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Launch at risk concept still is not at risk in Sweden following C-688/17

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Introduction

A key mechanism in patent litigation and specifically for generics is the concept of "launch at risk". In short the concept means that a product is launched prior to the expiry of a patent despite the risk that the patent proprietor in such case could initiate infringement proceedings which often includes requests for a preliminary injunction. The products are nevertheless launched since it is assumed that the patents will be revoked. If an interim injunction is laid down and the patent later on proves to be invalid, then the preliminary injunction has been laid down in error. In such case the patent holder is strictly liable (at least in Sweden) for any damage suffered by the injuncted party. According Article 9(7) of Directive 2004/48/EC (in short the Enforcement Directive) the member states shall ensure that judicial authorities have the authority, given certain circumstances, to provide the defendant appropriate compensation for any injury caused by provisional measures.

This concept was not considered too problematic up until article 9(7) was interpreted by the CJEU in C-688/17 (the Bayer judgment). Ever since the Hungarian court submitted their questions to the CJEU it has again been a matter of discussion, worry or anticipation. Even after the judgment that has not changed very much although the debate on how to interpret the judgment in C-688/17 has continued.

The focal point in the debate was if the the judgment in C-688/17 suggested a change of the launch at risk concept – especially for the concept of indemnification. A change to this concept would most certainly dramatically alter the competitive landscape on the pharmaceutical market.

The Swedish position before C-688/17

Sweden is one of the countries where a patentee in principle has a strict liability to indemnify a party that has been subjected to a preliminary injunction which in the end has proven to have been laid down in error. When implementing the Enforcement Directive (and particular article 9(7)) the Swedish legislator assessed the current legislation and found it (namely chapter 3, section 22 of the Swedish Enforcement Act and chapter 15, section 6 of the Swedish Code on Civil and Criminal Procedure) to be aligned with article 9(7) of the Enforcement Directive and that no amendments were needed. That position was also confirmed by the Swedish Supreme Court in its judgment NJA 2017 p. 9. Following C-688/17 the question therefore has remained unanswered as to whether the Swedish position would stand or not.

What's new then?

On 23 April 2021 the first instance, Attunda District Court, laid down a judgment in a matter where it considered a claim for damages raised by the generic manufacturer Orifarm against Novartis (case no T 6267-19). The ground for damages was that Orifarm had been subjected to a preliminary injunction for its rivastigmin products in error, which had been manifested later on by the patent being revoked. Orifarm argued the case along the traditional Swedish approach – i.e. that Novartis was strictly liable for all loss suffered by Orifarm due to the preliminary injunction. Novartis on its part argued i.a. that Orifarm was not entitled to damages since the request for preliminary injunction was not unfounded at the time of filing of the request (explicitly referring to the judgment in C-688/17).

In its judgment the court carefully assessed the Swedish position as outlined above. It then went on to assess C-688/17 and what impact – if any – that would have to Swedish legislation and Orifarm's right to damages in particular.

Strict liability

First, the Court confirmed that the rule of strict liability for damages was still in play. In its reasoning the District Court found that nothing in the CJEU's judgment or in the Enforcement Directive prohibits a member state from applying strict liability in these cases.

Appropriate compensation?

When assessing the appropriate compensation, the Court continued to find that C-688/17 clearly indicates that it is possible to have a more limited responsibility for damages in national laws and that the courts can take all circumstances into account whilst deciding upon what is *"appropriate compensation"*. The court found that the Swedish position was aligned with the principles laid down in C-688/17 and applied general principles of tort law.

Mitigating damages

When assessing the invoked circumstances for mitigation the Court firstly concluded that since the responsibility is strict, the parties' level of guilt cannot be compared. According to the Court, it instead has to assess what constitutes reasonable compensation to a negligent injured party. The Court concluded that Novartis had the burden of proof for that Orifarm had contributed to the loss or had not sufficiently mitigated the loss. Novartis had claimed that a number of circumstances were relevant in this context. For example Orifarm had not initiated revocation proceedings (before launch) and then delayed initiating such proceedings even though Orifarm was subject to a preliminary injunction. The Court concluded that the only relevant circumstances in this respect was that Orifarm did not initiate revocation proceedings earlier after the decision laying down a preliminary injunction and that Orifarm only appealed one of its preliminary injunctions. However, the court concluded:

"Nevertheless, it is clear that Orifarm has contested the preliminary injunctions. It must be strongly questioned whether a decision not appealed can motivate reduction of damages. In this case Orifarm did in fact appeal the district court's decision. The fact that Orifarm did not appeal the decision regarding all products can hardly be given any importance in this respect. It would be to reach too far to force a party that is subject to an injunction to initiate revocation proceedings

within a short period of time in order to be eligible to compensation for actual loss due to the injunction." [rough office translation]

The Court found Novartis to be strictly liable and awarded Orifarm damages.

Take aways

The judgment from Attunda District Court is a first instance judgment. Naturally it can be subject to an appeal and the Court of appeal could potentially come to another judgment. The judgment is however in our opinion very well-reasoned and also well aligned with expectations from a Swedish standpoint. It is also a based on a reasonable interpretation of C-688/17. As far as Sweden is concerned, we now have another indication that C-688/17 has very limited impact with regards to the concept of launch at risk. Strict liability for losses caused by a preliminary injunction subsequently lifted, hence continue to apply in Sweden. The Court's judgment can also be interpreted to confirm that is is not a prerequisite to clear the way by initiating revocation proceedings prior to launching a product at risk in order to be eligible to damages in the end.

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