WHO'S THERE? PHARMACEUTICAL BRANDING IN INDIA

Pharmaceutical companies in India are having to adapt to the World Health Organization's International Nonproprietary Names programme, as Lucy Rana and Pooja Thakur explain.

Patents are portrayed and envisioned as the indispensable reward to compensate pharmaceutical firms for the large cost, risk and years of research that are put into drug discovery and development. However, this monopoly right comes with an expiration period. Brand loyalty towards a trademark of an off-patent drug can enable the manufacturer to enjoy indefinite benefits from a patent beyond its expiration.

However, brand loyalty and extensive marketing may lead to market monopolisation, a barrier that is very difficult for generic drug manufacturers to overcome. From a public health perspective this has numerous downsides. For instance, it may lead to physicians prescribing brand-name drugs instead of generic substitutes. It can result not only in suppression of competition and reduction in consumer choice, but also in an increase in the price of drug to make up for the pharma company's investment in aggressive brand promotion.

The International Nonproprietary Names (INN) programme was established by the World Health Organization (WHO) to assign non-proprietary names to pharmaceutical substances so that each substance would be recognised by a unique name. The World Health Assembly endorsed resolution WHA 46.19 which states that trademarks should not be derived from INNs, and INN stems should not be used in trademarks. The assembly reasoned that such practice could frustrate the rational selection of INNs and ultimately compromise the safety of patients by promoting confusion in drug nomenclature.

Regulation of INN in India

The Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945 regulate the marketing approval, manufacture and distribution and sale of drugs in India. As per the rules, the proper name of the drug is required to be printed in a more conspicuous manner than the trade name, which must appear immediately after or under the proper name. However, it is pertinent to point out here that INNs are considered to be the proper name of the drug only where the concerned drug does not have any name under Schedule F, the official pharmacopoeia, or the National Formulary of India.

India has a decentralised drug regulatory structure with powers separated at the central and state level. The Drug Controller General of India (DCGI) discharges the functions attached to central government. Although the DCGI gives an initial marketing approval to a pharmaceutical substance, the manufacturing approval and subsequent marketing approvals fall within the state regulator's domain. The company has a choice to market the drug either by a brand or a generic name. If the company intends to market the drug under a brand name, it is required to disclose the brand name along with the generic name. The various state drug regulatory authorities can therefore regulate the use of INNs in coining brand names. However, in India

there is no specific regulation or guideline on how INNs are to be used in nomenclature of drugs.

The Trade Marks Act of India explicitly prohibits registration of INNs and names that are deceptively similar to INNs. It further states that any such registration shall be deemed (for the purpose of section 57 of the act) to be an entry made in the register without sufficient cause, or an entry wrongly remaining on the register, as the circumstances may require. However there have been reported incidents where WHO has objected to the practice of Indian pharmaceutical companies misusing INNs as trademark-protected brand names.

In 2008, WHO wrote a letter to the DCGI expressing concern over a trademark application filed by Cadila Pharmaceuticals for 'platin', used for antineoplastic agents. There were already 18 INNs ending with '-platin' at that time. Among several other objections, WHO objected to Docetax for being similar to the INN docetaxel, Prazole for being an INN by itself and Nanotaxel for including the INN stem '-taxel', and had wanted the Indian drug regulatory authorities to take remedial measures.

It is pertinent to point out that even where the WHO recommends a name as an INN, it does not come within the ambit of protection offered by the Trademarks Act unless it is notified as such by the Trade Marks Registrar. The registry recently published the list of INNs, enlisting 8151 pharmaceutical substances as INNs and as declared by the WHO. However, numerous marks that are mentioned as INNs in the list, including Ofloxacin, Lactulose and Retinol, are already registered in India. This notification renders them in violation of section 13 of the act.

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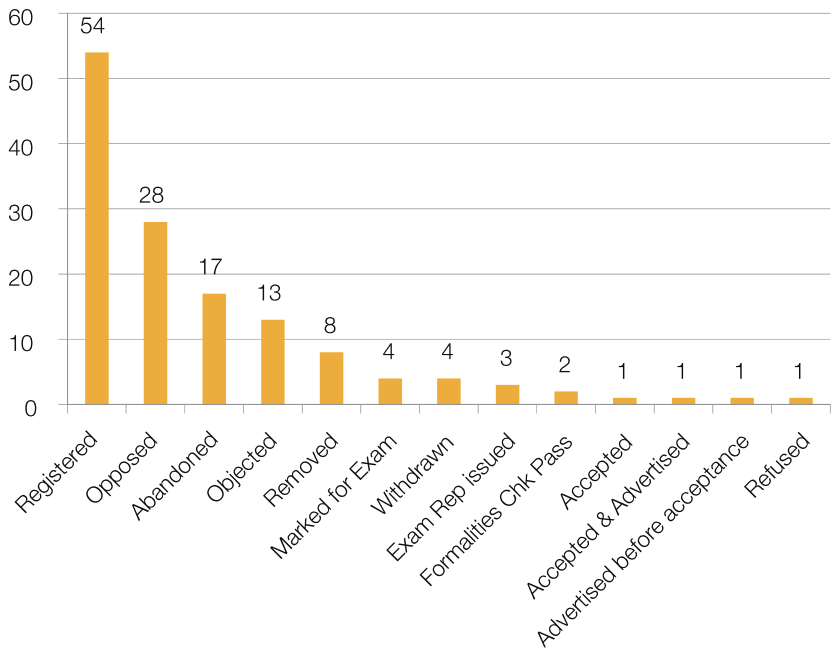
The Trade Marks Act empowers the registrar (or the appellate board) to pass appropriate orders for cancelling or varying the registration of a trademark on the grounds of any contravention or failure to observe any condition entered in the register in relation to the mark. Further, any aggrieved person can also complain to them that a mark has been registered without sufficient cause, or has been entered wrongly in the register.

Therefore, if a complaint is made to the registrar or the Appellate Board in relation to registration of a trademark coined from INNs, the entry in the register may be expunged or varied. Moreover, the registrar may *suo moto* decide such issues on its own motion and cancel the registration of such mark

In 2009-2010, 22,274 applications (about 15.8 percent of the total 141,943 applications) were filed in Class 5. The list of INNs as declared by the registry is therefore expected to help agents and applicants to assess their applications prior to filing for trademark registration, and to obviate expensive litigation later on. On the other hand, the INN-derived marks that are already registered are exposed to the risk of lawsuits by any public interest group, or other interested person, or the registrar. This may have repercussions for the businesses of drug manufacturers.

It is imperative that examiners are trained on the public health implications of the INN programme. The registry may also consider seeking information on the component/generic name of the drug from applicants who are applying for trademarks on drugs. It is necessary to generate awareness on the use of INNs in the pharmaceutical industry in India, as well as making sure that medical and legal practitioners understand the implications. ■

Status wise break up of trademarks identical to INNs declared by registry



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Lucy Rana has been advising *Fortune 500* companies and some of the world's most esteemed corporations from multifarious fields and has actively contributed to growth in every sphere of the firm, from prosecution to successful litigations. Having majored in Japanese language and business management, Rana has channelled her innovative and pioneering strategies for delivering efficient, high quality and cost-effective results to the clients.

Pooja Thakur is proficient in all aspects of trademark and copyright matters including registration of trademark, searching, drafting assignments, licences, prosecution before the Indian Trade Marks Office and providing opinions related to queries of trademarks.