Patent status declaration while seeking drug permission

Awareness about Intellectual Property Rights (IPR) is rapidly increasing in India. Since establishment of the World Trade Organization in 1995, several amendments were made to the existing IPR Laws in the years that followed. Some new IPR Laws also were introduced.

Section 16(1)(b) of the Companies Act, 2013 provides for seeking Rectification of a Company Name that is identical with or too nearly resembles a registered trade mark. Such Rectification can be sought by the Proprietor of the registered trade mark.

Paragraph VIII Declaration part of Form INC 32 Simplified Proforma for Incorporating Company electronically (SPICe) requires the applicant to accept/provide *inter alia* a Declaration, *"I have also used the search facility for checking the resemblances of the proposed name with registered trademarks and trade mark subject of an application under the Trade Marks Act, 1999 and other relevant search for checking the resemblance of the proposed name to satisfy myself with the compliance of the provisions of the Act for resemblance of name and Rules thereof."*

Form INC 32 does not require any Certificate from the Registrar of Trade Marks, but, a mechanism exists to reduce or eliminate the possibility of registering a Company with a name that is identical with or too nearly resembles a trade mark belonging to someone else.

The Legislature has introduced checks and balances to mitigate the risk of wrongly registering in favour of a person copyright in an artistic work which is used or is capable of being used in relation to any goods. Proviso to Section 45(1) of the Copyright Act, 1957 and Rule 70(6) of the Copyright Rules, 2013 require the applicant for registration of such copyright to first obtain from the Registrar of Trade Marks a Certificate to the effect that no trade mark identical with or deceptively similar to such artistic work has been registered under the Trade Marks Act, 1999 in the name of, or that no

application has been made under the Trade Marks Act, 1999 for such registration by, any person other than the applicant. Entry 14 of the Statement of Particulars to accompany application on Form XIV for registration of copyright requires such Certificate to be included with the application.

The World Health Organization (WHO) has a constitutional responsibility to "develop, establish and promote international standards with respect to biological, pharmaceutical and similar products". The International Nonproprietary Names (INN) Programme is a core activity embedded in the normative functions of WHO and has served the global public health and medicines community for over seventy years. The Programme was established to assign nonproprietary names to pharmaceutical substances so that each substance would be recognized by a unique name. Such names are needed for the clear identification, safe prescription and dispensing of medicines, and for communication and exchange of information among health professionals. INN can be used freely because they are in the public domain. In addition to being a basic component of many WHO medicines activities and programmes, INNs are used in regulatory and administrative processes in many countries. They are also intended for use in pharmacopoeias, labelling and product information and to provide standardized terminology for the international exchange of scientific information.

Section 13(b) of the Trade Marks Act, 1999 prohibits registration of a word as a trade mark if it is declared by WHO and notified in the prescribed manner by the Registrar of Trade Marks from time to time as an INN or a word which is deceptively similar to an INN. List of INNs available on the official website of the Trade Marks Registry can be accessed using the link: https://tmrsearch.ipindia.gov.in/tmrpublicsearch/#

Rule 122-B(1)(a) of the Drugs and Cosmetic Rules, 1945 provides that no new drug shall be manufactured for sale unless it is approved by the

Licensing Authority as defined in Clause (b) of Rule 21 of the said Rules. Rule 122-B(1)(b) of the said Rules provides that an application for the grant of approval to manufacture the new drug and its formulations shall be made in Form 44 to the Licensing Authority as defined in Clause (b) of Rule 21 of the said Rules and shall be accompanied by a fee. Form 44 requires particulars of new Drug to be stated at Paragraph 1 which includes at Serial No. (8), Patent status of the Drug.

Thus, an applicant submitting Form 44 is required to state Patent status of the Drug to be manufactured. The Drug Controller can refuse Drug Permission if manufacture or sale of the Drug would infringe someone's Patent. There appears to be no mechanism put in place to require a Certificate from the Controller of Patents to the effect that the applicant is the Patentee of the Drug or that no Patent for the Drug is in force.

If Drug Permission is granted on the basis of any false Patent status provided, such Drug Permission ought to be promptly revoked upon bringing to the knowledge of the Drug Controller that the applicant for the Drug Permission knowingly made a false statement on Form 44. Such procedure may eliminate the need to initiate Patent Infringement Proceedings and may serve as an efficacious remedy to reduce or prevent Patent infringement.

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