Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

1 October 2015 *

(Reference for a preliminary ruling — Article 267 TFEU — Obligation to bring the matter before the Court of Justice — Approximation of laws — Proprietary medicinal products — Medicinal products for human use — Marketing authorisation — Variation — Fees — Regulation (EC) No 297/95 — Regulation (EC) No 1234/2008 — Scope)

In Case C-452/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Consiglio di Stato (Italy), made by decision of 22 May 2014, received at the Court on 29 September 2014, in the proceedings

Agenzia Italiana del Farmaco (AIFA),

Ministero della Salute

v

Doc Generici Srl,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, A. Ó Caoimh, C. Toader, E. Jarašiūnas and C.G. Fernlund (Rapporteur), Judges,

Advocate General: N. Jääskinen,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Doc Generici Srl, by C. Marrapese, avvocato,

— the German Government, by T. Henze and J. Möller, acting as Agents,

— the Estonian Government, by N. Grünberg, acting as Agent,

— Ireland, by E. Creedon, A. Joyce and B. Counihan, acting as Agents, and C. Toland, Barrister,

— the European Commission, by L. Pignataro-Nolin, M. Šimerdová and A. Sipos, acting as Agents,

* Language of the case: Italian.

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

gives the following

Judgment

1 This application for a preliminary ruling concerns the interpretation of Article 267 TFEU and Article 3(2) of Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ 1995 L 35, p. 1), as amended by Commission Regulation (EU) No 273/2012 of 27 March 2012 (OJ 2012 L 90, p. 11) ('Regulation No 297/95').

2 The application has been made in proceedings between the Agenzia Italiana del Farmaco (AIFA) (Italian Medicinal Products Agency) and Doc Generici Srl ('Doc Generici') concerning the amount of fees payable for variations to several marketing authorisations.

Legal context

EU law

Regulation No 297/95

3 Article 1 of Regulation No 297/95, entitled 'Scope', provided as follows:

'Fees for obtaining and maintaining a Community authorisation to market medicinal products for human and veterinary use and for the other services supplied by the [European Medicines Agency (EMA)] shall be levied in accordance with this Regulation.

The amounts of these fees shall be laid down in euro.'

4 Article 3 of Regulation No 297/95, entitled 'Medicinal products for human use covered by the procedures laid down in Regulation (EC) No 726/2004', provided as follows:

'1. *Authorisation to market a medicinal product*

…

2. *Variation to a marketing authorisation*

(a) Type 1 variation fee

A type I variation fee shall apply for a minor variation to a marketing authorisation, as defined in Article 3(2) of [Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93 (OJ 2003 L 159, p. 24)]. For type IA variations, the fee shall be EUR 2 900. For type IB variations, the fee shall be EUR 6 700.

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations. …'

Regulation (EC) No 1234/2008

5 Recital 6 in the preamble to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ 2008 L 334, p. 7), as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012 (OJ 2012 L 209, p. 4) ('Regulation No 1234/2008'), states as follows:

'Each variation should require a separate submission. Grouping of variations should nevertheless be allowed in certain cases, in order to facilitate the review of the variations and reduce the administrative burden. Grouping of variations to the terms of several marketing authorisations from the same marketing authorisation holder should be allowed only insofar as all concerned marketing authorisations are affected by the exact same group of variations.'

6 Article 1(1) of Regulation No 1234/2008 is worded as follows:

'This Regulation lays down provisions concerning the examination of variations to the terms of all marketing authorisations for medicinal products for human use and veterinary medicinal products granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1)], 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)], Directive 2001/82/EC [of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1)], and [Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ 1987 L 15, p. 38)].'

7 Article 2 of Regulation No 1234/2008 provides as follows:

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

(1) "Variation to the terms of a marketing authorisation" or "variation" means any amendment to:

(a) the information referred to in Articles 12(3) to 14 of Directive 2001/82/EC and Annex I thereto, Articles 8(3) to 11 of Directive 2001/83/EC and Annex I thereto, Articles 6(2) and 31(2) of Regulation (EC) No 726/2004, or Article 7 of Regulation (EC) No 1394/2007 [of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83 and Regulation No 726/2004 (OJ 2007 L 324, p. 121)];

…

(2) "Minor variation of type IA" means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

…

(9) "Purely national marketing authorisation" means any marketing authorisation granted by a Member State in accordance with the acquis outside the mutual recognition or decentralised procedure and that has not been subject to a complete harmonisation following a referral procedure.'

8 Article 7 of Regulation No 1234/2008, entitled ‘Grouping of variations’, is drafted in the following terms:

‘1. Where several variations are notified or applied for, a separate notification or application in accordance with Chapters II, III, or Article 19 as appropriate shall be submitted in respect of each variation sought.

2. By way of derogation from paragraph 1, the following shall apply:

(a) where the same minor variation(s) of type IA to the terms of one or more marketing authorisations owned by the same holder are notified at the same time to the same relevant authority, a single notification as referred to in Article 8 or 14 may cover all such variations;

…’

9 Article 13a of Regulation No 1234/2008, entitled ‘Notification procedure for minor variations of type IA’, provides as follows:

‘1. Where a minor variation of type IA is made, the holder shall submit to the competent authority a notification containing the elements listed in Annex IV. This notification shall be submitted within 12 months following the implementation of the variation.

…’

10 Article 13d of that regulation, entitled ‘Grouping of variations to purely national marketing authorisations’, states as follows:

‘1. Where several variations are notified or applied for, a separate notification or application in accordance with Articles 13a, 13b, 13c, or 19 as appropriate shall be submitted to the competent authority in respect of each variation sought.

2. By way of derogation from paragraph 1, the following shall apply:

(a) where the same minor variation(s) of type IA to the terms of one or more marketing authorisations owned by the same holder are notified at the same time to the same competent authority, a single notification as referred to in Article 13a may cover all such variations;

…’

11 Annex II to Regulation No 1234/2008, entitled ‘Classification of variations’, is worded as follows:

‘1. The following variations shall be classified as minor variations of type IA:

(a) variations of purely administrative nature that are related to the identity and contact details of:

— the holder;

— the manufacturer or supplier of any starting material, reagent, intermediate, active substance used in the manufacturing process or finished product;

…’

12 Annex IV to Regulation No 1234/2008, entitled ‘Elements to be submitted’, provides as follows:

‘…

(5) In the case of variations to centralised marketing authorisations, the relevant fee provided for in Council Regulation No 297/95.

(6) In the case of variations to marketing authorisations granted by the competent authorities of Member States:

(a) a list of those Member States with an indication of the reference Member State if applicable;

(b) the relevant fees provided for in the applicable national rules in the Member States concerned.’

EMA notices

13 The EMA notice of 22 July 2013, entitled ‘Rules for the implementation of Regulation No 297/95 on fess payable to the European Medicines Agency and other measures’ (EMA/MB/358554/2013) (‘the notice of 22 July 2013’), provides in Article 4bis thereof as follows:

‘Grouping of variations and worksharing procedures for variations

1. The applicable fee as specified in Regulation No 297/95 or in these Rules shall be payable for each individual variation to a marketing authorisation that is grouped in a single notification or a single application made under the terms of Article 7 of Regulation No 1234/2008.

…’

14 The EMA notice of 9 December 2013, entitled ‘Explanatory note on fees payable to the European Medicines Agency’ (EMA/458574/2013) (‘the notice of 9 December 2013’), provides in section 1.1.5. thereof as follows:

‘Grouping and worksharing procedures for variations

1.1.5.1.
Grouping of extension and/or variations notified or submitted under the terms of Article 7(2) of Regulation No 1234/2008

…

In the case of grouping of the same type IA variations to the terms of several marketing authorisations owned by the same holder (as set out in Article 7(2)(a) of Regulation No 1234/2008), the applicable fee shall be payable for each individual type IA variation and for each marketing authorisation in the grouping.

The same marketing authorisation holder also means several marketing authorisation holders that are linked through a parent company. The fee for the grouping shall be payable by the marketing authorisation holder applying for the grouping procedure.

Where any extensions/variations included in a grouping are found not to be valid and the remainder are validated positively, the applicable fees as specified above shall be payable for each of the positively validated extensions/variations.

…’

Italian law

15 Decreto legislativo n. 44 — Attuazione direttiva 93/39/CEE, che modifica le direttive 65/65/CEE, 75/318/CEE e 75/319/CEE relative ai medicinali (Legislative Decree No 44 implementing Directive 93/39/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC concerning medicinal products) of 18 February 1997 (Ordinary Supplement, GURI No 54 of 6 March 1997) provided in Article 5(1) thereof as follows:

‘For the examination of applications for marketing authorisation for medicinal products and applications for variations or renewal of any authorisation issued pursuant to Legislative Decree No 178 of 29 May 1991 … fees corresponding to one-fifth of the amounts laid down in Regulation No 297/95 shall be payable to the Ministry of Health …’.

16 Article 158(11)(c) and (12) of Decreto legislativo n. 219 — Attuazione della direttiva 2001/83/CE (e successive direttive di modifica) relativa ad un codice comunitario concernente i medicinali per uso umano, nonché della direttiva 2003/94/CE (Legislative Decree No 219 implementing Directive 2001/83/EC (and subsequent amending directives) on the Community code relating to medicinal products for human use and Directive 2003/94/EC) of 24 April 2006 (Ordinary Supplement, GURI No 142 of 21 June 2006) was worded as follows:

‘11. The following are confirmed:

…

(c) the fees fixed for the examination of applications for marketing authorisations for medicinal products and applications for the variation and renewal of the authorisations themselves, in accordance with Article 5(1) of Legislative Decree No 44 of 18 February 1997.

12. … By decree of the Minister for Health, acting on a proposal from the AIFA, the amounts of the fees referred to in paragraph 11(c) only shall be updated in proportion to the changes in rates payable to the EMA. In any event, the fees referred to in paragraph 11(c) may not be less than one-fifth of the amount of the fees set by EU legislation in respect of the corresponding services provided by the EMA.’

17 The Decree of the Minister for Health of 24 May 2004 provided in section 2 of Annex 3 thereto as follows:

‘Variation of a marketing authorisation

A. Type I variation fee This fee shall be payable for minor variations to the marketing authorisation, in accordance with the Commission Regulation applicable thereto. In the case of an identical variation, this fee shall cover all authorised strengths, pharmaceutical forms and presentations [and shall be] EUR 1 392.’

18 The referring court has indicated that it is apparent from the legislation applicable at the material time that the amount of fees payable to the AIFA for Type 1A minor variations was EUR 600.

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

19 Doc Generici is the holder of 62 marketing authorisations issued by the AIFA. It notified that authority of the change of address of its registered office and, as a consequence, requested that each of the marketing authorisations it held be varied.

20 By letter of 23 March 2013, the AIFA sought payment from that company of a fee of EUR 600 for each of the 62 marketing authorisations for which such a variation was requested, namely EUR 37 200 ('the decision of 23 March 2013').

21 Doc Generici brought an action before the Tribunale amministrativo regionale del Lazio (Regional Administrative Court, Lazio) seeking annulment of the decision of 23 March 2013 and payment by way of damages EUR 36 600, being the difference between the sum paid to the AIFA (EUR 37 200) and the sum for which, in its view, it is liable (EUR 600).

22 That action was upheld on the ground that a single fee of EUR 600 is payable for a single variation to be made at the same time to all the authorisations in force. The court at first instance relied on the provision which states that 'the fee shall cover all authorised strengths, pharmaceutical forms and presentations', which appears in both Annex 3 to the Decree of the Minister for Health of 24 May 2004 and in Article 3(2)(a) of Regulation No 297/95. That court took the view that the latter provision also covered situations in which one and the same variation applies to several marketing authorisations. It was of the view that that interpretation was consistent with recital 6 in the preamble to Regulation No 1234/2008, which permits an identical set of variations to marketing authorisations owned by the same holder to be grouped together in a single notification in order to reduce the administrative burden entailed in processing them.

23 The AIFA brought an appeal against that decision before the Consiglio di Stato (Council of State), a court of final instance. In the order for reference, that court stated that it is clear from national legislation that, in accordance with the freedom of choice enjoyed by the Italian legislature, since 1997 the fee scheme applicable to marketing authorisations for medicinal products issued by the AIFA has closely followed EU legislation. The amount of the national fee is expressed as a percentage of that charged by the EMA under the centralised procedure

24 The Consiglio di Stato entertains doubts as to the validity of the interpretation of EU law adopted by the court at first instance. It considers that Article 3(2)(a) of Regulation No 297/95 applies to a case that is different from that in the main proceedings. If the legislature had intended, by that provision, to address situations such as that in the main proceedings, it would have expressly referred to 'all authorised medicinal products', thus removing any doubt on that score.

25 The Consiglio di Stato refers to the notice of 9 December 2013. While it is not a legislative measure, that document may constitute evidence of a common interpretation, within the European Union, of the rules applicable to fees.

26 Moreover, the referring court asks whether it is required, under Article 267 TFEU, as court of final instance and in the face of an objective contradiction between the interpretations of EU law proposed in the main proceedings, to make a reference to the Court of Justice for a preliminary ruling.

27 In those circumstances, the Consiglio di Stato decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must Article 3(2)(a) of [Regulation No 297/95] be interpreted as meaning that type I marketing authorisation variations — and, in particular, in respect of the case in the main proceedings, type IA variations — where an identical variation affecting several authorisations belonging to the same holder are concerned, are subject to a single fee, to the extent specified therein, or to as many fees as there are authorisations affected by the variation?

(2) In the circumstances in the present proceedings, may or must, as held by this court, the question be referred to the Court of Justice?'

Consideration of the questions referred

Question 1

28 By its first question, the referring court seeks to ascertain, in essence, whether Article 3(2)(a) of Regulation No 297/95 is to be interpreted as permitting a national authority to demand, in respect of the change of address of a marketing authorisation holder, payment of as many fees as there are authorisations requiring variation.

29 With regard to the fees applicable for services provided by the EMA in the case of a change of address of the marketing authorisation holder, it is apparent from a reading of Article 4bis of the notice of 22 July 2013 in conjunction with Section 1.1.5.1. of the notice of 9 December 2013 that, in the case of the grouping of the same variation to the terms of several marketing authorisations owned by the same holder, the EMA considers that the fee applicable, as fixed by Regulation No 297/95, is payable in respect of each individual variation and each individual marketing authorisation within the grouping. It is therefore clear that, for a variation of that kind, relating to several marketing authorisations owned by the same holder, the EMA's practice is to demand payment of as many fees as there are marketing authorisations requiring variation.

30 None the less, it is apparent from the title itself of Regulation No 297/95 that that regulation concerns fess payable to the EMA. Article 1 of the regulation, which establishes its scope, provides in that regard that '[f]ees for obtaining and maintaining a Community authorisation to market medicinal products for human and veterinary use and for the other services supplied by the Agency shall be levied in accordance with this Regulation'.

31 The dispute in the main proceedings does not concern the amount of fees payable in respect of services provided by the EMA. It relates only to the fees payable to the AIFA.

32 It follows that, contrary to the premiss on which the first question is based and notwithstanding the fact the relevant national legislation sets the level of fees payable to the AIFA by reference to Regulation No 297/95, that regulation does not impose any obligation on national authorities responsible for issuing marketing authorisations for medicinal products.

33 It must be recalled in this regard that, in the procedure laid down by Article 267 TFEU providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the national court with an answer which will be of use to it and enable it to determine the case before it. To that end, the Court may have to reformulate the questions referred to it. The Court has a duty to interpret all provisions of EU law which national courts require in order to decide the actions pending before

them, even if those provisions are not expressly indicated in the questions referred to the Court by those courts (see, inter alia, judgments in *Campina*, Case C-45/06, EU:C:2007:154, paragraphs 30 and 31, and *Fuß*, EU:C:2010:609, paragraph 39).

34 Consequently, even if, formally, the referring court has limited its questions to the interpretation of Article 3(2) of Regulation No 297/95, that does not prevent this Court from providing the referring court with all the elements of interpretation of EU law that may be of assistance in adjudicating in the case pending before it, whether or not the referring court has referred to them in the wording of its questions. It is, in this regard, for the Court to extract from all the information provided by the national court, in particular from the grounds of the decision to make the reference, the points of EU law which require interpretation in view of the subject-matter of the dispute (see, to that effect, judgment in *Fuß*, EU:C:2010:609, paragraph 40 and the case-law cited).

35 In the present case, the order for reference also refers to Regulation No 1234/2008. Article 1(1) of that regulation provides that the regulation 'lays down provisions concerning the examination of variations to the terms of all marketing authorisations for medicinal products for human use and veterinary medicinal products granted in accordance with Regulation (EC) No 726/2004, Directive 2001/83/EC, Directive 2001/82/EC and Directive 87/22/EEC …'. Accordingly, that regulation governs variations to all marketing authorisations for medicinal products for human or veterinary use, regardless of whether the authorisations were granted by the EMA under centralised procedures or by the competent national authorities under decentralised or purely domestic procedures.

36 In those circumstances, as Regulation No 1234/2008 is applicable to a situation such as that in the main proceedings, it is necessary to examine whether those provisions require a competent national authority to charge a fee for each marketing authorisation to be varied in order to reflect the change of the holder's address or whether they prohibit such an authority from so doing.

37 It is apparent from Section 1(a) of Annex II to Regulation No 1234/2008 that variations of purely administrative nature that are related to the identity and contact details of the marketing authorisation holder are classified as Type IA minor variations.

38 Article 7 of Regulation No 1234/2008 forms part of Chapter I, entitled 'General provisions', while Article 13d forms part of Chapter IIa of the regulation, entitled 'Variations to purely national marketing authorisations'. In their respective fields of application, those measures provide that, where the same Type IA minor variation to the terms of several marketing authorisations owned by the same holder is notified at the same time to the same relevant authority, a single notification may cover all such variations.

39 Thus, Regulation No 1234/2008 authorises the grouping in a single notification of several identical applications for Type IA minor variations submitted at the same time. According to recital 6 in the preamble to that regulation, such grouping is intended 'to facilitate the review of the variations and reduce the administrative burden', but only 'insofar as all concerned marketing authorisations are affected by the exact same group of variations'.

40 It should none the less be noted that Regulation No 1234/2008 does not contain any provision governing the amount of fees that may be charged by competent national authorities for processing such groupings of Type IA minor variations. The question whether those national authorities may demand payment of as many fees as there are marketing authorisations requiring variation, notwithstanding the fact that the applications for variation are grouped together, falls to be determined, in the absence of any legislative provisions adopted by the European Union, by national law.

41 It follows from all the foregoing considerations that the answer to the first question is that neither Regulation No 297/95 nor Regulation No 1234/2008 requires a competent national authority to demand, in respect of the change of address of a marketing authorisation holder, payment of as many charges as there are marketing authorisations requiring variation, and nor do those regulations prohibit such an authority from demanding such payment.

Question 2

42 By its second question, the referring court seeks to ascertain, in essence, whether, in circumstances such as those of the main proceedings, as set out in paragraphs 23 to 26 above, Article 267 TFEU must be interpreted as meaning that a national court or tribunal against whose decisions there is no judicial remedy under national law is required to comply with its obligation to bring the matter before the Court of Justice.

43 In accordance with the third paragraph of Article 267 TFEU, a court or tribunal against whose decisions there is no judicial remedy under national law is required, where a question of EU law is raised before it, to comply with its obligation to bring the matter before the Court of Justice, unless it has established that the question raised is irrelevant or that the provision of EU law in question has already been interpreted by the Court or that the correct application of EU law is so obvious as to leave no scope for any reasonable doubt (see, inter alia, judgments in *Cilfit and Others*, 283/81, EU:C:1982:335, paragraph 21, and *Boxus and Others*, C-128/09 to C-131/09, C-134/09 and C-135/09, EU:C:2011:667, paragraph 31).

44 In the present case, it is clear from the explanations provided by the Consiglio di Stato that it considers that it is obliged to make a reference to the Court of Justice for a preliminary ruling. Indeed, it is of the view that the dispute in the main proceedings raises a question of interpretation of EU law which is relevant and novel and the answer to which is not so clear as to leave no scope for any reasonable doubt as to the solution.

45 It follows from the foregoing considerations that the answer to Question 2 is that Article 267 TFEU must be interpreted as meaning that a court or tribunal against whose decisions there is no judicial remedy under national law is required, in circumstances such as those in the main proceedings, to comply with its obligation to bring the matter before the Court of Justice.

Costs

46 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 (Third Chamber) hereby rules:

1. **Neither Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, as amended by Commission Regulation (EU) No 273/2012 of 27 March 2012, nor Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012, requires a competent national authority to demand, in respect of the change of address of a marketing authorisation holder, payment of as many charges as there are marketing authorisations requiring variation, and nor do those regulations prohibit such an authority from demanding such payment.**

2. Article 267 TFEU must be interpreted as meaning that a court or tribunal against whose decisions there is no judicial remedy under national law is required, in circumstances such as those in the main proceedings, to comply with its obligation to bring the matter before the Court of Justice.

[Signatures]