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Does obtaining an MA pre-expiry of a patent constitute infringement?

Anders Valentin (Bugge Valentin) · Tuesday, September 13th, 2011

The issue of whether obtaining a marketing authorisation before the expiry of a patent covering the product that the marketing authorisation concerns will infringe upon the right of the patentee has now been settled by the Danish Supreme Court:

In December 2006 Teva filed for a marketing authorisation for a product that Teva during subsequent interlocutory proceedings did not contest the validity of the patent nor did Teva contest that its product – if marketed – would fall within the protective scope of a Novartis patent due to expire in February 2011. On that basis Novartis filed a request for an interlocutory injunction with the bailiff's court.

Teva stated both before and in connection with the interlocutory injunction proceedings that the primary aim of the application was to use Denmark as reference member state c.f. the decentralised European procedure for obtaining a market permit for pharmaceuticals and that Teva had no current intention of marketing a product under the marketing authorisation and the bailiff's court turned down the application.

On appeal, this decision was overturned by High Court (Eastern Division) and Novartis filed an obligatory confirmatory action at the Maritime and Commercial Court, which in turned revoked the interlocutory injunction granted by the High Court on appeal. The Maritime and Commercial Court decision was then appealed to the Supreme Court.

The Supreme Court held that a condition for granting an interlocutory injunction is that it is “established or rendered probable” that the defendant will carry out the exact actions which are sought prohibited by the injunction within a very short period of time.

Consequently, the Supreme Court held that neither filing the application several years before the expiry of the patent nor the grant of a marketing authorisation constitutes probability or proof of Teva's alleged intention to market pharmaceuticals in Denmark prior to expiry of the patent.

Interestingly, Novartis had initially requested that Teva sign an undertaking not to launch prior to the expiry of the patent and the Supreme Court held that Teva has been entitled not to do so.

The decisions seems to be in accordance with recent case law in other European jurisdictions.

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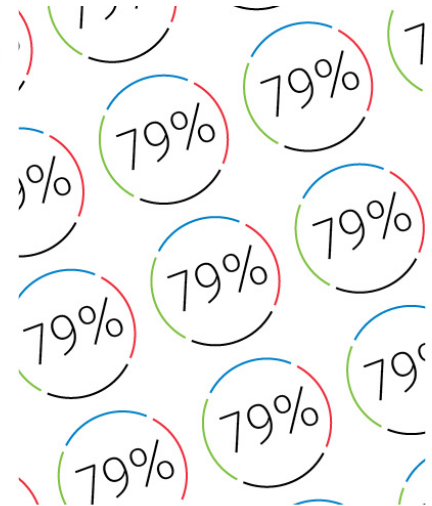
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