ORDER OF THE COURT (Eighth Chamber)

17 April 2007 *

In Case C-202/05,

REFERENCE for a preliminary ruling under Article 234 EC, by the High Court of Justice of England and Wales, Chancery Division (Patents Court) (United Kingdom), made by decision of 10 December 2004, received at the Court on 9 May 2005, in the proceedings

Yissum Research and Development Company of the Hebrew University of Jerusalem

v

Comptroller-General of Patents,

THE COURT (Eighth Chamber),

composed of E. Juhász, President of the Chamber, G. Arestis (Rapporteur) and J. Malenovský, Judges,

* Language of the case: English.

Advocate General: Y. Bot,
Registrar: R. Grass,

the Court, proposing to give its decision by reasoned order in accordance with the first subparagraph of Article 104(3) of its Rules of Procedure,

after hearing the Advocate General,

makes the following

Order

1 This reference for a preliminary ruling concerns the interpretation of Article 1(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), in the version resulting from the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1; 'Regulation No 1768/92').

2 The reference was made in the context of an action brought by the Yissum Research and Development Company of the Hebrew University of Jerusalem ('Yissum')

against the decision of the Comptroller-General of Patents (UK Patent Office, 'the Patent Office') refusing the application for a supplementary protection certificate ('SPC') which Yissum had filed for 'calcitriol'.

Legal context

3 Article 1 of Regulation No 1768/92 provides:

'For the purposes of this Regulation:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(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 defined in (b) 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.'

4 Article 3 of Regulation No 1768/92, which sets out the conditions for obtaining an SPC, provides:

'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 65/65/EEC or Directive 81/851/EEC, as appropriate. ...;

(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.'

The main proceedings and the questions referred for a preliminary ruling

5 Since 19 July 1989, Yissum has been the holder of a European patent entitled 'Cosmetic and dermatological compositions containing l-alpha-hydroxycholecalciferol'. That patent particularly concerns a composition, for use in topical treatment of skin disorders, containing a compound of l-alpha-hydroxycholecalciferol or of 1-alpha, 25-dihydroxycholecalciferol, commonly known as 'calcitriol'. The patent also covers the same composition in conjunction with a carrier suitable for the manufacture of a cream, an ointment or a lotion.

6 On 12 December 2001, Galderma Ltd was granted authorisation in the United Kingdom to place Silkis ointment on the market. That authorisation covers calcitriol as active ingredient, and liquid paraffin, white soft paraffin and alpha-tocopherol as carriers. It also states that the ointment is authorised for 'topical treatment of plaque psoriasis (psoriasis vulgaris) with up to 35% of body surface area involvement'.

7 On 11 June 2002, relying on that authorisation, Yissum applied to the Patent Office for an SPC for calcitriol. Primarily, an SPC was sought solely for calcitriol.

Alternatively, Yissum requested an SPC for a combination of calcitriol with an ointment base.

8 By decision of 29 July 2004, the Patent Office refused that SPC application on the ground that the authorisation to place the product on the market on which Yissum was relying was not the first such authorisation for that product as a medicinal product, as required by Article 3(d) of Regulation No 1768/92. Other medicinal products, such as Calcijex and Rocaltrol, containing calcitriol as sole active ingredient, had already been granted authorisation to be placed on the market before Silkis ointment. Calcijex is a sterile, isotonic, clear, aqueous solution containing calcitriol for intravenous injection and is used for the management of hypocalcaemia in patients undergoing dialysis for chronic renal failure. Rocaltrol consists of soft gelatine capsules, containing calcitriol and various inactive ingredients, and is administered orally to patients with chronic renal failure or post-menopausal osteoporosis.

9 Moreover, in that same decision, the Patent Office declared that an ointment base cannot be considered to be an active ingredient and, consequently, dismissed Yissum's SPC application in so far as it concerned a combination of active ingredients including an ointment base.

10 On 25 August 2004, Yissum brought an action against that decision before the national court. In support of its action, it maintains that its SPC application was for

calcitriol for a particular therapeutic use — namely, the topical treatment of psoriasis — different to that of products previously authorised. In the alternative, Yissum submits that its SPC application concerned a combination of active ingredients — Calcitriol and an ointment base — so that the first authorisation to place the product on the market was really that granted for Silkis ointment, as was alleged in its application.

11 Against that background, the High Court of Justice (England & Wales), Chancery Division (Patents Court) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'(1) In a case in which the basic patent protects a second medical application of a therapeutic agent what is meant by "product" in Article 1(b) of the Regulation [No 1768/92] and in particular does the application of the therapeutic agent play any part in the definition of "product" for the purpose of the Regulation?

(2) Does the term "combination of active ingredients of a medicinal product" within the meaning of Article 1(b) of the Regulation [No 1768/92] mean that each component of the combination must have therapeutic activity?

(3) Is there a "combination of active ingredients of a medicinal product" where a combination of substances comprising two components of which one

component is a substance with a therapeutic effect for a specific indication and the other component renders possible a form of the medicinal product that brings about efficacy of the medicinal product for that indication?'

12 By letter of 6 June 2006, the Registrar of the Court sent the national court a copy of the judgment in Case C-431/04 *Massachusetts Institute of Technology* [2006] ECR I-4089, requesting that court to inform it whether, in the light of that judgment, it wished to maintain the reference.

13 By written communication received by the Court on 9 March 2007, the national court informed the Court that, by judgment of 2 November 2006, it was withdrawing the second and third questions referred for a preliminary ruling but maintaining the first.

14 The Court is therefore called upon to answer only the first question referred for a preliminary ruling.

The question referred for preliminary ruling

15 In accordance with the first subparagraph of Article 104(3) of the Rules of Procedure, where the answer to a question referred for a preliminary ruling may be

clearly deduced from the existing case-law, the Court may, after hearing the Advocate General, at any time give its decision by reasoned order in which a reference is made to the relevant case-law. The Court considers that that is the position in the main proceedings.

16 As laid down in Article 1(b) of Regulation No 1768/92, 'product' means the active ingredient or combination of active ingredients of a medicinal product.

17 It is clear from *Massachusetts Institute of Technology*, and, in particular, from paragraphs 19, 21, 23 and 24 of that judgment, that the concept of 'product' referred to in Article 1(b) of Regulation No 1768/92 must be interpreted strictly to mean 'active substance' or 'active ingredient'.

18 It follows that the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent.

19 Moreover, the same interpretation can be inferred from paragraph 20 of the judgment in Case C-31/03 *Pharmacia Italia* [2004] ECR I-10001, in which the Court held that 'the decisive factor for the grant of the certificate is not the intended use of the medicinal product and ... the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product'.

20 Consequently, the answer to the question referred must be that Article 1(b) of Regulation No 1768/92 is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.

Costs

21 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 (Eighth Chamber) hereby orders:

Article 1(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, in the version resulting from the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.

[Signatures]