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Compulsory licensing in India – Must products be manufactured locally?

The first compulsory licence of an Indian patent since the TRIPS regime was implemented in India has been awarded. Although the licence relates to a pharmaceutical product, the grounds on which the licence was awarded are potentially relevant across all sectors of technology.

Indian patent law holds that a compulsory licence can be awarded on any of three grounds:

- that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- that the patented invention is not available to the public at a reasonably affordable price, or
- that the patented invention is not worked in the territory of India.

It is this last provision which is potentially of widest implication, as the Controller of Patents held that the requirement for "working" the invention was not satisfied by importation the product into India, but would require manufacture in India. This finding was based on Section 83 of the Indian Patents Act 1970 (as amended) which states that " Patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article". Given only one of the three grounds for the granting of a compulsory licence need be present, this decision, if followed, would enable a third party to obtain a compulsory licence of any patent protecting a product solely because that product is not being manufactured in India.

While it appears, on the face of it, that the Indian law in this respect has been correctly interpreted by the Controller of Patents, some commentators outside India doubt

whether this law complies with TRIPS Article 27, which states: "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

This decision is likely to be appealed, and it remains to be seen whether this decision will encourage other potential licensees to seek compulsory licences. If so, then there may be implications for markets beyond India. First, it may encourage other countries to apply liberal compulsory licensing regimes to encourage domestic manufacturing. Further, compulsory licensing in India creates the potential for parallel importation. Whilst the licence in this case was limited solely to the purpose of treating patients in India, and although it is expected that any future compulsory licences will be similarly limited, where compulsory licences are awarded there will nevertheless likely be a significant price differential between the Indian market and the markets in other territories. Whilst a third party buying the product in India and then exporting it to a different jurisdiction would be liable for infringement of any patent rights in the jurisdiction in which it is imported, such parallel importation has at times in the past proved difficult to monitor, and at the very least could increase the burden on a patentee seeking to enforce their rights.

For a variety of reasons then, developments in India will be watched with interest.

Further information on this case is available here and here.