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Biotech patents in Europe

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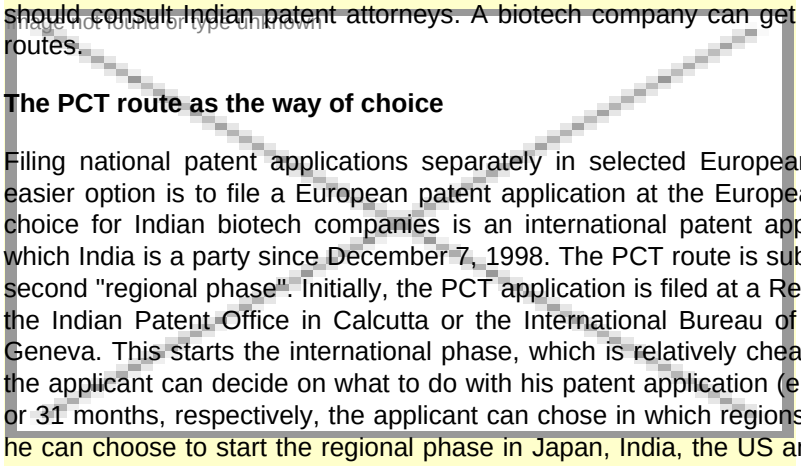
This article by Dr Ralph D Kirsch and Dr Thomas Westphal explores various options for Indian life sciences companies for filing and obtaining patents in Europe.

Before starting to think about getting a patent in Europe, we have to mention that there are certain national requirements in India, such as the compulsory filing of a national patent application in India first and the "foreign filing license", on which you should consult Indian patent attorneys. A biotech company can get patent protection for their inventions in Europe by three routes.



The PCT route as the way of choice

Filing national patent applications separately in selected European states is obviously complicated and expensive. One easier option is to file a European patent application at the European Patent Office (EPO) in Munich. However, the way of choice for Indian biotech companies is an international patent application under the Patent Cooperation Treaty (PCT) to which India is a party since December 7, 1998. The PCT route is subdivided in two phases, a first "international phase" and a second "regional phase". Initially, the PCT application is filed at a Receiving Office (RO), which can be, e.g. the head office of the Indian Patent Office in Calcutta or the International Bureau of the World Intellectual Property Organisation (WIPO) in Geneva. This starts the international phase, which is relatively cheap and usually takes 30 or 31 months time, during which the applicant can decide on what to do with his patent application (e.g. find a licensee or continue by himself). After those 30 or 31 months, respectively, the applicant can chose in which regions/countries he wants to continue with his application, e.g. he can choose to start the regional phase in Japan, India, the US and/or Europe and enter the European regional phase via the EPO.

Entering Europe: the new EPC2000

Ralf D Kirsch & Dr Thomas Westphal
Patent Attorneys and Attorney at Law Hamburg, Germany

Once having started the European regional phase via the EPO, the application is handled under European Patent law, i.e. the European Patent Convention (EPC). By December 13, 2007 at the latest, the new EPC2000 will come into force, which will revise and replace the older EPC of 1973. One of the few changes in material patent law of high relevance for biotech companies is the "purpose-related product protection" for any further medical uses of products. That means that the applicant can get protection for any further specific medical use of a compound, e.g. "formulation A for use in the treatment of disease Y", even if a first medical use of this formulation was already known for the treatment of disease X. At the moment, applicants still need to use the rather complicated "second medical use claim format" to get claims aimed at such medical uses, but the new EPC2000 will replace this with the easier wording shown above. This should be a real incentive for biotech companies all over the world to have a closer look at protecting the medical uses of their formulations.

For Indian pharmaceutical companies this should be of particular interest, since the patenting of new uses of known substances is not allowed in India under the Patents Act of 1970 (amended 2005). While such new medical uses of known substances are not protectable in India, they surely are in Europe, and this needs to be considered already at the stage of drafting the PCT application before the international filing date. Adding passages to the description that describe this new medical use of a known compound or formulation at a later stage after the international filing date is not possible and will not be accepted by the EPO. That means that Indian biotech companies need to consider very carefully what to put in their international patent application before filing if they plan to enter the European regional phase later on.

The European patent as a valuable asset

One thing to consider for e.g. a small Indian biotech company is that a European patent application as well as the granted European patent can be seen as a valuable "asset". That means that it is by no means necessary that the applicant has got to fight the patent through to grant in Europe by himself. There is also the possibility to find a licensee for the patent application, who will be willing to carry the somewhat more substantial costs in prosecuting the application to grant. Of course, there is also the option to sell the patent application or the patent. Irrespectively of whether the Indian biotech company wants to actually enter the European market itself, a European patent can be a valuable asset in an important market that can be sold or licensed to another company or used by the applicant himself to protect his position in Europe.

Dr Ralf D Kirsch and Dr Thomas Westphal are both patent attorneys and partners in the IP law firm GLAWE DELFS MOLL in Germany (Hamburg, Munich, www.glawe.de).

Dr Ralf D Kirsch studied biology and went into research in molecular biology, immunology and biochemistry at the University of Cambridge, UK, and at the Max-Delbrueck-Centre for Molecular Medicine in Berlin, Germany (kirsch@glawe.de).

Dr Thomas Westphal studied biology and spent years in research in genetics, molecular biology and biochemistry at the Lomonossow University in Moscow and at the Martin Luther University in Halle, Germany.