Reviewer's report

Title: A right to health compliant global tiered pricing framework?

Version: 2

Date: 14 October 2014

Reviewer: Richard Elliott

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Major Compulsory Revisions

Minor Essential Revisions

1. Abstract: TRIPs should be TRIPS in the list of keywords.

DISCUSSION

2. In first paragraph, when defining terms such as the right to health and a global TP framework, I think it’s better to say that “by X term, we mean Y” rather than “with”

3. Line 113: I think it should be “Programme” not “Program.”

4. Lines 121-125: I think there is a bit of reworking required here. (1) Lines 121-122: It’s not really accurate to say that whenever the TRIPS Agreement obliges governments to grant patents for medicines (whether essential or otherwise), it thereby signs away the power to set prices for those medicines. In fact, many countries maintain schemes for setting or regulating the prices of medicines, and in particular those under patent protection. Of course, the details of such systems may warrant criticism, and such mechanisms can be more or less effective. But merely granting a patent on a medicine, whether obliged to by a TRIPS requirement or not, does NOT automatically mean ceding all power to set or control prices. So that statement here should be worded not so categorically. Granting the patent-holder the temporary monopoly certainly creates the challenge of then dealing with the patent-supported monopoly pricing in which the patent-holder will almost certainly seek to engage. But that’s an issue that a remedy such as compulsory licensing, or price controls, or remedies under competition law for abuse of that dominant position through price gouging, are all intended to address. So, granting the patent on a medicine can indeed create an additional challenge for achieving the human rights obligation of the highest attainable standard of health for all – including affordability – and thereby raise the further question of what the state is going to do to address that and discharge its obligation.

5. Lines 124-125: Similarly, while it may appear (incorrectly) to some that it’s as if states signed a series of blank cheques to pharma companies (by signing on to TRIPS), I don’t think that’s quite correct – nor does it seem helpful to the authors’ argument to reinforce this notion, because it cedes ground that proponents (such the authors) of a more equitable system then (seem to) need to regain. It’s not
correct to say that “whenever these companies invent a new medicine, WTO member states are obliged to purchase and provide them at whatever price the patent-owning companies set.” There is nothing in law (e.g. TRIPS) that compels governments simply to be price-takers, at the mercy of patent-holding pharma companies – although certainly countering the influence of the industry can be a political (and sometimes legal) challenge, particularly when that influence is backed up by other powerful states. I repeat the point above about the policy measures states can – and arguably should – take to address excessive pricing. (And what may constitute “excessive” pricing can be determined in various ways, including perhaps by reference to the kind of indicators that the authors point to as touchstones in defining a more equitable tiered pricing framework. Therefore, pointing to the existence of price control mechanisms, while nothing their potential limitations, is perhaps useful for the authors in establishing the authority – and duty, under international human rights law – of states to control prices and prevent excessive pricing, which serves as a useful precedent for states engaging in compulsory licensing in a manner informed by the kinds of factors cited by the authors.)

6. Line 254: word “is” should be “are”

Discretionary Revisions

Some general comments below, then more specific ones organized by section of the manuscript, with pinpoint reference where possible and useful:

GENERAL:

7. In several places throughout the manuscript, there seems to be a somewhat clunky reference to “right to health based obligations.” I think in this kind of formulation, normal style would be for right-to-health-based to be hyphenated, since the whole phrase operates as the adjective modifying the noun obligations. But that gets clunky as well. I wonder if this problem could be avoided, and the text would flow more simply, if a slight rewording were done to avoid this kind of formulation and instead refer to states’ “obligations under the right to health” or states’ “obligations to realize progressively the highest standard of health for all,” etc., with some variations on this depending on the context of the specific sentence. A suggestion to be taken or left, as the authors see fit, offered with a view to making the text flow more nicely and also seem less heavy.

TITLE:

8. The title seems rather wordy, awkward and likely hard to follow for many a reader. It consists of a final noun after a long list of 4 adjectives modifying that noun (and one of them a compound adjective that should probably be written, if the current format of the phrase is maintained, as right-to-health-compliant). Much preferable would be to perhaps rewrite the title so that it is not quite so dense. Perhaps something along the lines of: “Can a global framework of tiered pricing for pharmaceuticals be made compliant with the human right to health?” or “Crafting a global framework for tiered pricing of pharmaceuticals that complies with the right to health” (if a statement rather than a question is preferred)… or something similar that opens up the title a bit and lets it “breathe”
more.

BACKGROUND

9. End of first para: In line 82, I think the word “conciliated” should probably be “reconciled”.

10. End of first para: The last sentence here reads rather vaguely and does not clearly communicate what is intended, especially, I would think, a reader not already familiar with the right to the health and the concept of compulsory licensing. Rather than imprecisely stringing together three concepts – a global TP framework, the right to health and compulsory licensing – with some vague phrase such as “within the context of,” perhaps it could be tightened up to be clearer about the relationship between the three that you’ll be positing in the manuscript? I understand the authors to be arguing that a global tiered pricing framework could function in a manner that is compliant with states’ obligations to realize the right to health if it enabled compulsory licensing in a fashion that is fair and equitable among countries by incorporating factors such as their varying disease burden and resources available for health. I think it would make sense to state your thesis here more clearly, at the outset of this introductory paragraph, so as to help the reader understand where you’re headed – and then the rest of the manuscript helps lay out the analysis for your proposal.

DISCUSSION

11. I debated whether this should be a major compulsory revision or not (and decided in the end that it was really more something that should remain discretionary), but let me flag a concern about the description of the global TP “framework” that is the core proposal in the manuscript: it’s always a little fuzzy and vague as to exactly what form it takes. This may be a deliberate choice by the authors. But it does at least warrant some reflection as to whether it should be defined in a more concrete way or not. It’s defined at the outset here, in the “Discussion” section, as “a set of global norms on tiered pricing, endorsed by international public health agencies.” You then say it should not be based on voluntary price reductions by pharma companies [the strong implication being that it should be non-voluntary in some way], but rather “should be based on international law and [again] endorsed by international public health agencies.” I get the basic concept being proposed and think it certainly has some merit and there is an interesting case laid out for it in the manuscript. But a “framework” (i.e. “a set of global norms”) means what, exactly? I understand that these would be norms “endorsed by international public health agencies.” But having WHO (and UNAIDS? Global Fund to Fight AIDS, TB and Malaria? RBM? GAVI? Others?) endorse a set of norms doesn’t amount to much unless all the key players abide by those norms… and if a voluntary approach to TP, defined and implemented by pharma companies, is NOT adequate (as the authors state), then what is going to make this better set of norms have some real impact? A treaty? An agreement adopted by WTO members at the TRIPS Council and/or the General Council that would effectively determine a priori circumstances in which Members’ use of compulsory licensing would be immune from challenge, whether judicial or political, as contrary to TRIPS (with perhaps some practical de
facto spill-over effect regarding the understanding of IP obligations under other treaties)? A resolution adopted via some other body (e.g. WHA? Human Rights Council?) – although these would seem to have less traction than a decision emanating from the WTO members, since the subject-matter is specifically about the use of a flexibility in IP law (albeit in pursuit of a health objective and human rights objective). Something else?

12. Line 130: Worth specifying that it was WTO Members, via the WTO Ministerial Council, that adopted the Doha Declaration?

13. Line 134: Perhaps worth a somewhat clearer definition of compulsory licensing for those readers not familiar with the concept? For example, “states can authorize manufacturers other than the patent-holder to produce cheaper generic equivalents…”? And perhaps specify that such a CL is non-exclusive, meaning that the patent-holder is not deprived of its ability to manufacture the product in question, and that other CLs may also be issued to other generic manufacturers? In my experience, these are things that are often not understood by those unfamiliar with CL’ing and TRIPS, and so it may be wise to anticipate confusion and head off possibly inaccurately-founded objections to the idea with a bit more detail and clarity in the explanation.

14. Line 138: Similarly, it would be nice to better explain, with just the addition of a phrase, the “Doha para 6” problem alluded to here. It’s not exactly clear to the person unfamiliar with this issue why the problem created by TRIPS Article 31 “particularly affects least developed countries without local manufacturing capacity.” However, it could be made clearer by adding a phrase such as “..., as a result of restricting the ability and ease of experts under such compulsory licences from countries that do have such manufacturing capacity.” In other words, make it clear that by creating a barrier on the export end of things, it ultimately creates the problem for the importing country that needs to import because of inadequate manufacturing capacity. (Also note that it’s not just LDCs who may lack adequate capacity and need to “make effective use of compulsory licensing” – to use the language of the Doha Declaration – and the final Aug 30, 2003 General Council decision of course was not just limited to LDCs. Given the never-ending effort by pharma and its allies to restrict the scope of any mechanism in just such ways, and that the authors’ own proposal for an equitable global TP framework would also not just be limited to LDCs, but would certainly face arguments by opponents that it should be so limited, it would be perhaps advisable to (a) avoid any formulations that inadvertently suggest any such limitations, and (b) to be explicit about the scope of the proposal as encompassing not just LDCs, and also reference the fact that other mechanisms that harness compulsory licensing and agreed previously, such as the Aug 30, 2003 Decision, do not suffer such limitations, which have been expressly rejected, as they were in the negotiations leading up to that decision).

15. Line 140: The Aug 30, 2003 Decision is not yet permanent; it was adopted in Dec 2005 in a format intended to become permanent once it takes effect, but it has not yet, because it has not yet received the requisite number of ratifications.
16. Line 141: I think a word such as “mechanism” is missing here.

17. Line 149: An important precision in use of terminology is advisable here. It’s not the case that the generic manufacturer in Canada “declined to renew the licence” it finally obtained in 2007 under Canada’s Access to Medicines Regime. Rather – and this is a very important point given the history and context – it chose not to start the process all over again of applying for a new licence to authorize additional exports of the HIV drug in question to Rwanda. The current wording inadvertently suggests that there was a simple option to renew the licence once issued. That is not the case. (As an aside, as the authors note that efforts to streamline the applicable legislation were defeated, you may find it interesting to cite to some NGO analyses’ of the mechanism under the Canadian law and also the opposition that ultimately led to the defeat of proposals – advanced by NGOs, but with widespread support, including public statements of commitment by the same generic company to attempt further use of the mechanism if streamlined as proposed in the legislation that will ultimately defeated; eg., one overview with this analysis is here: http://www.equilibri.net/nuovo/en/node/2374. It should probably also be noted that it was ultimately because of government opposition that these efforts were defeated – see the link to the voting record via www.medicinesforall.ca – which of course was heavily fomented by the opposition of the patented pharmaceutical industry, which opposition is correctly noted in the text. As these were legislative proposals, it was ultimately up to the votes of parliamentarians as to whether they would proceed or not.)

18. Line 162ff: In this paragraph, the authors assert that a global TP framework could solve some of these problems (meaning the challenges of using compulsory licensing), even if “it” (the framework?) did not have the power to set prices on behalf of patent-owning companies. Two comments:

a. (1) Such a framework would not likely address one of the immediate problem alluded to in the immediately preceding paragraph – namely the difficulty of using a mechanism such as Canada’s law implementing the Aug 30, 2003 WTO Decision, or with the difficulties of that underlying WTO Decision. The problem there is a combination of legislation/decision deliberately designed to create unnecessary hurdles and practical disincentives for each occasion of its use. The problem is not really the lack of a scale of pricing that would be equitable and which would, by virtue of being commonly agreed or endorsed (by international public health agencies?), provide some degree of certainty in using compulsory licensing. After all, the Canadian legislation – the challenging use of which is cited as an example of the difficulties with using the special compulsory licensing system agreed at the WTO in 2003 – actually included a well-defined sliding scale of royalties payable, that were based on an importing country’s ranking on the UN Human Development Index (which incorporates income as one of the statistics, as well as life expectancy – which indirectly reflects disease burden). The challenges there were ones of politics and of practical restrictions built into the compulsory licensing process. I’m not sure a global tiered pricing framework, whatever merits the idea has, would have addressed those particular problems.
b. (2) To pick up on the point noted earlier … It’s not entirely clear what the mechanism is by which a global TP framework would “solve” these problems, because it’s not firmly defined. Is it simply through the power of moral suasion, and providing a degree of political “cover”, for countries using compulsory licensing, that a “framework” would solve the problem of trying to use compulsory licensing to advance the right to health? It could be that it’s certainly useful as embodying a set of “soft” global norms about when compulsory licensing can/should be used, which could in turn have the effect of weakening a patent-holder’s attempt to use either domestic fora or another member state’s attempt to use a WTO complaint to impede such action). It could also be useful to human rights advocates in making a case that there is an obligation on a given state in a given context to take the measure of CL’ing as part of realizing the right to health. Is this what is meant? Or do you envision the global TP framework, as you define it and without any power to set prices directly, as operating in some other way to “solve” the problems of trying to use CL’ing that have been encountered to date.

19. Line 179-180: I’d suggest being careful here to avoid any implicit suggestion that a compulsory licence is only “legitimate” insofar as it achieves a price reduction that is proportionate to the country’s GNI per capita. This raises another, broader tactical question about the proposal – i.e., if a global TP framework exists to legitimate compulsory licensing when the price of a patented medicine is being kept excessively high for a country, taking into account it’s GNI per capita and disease burden, then will it also operate to prima facie delegitimize compulsory licensing if a country seeks a lower price than would be indicated by these two factors? Is that a desirable outcome? If it’s not, is it nonetheless an acceptable trade-off for the gains made?

20. Line 185: Again, this may relate to the fuzziness of definition of the “framework” – which seem to exist as a concept unanchored to any particular actors, except for the “endorsement by international public health agencies” – but when it’s stated here that, in applying the global TP framework as envisioned by the authors, the compulsory licence for Brazil “would have been cleared,” what is meant? Cleared by whom? And what does “cleared” mean? As noted, each country has the right under TRIPS – as affirmed by the Doha Declaration – to determine the grounds upon which it uses compulsory licensing. But the suggestion here is that the decision by Brazil in this case would have received approval somehow by “the framework.”

21. Lines 224-226: The list of countries here is rather striking for what they have in common: they are small countries, amounting to a very small number of people living with HIV (or, even thinking more broadly to all diseases, still a very small percentage of the global population), and hence largely insignificant in market terms. Perhaps it is worth commenting on this explicitly? Or do the authors feel the list speaks for itself in making this point?

22. Line 232-233: Do the authors assert that countries must move toward universal health coverage as a matter of their obligation to realize the right to
health? This is certainly a defensible position, but should just be clear about it.

23. Line 239-240: Again, the global TP framework is spoken of in terms that give it agency – it would “automatically paralyze the impact of the TRIPS Agreement and authorize compulsory licensing” – but who/what has the agency here? Does this impact arise from the mere existence of a framework endorsed by international public health agencies as a good idea, and nothing more? Or does it need to have some firmer anchoring in some mechanism, some body of decision-makers or norm-enforcers? And again I’d sound the caution about the framework “authorizing” CL’ing. Countries who are members of the WTO have this right, on grounds they determine; it seems troubling if the “framework” were to now play some additional “authorizing” function (with the inherent suggestion that a use of CL’ing that did not accord with the framework would not be “authorized”, as this would run contrary to what is clearly the right of sovereign states to do, including as part of their right to health obligations).

24. Line 259: I’m not sure I understand what is meant by the last phrase of the sentence. Why would a global TP framework be expected (or not expected) to “provide” things like removing financial barriers and greater public financing of health care? Perhaps it’s just a question of rewording a bit to say, as I think is intended, that multiple solutions to multiple barriers to universal access to medicines are needed – and that a global TP framework, as envisioned, could be part of the solution but won’t address other needs.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no financial competing interests. As for non-financial competing interests: my organization provides secretariat services to the UNAIDS Reference Group on HIV and Human Rights, of which the lead author (Ooms) is a member, and has on occasion in the past collaborated with the second author (Forman) in co-hosting an event on issues of mutual interest regarding the right to health and access to medicines. I don’t see this as competing interests or as creating a conflict of interest, but disclose them here in the interests of complete transparency.