

Preliminary injunctions in patent cases – what is required for it to be found likely that a granted patent will not hold up in an assessment as to whether it is invalid?

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A preliminary injunction may be awarded in a patent case where the claimant is able to establish on the balance of probabilities that a patent infringement has occurred.¹ In cases where the defendant has brought a declaratory judgment action that the patent is invalid,² case law shows that there is a strong presumption that a granted patent is valid. The main reason for this presumption is that a patent will only be granted after a thorough assessment has been made during the administrative process.

According to the Swedish Patent and Market Court of Appeal³ (PMCA), there should also be a corresponding strong presumption that supplementary protection is valid.

So what is required to overturn the presumption? The burden is on the defendant (the potential infringer) to prove that, due to new circumstances or new evidence that were not taken into consideration during the assessment made at the time the patent was granted or due to flaws or errors in this decision, it is likely that the patent will be declared invalid. In certain circumstances, new case law concerning the granting or upholding of patents should also be capable of overturning the presumption of validity according to the PMCA⁴.

Since the standard of proof in proceedings relating to an assessment of whether to grant a preliminary injunction is lower than that for the final assessment and the decision should not anticipate the final assessment, the reasons given for the decision should be limited. The assessment should be

¹ Chapter 9, section 57(b), paragraph 2 of the Swedish Patents Act.

² Chapter 9, section 61 of the Swedish Patents Act.

³ PMCA 12172-18.

⁴ PMCA 12172-18.

made promptly and generally be based on the written documentation submitted in the proceedings, which is significantly more limited than in the final assessment. Therefore, where a request is made for a preliminary injunction, the assessment at this stage is preliminary and only an elementary assessment should be made as to whether on the balance of probabilities an infringement has occurred.

We have looked in detail at four cases from the PMCA⁵ that shed further light on this issue.

The effect of EPO decisions and new opinions

In PMCA case 10991-18, the court found that the arguments advanced in the case were not sufficient to overturn the presumption that the patent was valid. The appeal was denied and, consequently, the preliminary injunction granted by the lower court remains in force. The patent holder brought an action for infringement in EP 138. The defendant argued that the EPO's declaration that EP 573 was invalid following a notice of opposition overturned the presumption that EP 138 was valid, since EP 573 was carved out from EP 138.

However, during the course of the appeal proceedings, the EPO Board of Appeal decided to uphold EP 573. Therefore, the earlier decision by the opposition division could not be regarded as constituting a new circumstance that could overturn the presumption that EP 138 was valid.

In this case, the court held that new evidence in the form of new expert opinions and opinions from experts on behalf of the parties could not be deemed to overturn the presumption that the patent was valid.

How are Markush claims assessed?

⁵ PMCA 10991-18 Sandoz A/S v. AstraZeneca
PMCA 12172-18 Sandoz A/S v. G.D Searle LLC *et al.*
PMCA 4865-18 Eli Lilly Sweden AB v. Sandoz A/S
PMCA 3565-17 Sandoz A/S v. ViiV Healthcare UK

In PMCA case no. 12172-18, the court found that the supplementary protection for the medicinal substance darunavir will probably be declared invalid and, consequently, the preliminary injunction granted in the lower court should be set aside.

The supplementary protection was granted in 2008 in accordance with applicable case law at the time. The basic patent in this case had what are referred to as "Markush claims"⁶ that indisputably cover the product darunavir, but do not specifically mention darunavir as an individual compound.

Pursuant to Article 3(a) of the SPC Regulation,⁷ the active ingredient or combination of active ingredients (the "product") must be protected by a basic patent in force.

In judgments from 2013 and 2018, the European Court of Justice⁸ held that Article 3(a) of the SPC Regulation should be interpreted to mean that a product is protected by the basic patent if it relates "*necessarily and specifically*" to the product, even if the product is not expressly mentioned. A person skilled in the art must be able to identify the product specifically in the light of all of the information disclosed by that patent on the basis of the prior art at the filing date or priority date of the patent concerned.

The PMCA held that these conditions, which arose in subsequent case law, were probably not satisfied, and that, consequently, the supplementary protection was probably invalid. It should be added that the application of Article 3(a) of the SPC Regulation to patents with Markush claims has not yet been determined by the European Court of Justice,

⁶ The patent claims are based on a general structural formula with a number of eligible substituents.

⁷ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

⁸ Judgments of the Court of Justice of the European Union of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:8355, paragraph 44; and 25 July 2018, *Teva*, C-121/17, EU:C:2018:585, paragraphs 36 and 37.

although a request has been submitted for a preliminary ruling.

There were two dissenting members of the court: an appeal judge and a technical expert.

Disagreed with the EPO on inventive step

In PMCA case 4865-18, the court found that the patent lacked an inventive step and was therefore not valid. Consequently, the court held that the preliminary injunction granted in the lower court should be set aside.

Based on the preliminary, elementary assessment made by the PMCA at this stage, the court decided that the solution according to the patent was probably obvious to a person skilled in the art. Even though it was not in dispute that the closest prior art was Daugan, which also formed the basis for the EPO's decision that resulted in the granted patent, the PMCA still made an assessment in respect of Daugan that ran counter to the EPO's assessment.

Patent limitation request

In PMCA case 3565-17, the court found that the claimant had failed to establish on the balance of probabilities that a patent infringement had been committed and, consequently, set aside the preliminary injunction granted by the lower court.

A declaratory judgment action that the patent was invalid was brought after the basic patent had expired, although the supplementary protection remained in force. The defendant contested the decision, requesting, in the first instance, that the patent be upheld and, in the alternative, that it be upheld in reworded form.

The claimant argued that a request for the patent to be reworded could not be considered within the scope of a preliminary assessment in an infringement case where the right no longer existed.

The court held that there was nothing to prevent a declaratory judgment action that the patent was invalid being brought

after the expiry of the period of protection for the patent and, furthermore, that there was nothing to prevent the patent holder in such a case submitting a request to limit the scope of such a patent.

The court held that the consequence of a patent limitation would be that the patent would only be declared invalid to a certain extent and, consequently, it is not a new right. In light of this, there was nothing to prevent the patent holder submitting its request for a preliminary injunction based on patent protection according to the existing request for a limitation (compare the Svea Court of Appeal's earlier decision in case Ö1674-06).

The PMCA found that, since it was not likely that the patent satisfied the requirement for novelty, the question was whether it was likely that the patent in reworded form would hold up in a final assessment. The court found that, based on the preliminary, elementary assessment made at this stage, each of the issues was subject to such uncertainties that it was unlikely that the patent in the requested reworded form would hold up in a final assessment.

Conclusions

What conclusions can be drawn from this? All of the cases relate to the pharmaceuticals sector and are no doubt of substantial financial importance to both parties. In three of the cases, it was held that the patents were probably invalid. This suggests that the defendant in these cases carried out an extensive analysis of the validity of the disputed patent and had a clear strategy when making its case. Furthermore, it is clear that it pays to appeal the decision to a higher court.

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