Supreme Court

KKO:2019:34

Revocation of a precautionary measure imposed on the basis of a supplementary protection certificate

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Background to the case and the issue to be decided

The judgment of the Supreme Court concerned the issue of whether a precautionary measure granted on the basis of a supplementary protection certificate for medicinal products (SPC) could be annulled, taking into account the new case-law of the Court of Justice of the European Union and its interpretation of the conditions under which a supplementary protection certificate may be granted.

A Ltd. had received a SPC issued in Finland on 3 December 2009 for a product which was a combination of the active ingredients tenofovir disoproxil and emtricitabine. The SPC was based on a European patent (basic patent) validated in Finland. The combination is used in a medicine for the treatment of HIV.

As a precautionary measure, the Market Court had prohibited B Ltd. from importing and marketing a generic medicinal product containing this combination.

B Ltd. requested that the precautionary measure be revoked on the grounds that it could no longer be deemed probable that the SPC granted to A Ltd. was valid. In its application, B Ltd. referred to the preliminary ruling of the Court of Justice of the European Union in the case Teva UK and Others, C-121/17, EU: C: 2018: 585, which had given more precise criteria to be used in the interpretation of Article 3(a) of 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.

The question before the Supreme Court was, first, whether the legal situation specified by the Court of Justice in its preliminary ruling could be grounds for revocation of a precautionary measure. After this, the question to be decided was whether the preliminary ruling in said case had undermined the presumption of validity of the SPC to such an extent that the conditions for granting the precautionary measure were no longer fulfilled.

Assessment by the Supreme Court

In accordance with Chapter 7, section 8 (1) of the Code of Judicial Procedure, a precautionary measure shall be revoked if the reason for which it had been undertaken no longer exists.

The Supreme Court held that the revocation of a precautionary measure may be based on changes in the factual circumstances on which the precautionary measure was based, but also on changes in the legal situation on which the assessment of the preconditions for the precautionary measure had been based. In considering a case concerning the revocation of a precautionary measure, it is necessary to assess the existence of the conditions for the precautionary measure in the changed circumstances.

In a case concerning precautionary measures, the point of departure is the presumption of validity, according to which the proprietor of a registered industrial property, such as a SPC, is already on the basis of registration assumed to have an exclusive right that may be protected by a precautionary measure. This is supported also by the effective remedies required under the TRIPS Agreement and the Directive on the enforcement of intellectual property rights (2004/48/EC). A person who seeks to contest the validity of a registered right has to demonstrate the grounds for the invalidity of the registration. The strength of the presumption of validity, however, is affected by which type of registered industrial right it is in question and by when the registration was made.

The Supreme Court examined the earlier case-law of the Court of Justice of the European Union on the meaning of Article 3 (a) of the Regulation, which provides that 'the product is protected by a basic patent in force'. The Court has held, inter alia, that the provision precluded the granting of a SPC relating also to active ingredients which were not specified in the wording of the claims of the basic patent (judgment of 24 November 2011, Medeva, C-322/10, EU:C:2011:773). The Court has further held that a SPC could be granted for an individual active ingredient even though it was not identified in the claims of the basic patent by a structural formula, as long as this ingredient was covered by a functional formula set forth in the claims and if it was possible to reach the conclusion that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question (judgment of 12 December 2013, Eli Lilly and Company, C-493/12, EU:C:2013:835).

In the judgment of the Grand Chamber of the Court of Justice in Teva UK and Others (C-121/17), which had been given after the precautionary measure had been granted, the criteria for the interpretation of the provision had been clarified in the case of a product composed of several active ingredients with a combined effect. Also in such a case, the patent provided protection only if the combination product in question had been expressly mentioned in the claims of the basic patent or the product was necessarily and specifically identified on the basis of the claims (paragraph 52). In respect of the latter situation, the Court of Justice made it a necessary condition that, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

- the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
- each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent (paragraph 57).

The Court of Justice further stated in respect of the SPC in question – a certificate which was analogous to that granted to A Ltd. – that the description of the basic patent contains no information as to the possibility that the invention covered by that patent could relate specifically to a combined effect of tenofovir disoproxil and emtricitabine for the purposes of the treatment of HIV. According to the Court of Justice, it did not seem possible that a person skilled in the art, on the basis of the prior art at the filing date or priority date of that patent, would be able to understand how emtricitabine, in combination with tenofovir disoproxil, necessarily fell under the invention covered by that patent (paragraph 56). However, it was for the national court to establish whether the criteria set out in the preliminary ruling had been fulfilled.

The Supreme Court held that in this case, the precautionary measure had provided the holder of the SPC already for the duration of the legal proceedings the rights it was claiming in the main proceedings. This consequently places a higher standard in the assessment of the probability of the rights of the holder. In assessing the validity of the SPC, the Supreme Court took into consideration, inter alia, the fact that the case-law of the Court of Justice had developed significantly since the SPC had been granted. Furthermore, the judgment of the Court in Teva UK and Others, C-121/17, had established a more specific condition for the validity of a SPC covering a combination of active ingredients, a condition that had not been disclosed in the case law at the time of grant of the SPC in question.

Claim 27 of the basic patent described the invention to be protected as follows: 'A pharmaceutical composition comprising a compound according to any one of claims 1 through 25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.' It had not been contested in the case that tenofovir disoproxil had been identified in claim 25 of the basic patent in the form of a chemical formula and that the other active ingredient covered by the SPC, i.e. emtricitabine, had not been mentioned in the patent claims. Nor did the specification of the basic patent otherwise specifically indicate that the invention described in the claims would be to combine tenofovir disoproxil specifically with emtricitabine. The Supreme Court held that protection of said combination by the basic patent could not be deemed probable solely on the basis of what appeared from the patent. The Supreme Court held further that said circumstances, together with the more specific conditions set out in the preliminary ruling, had undermined the presumption of the validity of the SPC.

As the holder of a supplementary protection certificate, A Ltd. had the burden of proving that a person skilled in the art could nonetheless understand that the patent specifically covered said combination of active ingredients. According to A Ltd. it would be clear to a person skilled in the art, when reading claim 27, that the term "other therapeutic ingredients" mentioned therein refers to ingredients that had the same therapeutic purpose with tenofovir disoproxil, i.e. treating viral diseases and in particular HIV. According to A Ltd., emtricitabine was such an ingredient.

The Supreme Court held that on the basis of the assertions presented by A Ltd, it could not in the summary assessment be deemed probable, that the conditions laid down in the preliminary ruling by the Court of Justice in Teva UK and Others were met. The Supreme Court held that the prerequisites for the precautionary measure were not fulfilled and revoked the precautionary measure.

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