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## Denmark: PI granted against Tadalafil »Mylan«

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On 1 February 2019, the Danish Maritime and Commercial Court granted an injunction against Mylan AB's sale of the product Tadalafil »Mylan« containing 5 mg tadalafil in Denmark.

On 7 September 2018, Eli Lilly Danmark A/S ("Eli Lilly") brought a case to the Danish Maritime and Commercial Court requesting a preliminary injunction against Mylan AB ("Mylan") marketing the drug Tadalafil »Mylan« in Denmark. Eli Lilly claimed that the marketing done by Mylan infringed their patent. Mylan did not dispute infringement, but argued that the patent-in-suit was valid.

The invention protected by the patent owned by Eli Lilly relates to a highly selective phosphodiesterase (PDE) enzyme inhibitor and to its use in a pharmaceutical unit dosage form. The patent-in-suit does not protect the active ingredient, tadalafil, itself, but rather the use of the active ingredient in a specific dosage form.

The main issue in the case was the assessment of the inventive step. The central point made by Mylan was that a person skilled in the art would consider a prior art patent (Daugan II) and thereby be motivated to carry out pre-clinical and clinical trials in an effort to arrive at the optimal dosage for tadalafil. Thus, it was argued, the trials carried out by Eli Lilly were very standard by nature and followed a strictly routine pattern.

Eli Lilly argued that such a construction would be contrary to the case law and practice of the EPO. If such a construction were to apply it would in theory exclude any invention resulting from an empirical, stepwise R&D effort with an advantageous technical effect. This construction would be very strict and prohibitive in relation to R&D based towards and effectively take away their incentive to carry out research in the field of dosage forms.

In the end the Danish Maritime and Commercial Court decided in favour of Eli Lilly, i.e. that Eli Lilly had rendered it probable that the patent-in-suit exhibited inventive step. Consequently, the Danish Maritime and Commercial Court granted a preliminary injunction against Mylan's sale of the product Tadalafil »Mylan« containing 5 mg tadalafil in Denmark. The Court's reasons were summary simply and only stated that Mylan did not lift its burden of proof.

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