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The curious case of generic Hep C drug sofosbuvir

Flip-flop around its patent in India points to need for developing nations to band for tech

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For more than a decade, an academic debate has raged among public health experts, the World Health Organsiation and governments on the capacity, cost effectiveness and the potential benefits of generic drug production in developing countries other than India and China.

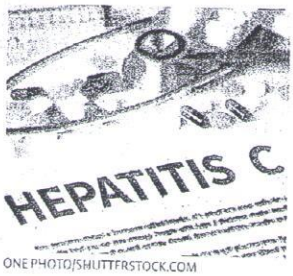
Hepatitis C and the revolution in the generic production and supply of new HCV medicines changed all that.

The first approvals by the European Medicines Agency and the US Food and Drug Administration of a new generation of HCV medicines, called direct-acting antivirals (DAAs), started with sofosbuvir in 2013. The US price tag of $84,000 for sofosbuvir and $47,000 in Europe brought to world attention the spiralling cost of patented medicines.

Governments and generic companies in countries like Egypt – where millions live with the virus and suffer from symptoms such as cirrhosis, liver failure and cancer – have developed a strong political will to make and market low-cost DAAs. They changed the way people think about quality generics.

Indian manufacturers – which have a reputation for their reverse engineering skills and were the first to market low-cost versions of life-saving cancer (imatinib) and HIV drugs (zidovudine) within two-three years of their US launch at the turn of the century – now face competition from Bangladeshi and Egyptian manufacturers. They launched the generic versions of sofosbuvir ahead of Indian companies in early 2015. Clearly, their governments were backing them using flexibilities available under WTO rules.

The Egyptian patent office found – after a technical examination of the sofosbuvir compound – that it is not novel chemically, and, therefore, does not fulfil the criteria of novelty and inventiveness, both of which are necessary for a pharmaceutical compound to be patented. Bangladesh took leadership in seeking as an LDC (least developed country) an extension to enforce patents and test data obligations with regard to pharmaceutical products until 2033 and beyond.



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Some major Indian manufacturers shrugged off the competition and were dismissive about their capacity to meet the quality requirement of procurers and the WHO. They entered into a deal with US drugmaker Gilead, which had filed numerous patent claims on sofosbuvir in India. Hidden in the deal were clauses that limited their capacity to export the active pharmaceutical ingredient (API) and supply to a number of high burden middle-income countries.

Egyptian pharmaceutical company Pharco, in the meantime, moved ahead by applying for WHO pre-qualification (a quality validation recognised globally) and entering into an agreement with Drugs for Neglected Diseases (DNDi) to supply sofosbuvir for a combination treatment trial in Thailand and Malaysia.

Bangladeshi firms forged ahead with generic versions of other DAAs that needed to be combined with sofosbuvir.

In Pakistan, the launch of generic versions of sofosbuvir in early 2016 led to considerable increase in the number of people starting treatment. A little known fact behind the revolution was the fact that a small but growing number of API producers in India were working independent of Gilead to establish exports of key raw materials needed to produce the drug and other DAAs in countries such as Egypt, Bangladesh, and Pakistan as also Latin America.

A technical partnership often talked about among developing governments but not taken forward was being executed by this partnership between Chinese intermediate suppliers, Indian API manufacturers, and new producers of finished formulations across the developing world.

But with one stroke the Indian Patent Office's decision to grant the patent on the base compound of sofosbuvir this week has provided Gilead with the tools to disrupt and stop future exports of the API from India, giving it significant control on the supply of API globally.

India's decision to reverse the patent rejection of 2015 to an order for grant in 2016 is going to cause short-term pain to producers in Egypt and other countries, which will now have to find alternative sources. But, intriguingly, it also undermines the government's recent efforts and policy to revive and boost the domestic API industry.

(The writer works on access to medicines in developing countries. The views are personal)