Reforming Canada's Access to Medicines Regime

In his recent *CMAJ* commentary, Amir Attaran significantly downplayed the importance of exceptions in patent law that permit generic drug production.[1] It is misleading to talk about the number of pharmaceutical patents in developing countries without mentioning the fact that India manufactures and provides the majority of the developing world's affordable generic medicines and well over 50% of its generic antiretroviral therapies.[2] Now that India must provide 20 years of patent protection on pharmaceuticals, it is uncertain where, and to what extent, affordable generic versions of patented drugs will be produced.[3] Given this grim prospect, abandoning Canada's Access to Medicines Regime would be shortsighted and careless. Attaran's all-or-nothing approach dismisses any role for Canadian generic drug manufacturers and fails to acknowledge the uncertainty in future sources for affordable, generic products.

Attaran is correct in stating that Canada's generic drug industry will have difficulty competing against pharmaceutical manufacturers in newly industrialized countries,[1] but it is too early to dismiss the Access to Medicines Regime in its entirety. First, many critics argue that Canada should instead incorporate clear commercial incentives into the regime to encourage production of Canadian generic drugs.[4] Second, recent evidence suggests that Canadian products can still be competitively priced. Last year, Apotex manufactured a fixed-dose combination antiretroviral product intended for shipment under Canada's Access to Medicines Regime and announced that it can offer the product to Médecins Sans Frontières at $0.39 per pill, a price comparable to that offered by Indian generic drug manufacturers.[5]

Finally, Attaran mentioned that poor countries are not using compulsory licensing but failed to mention one of main reasons for this: developing countries face formidable political pressure when trying to use such options, as illustrated most recently in Thailand.[6,7] In the context of this political reality, bold amendments to the Canadian legislation would give developing countries much-needed support for their legal right to take advantage of flexibilities in patent law to address their nations' public health needs.

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Amir Attaran's arguments that Parliament should not bother to reform Canada's Access to Medicines Regime[1] are not persuasive. First, experts have debunked his simplistic claim that patents have no significant impact on access to AIDS drugs in Africa because of limited patent coverage.[2] In any event, the law addresses the situation in which patent holders in Canada can bar the export of generic versions of their medicines. In some cases, there may be additional hurdles to overcome in the developing country importing the drugs, including the possibility that a compulsory licence will have to be issued in that country. However, this does not mean it is pointless to change Canada's law to make it easier for generic drug exporters to overcome the patent barriers in Canada.

Second, Attaran claims that Canadian manufacturers are unlikely to offer competitive pricing. Oddly, he cites generic drug prices in Canada, when it is the prices at which the drugs are offered to developing countries that are relevant. So far, one product, an AIDS drug, has been developed for possible export under Canada's Access to Medicines Regime; the manufacturer has stated publicly that it can and is willing to sell this drug for only a few cents more per tablet than the prices set by Indian generic drug manufacturers and that the price will come down further if the company succeeds in procuring the necessary active pharmaceutical ingredients more cheaply.[3,4]

Finally, Attaran accepts that Canada's law is "inefficient" and "user-unfriendly." Indeed, the law mandates a cumbersome process in which generic drug manufacturers must seek separate compulsory licences for each order, by a single country, of a predetermined quantity of a drug, after attempting in each instance to negotiate a voluntary licence from the company