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More on escitalopram PI cases in Denmark

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As reported in teh blog on 9 March, 2011, ratiopharm has managed on appeal to the High Court to overturn the first instance decision to grant a PI against ratiopharm which had initiated its own distribution of escitalopram products after the dominant wholesaler in Denmark was injuncted and the other wholesalers followed suit.

The hearing was conducted behind closed doors in order to take into account the ratopharm's legitimate interest to protect the trade secrets of itself and its suppliers, notably Dr. Reddy's in India.

The parties have nok agreed on releasing a redacted version of the decision, which has therefore become publicly availbale.

It is interesting that whereas thus far all PI courts have granted injunctions arguing, inter alia, that it could not be ruled out that not all of the product sold by the alleged infringer, the High Court has chosen to adopt a more classic approach to the assessment of the evidence.

First of all, the High Court ruled on the applicability of the reversed burden of proof provision (relating to new processes leading to new products) and the fact there the burden of proof bar in PI cases is "rendering probable" whereas the Patents Act only mentions "proof" without making any mention of which of the two burden of prof requirements should apply in PI cases.

The High Court states that the Patents Act is a lex specialis in relation to the Admininstration of Justice Act and should therefore take precedence and the alleged infringer must therefore lift the burden of proof of non-infringement. Even so, the High Court continues the burden of proof to be lifted must not be stricter than the one generally applicable in PI cases, ie. rendering probable.

The High Court then introduces a third level of burden of proof, namely "strengthened requirements for the degree of probability". It is unclear what the legal basis for this should be.

Lundbeck pointed to a number of inconsistencies in the batch records submitted to substantiate that a non-infringing method was the only one in use as Dr. Reddy's, but even though the High Court acknowledges this, the court finds that this in itself is not relevant to the infringement issue, but rather in relation to GMP – which is not pertinent to the issue of alleged patent infringement.

Decisive weight was attached by Lundbeck to the allegation that the detection of trace amounts of certain compounds in the final pharmaceutical constituted "fingerprints" of the Lundbeck method

having been used at least for parts of the production of the API.

The High Court also ruled that whereas the unilaterally retained experts relied upon by the respective parties disagreed on whether the compounds constituted “fingerprints”, still the experts of ratiopharm had “refuted with a sufficiently high degree of probability” the “fingerprints” theory. Again this particulat threshold of th eburden of proof appears to have no express legal basis, but rather to reflect the High Court’s own, arbitrary, construction.

Finally, the High Court found that a higher chiral purity in the allegedly infringing product was an argument against mixing of infringing with non-infringing material as alleged by Lundbeck.

Later this year it is expected the High Court will rule in parallel case based on similar facts, but with a different alleged infringer, so no doubt we have not heard the last of the escitalopram cases in Denmark.

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