

## **Press Release**

1. This Department issued a Discussion Paper on Compulsory Licencing of Patents in August 2010. We received 38 responses. Ten of these responses were received from stakeholders based in countries outside India including Thailand, South Africa, USA , UK and Japan. Eleven responses were received from pharma manufacturers associations, and business promotions councils/chambers. Fourteen were received from other stakeholders including academics and NGOs.

2. The question of whether guidelines need to be framed for the issue of compulsory licences has been carefully considered by Government. Articles 31 of the TRIPS Agreement sets out the requirements for the issuance of compulsory licences by a WTO member state. The framework of the Indian Patents Act and Rules fully meets all these obligations and provides adequate guidance for the issue of compulsory licences. The circumstances of application of each of the relevant sections will depend upon the facts of each case.

3. As the existing legal framework is comprehensive, Government has decided that there is no need to issue additional guidelines for the issue of compulsory licences .

4. However, to ensure that the power to grant CLs is exercised with due care and caution, the Controller General of Patents has been advised not to delegate this power to any subordinate authority. He has also been requested to ensure that all CL applications are decided promptly.

5. In addition, the Controller General has been advised to ensure prompt and effective compliance with all the reporting requirements of patentees stipulated in the Patents Act. In his Annual report to the government, the Controller General has been requested to specifically review the data received from patentees under Section 146 of the Patents Act.

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