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India Mulls Stricter Norms for Patents in Pharma Space

Indian Patent Office plans to make it mandatory to disclose WHO-assigned INN while applying for patent

**SOMNATH
NEW DELHI**

In a move that could usher in more transparency in the pharma patent landscape, the Indian Patent Office is considering a proposal that seeks to make it mandatory for drug firms to disclose the WHO-assigned generic names of drugs, whenever known, while applying for their patent.

The proposal, if accepted, will make India the first country in the world to mandate such a condition.

Experts say the move will make it easy for patent examiners, generic drug makers and public health groups to block 'trivialous' incremental patents from being granted. It will also make it difficult for innovator drug firms to get patents for incremental innovations, which do not show any enhancement in efficacy of an existing therapy.

The move comes at a time when Indian patent regime is already under severe criticism from the US and Europe for deviating from global norms and implementing unique policies customised for the needs of the developing world population.

"We are currently consulting key stakeholders on the feasibility of mandating disclosure of WHO-assigned INN (International non-proprietary names) in the pharma patent applications, wherever applicable," an official at the Indian Patent Office told ET on condition of anonymity. "A final decision, however, has not yet been taken on the matter."

The official added that inputs from the stakeholders would now be discussed with the Department of Industrial Policy and Promotions before a final call is taken on the issue. While top law firms, mainly those representing big pharmaceutical companies, said the move is not fea-



sible and would violate the country's obligations on Trade Related Aspects of Intellectual Property Rights (TRIPS), global patent experts and public health groups said. It would help sieve trivialous incremental innovations from valid ones and prevent grant of patents to them.

Termining the Indian Patents Office's move an "important step indeed", Carlos Correa, global patent expert and professor at the University of Buenos Aires, said: "Patent applicants seem to deliberately conceal the known INN to discourage oppositions (before and after a patent is granted) and challenges to the patent's validity. The absence of this information also complicates procurement of drugs and local production since it is difficult to know when a patent can be infringed."

Leena Meniganeey who works with global public health group Médecins Sans Frontières, said the move could prove to be a key second generation reform related to limiting the practice of evergreening of patents in India. She said, at present, multiple pat-

ent applications are filed for the same drug, which does not cite the common INN. This makes it difficult to identify which patent claims relate to which medicines out of the thousands of applications that are filed. But law firms representing pharma multinationals argue that the patent office is trying to put the cart before the horse.

"There are only three criteria for patentability — novelty, utility and non-obviousness. INN cannot be included as a fourth requirement," said Archana Shanker, senior partner at Anand and Anand. She said any administrative guideline which mandates such disclosure, would violate both the law of the land and TRIPS obligations of the country.

Ashwin Jitka, managing partner at Remity & Sagar, said: "Generally INN is not available at the time of filing a patent application and the same are assigned later. Therefore, in case disclosure of INNs is made mandatory, the applicant would have to keep track of the assignment of an INN to each and every com-

pound mentioned in the patent application or patent, which in itself is a cumbersome process and may not be feasible for the applicant."

This could be true of new drugs, counter public health groups, but most of the patents filed today are secondary in nature as the new drugs pipeline has dried up significantly and this disclosure can always be made mandatory for cases where INN has already been assigned.

Ramesh Adige, former executive director at Ranbaxy Labs, said IUPAC (International Union of Pure and Applied Chemistry) should be preferred over INN, as the former is more of a chemical nomenclature, allocated much before an INN. Maintaining that mandating such disclosure is not feasible for new chemical entities, he said: "India can mandate INN or IUPAC for incremental innovation in pharmaceuticals to help patent of examiners expedite search."

Law firms ET spoke to also said patent claims of a specific type, called Markush structure that involves a large number of compounds, would become infeasible to file here.

Early this year, the Indian patent regime was slammed, particularly by its western counterparts, for proactively implementing a policy that seeks to ensure that incremental innovations, which don't increase efficacy of an existing therapy, are not granted monopoly rights. It has also drawn flak from the same quarters for granting the country's first compulsory licence last year to make available a cheaper version of a cancer drug. However, a few of these "deviant" moves have found support among emerging economies like Brazil and South Africa, which are in the process of adopting some of India's policy innovations.

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