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DCGI doesn't infringe Indian patent laws

It is neither authorised by the law to assess patent issues nor does it have the institutional competence for this

ANAND GROVER

THIS is in regard to Uttam Gupta's recent column in *The Financial Express* ('Drug licensing must recognise patents', October 30, *goo.gl/DRPwZE*). The article not only betrays ignorance of patent and drug regulatory laws but also mixes up a number of issues.

Gupta makes four substantive points. One, that the drug regulatory regime under the Drugs and Cosmetics Act (DCA) does not consider patent status of drugs while granting licensing approvals. Two, that this allegedly allows generic companies to disregard patents while obtaining regulatory approval from the Drug Controller General of India (DCGI). Three, that this implies the government, namely, the DCGI, becomes a party to patent infringement. Finally, he suggests that the innovation of drugs is very costly and patients in India must get used to the idea.

These assertions could not be further from what is envisaged under the law. The Patents Act allows any pharmaceutical company to apply for registration during the subsistence of a patent (S. 107 A). This is pursuant to the TRIPS Agreement under Article 30 which permits a pharmaceutical company or research lab to undertake experimentation, generate and submit this data for approval during the subsistence of a patent. Pertinently, the WTO Dispute Settlement body first settled this position in the Canadian Pharmaceutical Patents case (DS114). Pursuant to this case, our law was changed to conform with Canada's patent law. Thus, using the originator's product to carry out experimentation or for obtaining approval of data thus derived is completely different from marketing the drug commercially, the latter being that which would attract infringement provisions. This is a fine distinction, which the column mentioned above fails to appreciate or deliberately ignores. The assertion in the column that "Surely, since DCGI ought to know that a patent right is held by a person/company over a product, it should reject an application for approval/registration of such products straight away if it is not supported by consent letter from the patent-holder?", is, therefore, totally unwarranted.

The column also conveniently ignores that its very proposition, that the DCGI ought to recognise patent linkage, was specifically rejected by the Delhi High Court in the Bayer versus Cipla case on the ground that the Indian patent law and the DCA do not recognise such patent-linkage. It was held, importantly, that the DCGI was neither authorised by the DCA to assess the validity of a patent, since it could be challenged at any point during its lifetime, nor does it possess the institutional competence to make such a determination.

Further, the assertion that new drugs cost money and are, therefore, priced higher is a myth which the column unfortunately perpetuates. Multinational pharmaceutical companies (MNPCs) have been peddling the myth that, at today's rates it costs around $2.5 billion to bring a new blockbuster drug (one that fetches a turnover of $1 billion in the first year of sales) to the market. These figures were sought to be supported by the MNC based-industry studies by Di Masi *et al* which selectively used data to project such a high figure. Independent studies conducted by the Congressional Budget Office of the US, Public Citizen and Light and Warburton strongly refute the figures claimed. It is estimated that the real expenditure is around $80 million, a cost which MNPCs easily recoup within a year of sales. Most MNCs, however, insist on charging sky-high prices for new drugs even where there are serious questions raise about their innovativeness. For example, the MNC, Gilead Sciences. Inc, has priced its Hepatitis C treatment drug, Sofosbuvir, which is critical for a cure, at $84,000 for a course; this is not only completely unjustifiable for the cost of innovation but also unconscionable. This exorbitant price has lead to rationing of treatment for patients, where only the most-ill are given preference by healthcare providers, so much so that there are protests and outrage across the patient, medical and scientific community in the US over the issue of pricing of new medicines. Pressed by health activists and patient groups, international health agencies like the World Health Organisation (WHO) are now, in earnest, deliberating on steps to de-link R&D costs from prices of medicines.

Surprisingly, the column bemoans the availability of cheap drugs in India. What is obviously not either understood or appreciated is that 30% of the world's poor live in India. Drugs priced today on the basis of patents—in some cases, even their generic equivalents—are unaffordable for the average man. For instance, Nexavar, the only drug for which a compulsory licence has so far been granted, was priced by Bayer at ₹2.8 lakh per month whereas generic versions offered by Natco and Cipla cost around ₹6,000-7,000 per month. It is surprising how sustainable development for India could be based on prices of patented drugs by MNCs.

Until 2005, most MNCs used the tiered-pricing model whereby they would employ different prices for the same drugs in India as compared to their home countries in the developed world. After 2005, most MNCs—barring Gilead, which has used voluntary licensing model and has thereby made available drugs at a different price through generic companies—are pricing their drugs uniformly across the world. Thus, Novartis' anti-cancer drug Glivec (Gleevec in the US, Canada and South Africa) costs the same in Switzerland as well as India. The same goes for Bayer's Nexavar.

The column also seems to suggest that quality of generic drugs and companies is not up to the mark as it repeatedly, and wrongly, equates low-cost with low-quality. This is a complete fallacy, as most reputed generic companies market brands of high quality and safety, assessed not only by Indian regulatory standards but also international standards set by the USFDA and WHO prequalification—90% of the anti-retroviral (ARV) medicines stocked by international procurement agencies like PEPFAR for supply in the developing world, particularly Africa, comes from Indian generic companies. This is the reason why leaders of African countries in the recent Indo-Africa Summit requested the Indian government to not take any steps that would threaten the supply of affordable generic medicines to Africans.

The recipe of patent linkage which Gupta suggests would not just defeat the access to affordable medicines—in that it would delay the entry of generics immediately after the expiry of the patent period—but it would also delay the availability of generic drugs even if a compulsory licence were to be issued.

The column's prescription is in line with the MNCs' point of view on this issue.

The author is a senior advocate who has fought cases for patients and generic drug companies. He is also director, Lawyers' Collective, which runs a programme on access to medicines

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