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IP NEWSLETTER

Edition: February, 2015

New Rules on Packaging and Labelling of Tobacco Products in India

The Central Government of India has introduced the Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2014, which shall come into force on April 1, 2015. These Rules stem from the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce Production, Supply and Distribution) Act, of 2003, which prohibits the advertisement of, and provides for the regulation of trade and commerce in, production, supply and distribution of, cigarettes and other tobacco products. These Rules have been passed by the Government after the Delhi High Court made a recommendation to the Government to consider the feasibility of implementing plain packaging for cigarettes and other tobacco products.

These Rules specify the content and the colour of warning message to be displayed on the tobacco product package and the sample pictorial representation of health warnings. According to these Rules:

1. The specified health warning shall cover 85% of the principal display area of the package of which 60% shall cover pictoral health warning and 25% shall cover the textual health warning and shall be positioned on the top edge of the package and in the same direction as the information on the principal display area.
2. The packaging shall not contain any messages, images or pictures that directly or indirectly promote the use of consumption of a specified tobacco brand or tobacco usage in general or any matter of statement which is inconsistent with, or detracts from, the specified health warning.
3. A pictorial representation of the ill effects of tobacco use on health shall be placed above the textual health warning, covering 60% of the principal package area.
4. The size of the specified health warning on each panel of the tobacco package shall not be less than 3.5 cm (width) x 4 cm (height), so as to ensure that the warning is legible, prominent and conspicuous.
5. The textual health warning shall be inscribed in the language used on the package.
6. The specified health warning on tobacco product package shall be rotated every twenty-four months from the date of commencement of these rules or before the period of rotation as may be specified by the Central Government by notification. During the rotation period, there shall be two images of specified health warning for both smoking and smokeless form of tobacco product and each of the images of the specified health warning shall appear consecutively on the package with an interregnum period of twelve months.

Novelty of Parent Lines of Extant Hybrid Varieties under Plant Varieties and Farmers' Rights Act, 2001

The Delhi High Court recently examined (*Maharashtra Hybrid Seed Co. vs Union Of India*, Order dated January 9, 2015) whether the parent lines of extant hybrid varieties can be considered as novel plant varieties for the purposes of registration under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (hereafter the 'Act').

The Petitioners contended that the hybrid seeds, obtained from crossing the parental lines, are distinct in traits and characteristics from the parent lines and cannot be considered as propagating or harvested material of the parental line varieties. It was contended that the propagating/harvested material of a variety would mean any part of a plant or seed, which is capable of regeneration into a plant having same characteristics as the original plant. Since regeneration of hybrid seed would not result in the parental lines but the hybrid plant variety that is distinct from the parent line varieties, the hybrid seeds obtained from crossing of parent lines could not be said to be propagating or harvested material of the parental lines. It was further submitted that a 'variety' is defined 'by the expression of the characteristics' and as the characteristics of the hybrid variety are different from the parental line, the parent lines could not be considered the same as the hybrid variety.

The Hon'ble High Court therefore examined whether the parental lines would be eligible for being considered as "novel" under Section 15(3)(a) of the Act, if the hybrid seeds of such parental varieties have been disposed of for producing the hybrid variety. Section 13 of the Act provides for maintaining of a register called the national register of plant varieties, which would record the name of all registered plant varieties along with names and address of their respective breeders and their rights in respect of such plant varieties. If the application for registration of an "essentially derived variety" or a "variety" is accepted and the said plant variety is registered, the Registrar is enjoined to issue a certificate of registration under Section 23(8) of the Act (in case of essentially derived variety) and Section 24 of the Act (in case of variety). By virtue of Section 24(6), the registration certificate is valid for a period of 9 years in case of trees and vines and 6 years in case of other crops. Section 15(1) of the Act provides "novelty, distinctiveness, uniformity and stability" to be the requisite criteria for the registration of a variety as a new variety. Section 15(2) of the Act also enables "extant variety" to be registered within a specified period if it conforms to the criteria of distinctiveness, uniformity and stability. As per Section 15(3)(a) of the Act, a new variety shall be deemed to be novel if the propagating or harvested material of such variety has not been sold or otherwise disposed of, prior than one year from filing of the application for registration, for the purposes of exploitation of such variety in India.

Under Section 15(1) of the Act, in order to qualify as a new variety registerable the plant variety must conform to the criteria of "novelty, distinctness, uniformity and stability". By virtue of Section 15(2) of the Act, an extant variety may also be registered even though the plant variety does not conform to the criteria of novelty. In other words a plant variety is registered as a "new variety" if it is novel in addition to being distinct, uniform and stable (i.e. meeting the 'DUS' criteria) and as an "extant variety" if the plant variety is not novel but meets the DUS criteria. In terms of Section 15(3) of the Act, a new plant variety would be deemed to be novel if the propagating or harvested material of such variety has not been sold or otherwise disposed of by or with consent of its breeder or his successor for the purposes of exploitation of such variety in India earlier than one year or in case it is disposed of outside India, earlier than four years from the date of application.

The Court held that a plain reading of Section 15(3) of the Act would indicate that if the seeds of parent lines have been commercially sold, the breeders cannot claim the parent lines to be novel. Even if one was to consider that language of Section 15(3) of the Act was ambiguous on the issue, the same would have to be resolved against the Petitioners. This is so because it is well settled that in case of ambiguity in the language of a statute, a purposive interpretation that furthers the intention of the Legislature must be adopted. The Legislative intent of the Act is to protect the rights of the farmers' and plant breeders. India had ratified the TRIPS agreement and, therefore, was obliged to protect the intellectual property rights in certain plant varieties. The protection as envisaged under the Act is to provide certain exclusive rights for a specified period of time. By virtue of Section 24(6) of the Act, the registration certificate issued in respect of a plant variety could be extended for a period up to 18 years from the date of registration in case of trees and vines and 15 years from the date of registration in other cases. In the case of extant varieties the validity of the registration certificate can be extended upto 15 years from the notification of that variety under Section 5 of the Seeds Act, 1966. In other words, the Parliament in its Legislative wisdom considered that providing exclusivity as specified under Section 24(6) of the Act was sufficient protection to the plant breeders. If the provisions of Section 15(3) of the Act are read in a manner as suggested by the petitioners, the effect would be to extend that period of protection many times over. In the first instance, a breeder would get protection in respect of the hybrid variety and assuming that there are two parent lines, the breeder could just before the expiry of the Registration Certificate in respect of a hybrid variety, register one of the parent variety and thus, extend its period of exclusivity for a further period of 15/18 years because protection of even one parent line would practically ensure exclusive rights in relation to the hybrid variety. In the same manner, before expiry of the registration period of that parent line, the breeder could register the other parent line as a new variety. In this manner a breeder could extend the protection for a period up to maximum 45/54 years instead of 15/18 years as contemplated under the Act. Clearly, this is not the legislative intent of the Parliament. Thus, the Court affirmed that if the hybrid falls under the category of extant variety about which there is common knowledge then its parental lines cannot be treated as novel.

Indian Patent Office rejects Gilead's Patent Application for Hepatitis C drug

The Indian Patent Office, vide its Order dated January 13, 2015, rejected Gilead's patent application for Hepatitis C drug, sofosbuvir, sold under the brand name 'Sovaldi'. The rejection was based on patent-eligibility of the claimed invention under Section 3(d) of the Patents Act, 2002 ("Act").

The Patent Office observed that under Section 3(d) of the Act, a novel and inventive substance is "considered to be the same substance, unless they differ significantly in properties with regard to efficacy". The Therapeutic efficacy may be proved by showing clinical trials so as to prove significant difference in the properties with regard to efficacy. Therefore the compound XI as disclosed in D1 is the closest prior art as being structurally closed to the presently claimed compound and therefore is the same compound to D1 in the eyes of the section 3(d). Furthermore the compound as disclosed in D1 and in the presently claimed compound are having the same use in the treatment of HCV infection and flavivirus infection . In such circumstances, the Applicants must have shown the therapeutic efficacy data to show the significant difference in the properties with regard to efficacy by providing the clinical trials etc. The Applicants showed the cytotoxicity data to prove the difference in properties which is insufficient to prove significant increase in the therapeutic efficacy. The data does not show any clinical trials to prove the improvement in the therapeutic efficacy.

The Patent Office held that a molecule with minor changes in addition to the novelty must show significantly enhanced therapeutic efficacy as compared to the nearest prior art molecule which is structurally and functionally close. Similar is the case here, the molecule as claimed in the present application is structurally and functionally similar to the molecule of Document D-1 (XIth compound may be novel due to the different orientation (stereo isomerism) of the fluoro group in the sugar moiety of the nucleoside but to qualify the requirement of section 3 (d) such novelty must result in significant enhancement of the therapeutic efficacy as compared to the cited molecule D1 compound XI therapeutic properties. However, there was no data on record filed by the Applicant to show the enhancement of therapeutic efficacy, and the Patent Office, accordingly rejected the application as being barred under Section 3(d) of the Act.