

# Irreparable harm discussion awakens from its slumber in Switzerland

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In most legal systems, preliminary injunctions in patent matters require the applicant to show that he would suffer an irreparable disadvantage without the approval of the requested preliminary injunction. In the different legal systems, there are different standards and requirements for the proof of irreparable harm.

While some jurisdictions require a completely irreparable disadvantage, others content themselves with a disadvantage that cannot easily be rectified even in the case of a verdict that backs the defendant's position in ordinary proceedings on the merits or in appeal proceedings.

Furthermore, in some jurisdictions, irreparable harm must only be proven if an injunction is to be issued without hearing the other party (*ex-parte* measures), but not in adversarial *inter partes* proceedings.

Some jurisdictions examine the irreparable harm in the framework of the balance of (in-)convenience test.

In Switzerland, the requirements for showing not easily reparable harm to obtain a preliminary injunction in patent matters have traditionally not been very high. This might be because in Switzerland *ex-parte* injunctions are rather rare and available only in typical situations. In addition, even in preliminary injunction proceedings the validity of the concerned patent is normally examined in detail. This largely eliminates the risk that a preliminary injunction is granted based on a patent that is later declared invalid.

In the past, the criterion of irreparable harm in Switzerland has therefore not attracted much attention in patent matters. In particular, in pharmaceutical patent litigation, the Federal Patent Court usually granted a preliminary injunction if the launch of a patent infringing generic was imminent or had taken place already, provided that the patent in question was considered valid in PI proceedings and the patentee or exclusive licensee proceeded with the necessary urgency against the presumed infringer. Irreparable harm was a topic that was hardly addressed in many PI decisions (see for example the following decisions of the Swiss Federal Patent Court S2013\_004 (para. 4.7) of 12 May 2014; S2014\_003 (para. 4) of 31 March 2014; and S2017\_006 (para. 6) of 30 August 2017).

Recently, however, there have been two judgments in which the existence of irreparable harm was in the focus of the debate.

The more recent judgment concerns a preliminary injunction obtained from the Swiss Federal Patent Court by ViiV against Sandoz concerning ViiV's SPC for the combination of the two active ingredients abacavir plus lamivudine. The original product of ViiV is Kivexa®. [Please note that MLL represented ViiV in this matter.]

The Federal Patent Court issued a preliminary injunction against Sandoz and prevented Sandoz from distributing its generic products comprising the combination of abacavir and lamivudine in *inter partes* PI proceedings (both parties could comment on the violation and validity of the SPC.)

Sandoz filed an appeal against this preliminary injunction with the Swiss Federal Supreme Court, asserting *inter alia* that the preliminary injunction should not have been granted because the patentee would not suffer irreparable harm even without the preliminary injunction.

Sandoz argued that the patentee did not market any medicines in Switzerland. Instead, the pharmaceutical Kivexa® is sold in Switzerland by another company of the same group of companies. According to Swiss practice, the patentee therefore cannot claim lost profits (but might still be entitled to infringer's profits or a reasonable royalty).

In addition, Sandoz asserted that the patentee did not claim that it was directly affected by declining sales figures of the original product in Switzerland. The patent owner had not put into evidence a license agreement or other evidence that showed that the patentee would earn smaller licence fees if fewer original products were sold in Switzerland. Furthermore, the patentee did not hold shares in the Swiss company that distributes the original product. The patentee and the Swiss distributor belong to two different lines of the same parent company.

Sandoz took the view that for those reasons the patentee was not directly affected by the launch of its generic product and that therefore there was no irreparable harm.

The Federal Supreme Court dismissed Sandoz's appeal and concluded that the Federal Patent Court did not arbitrarily affirm not easily reparable harm *inter alia* for the following reasons:

- According to the Swiss Federal Supreme Court, there was a risk that additional patent infringing products from other companies could enter the market, because they may be of the opinion that the patent could no longer be enforced because no preliminary injunction was issued.
- Furthermore, according to the Federal Supreme Court, it is not arbitrary to assume that the patentee at least indirectly suffers an irreparable disadvantage if another company from the same group of companies will have unreasonable difficulties proving financial losses (in particular lost profits) and asserting them in main proceedings on the merits. The Federal Supreme Court did not require the patentee to prove that there is a license agreement in place between the patentee and the Swiss distributor that would directly affect the patentee if there were fewer sales of the original product. Also, the patentee did not need to show that it holds a direct or indirect interest in the Swiss distributing company in order to show irreparable harm.

According to the Federal Supreme Court, at least in pharmaceutical cases in which the original products are marketed by a Swiss entity of the same group of companies as the patentee, there is not easily reparable harm if patent infringing products threaten to enter the market or have entered the market recently.

However, the Federal Supreme Court has left open the question of whether the infringement of a valid patent causes irreparable harm *per se*.

In a later decision the Federal Patent Court seems to assume, at least if there is no group structure and the risk that third parties with potentially infringing products may enter the market can be excluded, there is no automatic conclusion of irreparable harm in the case of a patent infringement. The Federal Patent Court examined whether the patentee can prove that it suffers a loss of income if the licensees, that are independent of the patentee and do not belong to the same group of companies, sell fewer products in Switzerland because of an alleged patent infringement (see judgment of 8 February 2019 in case no. S2018\_006). In that case, irreparable harm was only affirmed after the patentee was able to demonstrate that it sold products to its licensees and was therefore affected if the licensees would generate less sales in Switzerland.

In light of the aforementioned decision of the Federal Supreme Court it seems questionable whether it is actually necessary to show that the patentee is directly affected by fewer sales or license revenues. According to Swiss practice, the patent holder is entitled to the infringer's profit or a reasonable licensee fee, even if the patentee neither markets any patent-protected products nor obtains licence fees for the sale of patent-protected products. The exact amount of the infringer's profits and in particular the reasonable royalty fee are hardly easier to prove than lost profits. Thus, irreparable harm seems to exist also if the patent owner does not prove lost profits or a direct involvement in the sale of patent-protected goods or services.

In the most recent decision, in which the Federal Patent Court examined the requirements of a preliminary injunction, the court explicitly left open the question of whether any violation of intellectual property rights would lead to irreparable harm. Since the group of companies to which the patentee belonged had products on the market that competed with the infringing goods, the court found that the loss of market shares was a disadvantage that could not easily be remedied. It was irrelevant whether the product of the patentee's group of companies showed all features of the infringed patent claim. It was sufficient that the product of the patent holder or its affiliates was effectively competing with the infringing goods.

It will be interesting to see whether in view of the recent ruling of the Swiss Federal Supreme Court the discussion about not easily reparable harm will go back to sleep again or stay awake until the remaining elephant in the room has been addressed, namely whether a patent infringement should *per se* trigger a preliminary injunction.

This question also depends on the requirements regarding whether a party that had to comply with a preliminary injunction could claim damages if the preliminary injunction is subsequently lifted in ordinary proceedings on the merits or in appeal proceedings. One could argue that the lower the requirements for a financial compensation of the alleged infringer in case of a lifted preliminary injunction, the lower the requirements are also for showing of not easily reparable harm necessary in order to obtain a preliminary injunction. The alleged infringer suffers less if he could relatively easily claim a financial compensation from the applicant of the preliminary injunction. Although Swiss civil procedural law has an explicit provision that provides for financial compensation under certain conditions if a preliminary injunction is lifted, there is still no decision as to how this provision is to be interpreted in patent matters.