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 tian 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 fulfill 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.

For more than a decade, an academic debate has raged among public health experts, the World Health Organisation 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 world attention to 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 Bangladesh and Egyp-