Claiming preliminary and *ex parte* injunctions – what is needed to succeed?

Maria Zamkova, CEO at Fenix Legal, evaluates two recent cases to offer advice for claiming preliminary and *ex parte* injunction for successfully protecting a patent even before the patent is granted.

When you realize that someone is trying to infringe your protected patents it is necessary to act quickly to minimize the damages. But when is the right time to act, and what is needed to reach quick decisions from the court? The Swedish Patent and Market Court of Appeal have made a couple of indicative rulings that may assist in planning the court actions.

Case PMÖ 5185-22 (decision date May 19, 2022)

The three affiliated pharmaceutical companies Novartis AG (Switzerland), Novartis Pharma AG (Switzerland), and Novartis Sweden Aktiebolag (Sweden) sought a preliminary injunction, a final injunction, and a declaration of liability *per se* against two generics companies based on a patent expected to be granted soon. The Patent and Market Court dismissed the claim on the grounds that no patent had yet been granted.

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Novartis appealed the decision to the Patent and Market Court of Appeal (PMÖD), and requested the PMÖD to set aside the appealed decision and refer the case back to the Patent and Market Court for further proceedings. Novartis argued that the decision (on the patent) in written form from the Board of Appeal of the European Patent Office (EPO) that a patent should be granted was expected to be dispatched only at the end of June 2022. The patent was therefore estimated to be granted in August 2022. Even with such an adjusted schedule, the patent will be granted well before that a final decision in the case before the Swedish PMD can be counted.

The Patent and Market Court of Appeal noted that it is sufficient for admissibility based on the performance when the court rules on the merits of the claim. If it appears from the information provided by the claimant that performance has not taken place at the time of filing, the court must make an assessment as to whether the presented claim expires before the case is decided. The PMÖD further noted that the Technical Board of Appeal had ordered the Examining Division to grant the patent with the patent claim on which the claimants had based their infringement assertion. PMÖD held that, at the present stage,

Résumé

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it had to accept the Novartis assertion as to when patent grant was to be expected and that it was unlikely that the PMD would rule on the merits of the claim before that. PMÖD also observed that the record did not suggest that the conditions for advancing the case before patent grant were lacking. PMÖD thus found the claim for injunctive relief admissible.

The Patent and Market Court of Appeal has not allowed an appeal against the decision.

Case PMÖ 9563-22 (decision date August 6, 2022).

The question in the case was if there have been conditions to decide on an interim injunction under the Swedish Patent Act without hearing the other party (*ex parte* injunction).

Biogen International GmbH (Biogen) filed a lawsuit at the Swedish Patent and Market Court (PMD) against Neuraxpharm Sweden AB (Neuraxpharm) on July 19, 2022 and then presented, among other things, a request that Neuraxpharm be temporarily prohibited from disposing of the medicinal product Dimethyl fumarate Neuraxpharm in a certain way.

The claims were based on infringement of Biogen's European patent EP 2653873 B1. In the lawsuit, Biogen stated that the matter was urgent, i.e., because Neuraxpharm's product had been designated by the Tandvårds- och läkemedelsförmånsverket (Dental and Pharmaceutical Benefits Agency), TLV as the product of the period for August 2022, and because Neuraxpharm had already built up a stock of the product and acted for a full-scale launch that would cause Biogen great and hard-to-compensate damage. Biogen, therefore, requested that the court deal with the issue of an interim injunction as quickly as possible and suggested that the court should give Neuraxpharm a maximum of 14 days to respond to the interim request.

At the time of the lawsuit, the patent had not been validated in Sweden, but it was stated that this would happen as soon as possible, which was July 21, 2022. The Patent and Market Court issued a subpoena on July 20, 2022 and ordered Neuraxpharm to file a counterclaim within 14 days from that the company had received part of the lawsuit. At the same time, the court stated that any opinion on the interim claim must be submitted within the same time. On July 25, 2022, Biogen supplemented their action with a motion for the interim injunction to be issued without hearing Neuraxpharm.

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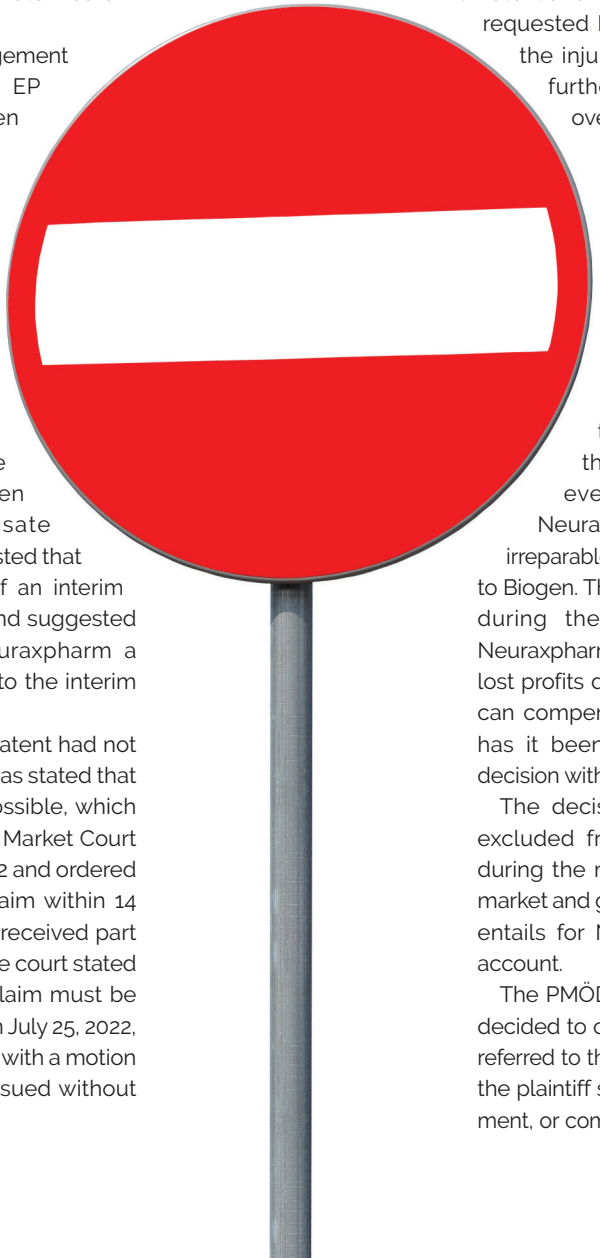

On July 29, 2022, Neuraxpharm confirmed that the subpoena had been received. Later that day, the Patent and Market Court granted Biogen's motion and issued an interim injunction – which went into effect immediately - without hearing Neuraxpharm.

The Patent and Market Court stated that the reason for the decision was that it was likely that the patent was valid and that the alleged infringement product infringed the patent. The reason for not hearing Neuraxpharm was that Neuraxpharm was delayed in confirming receipt of the subpoena even though they should have been aware that Biogen was planning to file the action, that it was likely that Biogen would lose basically all of its sales from August 1, 2022, if the alleged infringement product remained on the market, and – as Neuraxpharm was a start-up company with an unclear financial position - it was uncertain whether Neuraxpharm would be able to compensate the Biogen's damage if no injunction was issued.

Neuraxpharm appealed the decision to the Patent and Market Court of Appeal (PMÖD), and requested PMÖD to immediately decide that the injunction should be suspended until further notice and that PMÖD should overturn PMD's decision.

In support of the appeal, Neuraxpharm stated that: There have not been conditions for announcing a decision on an interim injunction without hearing Neuraxpharm. The fact that it took some time from the time the summons was issued to the time Neuraxpharm confirmed receipt of the summons does not mean that the requirement of danger in the event of delay has been met. Neuraxpharm's hearing could not cause irreparable damage of appreciable magnitude to Biogen. The damage that Biogen could suffer during the time it would take to allow Neuraxpharm to come forward consists solely of lost profits due to reduced sales. Neuraxpharm can compensate Biogen for any damage. Nor has it been propor-tionate to announce the decision without hearing Neuraxpharm.

The decision means that Neuraxpharm is excluded from practically the entire market during the month of August. Furthermore, the market and goodwill damage that an interim ban entails for Neuraxpharm must be taken into account.

The PMÖD upheld the suspension claim and decided to overturn the PMD's decision. PMÖD referred to the Swedish Patents Act stating that if the plaintiff shows probable cause that infringement, or complicity in infringement, occurs and if

that, diminishes the value of the exclusive right to the patent, the court may issue a ban on fines for the time until the case has been finally decided or something else has been decided. Before such a ban is announced, the defendant must have been given the opportunity to make a statement, unless a delay would entail a risk of damage.

PMÖD noted that in the present case, at the time the lawsuit was brought, the patent had admittedly not taken effect in Sweden and was prohibited and therefore could not be announced at that time. However, Biogen stated that the patent would be validated as soon as possible, or more precisely on July 21, 2022. Despite this, Biogen suggested in the lawsuit that Neuraxpharm would be given a response time of up to 14 days. Neither when the lawsuit was brought nor when the patent became effective in Sweden two days later, did Biogen thus express any need for an immediate decision. The question is whether the circumstances that Biogen subsequently adduced constitute a basis for a prohibition order without hearing the other party. These additional stated circumstances are essential for the patent to become effective in Sweden, that Neuraxpharm took the time to confirm receipt of the summons, that Neuraxpharm took certain additional administrative measures to be able to definitively launch its product in August 2022 and that Neuraxpharm is a relatively new company with unclear finances. According to the Patents and Markets Court of Appeal, these circumstances, neither individually nor together with other circumstances, can sufficiently justify an exception to the main rule regarding the hearing of the other party.

> **The Patent and Market Court of Appeal has not allowed an appeal against the decision.**

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So, what to learn from these decisions?

Case 1, PMÖ 5185-22, is important as it shows the possibility of pre-grant litigation. It also clearly indicates what evidence is needed in order to convince the court that the patent is soon to be granted – at least before the Patent and Market Court has made its final decision. Look at each status of your pending applications – it may well be possible to stop infringement even if your patent is not granted yet in Sweden.

Case 2, PMÖ 9563-22, is also a clear example on the importance to act quickly – raise your claims from the start, especially as *ex parte* injunction can mainly only be accepted if you can show the legal and financial risks for further delays.

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