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Escitalopram litigation – current status in Denmark

Anders Valentin (Bugge Valentin) · Wednesday, March 9th, 2011

The Danish patentee H. Lundbeck A/S has during the past few years enforced its patent rights to the active pharmaceutical ingredient Escitalopram in several jurisdictions as also reported in several cases on the Kluwer patent blog.

As previously reported (blog entry 3 May 2010), Lundbeck A/S has also successfully enforced its patent rights in relation to Escitalopram against a number of generics companies in Denmark.

As in Denmark, in PI proceedings, a defence based exclusively on a claim of invalidity is rarely successful except in cases where it is possible to document clear novelty destroying citations, mostly a Danish defence in PI proceedings brought by Lundbeck in Denmark have concerned the issue of infringement (and to a lesser extent the issue of whether or not the SPC should be held invalid).

Thus far, Lundbeck has been successful in obtaining PI's in Denmark in each instance where Lundbeck has sought interim relief, but reportedly a decision was granted on appeal by the Danish High Court (Eastern Division) yesterday in which the High Court overturned the bailiff's court's decision to grant an injunction against ratiopharm regarding an Escitalopram product based on an API manufactured in India.

In most of the PI cases on Escitalopram, the defendants have requested that the hearing be held behind closed doors on the grounds that much of the evidence presented for the defence was of a confidential nature and in fact constituted business secrets which the defendant should not be forced to make public in the course of defending a position of non-infringement.

PI courts (and now the High Court also) have accepted this premise in the Danish Escitalopram cases, probably because Lundbeck A/S has consistently invoked § 64a of the Danish Patents Act which calls for the reversal of the burden of proof under circumstances where a product patent leads to a new product (cf. CPC Art 35). In that connection, § 64a of the Danish Patents Act provides that due consideration shall be given to the defendant's interest in guarding its business secrets.

This is the first reported decision on the application of §64a and although (at least) one more PI decision on Escitalopram is pending on appeal before the High Court (Eastern Division), this first decision is likely to be of substantial interest to practitioners.

No version of the High Court appeal decision has as yet been made public and as the hearing was

held behind closed doors, only a redacted version of the decision is to be expected, but we will revert when such a decision is available.

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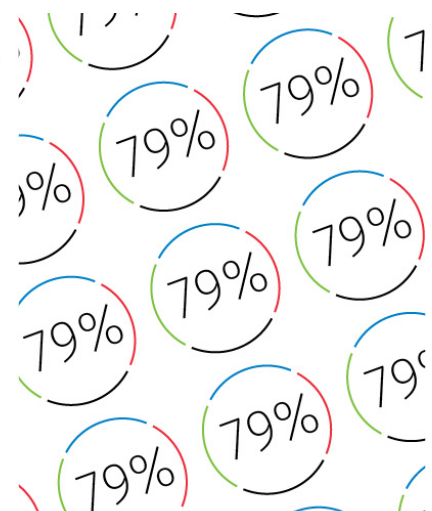
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