THE SWEDISH DOCTRINE OF EQUIVALENCE REDUX?
The Patent and Market Court of Appeal, PMT 8216-24.

INTRODUCTION

In a judgment handed down on 6 March 2026 in case PMT 8216-24, the Swedish Patent and Market Court of Appeal (PMCA) rejected Sandoz's request for a declaration of non-infringement in respect of its generic version of Elvanse/Vyvanse. The case concerned the doctrine of equivalents and provides much-needed clarification on when amendments made during prosecution or opposition proceedings can preclude reliance on that doctrine. Swedish equivalence doctrine has evolved slowly—from the restrictive approach applied before the entry into force of EPC2000 to the approach applied by the PMCA in this case. Even so, the judgment addresses only certain aspects. This article seeks to set out the doctrine more fully, as understood by the author.

THE LISDEXAMPHETAMINE JUDGMENT

Background

The dispute concerned the Swedish part of EP 1 664 019, held by Takeda, which covers certain forms of the prodrug lisdexamphetamine (L-lysine-d-amphetamine). As granted, the patent covered lisdexamphetamine or a pharmaceutically acceptable salt thereof. In opposition proceedings, the claims were limited to the free base and to the mesylate and hydrochloride forms. Sandoz's generic product contained lisdexamphetaminediadipate and was therefore in a form not expressly claimed. The case thus primarily turned on equivalence, although Takeda also alleged literal infringement.

The Judgment

The PMCA began by noting that infringement by equivalent means is ultimately a legal question, albeit one that must be decided on the basis of facts. The court held that it is for the patentee to introduce the relevant factual circumstances into the proceedings. Where such facts are disputed, the burden of proof will normally rest with the patentee.

Against that backdrop, the court restated the criteria for infringement by equivalence from its ruling in *Easypark*.[1] Under that test, four criteria must be met:

1. The inventive concept is used fully in the accused product.

[1] Judgment by the Patent and Market Court of Appeal of 17 November 2016, PMÖD 2016:14, *Suomalaiset Raha-Automaatit Payazzo Finland Oy Ab v. Easypark AB*.

2. The accused product—notwithstanding the differences between it and the patent claims—achieves the same technical result as the invention according to the patent.

3. The differences are close at hand for the person skilled in the art.

4. The infringing solution is equivalent to the protected invention.

It was common ground that the *Easypark* criteria were satisfied. The key issue was whether other considerations nonetheless precluded a finding of infringement by equivalent means. One such potential barrier was the nature of the invention. Under Swedish law, the scope for extending protection to equivalents has traditionally been regarded as very limited—effectively non-existent—for patents covering simple design solutions close to the prior art. By contrast, a pioneering invention may enjoy broader protection. The PMCA noted that the parties had not addressed whether the nature of the invention could operate as a barrier in this case. Takeda submitted that the invention represented an important technical achievement; the court saw no reason to question that submission, which Sandoz had not disputed.

Sandoz argued that three factors prevented extending the scope of protection to the equivalent salt of lisdexamphetamine:

i. It followed from the patent claims and the description that salt forms of lisdexamphetamine other than the mesylate and hydrochloride fell outside the scope of protection.

ii. The mesylate and hydrochloride forms of the prodrug were described as especially preferred in the description.

iii. The patent had been amended to exclude all salt forms of lisdexamphetamine not specified in the claims.

The PMCA dismissed factors (i) and (ii) with reference to the lower court's assessment. The lower court had emphasised that it was clear to the skilled person reading the claims and description of the patent that the invention is lisdexamphetamine regardless of form. It added that no firm conclusions could be made (likely based on the patent) as to why only three forms of lisdexamphetamine are specified in the patent.

The court then observed that the doctrine of equivalents cannot be used to secure protection for subject-matter that, in light of the prior art, lacked novelty or inventive step on the priority date. Where the patentee has limited the claims during prosecution in order to overcome prior art (i.e., to establish novelty or inventive step), the scope for extending protection to what was removed is very small. In such circumstances,

infringement by equivalence could arise only if the amendment was made even though the prior art did not, in fact, bar patentability.

The court noted that the amendment at issue was not driven by novelty or inventive step, but by the interest of avoiding added subject matter. It further observed that Swedish case law did not provide guidance on the significance of such amendments for the doctrine of equivalents. Unusually for a Swedish court, the PMCA therefore considered how other European jurisdictions have approached the issue, referring to Dutch, Swiss and German cases. The court highlighted the view in Dutch practice that that there is a difference between infringement and added matter, since, when applying Article 123(2) EPC, the EPO does not take potential equivalence into account. The added-matter assessment is therefore narrower than the infringement analysis required under Article 69 EPC and the Protocol on its interpretation. The PMCA considered that view well founded.

The court then considered whether the interest in foreseeability for third parties nonetheless called for the same restrictive approach as in the case of prior-art-driven amendments. In its view, the situations were not comparable. Prior-art-driven amendments are intended to narrow the scope of protection and amount to an intentional relinquishment of subject-matter that is not patentable. By contrast, amendments prompted by added-matter concerns generally do not reflect an intention relinquishing protection. Third parties could therefore not assume that a claim amendment was undertaken with the intention of limiting the scope of protection. The court thus held that there was no barrier to extending protection to equivalents where the claims had been amended to ensure support in the application as filed.

The court held that the criteria it had articulated embodied the balance between the patentee's interest in protection and third parties' interest in foreseeability contemplated by Articles 1 and 2 of the Protocol on the Interpretation of Article 69 EPC. On that basis, it considered that no further balancing was required once the criteria were met.

The court concluded that Sandoz's generic would infringe Takeda's patent under the doctrine of equivalents and therefore rejected the request for a declaration of non-infringement. The court permitted its judgment to be appealed to the Supreme Court, which is very rare in substantive patent law. However, no appeal was filed.

SOME THOUGHTS ON THE SWEDISH DOCTRINE OF EQUIVALENCE

The Swedish equivalence test

The doctrine of equivalence has long been recognised in Swedish law. Historically, it was applied relatively liberally, but that changed in 1988 when the Svea Court of Appeal

essentially reserved it for pioneering inventions.[2] Following that shift, there was no finding of infringement by equivalence for almost 15 years.

That restrictive approach changed with EPC2000 and, in particular, Article 2 of the Protocol on the Interpretation of Article 69 EPC, which requires due account to be taken of any element that is equivalent to a feature of the claimed invention. While there has been no surge in judgments finding infringement under the doctrine, the PMCA's judgment discussed above (the lisdexamphetamine case) suggests something of a renaissance.

The PMCA's test, as applied in the lisdexamphetamine case, fits neatly within the structure of the Protocol on the Interpretation of Article 69 EPC. It operates in two tiers. The first tier asks whether the allegedly infringing solution is equivalent. The second tier considers whether, notwithstanding equivalence, other factors preclude extending protection—reflecting the balance required by Article 1 of the Protocol between fair protection for the patentee and reasonable legal certainty for third parties.

Equivalence was assessed by reference to the *Easypark* test. That test has never been confirmed by the Supreme Court, which has only ruled on factors that may exclude the application of the doctrine. The *Easypark* test differs slightly from the approach taken by Svea Court of Appeal in *DeLaval*, the leading pre-*Easypark* case on equivalence.[3]

The second tier of the PMCA's test concerns whether any barriers preclude applying the doctrine. This aligns with the traditional Swedish approach, in which case law and commentary have focused heavily on exclusionary factors. A range of such factors has been identified, but it is common to refer to seven.[4] Their relationship to one another is not always straightforward, and there appears to be some overlap—both among the factors themselves and with the *Easypark* criteria. The seven factors are:

1. The inventive concept is not realised in the accused product.
2. The accused product – or rather the non-literal feature - is an improvement.
3. The difference between the claim and the accused product is too complicated for the person skilled in the art.
4. The nature of the invention (the invention is simple).
5. The missing feature is important for the patentability of the invention.

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[2] Svea Court of Appeal' s judgment on 7 October 1987 in case T 356/87, *Lännen Tehtaat Oy v Svedbro Smide Aktiebolag*.

[3] Svea Court of Appeal's judgment on 10 March 2008 in case T 10183-06, *Lely Industries N.V. et al. v. DeLaval International AB*.

[4] For example, Domeij, Patent och företagshemligheter, 3rd ed. (2023), p. 129 *et seq*.

6. The difference corresponds to a limitation (amendment or statement) made during prosecution.
7. The equivalent corresponds to prior art.

The list could likely be reduced to three or four factors. The first factor—whether the inventive concept is realised in the accused product—is already addressed by the *Easypark* test and is therefore redundant as a separate barrier. The same applies to the second and third factors. The *Easypark* criterion that the differences are "close at hand" for the skilled person makes it unnecessary to ask separately whether the difference is "too complicated". Likewise, the *Easypark* criterion that the same technical result is achieved despite the differences largely captures the question whether the non-literal feature amounts to an improvement. That would leave only the last four factors for the second tier.

In light of the PMCA's ruling in the lisdexamphetamine case, it can also be asked whether amendments or statements made during prosecution (or opposition) constitute independent barriers to equivalence. The PMCA indicated that it is the underlying conflict with the prior art—not the mere fact of amendment—that excludes equivalence. An amendment made for reasons other than a conflict with the prior art will not, on that view, prevent equivalence. This is reinforced by the PMCA's suggestion that the doctrine may still apply if patentability was not, in fact, barred by the prior art that prompted the amendment.

If this analysis is accepted the factors to consider in the second tier of the test for determining whether to apply the doctrine of equivalence would be:

1. The nature of the invention.
2. The missing feature is important for the patentability of the invention.
3. The equivalent corresponds to prior art.

These three barriers are explored further below on the premise that they are relevant to the balance of interests required by Article 1 of the Protocol on the Interpretation of Article 69 EPC. This premise is supported by the PMCA's statement that the criteria it articulated for assessing when an amendment is relevant to equivalence embody that balance. That, in turn, suggests that the PMCA may assess other barriers it did not have reason to consider as fully in the lisdexamphetamine case in a similar way.

<u>Conflict with prior art and amendments</u>

The PMCA confirmed the long-held principle that the doctrine of equivalence cannot be applied such that the scope of protection covers something that was not novel or

inventive on the priority date. This has long been the position of Swedish law.[5] Third parties must be able to trust that the scope of protection is not extended beyond what would have been patentable.

However, the PMCA's judgment suggests that third parties may not always be able to assume that an amendment made to overcome prior art forecloses reliance on equivalence in respect of the amended subject-matter. The PMCA indicated that equivalence may still come into play if the amendment was made even though the prior art did not, in fact, bar patentability. The PMCA did not set out the conditions under which protection by equivalence could be maintained in such circumstances. It therefore remains to be seen whether this possibility is confined to certain situations or is generally available where the applicant does not agree that the cited prior art bars patentability but nevertheless amends the claims to expedite grant. The court's focus on what third parties may assume about the applicant's intention to relinquish protection suggests that the applicant may need to make clear that it does not concede lack of patentability over the prior art and does not intend to relinquish protection. Otherwise, it may be difficult to ensure a reasonable degree of legal certainty for third parties.

Before the *lisdexamphetamine* judgment, it was not entirely clear whether any amendment made during prosecution could preclude reliance on equivalence. In first-instance practice, amendments made to avoid added subject matter had not been treated as excluding equivalence, but those cases never reached the PMCA.[6] In a subsequent decision on interim measures, however, the PMCA declined to extend protection to an equivalent that had been excluded by amendment during prosecution. The patentee argued that the amendment had been made to avoid added subject matter, which the defendant disputed. The court did not address the reason for the amendment and excluded equivalence on the basis of the amendment as such.[7] That decision created uncertainty as to whether the PMCA considered it irrelevant whether an amendment was made to overcome prior art or to avoid added subject matter. The PMCA's *lisdexamphetamine* judgment settles the issue, at least for the time being.

A related procedural question is whether the patentee must show that there is no prior art (or no prior-art-driven amendment) that bars equivalence. The PMCA has stated that it is normally for the patentee to prove circumstances supporting protection by equivalence. First, however, the statement is qualified by "normally", implying that there

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[5] Westlander & Törnroth, Patent - allmänna domstolars praxis åren 1983–1991 (1995), pp. 284-285.

[6] The Patent and Market Court's judgment on 31 January 2018 in cases PMT 2097-15 et al, Actavis Group PTC ehf, et al. v. Eli Lilly and Company (et v.v.) and judgment on 11 December 2020 in PMT 1248-18 et al., *Eli Lilly and Company v. Fresenius Kabi AB et al.*

[7] The Patent and Market Court of Appeal's decision on 11 October 2024 in PMÖ 10325-24, *Bayer Aktiebolag, et al. v. Stada Arzneimittel AG, et al.*

may be exceptions. Second, it is not clear whether it also covers the absence of circumstances that exclude equivalence. Requiring the patentee to prove, for example, the absence of any conflict with the prior art would in practice require that party to prove a negative. A patentee could, of course, produce the prior art considered during prosecution to show that there is no barrier to equivalence, but doing so would unnecessarily burden proceedings in cases where no such barrier is even alleged. It would be more efficient for the alleged infringer to identify and substantiate an asserted barrier. That need not mean that the alleged infringer bears the full burden of proof: one approach would be to require the alleged infringer to make the existence of the barrier probable, after which the patentee would have to show that there was, in fact, no conflict with the prior art.

The nature of the invention

In the case discussed above, the PMCA emphasised that the nature of the invention is a relevant factor in determining the extent to which the doctrine can be applied. Traditionally, this has been a very important consideration. Where an invention is characterised as a simple adaptation of the prior art, the formal consequence is not that infringement by equivalents is excluded, but that the scope for it is narrow. In practice, however, the effect is often tantamount to a barrier to equivalence, even if courts frequently combine a finding that an invention is "simple" with other relevant factors.[8]

In cases where the nature of the invention has excluded equivalence, courts have often focused on the degree of inventiveness. Simple adaptations of the prior art and combinations of individually known and straightforward elements are examples of inventions that have been considered not to merit protection against infringement by equivalents. That was the case in *Easypark*.[9] The patents in question are thus inventive enough to be valid, but not inventive enough to justify a scope of protection extending beyond the literal meaning of the claims.

Determining whether an invention is "simple" is not straightforward. Ultimately, it appears to involve an assessment of the patent's contribution. In doing so, at least the lower court has also accepted that the nature of the invention may be assessed in light of its practical consequences. The Patent and Market Court (first instance) has held that an invention that differs considerably from the closest prior art *or which has an effect that differs considerably from what was achieved in the state of the art* may enjoy protection against infringement by equivalents.[10] In those cases, the court emphasised that the expert

[8] The Patent and Market Court of Appeal's judgment on 20 December 2022 in PMT 7752-20, *Copan Italia S.P.A. v. Svenska Labratorieförsäljningen Aktiebolag, LABFAB*.
[9] Cited in footnote 1 above.
[10] Cited in footnote 6 above.

evidence showed that the invention had, among other things, enabled the treatment of a specific form of cancer. The lower court's judgment was not appealed.

The nature of the invention differs from the other exclusionary factors in that it does not primarily concern legal certainty for third parties. The other side of the scale under Article 1 of the Protocol on the Interpretation of Article 69 EPC is fair protection for the proprietor. The reference to "fair" protection appears to allow more valuable inventions to be afforded more extensive protection. Put differently, the interest in legal certainty will typically outweigh the interest in extended protection where the invention is a simple one.

In the case at hand, the PMCA noted that Sandoz had not contested Takeda's submission that the invention represented an important technical advance and added that it found no reason in the record to call it into question. While this may be viewed as a formal point, the conclusion appears to sit uneasily with the PMCA's statement that it is normally for the patentee to bear the burden of proof for circumstances supporting equivalence. Under Swedish procedural law, a circumstance is normally regarded as disputed even if the other party has not expressly contested it, or has remained silent. There are exceptions, but courts are expected to apply them restrictively.[11] If the burden of proof rested with Takeda, the PMCA should therefore not have accepted an unproven allegation as to the invention's importance.

Other explanations are possible, although the court's reasoning offers no clear indication. One possibility—albeit not supported by the stated reasons—is that the burden of proof rested with Sandoz on this point. As noted, the PMCA qualified its initial statement on the burden of proof by stating that this is "normally" the case. In some respects, it may be more efficient to require the defendant to identify and substantiate circumstances said to constitute a barrier to equivalence. As mentioned above, it would be inefficient for the patentee to have to prove the absence of any conflict with the prior art, which would effectively amount to proving a negative. The same difficulty does not appear to arise in relation to whether the invention is pioneering or merely a simple adaptation.

<u>The feature is important for the invention</u>

Infringement by equivalents may be excluded if the missing feature is especially important for the invention. This barrier to equivalence has been expressed somewhat differently in different cases.

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[11] The Supreme Court's judgment 17 December 2025 in case T 1989-24, *Chantelle SA v. Twilfit AB*, at paras. 28-30.

In *Eli Lilly (fluoxetine)*, the patent at issue claimed a pharmaceutical formulation comprising three specified disintegrants. The accused product comprised a different disintegrant. The Supreme Court found that the patent document indicated that it was the combination of the claimed compounds that constituted the patentable element of the invention.[12] The court noted that the disintegrants were specified in the claim and that the description taught that the choice of disintegrant was among the most important steps. For those reasons, the Supreme Court held that protection for an equivalent disintegrant was precluded. At the same time, the court emphasised that the mere fact that a patent specifies exactly which components are to be used does not, as such, exclude infringement under the doctrine of equivalents if one component is replaced by a technical equivalent. It was therefore the combination of (i) the express specification and (ii) the teaching in the description that made the choice of disintegrants decisive.

In *DeLaval*, the Svea Court of Appeal upheld the District Court's assessment that the missing feature could not be regarded as so central to the patentability of the invention that protection by equivalence should be limited.[13] The court assessed the importance of the feature for patentability in light of the inventive concept. Unlike the Supreme Court in *Eli Lilly (fluoxetine)*, Svea Court of Appeal did not emphasise the teaching of the description. In an earlier case, Svea Court of Appeal assessed the centrality of the missing feature against the prior art as of the filing date of the patent at issue.[14]

In conclusion, Swedish case law on the centrality of a missing feature is not entirely consistent as to the criteria for treating a feature as central to the invention. On the one hand, there are cases in which the feature's relationship to the invention's patentability is assessed—either more abstractly, as in *DeLaval*, or by reference to the prior art. It has also been suggested that features that are the primary characterising features of the invention are protected only according to the literal meaning of the claim, and that only more tangential features can be extended to equivalents.[15] On that understanding, it may be asked what this "centrality" factor adds beyond the two other barriers discussed above.

On the other hand, the Supreme Court's decision in *Eli Lilly (fluoxetine)* focuses on the claim in combination with the teaching of the patent. The ruling predates the entry into

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[12] The Swedish Supreme Court's decision on 20 December 2002, NJA 2002 p. 660, Eli Lilly Sweden AB et al. v. ratiopharm AB.

[13] Cited in footnote 3 above.

[14] Svea Court of Appeal's judgment of 18 October 2002 in case in T 8915-01, *Hattos Patent AB v Peak Performance Production AB*.

[15] Domeij, Patent och företagshemligheter, 3rd ed. (2023), p. 136, see also Domeij, The Swedish Doctrine of Equivalence, in ATRIP conference proceedings 2010 / [ed] Jan Rosén (2011), p. 10, available at https://uu.diva-portal.org/smash/record.jsf?pid=diva2%3A391087&dswid=722.

force of EPC 2000, but its analysis appears aligned with the balance of interests under the Protocol on the Interpretation of Article 69 EPC. Legal certainty for third parties comes into play where a patent indicates that a particular feature is especially important for achieving the invention's technical effect. Under that approach, the centrality factor is distinct from the other two barriers: the prior-art factor excludes protection for what was not patentable on the priority date, while the nature-of-the-invention factor limits extended protection for inventions that do not sufficiently distinguish themselves from the prior art.

In the *lisdexamphetamine* case the PMCA seems to have understood the centrality of the feature in this latter way. Sandoz argued that it followed from the claim that all other salt forms of the prodrug fell outside the scope of protection and that the two claimed salt forms were taught as being preferred. The PMCA simply rejected these objections with reference to the lower court's assessment in this respect. The lower court emphasised that it was clear to the skilled person reading the claims and description of the patent that the invention is lisdexamphetamine regardless of form. It added that no firm conclusions could be made (likely based on the patent) as to why only three forms of lisdexamphetamine are specified in the patent.[16] The lower court's analysis thus focused on what could be understood based on the patent as such. The PMCA could thus be understood to have favoured this approach to the centrality of the feature.

The fact that the scope of protection is limited to the claimed subject-matter does not really go to the centrality of any specific claim feature. Where the applicant had limited the claims to a specific embodiment, it was considered a factor limiting the possibility of infringement by an equivalent in the more restrictive approach historically mandated by Svea Court Appeal.[17] That approach was criticised at the time.[18] The ruling in *Eli Lilly (fluoxetine)* appears to shut the door on the claim as such excluding equivalence for components specified therein. That effect could only be achieved in combination with teaching that supports a limitation in this respect.

If the centrality of the feature is considered in the context of the balance of interest under the Protocol of the Interpretation of Article 69 EPC there must likely be a relatively clear indication in the patent that the missing feature is especially important for achieving the effect of the invention. It is reasonable that third parties are allowed to trust such indications. The fact that the mesylate and hydrochloride were taught as being preferred, which was the second factor argued by Sandoz in the

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[16] The Patent and Market Court's judgment on 15 May 2024 in PMT 17180-22, *Sandoz A/S v. Takeda Pharmaceutical Company Limited*.
[17] Westlander & Törnroth, Westlander & Törnroth, Patent - allmänna domstolars praxis åren 1983–1991 (1995), pp. 139-143.
[18] Ibid.

lisdexamphetamine case, does not indicate that those salt forms are necessary to achieve the invention. It is merely an indication that they are the best options to do so.

Is the lisdexamphetamine judgment the last word?

The PMCA's judgment has not been appealed. The fact that the PMCA gave leave to appeal indicates that it wanted the Supreme Court to provide guidance on the issues before it. The last word on the test for applying the doctrine of equivalents in Sweden has therefore not been said. However, the PMCA's cases now provide guidance on most aspects of the doctrine. This case law will be followed by the Swedish patent and market courts until such time as the Supreme Court provides guidance on the subject.