Pharma & Healthcare Update

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PATENTEE TO BE HEARD IN PROCEEDINGS FOR COMPULSORY LICENSING FOR EXPORT

Section 92-A of the Patents Act, 1970 dealing with compulsory license for export to underdeveloped countries, was again under scanner on July 4, 2008 at the Patent Office. The Patent Office rejected Natco Pharma Limited ("Natco")'s petition opposing the Patent Office's move to seek Pfizer's say on Natco's application for compulsory license.

Natco, a Hyderabad based pharmaceutical company has applied for the grant of a compulsory license to manufacture and export generic version of Pfizer's patented cancer medicine 'Sunitnib Malate', sold with a brand name 'Sutent'', to Nepal. While considering Natco's application, the Patent Office, gave an opportunity to the patentee (Pfizer) of being heard. Natco contended that Section 92-A of the Patents Act or the Rules do not prescribe that an opportunity of hearing shall be given to the patentee. The Patent Office was of the opinion that hearing the patentee would not only serve as an aid in deciding upon the application but would also prevent any abuse of the provisions of Section 92-A.

BACKGROUND

Section 92-A was introduced by the 2005 Amendment to the Patents Act, 1970, when the product patent regime was introduced. This is the only provision of the Compulsory Licensing chapter that specifically deals with pharma patents and enunciates that a compulsory license can be issued for the manufacture and export of patented 'pharmaceutical products' to any other country having insufficient or no manufacturing capacity in the pharma sector for the concerned product. This provision has been inserted with a view to address the health problems of poor and economically weaker countries, which lack the capability of manufacturing such pharmaceutical products. Another important condition attached to such a grant of compulsory license is that the importing country should have issued a notification or otherwise should have allowed importation of such pharmaceutical products.

Section 92-A is based on Paragraph 6 of the 'Declaration on TRIPS Agreement and Public Health' and Article 31bis of the TRIPS Agreement. The issues relating to Public Health have been of material consideration and have been discussed strongly under the TRIPS Agreement at various levels of the WTO. The Ministerial Council had adopted the 'Declaration on TRIPS Agreement and Public Health' on November 20, 2001. Paragraph six of the Declaration stated, "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002." Subsequently, the General Council adopted the Protocol amending the TRIPS Agreement on December 6, 2005 and submitted the same for the acceptance of the members. The said amendment to the TRIPS Agreement introduced Article 31bis. This Article of the TRIPS Agreement lays down the obligations of a member nation with respect to grant of compulsory license for the purposes of export of patent pharmaceutical products to an eligible importing member. An eligible importing member has been defined in the Article to include any least developed country and any other member that has made a notification to the TRIPS Council in this regard.

Natco is the first and so far the only generic drug maker that seeks to apply for a compulsory license under Section 92-A.

PATENT OFFICE APPLIES PRINCIPLES OF NATURAL JUSTICE

Rule 96 of the Patent Rules, 2003 (as amended in 2005) prescribes that an application made under Section 92-A has to be made in Form 17 to the Controller of Patents and the applicant needs to disclose his interest in seeking the license, and the terms and conditions of the license that he is willing to accept. Further, Rule 97 provides that the Controller shall notify the applicant if upon consideration of the evidence the Controller is satisfied that a prima facie case has not been made out. In case if the applicant requests to be heard within a period of one month, the Controller shall give the applicant an opportunity of being heard. The Controller then determines whether the license should be granted or whether the application should be refused. A bare perusal of the said Section and other relevant provisions of the Act, and the Rules framed under it do not explicitly envisage any such opportunity to the patentee in matters of compulsory licensing under Section 92-A. At the same time, such an opportunity to the patentee has not been explicitly excluded. The Act or the Rules do not provide as to whether or not, the opponent i.e. the patentee against whom a compulsory license has been sought, will be entitled to present his case or whether a license under Section 92-A can be issued based solely upon the applicant's contentions and representations.Under Section 87 of the Act, a patentee is allowed to oppose the application for a compulsory license made under Sections 84 and 85 (which are for domestic sales), however, a similar provision in respect of Section 92-A is absent from the Act. Similarly, the said Section does not speak of royalties but leaves it to the Controller to decide upon the terms and conditions of the grant of license.The Controller of Patents has filled in an important and debatable lacuna in the proceedings under Section 92-A, as while deciding upon the Natco application it provided an opportunity to the patentee to put forward its contentions.The decision of the Controller to grant an opportunity to the patentee (Pfizer) clearly demonstrates an inclination on the part of the Controller and the Patent Office to uphold the interests of

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patentees and to ensure that Section 92-A is not abused. In the absence of any explicit provision to hear the patentee under Section 92-A, the Patent Office has taken a commendable step. It is one of the fundamental tenets of the principles of natural justice that a party whose interests are being affected should be given an opportunity of being heard. Thus the Patent Office's move of considering a patentee's contentions upholds one of the basic principles of law. It should be borne in mind that protection of vested and public interests are just two facets of Patent Law and it is essential to strike an optimum balance between the two.

- Uphar Shukla & Gowree Gokhale

Sources:

- Business Standard dated July 7, 2008,
- Declaration in document WT/MIN(01)/DEC/2
- General Council in document WT/L/641

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