Amendment of Article 31(f) is far from a ‘solution’

Sir,

Apropos the Letter to Editor of Janodia et al on the contentious issue of Article 31 (f) of the TRIPS agreement and some recent developments especially at the WTO. In their well articulated letter, the authors have primarily looked at the issue from the TRIPS Council perspective ignoring the concerns of the exporting and importing countries at the ground level. More importantly, from the perspective of access to affordable health care which has been the core theme of our article. They have also liberally used the terms solution and resolved. Our argument has been that the issue is far from resolved. Mere transformation of a ‘waiver’ into a ‘permanent amendment’ by the General Council of the WTO does not tantamount to finding a solution to the primary objective of the amendment (and the Doha Declaration) which is to provide access to medicines to poor countries that lack both the manufacturing capability, and the money to buy cheap medicines. Interestingly, the very experience of countries quoted by the authors - Canada and Rwanda - bears us out that 31 (f) is far from being a ‘solution’, much less an ‘expeditious solution’ (see below).

First and foremost, any discussion and/or proposed amendment of the TRIPS agreement since its enforcement in 2005 in the developing (DCs) and least developed countries (LDCs) (which were given an additional 10 years) centres around systems and mechanisms to balance the rights and obligations of WTO member countries to ensure that the IP protection regimes do not run counter to their public health policies and do not impede access to affordable health care to the poor. Which is the reason why the Doha meeting was held and one of its historic declarations states that “… the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. “… while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (emphasis ours). In view of the dire need of various LDCs to affordable medicines mainly for HIV/AIDS, Para 6 of The Doha Declaration instructs the TRIPS Council ‘to find an expeditious solution to this problem and to report to the General Council before the end of 2002’ (emphasis ours). As the Médecins Sans Frontières (MSF) wryly commented, the August 30, 2003 decision was ‘neither expeditious, nor a solution’. That this proposed waiver of 31 (f) could hardly be a viable solution on the issue of providing affordable drugs to poor countries was anticipated. Several other better options/solutions were suggested before and after the issue was decided at the WTO. In fact, the European Union from developed countries and many developing countries proposed some innovative and pragmatic proposals including modifying article 30, removal of 31 (f) etc., that would have truly facilitated quick access to affordable medicines to the LDCs (See).

Thus, the operationalization of 31 (f), for its intended purpose of promoting access to affordable (generic) drugs to poor countries, is cumbersome, and a disaster. This could best be illustrated by the Canada-Rwanda episode. The global charity MSF tested the expediency and efficacy of the implementation of the August 30 decision in close collaboration with the Government and other groups in Canada.

In September 2003 Canada became the first country to incorporate the August 30 decision into its national patent law and the process could be completed in May 2004. Despite identifying five HIV/AIDS drugs urgently needed
by poor countries, no generic manufacturer in Canada was interested in the proposal. Finally, the MSF could persuade one company Apotex agree to produce a fixed-dose combination (FDC) for HIV/AIDS. Rwanda and Canada could intimate the TRIPS Council in July and October 2007 respectively, about four years after the initiation of the process\(^8\). The MSF found it very difficult to find a Canadian company prepared to undergo the hassles of approvals, notifications and manufacture the exact limited quantity of drugs required to the importing country that should be specifically labelled and exported at costs that are economically unviable. Countries interested in using 31(f) should amend their patent laws and issue notification to the WTO etc.\(^6,7\). To the best of our knowledge, only Canada, the European Union, The Netherlands, Switzerland, India and Norway have initiated steps to change their legislation. In the case of Norway it is considered as merely symbolic as the country does not manufacture medicines needed by poor countries\(^7\).

It is thus clear that the process to work towards expeditiously providing cheap medicines to a looming public health crisis is quite cumbersome\(^3,6,8\). In fact the Director-General of the European Generic Medicines Association told the European Parliament that it is unlikely that any European (generic) company would make use of the mechanism\(^9\). The tedious process as the MSF summed up includes:\(^5\) (i) prior negotiation necessary before compulsory license granted; (ii) anti-diversion measures kill incentives for generic production; (iii) notification of intention to use the August 30\(^{th}\) Decision; and (iv) the decision is not automatic, but a succession of complex procedural steps. Yet, even this was not the best solution as the eventural cost per tablet of the generic FDC by Apotex was expected to be about US$ 0.405 while Indian companies could have easily supplied for US$ 0.14 per tablet\(^8\). That nearly five years on from the August 30\(^{th}\) Decision, not a tablet of medicine has reached a single patient to any LDC under this WTO mechanism\(^5\). And this despite the MSF devoting considerable time and energy by closely working with the very co-operative Canadian government, find an NGO willing to pay the cost of medicines and with both the exporting and importing countries committed to working together. What is more worrying is the fact that after threats by the US, many developing countries like Brazil, Thailand\(^8\) (and India \(?\)) are unwilling to resort to the compulsory licensing (CL) route. An event that is now being keenly watched with tremendous interest is the application for CL under Sec 92(A) filed by an Indian company Natco Pharma to export two anti-cancer drugs Roche’s erlotinib (brand name Tarceva) and Pfizer’s sunitinib (brand name Sutent) to Nepal, a LDC with no manufacturing capacity\(^10\).

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