

Applying the doctrine of equivalence following amended patent claims – new guidance from the Swedish Patent and Market Court of Appeal

On the conditions for interpreting equivalence when patent claims have been amended during the application or opposition proceedings.

Judgment of the Patent and Market Court of Appeal of 6 March 2026 in case PMT 8216-24

In a judgment delivered on 6 March 2026, the Patent and Market Court of Appeal (PMCA) held that infringement by equivalence had occurred in relation to a pharmaceutical patent. Infringement by equivalence arises where a product or method does not fall within the literal wording of the patent claims but nevertheless utilises the inventive concept underlying the patented invention, and therefore falls within the scope of the patent's protection. In this case, the patent holder had amended the patent claims during the opposition proceedings at the EPO due to a lack of support in the application as filed. The PMCA held that these amendments did not prevent a finding of infringement by equivalence. The judgment thereby provides important clarifications regarding the circumstances in which an infringement action based on the doctrine of equivalence may succeed in Sweden. The judgment also addresses a procedural issue: To which extent a claim to amend a lower court's decision regarding an obligation to reimburse the opposing party for legal costs also includes a claim to amend said decision even if the appealed judgment is not altered on the merits.

The judgment is commented on by Anna Bladh Redzic and David Ramsjö, Sandart & Partners Law Firm.

1. The case in brief

The Japanese pharmaceutical company Takeda Pharmaceutical Company Limited (**Takeda**) held the Swedish part of a European patent validated in Sweden (**the Patent**). The Patent concerned certain anti-abuse amphetamine conjugates (amphetamine compounds) in the form of L-lysine-d-amphetamine (in free base form) and the salts L-lysine-d-amphetamine mesylate and L-lysine-d-amphetamine hydrochloride. These compounds reduce the euphoric effect associated with amphetamine in the treatment of conditions for which amphetamine is used, such as ADHD.

Takeda markets the medicinal product Elvanse on the Swedish market for the treatment of ADHD. The Patent, filed on 1 June 2004, was maintained in amended form in February 2018.

Sandoz A/S (**Sandoz**) applied for and obtained marketing authorisation in Sweden for medicines containing the compound L-lysine-d-amphetamine diadipate under the product names Dexhility and Oferlanz. The medicines were generic versions of Elvanse.

In November 2022, Sandoz brought a negative declaratory action before the Patent and Market Court (**PMC**), seeking a declaration that it was not prevented from manufacturing, offering for sale, placing on the market, using, importing or possessing its medicines containing L-lysine-d-amphetamine diadipate in Sweden.

Takeda contested Sandoz's claim, arguing that the planned launch of such products would infringe the Patent, either according to the literal wording of the claims, or in any event, under the doctrine of equivalence.

At first instance, the PMC found that Sandoz's launch of its medicinal product would not constitute infringement under the literal wording of the Patent. This was because L-lysine-d-amphetamine diadipate, which was to be included in Sandoz's medicinal product, is chemically distinct from the amphetamine compounds covered by the Patent.

However, the PMC concluded that the medicines Sandoz intended to launch would infringe at least two of the patent claims by way of equivalence.

The questions for the PMCA to answer were therefore whether Sandoz's planned launch constituted an infringement of the Patent, either under the literal interpretation of the claims or under the doctrine of equivalence.

2. Amendments to the patent claims during the opposition proceedings did not prevent infringement by equivalence

The assessment of whether infringement by equivalence can be established follows a two-step model. The criteria were previously established by the PMCA in the *Easypark* case (PMCA 2016:14) and were reiterated by the PMCA in the present judgment.

First, the court must determine whether the following four conditions are met:

- the inventive concept of the patent is fully utilised by the allegedly infringing product,
- despite the differences between the product and the wording of the patent claims, the product achieves the same technical result as the patented invention,
- the modification in the allegedly infringing product relative to the patent claims would be obvious to a person skilled in the art, and
- the allegedly infringing solution is equivalent to the patented solution.

In the present case, Takeda and Sandoz agreed that these requirements were satisfied.

In the second step, the court must determine whether infringement by equivalence should nevertheless be excluded. This requires an assessment of whether specific circumstances in the individual case militate against infringement. Relevant considerations may include:

- the nature of the invention, in particular its distance from the prior art,
- whether the disputed feature is described in the patent description as being particularly characteristic of the invention, and
- whether the patent holder, during the application procedure, intentionally limited the scope of protection of the patent claims in a relevant manner in relation to the prior art, for example to establish novelty and inventive step.

Sandoz argued, *inter alia*, that infringement by equivalence should be excluded as the patent claims as filed had covered unspecified salts of L-lysine-d-amphetamine. According to Sandoz, the patent holder had expressly renounced this broader protection by limiting the claims during opposition proceedings.

The amendments to Takeda's patent claims were made after the EPO had found that the claims lacked support in the application as originally filed. The amendments were therefore introduced

to comply with the requirement that the claims be supported by the application as filed, rather than to distinguish the invention from the prior art to fulfil the criteria of novelty or inventive step.

The PMCA began by noting that, to the best of its knowledge, this situation had not previously been addressed in Swedish case law.

The PMCA found that there were good reasons to take into account approaches developed in foreign case law. In those cases, courts had held that infringement by equivalence may still exist even where patent claims have been amended due to a lack of support in the application as filed. As the PMCA emphasised, the purpose of the support requirement – i.e. that all changes to a patent application must be supported by the application as originally filed – is to prevent applicants from obtaining an unfair advantage by modifying the invention after the filing date and thereby improving their position. However, the court considered this situation to be different from amendments made to overcome prior art objections relating to novelty or inventive step. Such amendments generally constitute a deliberate relinquishment of a certain part of the scope of protection in order to avoid covering subject matter that is not patentable.

By contrast, amendments made to address a lack of support in the original application documents do not normally indicate that the patent holder intended to limit the scope of protection in relation to prior art.

The PMCA therefore agreed with the PMC's assessment and held that amendments made for lack of support did not prevent a finding of infringement by equivalence.

In summary, the PMCA concluded that Takeda had demonstrated that it had not waived protection for all salt forms other than those specified in the patent claims. The court further found that the company had demonstrated that the conditions for infringement by equivalence were satisfied in relation to the diadipate salt contained in Sandoz's medicinal product. Accordingly, the PMCA found that Sandoz's medicinal product would infringe the Patent by equivalence, at least in respect of certain claims, and that Sandoz's action for a negative declaration could not be upheld.

Sandoz also requested that the PMCA amend the allocation of legal costs awarded by the PMC. However, the PMCA found that this request had been submitted after the expiry of the appeal period. The PMCA therefore dismissed the request as inadmissible.

The PMCA granted leave for the judgment to be appealed to the Supreme Court. However, no appeal was lodged before the expiry of the appeal period.

3. Analysis – the PMCA clarifies the conditions for infringement by equivalence and the allocation of the burden of proof in infringement cases

A recurring issue in patent infringement cases is whether an alleged infringing product or method falls within the scope of protection of a patent through the doctrine of equivalents. The present case contributes to greater predictability in this assessment.

The PMCA reiterates the criteria in the *Easypark* case and clarifies that amendments made to satisfy the requirement that a granted patent must be supported by the application as filed do not preclude a finding of infringement by equivalence.

The judgment also provides guidance on the allocation of burden of proof in infringement cases. Although the question of infringement by equivalence is ultimately a legal issue to be assessed independently by the court, the patent holder must invoke and prove the circumstances supporting that an invention may benefit from protection by equivalence.

Accordingly, the general principle of the burden of proof in patent cases – that the patent holder must prove infringement – also applies to claims based on equivalence. The PMCA further clarifies that this principle applies regardless of the procedural posture of the case. It is therefore irrelevant whether the allegation of infringement arises in an infringement action brought by the patent holder or, as in the present case, as a defence to a negative declaratory action brought by the alleged infringer.

This approach is well founded, as the reasons underlying the patent holder's burden of proof apply equally whether the issue of infringement is raised in the context of the patent holder's own infringement action or as a defence to a non-infringement action.

Although Takeda ultimately succeeded with its argument based on the doctrine of equivalence, it should be noted that such claims remain relatively difficult to succeed with before Swedish courts. Over the past ten years infringement by equivalence has reportedly been invoked in ten cases (including the present one), of which only three have been successful. Two of these cases, moreover, concerned the same patent.

A common feature of the cases in which Swedish courts have found infringement by equivalence is that they concerned pharmaceutical patents involving inventions regarded as significant technical advances. In those cases, the allegedly infringing products were generic products in which the features falling outside the literal wording of the claims were nevertheless considered technically equivalent, utilised the inventive concept of the patent and would have been obvious to a person skilled in the art.

The Takeda judgment also raises certain strategic considerations. Many generic pharmaceutical companies operate on a so called *'launch at risk'* basis, meaning that they launch their products while a patent is still in force, and subsequently defend themselves in infringement proceedings, often by challenging the validity of the patent. In the present case, however, Sandoz instead brought a negative declaratory action, which remains relatively uncommon in Sweden. Such *'clear the way'* actions are generally most effective when the patent is still in force and can be expected to continue to do so even after the infringement issue has been finally resolved.

In the present case, however, the action was brought only two years before the expiry of the patent. It was therefore foreseeable that a final judgment on appeal would be delivered after the patent had expired – which indeed proved to be the case. Against this background, one might ask what motivated Sandoz to choose this strategy.

For Swedish litigators, the judgment also serves as a reminder of the importance clearly formulating requests for amendments of the lower court's judgement. This is particularly relevant

where a party wishes the PMCA (or, where applicable, the Court of Appeal) to amend the lower court's allocation of legal costs regardless of the outcome of the main proceedings on appeal.

Sandoz's request that the PMC's allocation of costs be amended regardless of the outcome in the Court of Appeal was never examined by the PMCA but was instead dismissed as inadmissible. The court found that Sandoz had not submitted such a request in its appeal or within the appeal period, although one judge dissented on that point.

The case law from the courts of appeal (and also in the PMCA) appears to be inconsistent on this issue. This was likely the reason why the PMCA granted a leave for the judgment to be appealed to the Supreme Court. As no appeal had been lodged by the end of the appeal period, further clarification from the Supreme Court will have to await a future case.

The judgment is available [here](#).

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