

Guidance on preparatory patent infringement

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Background

Decision

Comment

When and under what circumstances can a patent owner obtain an injunction against imminent infringement or, as expressed in the Patents Act, preparatory acts of infringement? This question is of particular interest for pharmaceutical patents during the regulatory process relating to authorisations of generic medicinal products.

Background

The claimants were the holder and licensees of a supplementary protection certificate for the active substance tadalafil. The defendant had acquired a marketing authorisation for a pharmaceutical product containing tadalafil. In addition to obtaining the marketing authorisation, the claimants brought forward other circumstances to demonstrate that a preparatory patent infringement had occurred:

- The defendant submitted product samples containing the active substance to the Medical Products Agency, with placebo product samples sufficient for ensuring that packaging and package inserts complied with regulatory requirements.
- The defendant did not confirm that it would refrain from marketing the product on the Swedish market during the term of the supplementary protection certificate, nor that it would refrain from undertaking other infringing measures or preparing for such an infringement, despite having given such a confirmation in other jurisdictions. The defendant had stated in only general terms that it intended to respect the claimants' valid patent rights.

Decision

The Stockholm District Court (T 10911-15) began by reiterating the legislative history of the provision on preliminary injunctions and the considerations made when the EU Enforcement Directive was implemented into Swedish IP legislation (particularly Article 9.1a on interim injunctions against imminent infringement). The court noted that it was for the national courts to decide on the precise requirements for when imminent infringement is at hand. According to legislative history, the term 'preparation' in the Patents Act should have the same meaning as in the Penal Code. The court concluded that a preliminary injunction may therefore be granted against someone who, having the intention to commit or promote a patent infringement, procures, receives, keeps, conveys or engages in any other similar activity concerning something that is particularly suited to aid patent infringement.

The court went on to state that the defendant's failure to provide the claimants with requested confirmation could not be considered as falling under this wording. More is required to prove preparatory patent infringement.

The court considered the obtaining of marketing authorisation and submission of product samples to the Medical Products Agency. The court noted that these acts may fall under the wording of the requirements for preparatory infringement, but in any event such acts must have been carried out with the intent to commit or promote patent infringement. Although the defendant was somewhat

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compromised by its belated reply and stated only in general terms that it would respect valid patent rights, the court found that the facts before it were not sufficient to conclude that the defendant had obtained the marketing authorisation and submitted the product samples with the intent to commit and promote patent infringement. The request for a preliminary injunction was consequently denied.

The claimants appealed, but the appeal was later withdrawn.

Comment

The decision is a further piece of the puzzle in understanding preparatory patent infringement in the context of pharmaceutical patents.

In its reasoning, the court underlined the connection in legislative history to the Penal Code provisions on preparation of a crime. The reference to criminal law is difficult to understand in the context of civil patent law, as the provision in question specifically deals with the following:

"to present or receive money or anything else as pre-payment or payment for the crime or to procure, construct, give, receive, keep, convey or engage in any other similar activity with poison, explosive, weapon, picklock, falsification tool or other such means."

The court refrained from making a clear statement on whether marketing authorisations and product samples could be considered particularly suited for aiding patent infringement. As a result, the question remains unanswered.

In this context, it is worth highlighting a 2015 case that concerned parallel importation and its specific mechanism under EU law. The Stockholm District Court found that the application and granting of a parallel distribution (PD) notice (issued by the European Medicines Agency, following a notification of an intended parallel importation and submission of certain documentation) could constitute an act of preparatory infringement. In its assessment, and taking all circumstances into account, the court stressed that the application for a PD notice referred to the country to which the specific mechanism applied, as opposed to being a general notice or permission that could involve a non-infringing parallel importation. It therefore granted a preliminary injunction.

However, in the *tadalafil* case, the court was clear that it must be demonstrated that the preparatory acts are undertaken with the intent to commit or promote patent infringement. It may, of course, be difficult for a claimant to prove the defendant's intent.

The decision appears to indicate that stating in general terms that valid patent rights will be respected is sufficient to oppose claims of preparatory infringement. An explicit, binding undertaking not to launch would thus not be required, at least if there are no other circumstances suggesting such an intention.

Additional guidance from the newly implemented Patent and Market Appeal Court would be welcome and to the benefit of patent owners and potential defendants.

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