SUPREME COURTS

DECISION

Mål nr

notified at Stockholm on 20 December 2022Ö 5978-21

PARTER

Complainant

AstraZeneca AB, 556011-7482

151 85 Södertälje

Representatives: the Patent Attorneys HR and MB

Counterparty

Swedish Patent and Registration

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SECTOR

Complaint about the Judicial Villa

PREVIOUS DECISION

Svea Court of Appeal, Patent and Market Court, decision 2021-04-07 in case PMÖÄ 1213-20

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SUPREME COURT RULING

The Supreme Court sets aside the decision of the Patent and Market Court of 7 April 2021 in PMÖÄ 1213-20 and remands the case to the Patent and Market Court for further consideration.

PLEAS IN LAW IN THE SUPREME COURT

AstraZeneca AB has requested the Supreme Court to set aside the decision of the Patent and Market Court on the ground of miscarriage of justice and to refer the case back to the Patent and Market Court for further consideration.

The Patent and Registration Office (PRV) has opposed the claim.

SKÄL

What the case concerns

1. The main issue in the case is whether the failure to obtain a preliminary ruling from the European Court of Justice in the ordinary procedure constituted an error of law.

Background

2. In February 2014, AstraZeneca was granted a supplementary protection certificate (SPC) under the SPC Regulation[1] for the active substance/authorised product dapagliflozin. The basic patent was a European patent relating to "C-aryl glucoside SGLT2 inhibitors and method". The marketing authorisation on which the SPC was based was for the medicinal product Forxiga. The term of validity of the SPC was stated to be from 16 May 2023 to 11 November 2027.

[1] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning supplementary protection certificates for medicinal products.

3. In July 2014, AstraZeneca applied to the PRV for supplementary protection for a product consisting of a combination of the substances dapagliflozin and metformin. In support of the application, AstraZeneca invoked the same basic patent. Furthermore, AstraZeneca relied on a first marketing authorisation in Sweden for the medicinal product Xigduo, granted on 16 January 2014. The PRV rejected the application on the basis that AstraZeneca had already been granted a supplementary protection certificate based on the same basic patent.

4. The Patent and Market Court rejected AstraZeneca's appeal against the PRV's decision.

5. The Patent and Market Court rejected the appeal on the grounds that a supplementary protection certificate had already been granted. The Court of First Instance decided the case without expressly ruling on the need for a preliminary ruling from the Court of Justice of the European Union. None of the parties had requested a preliminary ruling. No appeal was allowed against the decision of the Court of First Instance.

The case in the Supreme Court

6. In support of its appeal against the judgment, AstraZeneca submits, inter alia, that the failure of the Court of First Instance to obtain a preliminary ruling from the Court of Justice of the European Union on the interpretation of Article 3(c) of the Supplementary Protection Regulation constitutes a serious procedural irregularity which may be presumed to have affected the outcome of the case.

7. The PRV has argued that it was not necessary for the Patent and Market Court to obtain a preliminary ruling in order to decide the case. According to the PRV, the CJEU has essentially clarified the interpretation of Article 3(c) in a case such as the present one, even if the circumstances of the present case are not exactly the same as in the CJEU case.

The obligation to request a preliminary ruling

8. Under Article 267 of the Treaty on the Functioning of the European Union (TFEU), the Court of Justice of the European Union has jurisdiction to give preliminary rulings on, inter alia, the interpretation of acts of the institutions, bodies, offices and agencies of the Union. Where such a question arises in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal is, in principle, required by the third paragraph of the Article to refer the matter to the Court of Justice of the European Union.

9. The obligation to request a preliminary ruling is waived only if the question raised is irrelevant, if the Court of Justice of the European Union has already ruled on the same or a similar issue or if the correct application of Union law is obvious. In determining whether there is any exception to the obligation, the national court must take account of the specific features of Union law, the particular difficulties of its interpretation and the risk of differences in case-law within the Union (see, inter alia, Cilfit[2] p. 21 and Consorzio Italian Management[3] p. 33).

10. The existence of extensive case law from the European Court of Justice on a particular issue may indicate difficulties of interpretation and the risk of divergences in case law across the Union. This means that it is not self-evident that an abundance of CJEU case law on a particular issue means that the issue is settled; it may indicate the opposite (cf. Ferreira da Silva e Brito[4] p. 43-45.)

[2] Cilfit and others, 283/81, EU:C:1982:335.
[3] Consorzio Italian Management and Catania Multiservizi, C-561/19, EU:C:2021:799.
[4] Ferreira da Silva e Brito and others, C-160/14, EU:C:2015:565.

Supplementary Protection Order

11. The aim of the SPC Regulation is to create uniform rules in the EU on the extended legal protection of patented medicines. The preamble to the Regulation states that the time needed to obtain authorisation for a medicine is so long that the period of effective patent protection is too short for the return on investment in research to be covered by the product. By introducing supplementary protection rules, the EU has sought to avoid the risk of pharmaceutical research centres located in Member States relocating to countries offering better protection (see recitals 3-8).

12. Article 3 lays down a number of conditions that must be fulfilled for supplementary protection to be granted. According to Article 3(a), the product must be protected by a valid basic patent. A product means the active ingredient or combination of active ingredients of a medicinal product (see Article 1(b)). A basic patent is a patent which protects a product as such, a method of manufacturing a product or a use of a product and which is invoked by the holder as a basis for granting a supplementary protection certificate (see Article 1(c)). In addition to a basic patent, the applicant must also invoke a valid authorisation to market the product as a medicinal product which is the first authorisation for that product (see Article 3(b) and 3(d)).

13. Under Article 3(c), an additional condition is that no supplementary protection certificate has been granted before. The English translation states that the medicinal product must not have previously been granted a supplementary protection certificate. However, a comparison with other language versions of the Regulation makes it clear that what is meant is that the product must not have previously been granted a supplementary protection certificate.

Interpretation of Article 3(c) of the Supplementary Protection Regulation by the Court of Justice

14. The condition in Article 3(c) that the product must not have previously been granted supplementary protection has been interpreted by the European Court of Justice on several occasions. In particular, the cases of Actavis[5] , Georgetown[6] and Boehringer[7] are worth mentioning.

15. From these rulings - in any case - the following can be deduced. Under certain conditions, it is possible to grant a second supplementary protection certificate based on the same basic patent. It is then necessary that several different products are protected separately as such in the basic patent (see Georgetown p. 30). Where the first SPC relates to a medicinal product consisting of an innovative active ingredient as the sole active ingredient, a second SPC cannot relate to a medicinal product consisting of a combination of the innovative active ingredient and another active ingredient, which has not been named in the patent claim relating to that type of combination (see Actavis). It makes no difference if the patent proprietor subsequently adds a claim in which the other active ingredient of the combination product is named (see Boehringer). On the other hand, if a supplementary protection certificate is first granted for a medicinal product consisting of a combination of several active ingredients protected by the patent, it is possible to obtain a second supplementary protection certificate for a medicinal product consisting of one of these active ingredients which is also protected individually by the patent (see Georgetown).

[5] Actavis Group PTC and Actavis UK, C-443/12, EU:C:2013:833.
[6] Georgetown University, C-484/12, EU:C:2013:828.
[7] Actavis Group PTC and Actavis UK, C-577/13, EU:C:2015:165.

A preliminary ruling should have been obtained from the Patent and Market Court

16. In the Actavis and Georgetown cases, the CJEU expressly stated in the answers to the questions for interpretation that what is said in the answers applies in circumstances such as those at issue in the national case. The details of the national cases must therefore be given particular weight in assessing the extent to which the CJEU has clarified the meaning of Article 3(c) of the SPC Regulation through these judgments.

17. The interpretation of Article 3(c) given by the Court of Justice in its case-law means that the Article imposes greater obstacles to supplementary protection than the wording of the Article would suggest. The fact that the case law is restrictive for individual patent proprietors suggests caution in giving it significance for contentious issues which are not identical to those under consideration. In that case, it should be required that the earlier decision unambiguously answers the questions at issue.

18. This makes it difficult to assess, on the basis of the more general statements also made in the Actavis, Georgetown and Boehringer cases, a case in which the circumstances differ in certain respects from those in those cases.

19. Furthermore, in the period following the Actavis, Georgetown and Boehringer cases, the CJEU has issued two rulings, Teva[8] and Royalty Pharma[9] , on the interpretation of Article 3(a) of the SPC Regulation, i.e. on the question when a product is protected by a basic patent. In these judgments, the Court of Justice of the European Union emphasises the main role of the patent claim in the assessment. Amongst other things, the judgments show that the concept of "the essence of the innovative activity" is not

[8] Teva UK and others, C-121/17, EU:C:2018:585.
[9] Royalty Pharma Collection Trust, C-650/17, EU:C:2020:327.

relevant to the interpretation of Article 3(a) and that it is not necessary for the protection of a combined product that each active ingredient is explicitly mentioned in the claims as long as a certain model of interpretation set out by the Court of Justice of the European Union results in the claims protecting the product in question.

20. It is true that in the Actavis case (p. 44), the CJEU ruled that the SPC sought in that case could not be granted regardless of whether the combination of active ingredients in question was protected as such by the basic patent within the meaning of Article 3(a). However, it is not possible to conclude with certainty whether the statements made in the Teva and Royalty Pharma cases have any bearing on the interpretation of Article 3(c). This question has not been examined by the CJEU.

21. The circumstances of the case in the Patent and Market Court differ somewhat from those in, inter alia, the Actavis case, in particular in that the claim in the AstraZeneca patent relating to the combined product also mentions the other active ingredient by name and is thus more specific than the corresponding claim in the patent at issue in the Actavis case. This alone militates to some extent against the question of the interpretation of Article 3(c) in the present case being considered to be settled.

22. AstraZeneca has pointed out that a large number of other Member States have found that Article 3(c) does not preclude the granting of similar applications in those States, as was also argued in the ordinary procedure. That fact also suggests that there is uncertainty as to how Article 3(c) of the SPC Regulation is to be interpreted in a situation such as the present one.

23. The fact that the interpretation of Article 3(c) of the SPC Regulation has given rise to a large number of preliminary rulings also suggests that there was an exception to the obligation to refer the question of interpretation (see p. 10). After the Patent and

In addition, two courts (the Market Court of Finland and the Supreme Court of Ireland) have decided to refer questions to the European Court of Justice following the decision of the Market Court.[10] The referrals indicate that there are significant similarities between the Finnish and Irish cases on the one hand and the case before the Court of First Instance on the other.

24. Taken together, the previous decisions of the European Court of Justice cannot be considered to provide an unequivocal answer to the questions at issue in the case before the Court of First Instance (see p. 17). Instead, the ambiguities regarding the interpretation of Article 3(c) of the Supplementary Protection Regulation in a situation such as that at issue in the present case were so great that it was not possible to conclude that the issue was settled. Nor was it manifestly clear or irrelevant to the assessment. A preliminary ruling on the interpretation of Article 3(c) was therefore required. As the Court of First Instance was the final instance in the matter, it was obliged to obtain a preliminary ruling.

Provisions applicable to the extraordinary review

25. AstraZeneca's complaint of miscarriage of justice shall be assessed in accordance with the Act (1996:242) on Court Matters (Erendelagen, see Chapter 3, Section 2 of the Act, 2016:188, on Patent and Market Courts).

26. The special legal remedies are regulated in Article 42 of the Procedural Law. According to this paragraph, Chapter 58(1) and Chapter 59(1) of the Code of Judicial Procedure also apply to cases decided under the Rules of Procedure. An application for relief or a complaint against a miscarriage of justice must therefore be examined in accordance with the grounds applicable to civil proceedings. Article 42 of the Code of Procedure further provides that restitutio in integrum may be granted

[10] Court of Justice cases C-119/22 and C-149/22.

even in cases other than those provided for in Chapter 58 of the Code of Judicial Procedure, namely where there are exceptional grounds.

27. The fact that a court has failed to obtain a preliminary ruling from the Court of Justice of the European Union has previously been examined both under the res judicata provision on manifestly unlawful application of the law and under the rules on miscarriage of justice (see, for example, the "Airport case" NJA 2004 p. 735 and "Slite waste disposal plant" NJA 2009 p. 667).

28. The question of whether a preliminary ruling should be sought can be seen from a procedural perspective and a decision on the question can then constitute a procedural measure and part of the procedure before the national court. From this point of view, the most obvious solution in an extraordinary procedure before a Swedish court is to apply the rules on appeals for a preliminary ruling. At the same time, it is clear that the review - in both ordinary and extraordinary proceedings - will to a large extent be concerned with the interpretation of substantive rules of Union law.

29. More specifically, it will be a question of assessing whether the substantive rule is clear or settled or whether there is a question of interpretation that should be referred to the European Court of Justice. In this sense, an extraordinary case will not infrequently focus on the assessment of the substantive content and meaning of Union law for an individual party or, in other words, on the application of the law in the ordinary case. The examination may thus also give rise to an assessment of the kind required by the rules on appeal, namely whether the substantive application of the law is manifestly contrary to law. There is also some overlap between the rules on restitutio in integrum and those on miscarriage of justice.

30. However, the key point is that the Swedish rules on extraordinary remedies must now be seen in the light of Union law and that their application may need to be adapted to some extent to take account of this,

without prejudice to the domestic

the division between resurrection and delusion need always be given decisive weight.

31. The provision to which a complainant has referred is not in itself binding on the court, which has to classify the facts relied on in law. However, the appellant submits that the failure to obtain a preliminary ruling constitutes an error of law. In the present case, it seems natural to examine that question first.

Other serious procedural irregularities

32. A judgment which has acquired the force of res judicata must be set aside on the ground of a miscarriage of justice if there has been a serious procedural irregularity in the proceedings which may be presumed to have affected the outcome of the case (Chapter 59, Section 1, paragraph 4 of the Code of Judicial Procedure). Such a procedural irregularity is present where a rule governing the procedure has been infringed or misapplied.

33. For a procedural irregularity to be considered as serious, it is not necessary that the court has acted negligently. Rather, the assessment depends primarily on the nature of the rule which has been infringed. If the rule is particularly important, its infringement will in many cases be regarded as a serious procedural irregularity. It is also often justified to presume that the error affected the outcome of the case.

The question whether failure to obtain a preliminary ruling constitutes an error of law

34. The obligation under Article 267 TFEU for a court of last instance to make a reference for a preliminary ruling exists whether or not the parties have requested it. This rule is intended to ensure that Union law is correctly applied and uniformly interpreted in all Member States and to prevent, within the Union

differences in case law on Union law issues. A breach of this rule may constitute a breach of the Treaty.[11]

35. There can be no doubt that Article 267 TFEU is a procedural rule. Its infringement or misapplication must therefore be regarded as a procedural irregularity.

36. The preliminary ruling rule is important to ensure uniform and correct practice in matters of Union law. It is clear that a procedural irregularity consisting in a departure from this rule must, at least in certain situations, be regarded as serious. This should in any event be the case where a court of last instance decides with precedent effect a case in which the question of Union law at issue is entirely decisive for the outcome of the case. Where the procedural irregularity is regarded as serious, it should also be presumed to have had an impact on the outcome of the case (see p. 33).

37. However, it should be possible in other situations not to regard the procedural irregularity as serious. An assessment should be made of the harm to the protected interest caused in the individual case by the failure to request a preliminary ruling. It will be important, for example, whether the national decision is indicative and how important the question of EU law was for the outcome of the case.

The assessment in this case

38. As noted, the Patent and Market Court was obliged to request a preliminary ruling on the matter (see p. 24); its failure to do so constitutes a procedural error (see p. 35).

39. The Patent and Market Court ruled on the merits of the case and the ruling had a precedent effect. The assessment of Union law

[11] See Commission v France (Advance tax), C-416/17, EU:C:2018:811.

question was absolutely crucial to the outcome. The procedural irregularity must therefore be regarded as serious and must be presumed to have affected the outcome of the case (see p. 36).

40. The decision of the Patent and Market Court should therefore be set aside and the case returned to the Court of Justice for further consideration. In the light of that outcome, there is no need to examine AstraZeneca's other pleas in law in support of its application for a declaration of inadmissibility.

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Gudmund Toijer, Johnny Herre, Svante O. Johansson, Malin Bonthron (Rapporteur) and Cecilia Renfors, Judges; Elin Dalenius, Registrar, was the Rapporteur.