenda of monopolizing the market and not MPP's agenda of facilitating access to affordable medicines.
- By controlling API supply, it inhibits competition by generic industry, in India and other countries, both included and excluded territories.

IMPACT ON ACCESS TO MEDICINES

“The markets for APIs are generally more sensitive to economies of scale and scarce know-how, and hence more concentrated than are markets for finished products. By segmenting the developing country markets into approved and unapproved manufacturers and licensed and unlicensed territories, Gilead has likely increased the prices for generic APIs in all segments of the market, but particularly for the areas where there are no patents, and certainly for countries excluded from the licensed territory.”

*KEI complaint to Federal Trade Commission, US,
12 February 2007*

IMPACT ON ACCESS TO MEDICINES

“Gilead seeks to cut off the supply of generic APIs ... outside of the licensed territories.

“The partitioning of the generic API market between approved and non-approved sellers and licensed and non-licensed territories will lead to less competition, less efficient economies of scale in the market for generic ... APIs.

“Persons living in developing countries excluded from the licensed territories will be harmed by a less competitive and less efficient market for generic APIs.

“This will lead to higher prices of products ...”

KEI complaint to Federal Trade Commission, US, 12 February 2007

IMPACT ON ACCESS TO MEDICINES

- Pertinently, Indian generic companies are the only ones who can seek sub-licenses under the MPP license.
- **The USP of Indian generic industry is the ability to have better and more efficient processes and be competitive and lower prices.**
- Any model that seeks to facilitate access by increasing competition would have promoted this forte.
- **Giving back “Improvements” on technology by generics to Gilead (not to MPPF) free of charge is a disincentive for the Indian generic industry to develop new and superior processes.**

IMPACT ON ACCESS TO MEDICINES

- Restrictions on pediatric formulations:
 - The MPP license grants a right to sub-licensee to develop **only dispersible** tablets and liquids for children under the age of 12. This is **royalty-free**.
 - This is granted back **not to MPPF**, but only to **Gilead and its Licensed Product Suppliers** (other Gilead licensees or sub-licensees).
 - There is no real incentive to develop **any formulations**.

IMPACT ON TRIPS FLEXIBILITIES

- TRIPS provides a **broad range of flexibilities**. These have been compromised by the MPP license.
- **Transition period:**
 - LDCs have until 2016 to comply with TRIPS and provide patent protection.
 - MPP license allows Gilead to obtain royalties even in LDCs, even where no patent exists.
 - Undermines the flexibility

IMPACT ON TRIPS FLEXIBILITIES

- **Legitimizes evergreening:**
 - TRIPS allows countries the flexibility to set patentability criteria **to disallow** patents and monopolies on **new forms, new uses** and **combinations**
 - The MPP license **legitimizes patents and patent applications** and allows Gilead to claim royalty on
 - **new forms of drugs** (tenofovir disoproxil and tenofovir disoproxil fumarate; stable crystal of elvitegravir)
 - **combinations** (tenofovir + emtricitabine + elvitegravir + cobicistat)
- [See definition of “Patents” and “Appendix 2” to MPP License]

IMPACT ON TRIPS FLEXIBILITIES

- **Legitimizes evergreening:**
 - The MPP license **legitimizes claims on use and payment of royalty**, whether a patent exists or not, on **new use** of a known molecule. [See definitions of “Field” (this includes, for example TDF use for Hep B) and “Patent” (*to the extent the claims cover the .. use .. of API*)]
 - The MPP license allows royalty to be claimed on staggered patent applications as long as a **patent application remains pending and all avenues of legal challenge have not been exhausted.**

IMPACT ON TRIPS FLEXIBILITIES

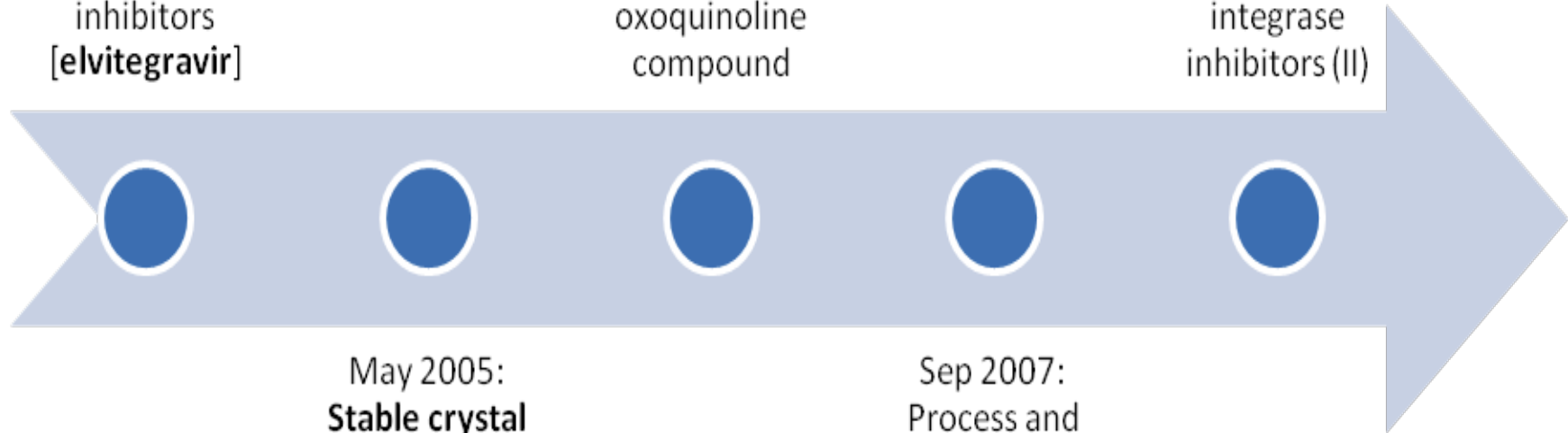
Nov 2003: 4-oxoquinoline **compounds** and utilisation thereof as HIV integrase inhibitors [**elvitegravir**]

Mar 2007: Method for producing 4-oxoquinoline compound

Sep 2008: Process and intermediates for preparing integrase inhibitors (II)

May 2005: **Stable crystal** of 4-oxoquinoline compound [crystal form of elvitegravir]

Sep 2007: Process and intermediates for preparing integrase inhibitors (I)



IMPACT ON TRIPS FLEXIBILITIES

- **Patent oppositions:**
- In 2006 Gilead licenses: required Indian generic companies to withdraw patent oppositions. This was dropped before the MPP license.
- 2011 MPP license: the implication is that every patent application – claims covering forms, combinations, use, process etc – has to be opposed. (Otherwise royalty is payable; Supply is not possible to excluded countries)
- Even if patent oppositions are successful, royalty will still required to be paid and supply would not possible while Gilead challenges the patent rejection and exhausts all avenues of challenge (e.g. IPAB → High Court → Supreme Court)

IMPACT ON TRIPS FLEXIBILITIES

- **Use of compulsory license is recognized TRIPS flexibility**
- **Compulsory licenses** [Section 5.2(c) of MPP license and section 10.3(d) of sub-license]:
 - Safeguard not available to included territories.
 - Excluded territories have to issue a compulsory license or notification and rely on the cumbersome 30 August mechanism.
- **Compulsory license (CL) for export to country X**
 - X issues a CL (no certainty if sub-licensee can apply for CL)
 - X notifies TRIPS Council (with details of specific quantity)

IMPACT ON TRIPS FLEXIBILITIES

- Compulsory license (CL) for export to country X
 - Application filed under section 92-A in India (No certainty if sub-licensee would apply for CL under separate deals)
 - Gilead can oppose the grant of CL, the text has been interpreted in the Natco cases
 - **CL granted in India**
 - Thereafter, **Gilead's consent** is required again about the existence, scope and content of CL, with **Gilead's consent not unreasonably withheld**. [No indication of how many days, etc]
 - If Gilead withholds consent, sub-licensee has to seek “secret” arbitration in London.
 - Sub-licensee has to comply with 30 August mechanism (separate packaging, etc) to supply to X.
 - Is it really an advance on the *status quo*?

IMPACT ON TRIPS FLEXIBILITIES

- Parallel importation:
 - Under TRIPS, countries can determine the exhaustion of IP rights [Article 6]
 - MPP license allows Gilead to control the supply chain of sub-licensees.
 - Sub-licensees and its resellers can only sell in included territories.
 - If products is sold or diverted outside the included territory or used for purposes other than the “field”, Gilead can terminate sub-licensee's agreement with its third party resellers [Section 2.4(g) of MPP sub-license]
 - This undermines the basis of parallel importation.

IMPACT ON ACCESS TO MEDICINES

- **12 July 2011:**

- London: MPPF announces its license with Gilead.

- **12 July 2011**

- Hyderabad, India: Gilead announced voluntary licenses with four Indian generic companies – Hetero, Matrix, Ranbaxy and Strides Acrolab (Preferred Partners).
- THIS SHOWED BAD FAITH: WHY NOT CANCEL AG
- Gilead has granted exclusive licenses to these companies for elvitegravir, cobicistat and Quad.
 - It appears that royalty is 10-15 percent.
 - Strides Acrolab: Ecuador, El Salvador, Indonesia, Kazakhstan and Turkmenistan
 - Matrix: Sri Lanka and Thailand
 - Ranbaxy and Hetero: Botswana and Namibia.

IMPACT ON ACCESS TO MEDICINES

- These licenses are secret.
 - Can these companies supply to excluded territories if they issue CL?
 - Do these licenses have the same “safeguards”?
 - Do they have the termination clause? Unbundling clause?
 - USBIC was on the press release re separate deals
 - Why did the MPP license not have a clause that Gilead cannot have a separate deals in respect of the field, product covered by the MPPF agreement?
 - Therefore where is the added value?
 - By negotiating these separate licenses, Gilead has undermined the work of the MPPF.
- Is there an added value the license in the MPPF agreement? Well the Indian generics have not gone for the MPP license!

Ethical Issues relating to MPPF

- Under the MPP license, MPPF gets a commission.
- What is the rationale for such a commission?
- MPPF is fully supported financially by UNITAID.
- This raises issues of conflict of interest and ethics of MPPF.
- Was this discussed with advisory board, permanent or ad hoc?
- Also when IMAK raised the issue, the response from the MPPF was not that expected of a foundation with avowed aims ensuring access to medicines to the community.