



ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA

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OPPI Position on IPR & Indian Patent Act, 2005

OPPI has been a strong supporter of adequate and effective protection to inventions in the field of drugs and pharmaceuticals right from its inception. The position of OPPI on the Indian Patent Law 2005 is briefly outlined below.

OPPI firmly believes that only a strong Patent Law can encourage, stimulate and sustain innovation in the field of Pharmaceuticals which is a research-based and technology intensive Industry. Proper implementation of world class Patent Law will encourage foreign direct investment, technology transfer, stimulate local research by Indian and International Companies and will be beneficial not only to the Indian Pharmaceutical Industry but also to the people of India, leading to a more progressive healthcare system and availability of newer and better medicines.

OPPI, which represents research-based Indian and International Pharmaceutical Companies, is committed to the establishment of world class standards of intellectual property protection. It welcomes the new Patents (Amendment) Act, 2005, introducing product patents in the fields of pharmaceuticals, chemicals, biotechnology and food. However, there are few areas of concern on which OPPI has made representations to the Government, which are as follows:

1. Patentability
2. Pre & Post Grant Opposition
3. Compulsory Licensing (CL)
4. Regulatory Data Protection

1. Patentability:

The Indian Parliament passed the Patents Act 2005 on 23rd March, 2005, reestablishing product patent protection in all fields, including food, agrochemicals and pharmaceuticals for a period of twenty years. The Act precludes salts, esters, isomers, polymorphs, metabolites, pure form, particle size, combinations, derivatives of known substances, etc. from patent protection unless "they differ significantly in efficacy", thus effectively restricting the patentability to only "NCEs" (New Chemical Entities). OPPI believes that apart from NCEs all other forms should be patentable as long as they meet the criteria of patentability like novelty, non-obviousness and commercial applicability.

2. Pre & Post Grant Opposition:

Both pre and post-grant opposition have been introduced allowing oral hearings. Opposition can be filed any time after the date of publication of the patent application to the date of grant. This could result in several pre-grant oppositions being filed causing delay in the patent granting process. In addition, 'serial' pre-grant oppositions may cause further delay in the grant of patents. OPPI does not approve pre-grant opposition

3. Compulsory Licensing (CL):

Scope of CL has been broadened to include affordability, non-working of patent, etc. The patent holder will be entitled for compensation from the licensee. CL will be available for export to any country having insufficient or no manufacturing capacity to address public health needs. While OPPI has no objection to granting of CL in national emergency, it feels that broadening the scope for affordability, etc. could result in abuse of this provision. Moreover, the criteria of "working" and "non-working" of patent have not been properly defined or explained neither in the Patent Law nor in the Draft Patent Manual.

4. Regulatory Data Protection (RDP):

Regulatory Data Protection is an integral part of IPR. Lack of RDP provision will be a disincentive to R&D based companies and innovators. A Committee chaired by Ms. Satwant Reddy, Secretary, Department of Chemicals and Petrochemicals, Government of India, has already submitted its report on Regulatory Data Protection. The report is inconclusive and recommends a calibrated approach for RDP through a transition period. OPPI has asked for minimum 5 years of RDP after grant of marketing approval in India.

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