PHARMABIZ.com
india's most comprehensive pharma portal

NGOs warn against proposal to link marketing approval with patent status

Wednesday, November 18, 2009 08:00 IST
Joseph Alexander, New Delhi

The public interest groups have again warned the Health Ministry against any attempt to link marketing approval with patent status as being pushed by the multinational companies, saying that it would turn the drug regulator into India's patent police.

Most regulatory authorities, even the US FDA, do not have the required expertise or resources to review patent information. The patent linkage will therefore put a significant burden on the office of the DCGI that has neither the expertise to assess patent status nor the authority to enforce private patent holder rights, according to the NGOs.

A number of NGOs held a discussion meeting recently in the Capital and have identified the issue of patent linkage as one of key matters to be dealt with and opposed in the immediate future. They have decided to chalk out different steps in this regard. According to the proposal, the DCGI was planning to link the patent status and marketing approval. The DCGI would ensure before granting marketing approval to a generic medicine that it is not patented and its all aspects relating to the patent status.

"The preamble of the TRIPS agreement recognizes that intellectual property rights are private rights. However, with the implementation of patent linkage, the DCGI's office which is meant to ensure safety of medicines for the public will enforce patents for MNCs. Patent holders will be spared the expenses and embarrassment of being seen to enforce their rights publicly in the courts. The DCGI will be reduced to enforcing private commercial rights and will become in effect the patent police," the discussion paper by the NGOs said.

Noting that many countries refused to assign this role to the drug controllers as they do not have the legal authority of mandate to implement patent linkages, the public activists have warned that any such move would affect the access to affordable medicines. They have also pointed out the case of AIDS treatment as perfect example in which the medicines prices came down drastically with the arrival of generic anti-retrovirals from Indian companies.

"Patent linkage will enforce invalid patents and prevent generic competition. If the patent linkage is introduced, the DCGI, regardless of the validity of the patent will refuse to grant marketing approval for a generic version of the drug. Currently, in such situations where the patent granted is not valid, the generic manufacturer can challenge the patent by marketing the drug and filing for revocation if the patentee files an infringement," the paper explained.

By implementing patent linkage, the DCGI may interfere in the jurisdiction of the courts to examine whether patent was properly awarded or not. The drug regulator may also

end up enforcing a patent that was granted improperly, the NGOs said, suggesting the case of valganciclovir and the ruling of the Delhi High Court in the case of Hoffmann-La Roche vs Cipla Ltd.