EXECUTIVE BRIEFING

Compulsory Licensing for Export in the European Union (EU)

Background

European Union (EU) Regulation (EC) No 816/2006 permits the compulsory licensing of any patented medicine marketed in the region. A compulsory license issued under the Regulation would permit a non-patent holder in the EU to locally manufacture within the EU a patented medicine for export to a requesting foreign country. The Regulation implements the World Trade Organization (WTO) Doha Declaration on TRIPS and Public Health (November 2001) and the WTO Doha Decision (August 2003), which addresses the needs of WTO member countries that lack local manufacturing capacity.

Of particular note is not only that the Doha Declaration acknowledges that patents may pose a potential obstacle to patient access to medicines, but also that *price can be a legitimate trigger for unilaterally invoking compulsory licensing*. It was the first time that a multilateral trade agreement tied the loss of patent rights for a medicine to the price of the medicine. Of note also is that the written statement of the TRIPS Council Chairperson, which set forth the political agreement concerning the Doha Decision, cautioned that compulsory licensing should "not be [used as] an instrument to pursue industrial or commercial policy objectives."

Discussion

The scope of the compulsory licensing under the EU Regulation is broad. It is not limited to only those medicines that are indicated for diseases prevalent in developing countries, such as malaria. It can impact any patented medicine marketed in the EU. Nor is compulsory licensing for export restricted to only those countries that are lesser-developed or least developed. Moreover, there is no requirement of a public health emergency or urgency in the importing country – a declaration by that country of a public health need will suffice as justification.

Under the provisions of the Regulation, the patent holder has no due process rights. The patent holder has no right of first refusal to supply its patented medicine for export, no right of appeal, and no right to even comment on the proposed issuance of a compulsory license. The only thing that the patent holder has a right to is to be notified by the local authority in the EU that an application for a compulsory license for its patented product has been received.

In contrast to the denial of due process to the patent holder, the local company that applies for the right to manufacture under a compulsory license within the EU is not only provided with the right to be heard by the local authority, it also has the right "to rectify" an application that it is has already submitted.

Of note is that manufacture for export under a compulsory license is not permitted to member countries of the EU and the European Economic Area (EEA), as well as a multitude of other developed countries:

Australia, Austria, Belgium, Canada, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the UK and the US.

Outlook

Although the EU has not as yet issued a compulsory license under the Regulation, it should be noted that the list of excluded countries does not include the so-called BRICs, namely Brazil, China, India and Russia – markets that at one time held the greatest promise for the drug sector. Both Brazil and India have invoked the Doha TRIPS accord using pricing as the trigger for compulsory licensing - but at this time neither has filed a request with WTO for supply from the EU.