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Supreme court confirms that "Bolar Provision" does not apply retrospectively

Miquel Montañá (Clifford Chance) · Thursday, November 17th, 2011

In a judgment handed down on 11 November 2011, the Spanish Supreme Court has rejected an appeal filed by four Spanish pharmaceutical companies against a judgment from the Court of Appeal of Barcelona (Section 15), which had rejected a revocation action filed against patent EP 409,281 (Calcium salt of Atorvastatin) owned by Warner-Lambert. Applying the EPO's "2-list principle" enshrined in Decision T 12/81, the Supreme Court has confirmed that since choosing the calcium salt of Atorvastatin required selections from 2 lists of some length, the product was new. In addition, the Supreme court has further confirmed that articles 27.1 and 70 of TRIPS trumped the effect of Spain's Reservation to the European Patent Convention and that, therefore, the effects of the Reservation can no longer be used to challenge the effects of a patent filed while the Reservation was in force.

In the same judgment, the Supreme Court has reversed the part of the judgment that had found that the "preparatory" acts carried out by the four Spanish companies were covered by the "Bolar Provision" introduced by Law 29/2006 which, in turn, implemented Directive 2004/27. This new judgment further confirms the view expressed by the Supreme Court in its judgment of 30 June 2010, where the Court already highlighted that the "Bolar Provision" and the "Experimental Use" exception are two different exceptions and that, as such, the former may not be applied to acts carried out before Law 29/2006 came into force. There are still many unanswered questions that will need to be clarified in future judgments, such as whether or not the "Bolar Provision" applies to preparatory acts conducted by innovative companies.

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