



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt., of India)

Date: 6<sup>th</sup> December, 2012

### Getting patent claims accepted: procedural issues

Because the Indian *Patents Act* was amended to comply with provisions of TRIPS only quite recently, in 2005, the Indian patent system is still evolving and patent litigation in its nascent stages. So far, the patent cases decided by the courts have related to whether subject matter qualifies for Patent protection and whether, procedurally, the grant was in order. In other words, litigation has not matured to the point where the courts are construing claims and dealing with related issues.

Patent applicants should be aware of the following judicial precedents that have been established in relation to key aspects of patent law and practice:

1. Clarification as to when a patent can be said to have been granted under the Patent Act 1970 (the Act). The lack of clarity that existed led to scrutiny, in this case, of both the relevant provisions the Act and the Office procedure pursuant to which there was a time gap between the grant and the issuance of the patent certificate. (*Dr Snehlata C. Gupte v. Union of India & Ors* (W.P. (C) No 3516 and 3517 of 2007)
2. Deemed abandonment of patent application. The law provides that unless the applicant has complied with all requirements within the prescribed period, the application will be deemed to be abandoned. Two cases have dealt with the issue. In the first, the court held that the right to grant a hearing is an inherent part of the Controller's judicious exercise of discretion while making a decision whether a patent application has been abandoned. In the second case, the Court found that if replies to the objections raised in an examination report do not comply with the requirements of the Act, then the Controller should refuse the application, or require it to be amended to his satisfaction, rather than deeming the application abandoned. This, in effect, gives the applicant an opportunity to appeal. *Universidad Politecnica De Valencia v. Union of India & Ors* (Writ Petition No. 1435 of 2007; Bombay High Court), and *Telefonaktiebolaget LM Ericsson v. Union of India & Ors* (W.P.(C) 9126 of 2009; Delhi High Court).
3. A recent case confirmed that timelines prescribed by the patent law are sacrosanct. Nippon Steel's patent agent had inadvertently missed the deadline for filing a Request for Examination (RFE). The

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Act provides that an RFE must be filed within a period of forty-eight months from the date of priority or the date of filing the application, whichever is earlier.

The agent, having missed the deadline, sought to amend the priority date of the application to the international filing date of the PCT application, which would have had the effect of extending the date for filing the RFE. The Patent Office, however, informed the agent that the amendment could not be effected, as due to non-filing of RFE within the prescribed period, the application was time barred and deemed to have been withdrawn. The court, upholding the decision of the Patent Office, stressed the legislative intent behind the provisions saying that the time limits are 'mandatory', not merely 'directory'. (*Nippon Steel Corporation v. Union of India* W.P. (C) 801 of 2011)

2. Then there is the famous litigation on the interpretation of section 3(d), i.e. the Novartis case. A number of recent cases have also considered pharmaceutical patents; however, it is to be noted that these are mostly related to novelty and inventive step and the issue of ever greening of patent by claiming a polymorph of an already patented molecule.

As noted above, there have been no relevant decisions dealing with claim construction. The issues surrounding claim construction are of particular concern to US and European companies entering India via PCT route and wanting the claims to be accepted in India in the form they have been accepted elsewhere. In the absence of any precedents, the scenario is still not very clear.

1. In the case of modified gene sequences, though a claim for a sequence may be granted, a claim for a host cell containing that sequence will not be granted because of the exceptions enumerated in the Patents Act.
2. Further, certain terms like 'plurality', 'at least' and 'substantially' more often than not are objected by the Indian Patent Office, with the Controller requiring either deletion of the term or a restricted definition in order to provide clarity.
3. In claims pertaining to devices and apparatus, where figures with reference numerals are an integral part of the invention, the Indian Patent Office specifically requires the reference numerals be included in the claims in parentheses. This is general practice in Europe and does not limit the scope of the claim. It is not, however, clear that that will be the case in India. There are currently no precedents in relation to the

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determination of the scope of such claims.

### **Technologies proving difficult to patent**

1. Given India's huge generics industry, the patenting of pharmaceutical technologies is a hot topic. The debate, however, generally focuses on section 3(d) of the Patent Act, which provides that a new use of a known substance and a new form of a known substance are not patentable. Pricing of drugs is the major factor which is driving heat over drugs. High-priced drugs are being targeted and a public interest case in relation to the pricing of life saving drugs is currently being considered by the Supreme Court.
2. Besides pharma related patents, technologies relating to gene or nucleotide sequences are also coming under scrutiny, as isolated sequences are not patentable. Further, living organisms or parts thereof, are not considered appropriate subject matter for protection. The Patent Office practice in relation to claims for these technologies is, therefore, very stringent  
  
e.g. a modified gene sequence may be patentable; however, a host cell that has the gene sequence, or the process of making it if it involves any biological procedure of propagation, will not be.
3. Web based applications and technological inventions falling within the category of computer programs per se are another problematical area; computer programs per se are not patentable, but computer programs in conjunction with hardware are. Getting a patent in this area can be tricky.

Source: Lexology

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