2. If the answer to Question 1 is that Article 27 does not require that interpretation, does a national procedural rule breach the principle of effectiveness if it operates so as to prevent the person concerned from relying, in the context of the consent application, upon a relevant judgment of the Court of Justice of the European Union delivered in the period of time after the order for surrender?

(1) 2002/584/JHA: Council Framework Decision of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States — Statements made by certain Member States on the adoption of the Framework Decision (OJ 2002, L 190, p. 1).

Reference for a preliminary ruling from the Supreme Court (Ireland) made on 2 March 2022 — Merck Sharp & Dohme Corp v Clonmel Healthcare Limited

(Case C-149/22)

(2022/C 191/27)

Language of the case: English

Referring court

Supreme Court

Parties to the main proceedings

Plaintiff: Merck Sharp & Dohme Corp

Defendant: Clonmel Healthcare Limited

Questions referred

1. (a) For the purpose of the grant of a supplementary protection certificate, and for the validity of that SPC in law, under Article 3(a) of Regulation (EC) No 469/2009 (1) concerning the supplementary protection certificate for medicinal products, does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

   (b) If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC?

2. Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

3. Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

4. If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC;

a) only to the single molecule if marketed as a product;

b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or

c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?

And if any of the above, why?

(1) 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 (OJ 2009, L 152, p. 1).

Appeal brought on 3 March 2022 by Gmina Miasto Gdynia and Port Lotniczy Gdynia-Kosakowo sp. z o.o. against the judgment delivered by the General Court on 21 December 2021 in Case T-263/15 RENV, Gmina Miasto Gdynia and Port Lotniczy Gdynia-Kosakowo v Commission

(Case C-163/22 P)

(2022/C 191/28)

Language of the case: Polish

Parties

Appellants: Gmina Miasto Gdynia and Port Lotniczy Gdynia-Kosakowo sp. z o.o. (represented by: K. Gruszecka-Spychała and P. K. Rosiak, radcy prawni)

Other parties to the proceedings: European Commission, Republic of Poland

Form of order sought

The appellants claim that the Court should:

— set aside the judgment of the General Court delivered on 21 December 2021 in Case T-263/15 RENV, *Gmina Miasto Gdynia and Port Lotniczy Gdynia-Kosakowo* v *Commission*;

— give final judgment in the case, declaring the first, fourth and sixth pleas in law of the original action well founded in so far as the present appeal is concerned and annulling the contested decision in accordance with the original form of order sought;

— rule in the judgment referred to in the second indent above on the costs of the proceedings at first instance and of the appeal proceedings.

Grounds of appeal and main arguments

First ground of appeal, alleging that the General Court erred in law in interpreting Article 107(1) TFEU in the context of the analysis of the first part of the first plea in law of the original action in respect of the incorrect identification of the advantage and the incorrect determination, raised in the context of the fourth plea in law of the original action, of the amount of aid to be recovered.

Second ground of appeal, alleging that the General Court erred in law by failing to take into account, when examining the second complaint of the sixth plea in law of the original action concerning the unlawfulness of the withdrawal of Decision 2014/883/EU (1) and its replacement by the contested decision, the principle of the protection of legitimate expectations, the principle of legal certainty, and the principle of effective legal protection, in that it adopted an unlawful interpretation that enables the Commission to freely withdraw its own legal measure which has already been contested before the General Court and to freely amend its content, without taking into account the interests and expectations of the party that has contested that measure.