Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

14 February 2019*

(Reference for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Article 11 — Generic medicinal products — Summary of product characteristics — Exclusion of references referring to indications or dosage forms still covered by patent law at the time when the generic medicine was marketed)

In Case C-423/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the Gerechtshof Den Haag (Regional Court of Appeal, The Hague, Netherlands), made by decision of 4 July 2017, received at the Court on 13 July 2017, in the proceedings

Staat der Nederlanden

v

Warner-Lambert Company LLC,

THE COURT (Sixth Chamber),

composed of A. Arabadjiev, President of the Second Chamber, acting as President of the Sixth Chamber, C.G. Fernlund (Rapporteur) and S. Rodin, Judges,

Advocate General: J. Kokott,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 14 June 2018,

after considering the observations submitted on behalf of:

– Warner-Lambert Company LLC, by C. Schoonderbeek, avocate, and by S. Dack, J.A. Dullaart and P. van Schijndel, advocaten,

– the Netherlands Government, by M. Gijzen and M.K. Bulterman, acting as Agents,

– the European Commission, by E. Manhaeve and A. Sipos, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 4 October 2018,

gives the following

* Language of the case: Dutch.

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 11 and Article 21(3) 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 by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1) ('Directive 2001/83').

2 The request has been made in proceedings between the Staat der Nederlanden (Netherlands State) and Warner-Lambert Company LLC ('WLC') concerning the publication of information on the patented uses of a reference medicinal product during the decentralised marketing authorisation procedure for a generic medicinal product provided for in Article 28 of Directive 2001/83.

Legal context

Directive 2001/83

3 Article 6(1) of Directive 2001/83 provides:

'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 or an authorisation has been 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),] …

When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).'

4 Article 8(3)(i) and (j) of that directive is worded as follows:

'The application shall be accompanied by the following particulars and documents, submitted in accordance with Annex I:

…

(i) Results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– pre-clinical (toxicological and pharmacological) tests,

– clinical trials;

…

(j) A summary, in accordance with Article 11, of the product characteristics, a mock-up of the outer packaging, containing the details provided for in Article 54, and of the immediate packaging of the medicinal product, containing the details provided for in Article 55, together with a package leaflet in accordance with Article 59'.

5 Under Article 10(1) of that directive:

'By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit, within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

…'

6 Article 10(2) of Directive 2001/83 defines a 'generic medicinal product' as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated.

7 The first paragraph of Article 11 of that directive lists the information knowledge of which is essential for proper administration of the medicinal product and which must be listed in the summary of product characteristics of the pharmaceutical product. The second paragraph of that article provides:

'For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.'

8 Article 21(2) and (3) of the directive provides:

'2. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the marketing authorisation is issued or subsequently.

3. The national competent authorities shall, without delay, make publicly available the marketing authorisation together with the package leaflet, the summary of the product characteristics and any conditions established in accordance with Articles 21a, 22 and 22a, together with any deadlines for the fulfilment of those conditions for each medicinal product which they have authorised.'

9 Article 59(1) of Directive 2001/83 provides that the package leaflet is to be drawn up in accordance with the summary of the product characteristics.

Regulation No 726/2004

10 Article 3(3) of Regulation No 726/2004, as amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 316, p. 38) ('Regulation No 726/2004') provides as follows:

'A generic medicinal product of a reference medicinal product authorised by the Community may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC and 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),] under the following conditions:

(a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC or Article 13 of Directive 2001/82/EC;

(b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed, …

…'

Regulation (EC) No 1234/2008

11 Article 4(1) of 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'), provides that the European Commission is to draw up guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of that regulation, as well as on the documentation to be submitted pursuant to those procedures.

12 Article 9 of Regulation No 1234/2008, which is in Chapter II thereof, defines the notification procedure for minor type IB variations. Article 10 of that regulation, which is in the same chapter, establishes the notification procedure for minor type II variations.

13 In accordance with Article 4(1) of Regulation No 1234/2008, the Commission has adopted the guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Regulation No 1234/2008 and on the documentation to be submitted pursuant to those procedures (OJ 2013 C 223, p. 1). It is apparent from point C.I.6(a) and (b) of the annex to those guidelines, first, that the addition of a new therapeutic indication or the variation of an approved indication constitutes a major type II variation and, second, that the deletion of a therapeutic indication constitutes a minor type IB variation.

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

14 It is apparent from the explanation provided by the referring court that WLC is a company belonging to the Pfizer pharmaceutical group, which markets the medicinal product Lyrica, whose active ingredient is pregabalin. That medicinal product is intended for the treatment of epilepsy, generalised anxiety disorder and neuropathic pain.

15 On 6 July 2004, Lyrica obtained a marketing authorisation under the centralised procedure.

16 At the material time in the main proceedings, use of pregabalin for the treatment of epilepsy and generalised anxiety disorder was no longer covered by a patent. WLC was, however, the holder of European Patent EP 0 934 061 B3, granted on 28 May 2003 ('Patent EP 061'), which covered the used of pregabalin for the treatment of, inter alia, neuropathic pain. That patent expired on 17 July 2017.

17 In the Netherlands, the College ter Beoordeling van Geneesmiddelen (Medicinal Product Evaluation Board, 'the CBG') is the autonomous administrative body responsible for monitoring and assessing the efficacy, risks and quality of medicinal products. The CBG publishes on its website, inter alia, the terms of the marketing authorisation, the package leaflet and the summary of product characteristics for each medicinal product.

18 The referring court notes that producers of generic medicinal products sometimes fail to mention on the package leaflet and in the summary of the product characteristics information on a reference medicinal product relating to indications or dosages which are still covered by a patent. Until 2009, it was the CBG's practice to publish on its website the package leaflets and summaries of product characteristics not mentioned by marketing authorisation holders or applicants for generic medicinal products.

19 During 2009, the CBG abandoned that policy and decided to systematically publish all the information on the reference medicinal product, even when the applicant informed the CBG of its intention to omit certain information.

20 During 2015, several producers of generic medicinal products obtained marketing authorisation for pregabalin from the CBG under the decentralised procedure. One of those producers, Aurobindo, informed the CBG, before placing its medicinal product on the market, that it intended not to include the package leaflet and the summary of product characteristics in the information relating to the treatment of neuropathic pain. That company asked if it could publish only part of the package leaflet and of the summary of product characteristics, but the CBG refused.

21 WLC brought an action before the rechtbank Den Haag (District Court, The Hague, Netherlands) seeking, in essence, an order that CBG abandon its practice of publishing in full on its website package leaflets and summaries of product characteristics of generic medicinal products and instead publish the edited version of those documents. WLC maintains, inter alia, that the CBG's policy of full publication constitutes a direct infringement of Patent EP 061 as it offers pregabalin for sale for a patented indication and an indirect infringement in that it encourages third parties to engage in infringements. WLC also claims that the CBG's policy is contrary to Article 11 of Directive 2001/83.

22 By judgment of 15 January 2016, the rechtbank Den Haag (District Court, The Hague) upheld WLC's action concerning pregabalin and rejected the claims concerning other medicinal products due to insufficient interest. That court found that full publication of the package leaflet and the summary of product characteristics of a medicinal product does not constitute an infringement of Patent EP 061, and is incompatible with the CBG's duty of care.

23 On 11 February 2017, the Netherlands State filed an appeal against that judgment with the referring court. WLC also lodged a cross-appeal with that court.

24 After delivery of that judgment, the CBG changed its administrative practice. It publishes the full version of the package leaflet and the summary of product characteristics in its medicinal products database. However, when the holder of a marketing authorisation for a generic medicinal product informs the CBG that certain indications have been omitted, the CBG indicates this by means of an asterisk, together with the following text:

'* This indication is protected by a patent … of another marketing authorisation holder. Further information in this regard may be found on the CBG website, www.cbg-meb.nl.'

25 The referring court takes the view that the outcome of the dispute in the main proceedings depends on the interpretation of EU legislation on medicinal products, in particular, that of Article 11 of Directive 2001/83.

26 The parties to the main proceedings agree that that provision allows the applicant for marketing authorisation in respect of a generic medicinal product not to mention indications that are still covered by a patent in the package leaflet and the summary of product characteristics. On the other hand, their positions differ as to the consequences for the national authority of a declaration whereby a marketing authorisation applicant indicates that it intends to avail itself of that option and to opt for publication of an edited version.

27 In the first place, the parties in the main proceedings are in dispute as to whether notification of the intention to publish an edited version aims to limit the marketing authorisation in so far as it will not cover patented indications or dosage forms. If this is so, then the CBG should limit the marketing authorisation and publish the package leaflet and the summary of product characteristics in accordance with the applicant's wishes, in their edited version.

28 In the second place, WLC maintains that, in any event, notification of the intention to publish an edited version requires the national authority to publish the package leaflet and the summary of product characteristics omitting the redacted information, because their full publication is contrary to the objective of the EU legislature, which is to protect the interests of patent holders. Full publication would encourage general practitioners to prescribe generic versions of medicinal products for indications or dosage forms which are still patented.

29 In those circumstances, the Gerechtshof Den Haag (Regional Court of Appeal, The Hague, Netherlands) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Must Article 11 of Directive [2001/83] or any other provision of EU law be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicinal product, within the meaning of Article 10 of [that directive], notifies the competent authority that he does not intend to include in the summary of product characteristics or the package leaflet those parts of the summary of product characteristics of the reference medicinal product which refer to indications or dosage forms covered by the patent of a third party should be regarded as a request to limit the marketing authorisation, which must result in the marketing authorisation not applying, or no longer applying, to the patented indications or dosage forms?

(2) If the answer to Question 1 is in the negative, do Articles 11 and 21(3) of Directive [2001/83] or any other provisions of EU law preclude the competent authority from making public, by means of an authorisation granted under Article 6 in conjunction with Article 10 of [that directive], the summary of product characteristics and the package leaflet, including those parts which refer to indications or dosage forms covered by the patent of a third party, where the marketing authorisation applicant or holder has notified the authority that he does not intend to include in the summary of product characteristics or the package leaflet those parts of the summary of product characteristics of the reference medicinal product which refer to indications or dosage forms covered by the patent of a third party?

(3) Does it make any difference to the answer to Question 2 that the competent authority requires the authorisation holder to include in the package leaflet which the authorisation holder must insert in the packaging of the medicinal product a reference to the authority's website on which the summary of product characteristics is published, including the parts which refer to indications or dosage forms covered by the patent of a third party, even though, under Article 11 of Directive 2001/83, those parts to not have to be included in the package leaflet?'

Consideration of the questions referred

The first question

30 By its first question, the referring court asks, in essence, whether the second paragraph of Article 11 of Directive 2001/83 must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

31 It must be noted at the outset that, in accordance with the essential aims of Directive 2001/83, inter alia, that of safeguarding public health, Article 6(1), first subparagraph, of that directive 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 State in accordance with that directive or an authorisation has been issued in accordance with the centralised procedure provided for in Regulation No 726/2004 for the medicinal products referred to in the annex to that regulation (judgments of 29 March 2012, *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraph 26, and of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 53).

32 The principle of a mandatory marketing authorisation also applies, according to the second subparagraph of Article 6(1) of Directive 2001/83, when a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph of that provision, in so far as, in that case, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions are also to be granted an authorisation in accordance with that first subparagraph or be included in the initial marketing authorisation (judgment of 21 November 2018, *Novartis Farma*, C-29/17, EU:C:2018:931, paragraph 70).

33 Additionally, in order to verify whether a medicinal product meets the information needs of patients and health professionals, Article 8(3)(j) of Directive 2001/83 requires that the application for authorisation to place a medicinal product on the market be accompanied, inter alia, by a summary of the product characteristics, whose content is defined in Article 11 of that directive together with the package leaflet for the medicinal product concerned, which should be drawn up, under Article 59(1) of the directive, in accordance with the summary of the product characteristics. In that regard, Article 21(2) of Directive 2001/83 provides that 'the competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the marketing authorisation is issued or subsequently'.

34 It follows from those provisions, first, that the package leaflet and the summary of product characteristics form part of the marketing authorisation, second, that the medicinal product placed on the market must fulfil the conditions of the marketing authorisation, which must be reflected in the summary of product characteristics and, third, that the marketing authorisation holder may not amend the package leaflet or the summary of product characteristics without notifying the competent authority in order to obtain its approval.

35 In addition, in order to encourage the market entry of generic medicinal products, Article 10 of Directive 2001/83 provides for an abridged marketing authorisation procedure, by exempting marketing authorisation applicants for generic medicinal products, subject to compliance with certain conditions, of the duty to submit the results of pre-clinical tests and clinical tests.

36 Article 10(2)(b) of Directive 2001/83 requires that generic medicinal products have the same quantitative and qualitative composition in active substances and the same pharmaceutical form as the reference medicinal product and that its bioequivalence with the reference medicinal product has been demonstrated.

37 Taking into account that requirement that the reference medicinal product and the generic medicinal product covered by the abridged marketing authorisation procedure should be the same, the application for marketing authorisation of a generic medicinal product may not go beyond the indications covered by the marketing authorisation of the reference product, but must, in principle, be limited to those indications. Consequently, the summary of product characteristics accompanying the application for a marketing authorisation of a generic medicinal product cannot cover indications or dosage forms which are not consistent with those covered by the wording of the marketing authorisation of the reference product.

38 Those factors are corroborated by the fact that when, as in the case in the main proceedings, the marketing authorisation procedure for a generic medicinal product laid down in Article 10 of Directive 2001/83 concerns a reference medicinal product authorised by the centralised procedure provided for by Regulation No 726/2004, Article 3(3)(b) of that regulation expressly states that 'the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the [Union]'.

39 As an exception to that principle that the marketing authorisation of a generic medicinal product and that of a reference product must tally, the second paragraph of Article 11 of Directive 2001/83 provides, as regards applications for marketing authorisation of generic medicinal products, that 'those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included'.

40 That provision therefore confers on the applicant for a marketing authorisation of a generic medicinal product the option of derogating from the principle that the marketing authorisation of a generic medicinal product and that of a reference product must tally by reducing the scope of its application to indications or dosage forms which are not covered by patent law.

41 The rationale behind this exception is not to delay entry on the market of generic medicinal products until expiry of all patents which may include several indications or dosage forms of the reference medicinal product, without any relaxation of the requirements of safety and efficacy which must be met by generic medicinal products (see, to that effect, judgment of 23 October 2014, *Olainfarm*, C-104/13, EU:C:2014:2316, paragraphs 27 and 28).

42 Under a decentralised procedure, such as that at issue in the main proceedings, if the marketing authorisation applicant or holder for a generic product avails himself of the option provided for in Article 11 of Directive 2001/83, then the marketing authorisation for that product covers only the indications and dosage forms which are not patented.

43 It is clear from a combined reading of Article 8(3)(j) and the second paragraph of Article 11 of Directive 2001/83 that failure to include in the summary of product characteristics of a generic medicinal product certain indications or dosage forms of the marketing authorisation for the reference medicinal product means that those indications or dosage forms are not covered by the marketing authorisation application. By making use of the option given by the second paragraph of Article 11, the marketing authorisation applicant thus limits the scope of his application and the competent national authority does not have any discretion in that respect, as the Advocate General stated in point 57 of her Opinion.

44 Even though all the parties which submitted observations to the Court agree on that point, the Netherlands Government maintains that if the marketing authorisation holder of a generic product decides to make use of the option provided for in the second paragraph of Article 11 of Directive 2001/83, that decision has no effect on the scope of the marketing authorisation of the generic medicinal product.

45 However, such an interpretation of Directive 2001/83 is incompatible with the principle recalled in paragraph 34 of this judgment, according to which any medicinal product placed on the market must comply with marketing authorisation conditions, which must be reflected in the summary of product characteristics. In accordance with that principle, in circumstances such as those set out by the Netherlands Government, it will be for the competent national authority to amend the marketing authorisation in order to ensure it reflects the summary of product characteristics. The communication of a summary of product characteristics which does not include certain marketing authorisation indications constitutes the removal of therapeutic indications covered by minor type IB variations which are subject to the procedure laid down in Article 9 of Regulation No 1234/2008.

46 Contrary to the Netherlands Government's claims, that interpretation is not invalidated by the fact that it imposes on the marketing authorisation holder the responsibility of requesting a new variation of the authorisation when, upon expiry of the protection period by a patent of an indication covered by the marketing authorisation of the reference medicinal product, the holder wishes to add that indication to those already authorised for the generic product. In such a situation, the marketing authorisation holder may request a type II variation, in accordance with the procedure provided for in Article 10 of Regulation No 1234/2008.

47 In the light of all the foregoing considerations, the answer to the first question is that the second paragraph of Article 11 of Directive 2001/83 must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or a summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

The second and third questions

48 By its second and third questions, the referring court asks, in the event that the first question is answered in the negative, whether Article 11 of Directive 2001/83 must be interpreted as precluding publication by a national authority of a full version of the package leaflet or the summary of product characteristics of a generic medicinal product in respect of which the marketing authorisation holder has made use of the option given by that provision not to include certain indications or dosage forms in the package leaflet or summary of product characteristics of the medicinal product in question.

49 Having regard to the positive answer given to the first question, there is no need to answer those questions.

Costs

50 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 (Sixth Chamber) hereby rules:

The second paragraph of Article 11 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 by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or a summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

[Signatures]