JUDGMENT OF THE COURT (Seventh Chamber)

7 December 2017 (*)

(Reference for a preliminary ruling — Industrial and commercial property — Patent law — Medicinal products for human use — Regulation (EC) No 469/2009 — Article (3)(b) — Supplementary protection certificate — Conditions for obtaining — Article 10(3) — Granting of the certificate or rejection of the application for a certificate — Directive 2001/83/EC — Article 28(4) — Decentralised procedure)

In Case C-567/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Chancery Division, Patents Court, made by decision of 4 October 2016, received at the Court on 10 November 2016, in the proceedings

Merck Sharp & Dohme Corporation

v

Comptroller General of Patents, Designs and Trade Marks,

THE COURT (Seventh Chamber),

composed of C. Toader (Rapporteur), acting as President of the Chamber, A. Prechal and E. Jarašiūnas, Judges,

Advocate General: H. Saugmandsgaard Øe,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 7 September 2017,

after considering the observations submitted on behalf of:

– Merck Sharp & Dohme Corporation, by K. Bacon QC, T. Hinchliffe QC, S. Bennett, advocate, and L. Whiting, Solicitor,

– the Czech Government, by M. Smolek and J. Vláčil, acting as Agents,

– the European Commission, by A. Sipos and J. Samnadda, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 3(b) and 10(3) 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 (OJ 2009 L 152, p. 1) (‘the SPC Regulation’) and of Article 28(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended, as regards pharmacovigilance, by Directive 2010/84/EU of the

European Parliament and the Council of 15 December 2010 (OJ 2010 L 348, p. 74) ('Directive 2001/83').

2 The request has been made in proceedings between Merck Sharp & Dohme Corporation ('MSD') and the Comptroller General of Patents, Designs and Trademarks ('the Comptroller') concerning the latter's rejection of an application for a supplementary protection certificate lodged by MSD, on the ground that, in the absence of an authorisation to place a medicinal product called 'Atozet' on the United Kingdom market, it did not meet the requirements laid down in Article 3(b) of the SPC Regulation, an irregularity which, in the view of the Comptroller, could not be rectified under Article 10(3) of the SPC Regulation.

Legal context

EU law

Directive 2001/83

3 Recitals 2, 3 and 6 of Directive 2001/83 are worded as follows:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

…

(6) In order to reduce the disparities which remain, rules should be laid down on the control of medicinal products and the duties incumbent upon the Member States' competent authorities should be specified with a view to ensuring compliance with legal requirements.'

4 Article 6(1) of Directive 2001/83 provides that 'no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive …'.

5 Article 17(1) of the directive states as follows:

'Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 210 days after the submission of a valid application.

Applications for marketing authorisations in two or more Member States in respect of the same medicinal product shall be submitted in accordance with Articles 28 to 39.'

6 Article 28 of Directive 2001/83 provides as follows:

'1. With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as "reference Member State" and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3.

2. Where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report on the medicinal product or, if necessary, to

update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be sent to the concerned Member States and to the applicant.

3. In cases where the medicinal product has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The reference Member State shall prepare these draft documents within 120 days of receipt of a valid application and shall send them to the concerned Member States and to the applicant.

4. Within 90 days of receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

5. Each Member State in which an application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement.'

7 Article 29(1) of Directive 2001/83 states as follows:

'If, within the period laid down in Article 28(4), a Member State cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on the grounds of serious potential risk to public health, it shall give a detailed exposition of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be forthwith referred to the coordination group.'

The SPC Regulation

8 Recitals 4, 5, 8 and 10 of the SPC regulation read as follows:

'(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

…

(8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

…

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

9 Article 1 of the SPC Regulation, headed 'Definitions', provides as follows:

'For the purposes of this Regulation, the following definitions shall apply:

(a) “medicinal product” means any substance or combination of substances presented for treating or preventing disease in human beings …;

(b) “product” means the active ingredient or combination of active ingredients of a medicinal product;

(c) “basic patent” means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(d) “certificate” means the supplementary protection certificate;

…’

10 Article 3 of the SPC Regulation, entitled ‘Conditions for obtaining a certificate’, is worded as follows:

‘A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with [Directive 2001/83] …;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.’

11 Article 7 of the SPC Regulation, headed ‘Application for a certificate’, states as follows:

‘1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

…

3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5 . Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006 [of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, (OJ 2006 L 378, p. 1)] the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.’

12 Article 8 of the SPC Regulation provides as follows:

‘1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

…

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive [2001/83] …;

(c) if the authorisation referred to in (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication;

…’

13 According to Article 9(1) of the SPC Regulation:

‘The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.’

14 Article 10 of that regulation provides as follows:

‘…

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

…’

15 Article 13 of the SPC Regulation, headed ‘Duration of the certificate’, is worded in paragraph 1 thereof as follows:

‘The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.’

United Kingdom law

16 In the United Kingdom, the Human Medicines Regulation 2012, which transposed Directive 2001/83, governs the grant of marketing authorisations by the Medicines and Healthcare Products Regulatory Agency.

The dispute in the main proceedings and the questions referred for a preliminary ruling

17 MSD, a company incorporated in New Jersey (United States), is part of a group of pharmaceutical companies whose ultimate parent company is Merck & Co. Incorporated.

18 Merck & Co. Incorporated was the holder of European Patent (UK) No EP 0 720 599, for which an application was filed on 14 September 1994, with an earliest priority date of 21 September 1993, and which was granted on 19 May 1999. The patent covered the active ingredient ezetimibe and combinations of ezetimibe with other active ingredients.

19 In September 2006 MSD, began development of a fixed dose combination of two active ingredients in tablet form. As it encountered problems in establishing a satisfactory formulation, this work continued until 2013.

20 In September 2013, MSD submitted applications based on an identical dossier in a number of Member States, under the decentralised procedure laid down in Article 28 of Directive 2001/83, with a view to being granted a marketing authorisation in each of those Member States and requested the Federal Republic of Germany to act as the reference Member State for the medicinal product Atozet, a medicinal product for adults intended to reduce the overall level of cholesterol.

21 As is apparent from the file submitted to the Court, the validity of those applications was acknowledged only on 13 February 2014.

22 On 10 September 2014, that is 209 days after the valid marketing authorisation applications had been submitted and, therefore, within the period laid down in Article 17 of Directive 2001/83, the Bundesinstitut für Arzneimittel und Medizinprodukte (the German Medicinal Products Agency) issued an end of procedure notice, in accordance with Article 28(4) of the directive.

23 On 12 September 2014, the first marketing authorisation for Atozet in the European Union was granted by the competent French national authority.

24 On the same day, MSD filed an application for a supplementary protection certificate (‘SPC’) with the United Kingdom Intellectual Property Office (‘the UKIPO’), on the basis of the patent referred to in paragraph 18 above.

25 That application related to the two active ingredients of which Atozet is composed, namely ezetimibe and atorvastatin, or pharmaceutically acceptable salts thereof.

26 With the SPC application in the United Kingdom, MSD provided a copy of the end of procedure notice issued on 10 September 2014 by the German Medicinal Products Agency. In the letter accompanying that application, MSD contended that the effect of the notice was that all Member States concerned, including the United Kingdom, had agreed to grant marketing authorisations for Atozet and requested that it be permitted to supplement the SPC application when the UK marketing authorisation was granted.

27 On 13 September 2014, MSD’s patent referred to in paragraph 18 above expired.

28 On 17 September 2014, the UKIPO’s examiner wrote to MSD raising an objection to the SPC application in the United Kingdom, on the ground, inter alia, that the application did not comply with the requirements laid down in Article 3(b) of the SPC Regulation since MSD did not hold a valid UK marketing authorisation.

29 On 10 October 2014, the Medicines and Healthcare Products Regulatory Agency granted a marketing authorisation for Atozet in the United Kingdom to MSD’s UK subsidiary, Merck Sharp & Dohme Ltd.

30 On 17 November 2014, MSD sent a letter to the UKIPO, enclosing a copy of the UK marketing authorisation, together with the authorisation granted in France on 12 September 2014. In that letter, MSD requested that those documents be taken into account to rectify any irregularities which might invalidate the SCP application in the United Kingdom.

31 The UKIPO's examiner declined to comply with that request on the ground that, where no marketing authorisation has been granted, that does not constitute an irregularity that may be rectified for the purposes of Article 10(3) of the SPC Regulation. Following a hearing on 3 September 2015, the examiner's position was confirmed on behalf of the Comptroller by the UKIPO's hearing officer.

32 MSD brought an action against the Comptroller's decision before the referring court, the High Court of Justice (England and Wales), Chancery Division, Patents Court.

33 According to that court, the Comptroller's decision is correct. It considers that the granting of a marketing authorisation following the issue of an end of procedure notice is not a mere administrative formality. Thus, that notice is not equivalent to a marketing authorisation within the meaning of Article 3(b) of the SPC Regulation.

34 Moreover, the referring court is of the view that the irregularity invalidating MSD's SPC application in the United Kingdom cannot be rectified under Article 10(3) of the SPC Regulation.

35 The referring court observes, nonetheless, that the SPC applications submitted by MSD in Portugal and Sweden were rejected on the same ground as that on which the SPC application filed in the United Kingdom was refused. On the other hand, such applications were granted in Denmark, Greece, Italy and Luxembourg. In the Netherlands, the only ground for refusal was non-compliance with Article 3(c) of the SPC Regulation, which requires that, at the date of the SPC application, the product has not already been the subject of a certificate in the Member State in which the application is submitted.

36 In those circumstances, the High Court of Justice (England and Wales), Chancery Division, Patents Court, decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is an end of procedure notice issued by the reference Member State under Article 28(4) of Directive [2001/83] before expiry of the basic patent to be treated as equivalent to a granted marketing authorisation for the purpose of Article 3(b) of [the SPC Regulation], such that an applicant for [an SPC] in the Member State in question is entitled to apply for and be granted [an SPC] on the basis of the end of procedure notice?

(2) If the answer to question 1 is no: in the circumstances in question, is the absence of a granted marketing authorisation in the Member State in question at the date of the application for [an SPC] in that Member State an irregularity that can be cured under Article 10(3) of [the SPC Regulation] once the marketing authorisation has been granted?

Consideration of the questions referred

The first question

37 By its first question, the referring court seeks to ascertain, in essence, whether Article 3(b) of the SPC Regulation is to be interpreted as meaning that an end of procedure notice issued by the reference Member State in accordance with Article 28(4) of Directive 2001/83 before the expiry of the basic patent, as defined in Article 1(c) of the SPC Regulation, may be treated as equivalent to a marketing authorisation within the meaning of Article 3(b) of that regulation, with the result that an SPC may be obtained on the basis of such a notice.

38 It should be observed at the outset that Article 3(b) of the SPC Regulation requires, in order for an SPC to be granted for a product as a medicinal product, a valid marketing authorisation to have been obtained in accordance with Directive 2001/83.

39 It should be noted in that regard that, on any natural reading, the word 'granted' in Article 3(b) of the SPC Regulation can only refer to an action that has already been completed.

40 Moreover, with regard to the context of that provision, it is clear that the legislature established a connection between the SPC Regulation and Directive 2001/83 by linking the grant of an SPC to the

grant of a marketing authorisation under the directive.

41 It follows that, for the purposes of Article 3(b) of the SPC Regulation, a 'valid authorisation to place [a] product on the market' must be in the form of a document which meets the requirements laid down by Directive 2001/83 under the decentralised procedure, which is based on the principle of mutual recognition and is applicable where the medicinal product in question has not yet been the subject of a marketing authorisation in a Member State, as was the case in the main proceedings.

42 The decentralised procedure provided for in Article 28 of Directive 2001/83 entails a number of stages, commencing with the submission by the applicant of an application for marketing authorisation in all the Member States concerned and of an application to one Member State to act as the reference Member State. Article 28(4) of the directive provides that the reference Member State is to record the agreement of all parties, close the procedure and inform the applicant accordingly. Under Article 28(5) of the directive, each Member State is to adopt a decision authorising the marketing of the product concerned, in conformity with the approved assessment report and the related documents, within 30 days of acknowledgement of the agreement of all the parties.

43 It follows that the adoption of the end of procedure notice under Article 28(4) of Directive 2001/83 represents an intermediate stage in the decentralised procedure and that the notice does not have the same legal effects as a 'valid' marketing authorisation, since such a notice does not authorise the applicant to place the medicinal product on a particular market.

44 In that regard, while, at the hearing before the Court, MSD pleaded in aid the fact that some of the functions of a marketing authorisation — in particular, the functions of providing a guarantee that the product is safe, identifying the product to which the SPC relates and calculating the duration of the SPC — may be fulfilled by the end of procedure notice, it nonetheless acknowledged that such a notice does not allow what is in fact the essential feature of a marketing authorisation, namely the placing on the market of the medicinal product at issue in the main proceedings.

45 It is also apparent from the Court's case-law that, unless it has been granted a marketing authorisation as a medicinal product, a patented product may not give rise to the grant of an SPC (judgment of 15 January 2015, *Forsgren*, C-631/13, EU:C:2015:13, paragraph 34).

46 In the light of all the foregoing considerations, the answer to the first question is that Article 3(b) of the SPC Regulation is to be interpreted as meaning that an end of procedure notice issued by the reference Member State in accordance with Article 28(4) of Directive 2001/83 before the expiry of the basic patent, as defined in Article 1(c) of the SPC Regulation, may not be treated as equivalent to a marketing authorisation within the meaning of Article 3(b) of that regulation, with the result that an SPC may not be obtained on the basis of such a notice.

The second question

47 By its second question, the referring court asks whether Article 10(3) of the SPC Regulation is to be interpreted as meaning that the fact that no marketing authorisation has been granted by the Member State concerned at the time the SPC application is lodged in that Member State constitutes an irregularity that can be cured under that provision.

48 Article 3(b) of the SPC Regulation, which sets out the 'conditions for obtaining' an SPC, provides that an SPC certificate is to be granted if, in the Member State in which the application referred to in Article 7 of the regulation is submitted and at the date of that application, a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83.

49 It is clear from the wording of that provision, in particular the phrase 'if … a valid authorisation to place the product on the market as a medicinal product has been granted', that one of the conditions which the product must satisfy is that a marketing authorisation has been granted in the Member State concerned.

50 It follows that, under Article 10(2) of the SPC Regulation, the authority referred to in Article 9(1) of the regulation must reject the SPC application if the application or the product to which it relates does not meet the conditions laid down by the regulation.

51 Article 10(3) of the SPC Regulation states that, where the SPC application does not meet the conditions laid down in Article 8 thereof, the authority referred to in Article 9(1) of the regulation is to ask the applicant to rectify the irregularity.

52 Thus, it is clear from the wording itself of Article 10(3) of the SPC Regulation, in particular the phrase 'if the [SPC] application does not meet the conditions', that only an irregularity affecting the SPC application can be rectified under that provision.

53 It follows that the absence of a marketing authorisation does not constitute an irregularity which the applicant can rectify *ex post* under Article 10(3) of the SPC Regulation, since it constitutes an irregularity in connection with the product, as a medicinal product, not an irregularity in connection with the SPC application. Moreover, with regard to the marketing authorisation, the conditions laid down by Article 8 of the SPC Regulation, which are referred to in Article 10(3) thereof, relate not to the actual existence of the marketing authorisation — which is a requirement under Article 3(b) of the regulation — but simply to various items of information and documents to be produced in order to prove that the marketing authorisation exists and to identify that authorisation when the SPC application is lodged.

54 In the light of the foregoing considerations, the answer to the second question is that Article 10(3) of the SPC Regulation is to be interpreted as meaning that the fact no marketing authorisation has been granted by the Member State concerned at the time the SPC application is lodged in that Member State does not constitute an irregularity that can be cured under that provision.

Costs

55 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Seventh Chamber) hereby rules:

1. **Article 3(b) 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 is to be interpreted as meaning that an end of procedure notice issued by the reference Member State in accordance with Article 28(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, as regards pharmacovigilance, by Directive 2010/84/EU of the European Parliament and the Council of 15 December 2010, before the expiry of the basic patent, as defined in Article 1(c) of Regulation No 469/2009, may not be treated as equivalent to a marketing authorisation within the meaning of Article 3(b) of that regulation, with the result that a supplementary protection certificate may not be obtained on the basis of such a notice.**

2. **Article 10(3) of Regulation No 469/2009 is to be interpreted as meaning that the fact that no marketing authorisation has been granted by the Member State concerned at the time the supplementary protection certificate application is lodged in that Member State does not constitute an irregularity that can be cured under that provision.**

Toader Prechal Jarašiūnas

Delivered in open court in Luxembourg on 7 December 2017.

A. Calot Escobar

C. Toader

Registrar

Acting as President of the Seventh Chamber

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* Language of the case: English.