Annex to UNTAID EB17 Resolution 9 (Lawyers Collective)

Clarifications/ Issues to be addressed:

Notwithstanding other information and clarifications that may be sought as part of the grant agreement and project plan development process, the Secretariat and/or the PRC specifically requires:

- Where not already covered by other efforts such as the Medicines Patent Pool (MPP) the proponent should provide a clear and robust analysis of the current landscape on ARV patenting, and discuss and explain the extent of the problem (how big is the problem, for which specific medicines). This should include the situation and trends in India, as well as any knowledge the proponents have on the situation in other LICs and MICs.
- The proponents need to provide information and clarify how long a patent opposition takes in India depending on when the final decision is made. For example, how long does it take if the matter ends with a successful opposition at the patent office? What about if the matter goes to the specialised tribunal? What if it goes further to the High Court and onwards to the Supreme Court? This information is important to assess the feasibility of the project and timeframes, as well as the transition plan.
- The proponents need to provide a methodology on how to approach the number of cases to be pursued.
- While the proponents have identified some risks and explained how to mitigate them, there is a range of risks that the proponents have not considered or addressed in the proposal. Some of the risks that need to be discussed include:
    - Whether the proponents could lose a case and be asked to pay legal costs to the other party?
    - What happens if an opposition is successful in India but patents remain in other LICS and MICs?
- In project development, please provide a more robust transition plan, including any opportunities to make the process cheaper of faster (e.g. development of a methodology or tools) that would aid the process. A clear link needs to be made between the activities described in the narrative and the Logframe. This should include a strategy about which drugs will receive priority consideration.
- The indicators of success could be clearer. Please develop these in more detail in collaboration the Secretariat's M and E team. The discussion on the assumptions made by the proponents needs to be improved and strengthened ensuring that it is comprehensive.
- There is relatively little detail of how this project will leverage other UNITAID-funded projects or external resources of other organisations. For example, the proposal talks about

a database of important medicines, landscaping the patent situation around these medicines but there is no discussion on how the project would leverage the work of the Medicines Patent Pool, WIPO landscaping work under the Development Agenda and such other initiatives.