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Danish Supreme Court turns down Lundbeck in Escitalopram PI case

Anders Valentin (Bugge Valentin) · Tuesday, November 19th, 2013

In Denmark, as in many other European countries, Escitalopram patent cases that have been conducted in recent years.

One of these cases in which an interlocutory injunction was granted by the bailiff's court at Elsinore and subsequently upheld on appeal, was admitted to the Danish Supreme Court which granted leave of appeal and ended up overturning the interlocutory injunction.

In its ruling, the Supreme Court, inter alia, set a precedent on the application of the Danish equivalent to the provision in TRIPS article 34 which reverses the burden of proof in relation to alleged infringement of process patents concerning new products.

Pursuant to the Danish Administration of Justice Act, an interlocutory injunction may be granted if it is either proven or rendered probable that the actions that are to be prohibited will infringe upon the right invoked by the plaintiff.

Thus, the plaintiff in interlocutory injunction proceedings may benefit from a relatively lower evidentiary requirement ("render probable") as opposed to what applies in proceedings on the merits (civil proceedings) where the evidentiary requirement remains that the plaintiff must prove its allegation.

In the Danish adaptation of TRIPS article 34 (§ 64a), it is stated that with regard to process patents for new products, the same product when manufactured by someone other than the patentee, shall be regarded as having been manufactured according to the patented process, unless the opposite is proven.

Furthermore, § 64a states that in connection with a defendant's attempt to prove that a process other than the one patented has been used, the defendant's legitimate interest in preserving its business secrets shall be taken into account.

As with TRIPS article 34, the reason for the reversed burden of proof is that it is rather more difficult to prove infringement of a patented process than infringement of a patented product as only for the latter will it be possible to make a direct comparison between the patent and the allegedly infringing product. Consequently, it is generally assumed that the actual legal protection conferred by a process patent is – relatively speaking – weaker than that of a product patent, and this of course if the reason why the threshold of the burden of proof is lowered for the benefit of

the proprietor of a process patent.

The Supreme Court confirmed that in interlocutory injunction proceedings under Danish law it is sufficient for a plaintiff to render it probable (rather than prove) that an infringement has taken place, but the Supreme Court ruled that a defendant/alleged infringer cannot rely on the same mitigation with regard to the threshold of the burden of proof when the reversed burden of proof has been applied as a result of § 64a (TRIPS article 34).

Thus, said the Supreme Court – even in interlocutory injunction proceedings – when §64a applies, the defendant must prove that a process other than the one patented has in fact been used.

The Supreme Court also confirmed the generally accepted practice pursuant to which in the framework of interlocutory injunction proceedings, the parties are generally allowed a relatively wider access to providing evidence, e.g. in the form of unilaterally retained experts' evidence etc. That peculiar aspect, said the Supreme Court, must also be taken into account by the court assessing the evidence when the reversed burden of proof applies to the defendant/alleged in interlocutory injunction proceedings.

Having established these parameters, the Supreme Court found that Actavis had proven that not only was its supplier of Escitalopram API able to manufacture Escitalopram API on an industrial scale, but also Actavis had, within the legal and practical framework of interlocutory injunction proceedings, proven that the Esctialopram API in its tablets for the Danish market had been manufactured exclusively pursuant to the method developed by the Indian API manufacturer, Dr. Reddy's.

At the same time, the Supreme Court noted that Lundbeck, on its part, had not lifted its burden of proof (i.e. rendered it probable) that the Escitalopram API in the Actavis tablets had been manufactured pursuant to the patent-in-suit (SPC).

As a result, the interlocutory injunction granted and upheld on appeal was lifted.

This entry was posted on Tuesday, November 19th, 2013 at 10:38 pm and is filed under Denmark
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