Reports of Cases

OPINION OF ADVOCATE GENERAL
Szpunar
delivered on 30 June 2016 [1]

Case C-276/15

Hecht-Pharma GmbH
v
Hohenzollern Apotheke, owned by Winfried Ertelt

(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))

(Medicinal products for human use — Directive 2001/83/EC — Scope — Articles 2(1) and 3, points 1 and 2 — Medicinal products prepared industrially or manufactured by a method involving an industrial process — Exceptions — Medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia)

I – Introduction

1. The substance of (frank)incense has intrigued Europe for its spiritual, therapeutic and olfactory properties ever since one of the wise men, Melchior, sourced it from his native Arabia. [2] The case at issue in which a German pharmacy produces incense capsules and sells these to local patients is no exception to this, even though its facts are rather more mundane than the quest of the three wise men.

2. In the present preliminary reference from the Bundesgerichtshof (Federal Court of Justice), the Court is asked whether certain manufacturing activities of a pharmacy fall within or outside the scope of Directive 2001/83/EC [3]. Should the pharmacy's activity fall within the scope of Directive 2001/83, then a market authorisation would be needed, which is an arduous process that an individual pharmacy cannot possibly undertake successfully. Should it fall outside the scope of the directive, the pharmacy's product would exist alongside other products, which have been produced on an industrial scale, undergone the authorisation process and are marketed EU-wide.

1 — Original language: English.

2 — Matthew 2, 2-11, referring to the three wise men, writes: '… and when they had opened their treasures, they presented unto him gifts; gold, and frankincense and myrrh.' (King James Version).

3 — Directive 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 last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1).

II – Legal framework

A – *EU law: Directive 2001/83*

3. Article 2(1) of Directive 2001/83 provides:

‘This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.’

4. Article 3 of Directive 2001/83 is worded as follows:

‘This Directive shall not apply to:

1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).

2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula).

…’

5. According to Article 6(1) of Directive 2001/83

‘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)], read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use [OJ 2006 L 378, p. 1] and 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).’

6. Under Article 87(1) of Directive 2001/83:

‘Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Community law.’

B – *German law*

7. Paragraph 3a of the German Gesetz über die Werbung auf dem Gebiete des Heilwesens (Heilmittelwerbegesetz) (Law on the advertising of medicines: ‘the HWG’) contains a prohibition on advertising medicinal products that are not authorised. That provision establishes an advertising prohibition only in relation to medicinal products for which authorisation is required. The referring court points out that the advertising prohibition does not apply where the medicinal product does not require authorisation.

8. Pursuant to Paragraph 21(2), point 1, of the Arzneimittelgesetz (Law on medicinal products; 'AMG'), no authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing up to one hundred packages per day ready for dispensation and intended for supply within the framework of the existing pharmacy operating licence. [4]

III – Facts, procedure and questions referred

9. Hecht Pharma GmbH, [5] the applicant in the main proceedings, sells incense capsules in Germany as a food supplement under the designation 'H 15 Weihrauch' (H 15 incense). Mr Ertelt, the defendant in the main proceedings, owns a pharmacy, the Hohenzollern Apotheke where he manufactures incense capsules and sells these, as a medicinal product, under the designation 'Weihrauch-Extrakt-Kapseln' (incense extract capsules). He does not have a marketing authorisation for this medicinal product. The parties are agreed that the defendant manufactures the capsules as part of a normal pharmacy business and in compliance with the other requirements of point 1 of Paragraph 21(2) of the AMG.

10. The defendant promoted his 'incense extract capsules' in an 'information sheet for patients' and a brochure. The applicant complained that the promotional claims set out in those documents were contrary to (national) competition rules, claiming that these contravened the prohibition on advertising medicinal products that are not authorised. It applied for an injunction to restrain the defendant from promoting in the course of trade his pharmacy's medicinal product designated 'incense extract capsules: 100 capsules' and 'incense extract capsules: 200 capsules'.

11. The defendant contested the action, claiming that the prohibition on advertising medicinal products that are not authorised was not applicable in the present case. In the defendant's view, that prohibition is linked to the requirement of a marketing authorisation for the medicinal product advertised. However, the 'incense extract capsules' he advertised, as a medicinal product falling within the category of 'Defekturarzneimittel' in accordance with point 1 of Paragraph 21(2) of the AMG, do not, he contends, require authorisation.

12. The Landgericht (Regional Court) rejected the action for an injunction. The appellate court dismissed the applicant's appeal against that judgment. By the present appeal on a point of law ('Revision'), for which leave was granted by the Bundesgerichtshof (Federal Court of Justice), the applicant continues to pursue its claim in full. The defendant argues that the appeal should be dismissed.

13. The referring court is of the view that the outcome of the appeal depends on whether the 'incense extract capsules' medicinal product advertised by the defendant must be authorised under the law on pharmaceutical products. That in turn depends on the interpretation of points 1 and 2 of Article 3 of Directive 2001/83.

14. It is for this reason that, by order of 16 April 2015, received by the Court on 9 June 2015, the Bundesgerichtshof (Federal Court of Justice) referred the following questions for a preliminary ruling:

'(1) Do points 1 and 2 of Article 3 of Directive 2001/83 preclude a national provision such as point 1 of Paragraph 21(2) of the [AMG] according to which no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential

4 — Such medicinal products are known in German as 'Defekturarzneimittel'.

5 — Hereinafter referred to as 'Hecht Pharma'.

manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing up to one hundred packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence?

If Question 1 is answered in the affirmative:

(2) Does this conclusion also apply where a national provision such as point 1 of Paragraph 21(2) of the [AMG] is interpreted to mean that no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such are carried out in a pharmacy as part of the normal pharmacy business producing up to one hundred packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence, provided that the medicinal product is either supplied to an individual patient in accordance with a medical prescription, not necessarily submitted before the preparation of the medicinal product, or is prepared in the pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to patients?'

IV – Analysis

15. By its two questions, which should be examined together, the referring court, in essence, seeks to ascertain whether Article 3, points 1 or 2, of Directive 2001/83 preclude a pharmacy manufacturing medicinal products under the conditions of Paragraph 21(2), point 1, of the AMG.

16. Despite the fact that it is not apparent from the text of Directive 2001/83 or from systematic or teleological considerations relating to the interpretation of that directive,[6] the Court has now clarified in *Abcur* that 'in order to fall within the scope of Directive 2001/83, the product in question, firstly, must satisfy the conditions laid down in Article 2(1) of that directive and, secondly, must not fall within one of the exceptions expressly provided for in Article 3 of that directive'.[7]

17. As a consequence, just as in *Abcur*,[8] the questions of the referring court should be extended so as to include Article 2 of Directive 2001/83 in the analysis.[9]

A – *On Article 2(1) of Directive 2001/83*

18. By virtue of Article 2(1) of Directive 2001/83, that directive applies to medicinal products 'prepared industrially or manufactured by a method involving an industrial process'.

19. Directive 2001/83 does not define the concepts of 'prepared industrially' and 'manufactured by a method involving an industrial process'.[10] The Court has clarified in *Abcur* that those terms must 'include, at the very least, any preparation or manufacture involving an industrial process' and that 'such a process is characterised in general by a succession of operations, which may, in particular, be mechanical or chemical, in order to obtain a significant quantify of a standardised product'.[11]

6 — See my Opinion in Joined Cases *Abcur* (C-544/13 and C-545/13, EU:C:2015:136, points 23 to 29).

7 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 39).

8 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 36)

9 — I note, incidentally, that the referring court itself refers to Article 2 of Directive 2001/83 in its order for a preliminary reference.

10 — See also judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 44).

11 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 50).

Accordingly, the Court found that 'the standardised production of significant quantities of a medicinal product to be stocked and sold wholesale and the large-scale or serial production of magistral formulae in batches [were] characteristic of industrial preparation or manufacture by a method involving an industrial process'. [12]

20. In *Abcur*, a pharmaceutical laboratory produced medicinal products on a large scale. Consequently, the Court held that the products in question fell within the scope of Article 2 of Directive 2001/83. [13]

21. By contrast, I would submit that the circumstances of the case in the main proceedings are clearly distinct from those in *Abcur* and that, in casu, we are not dealing with medicinal products 'prepared industrially or manufactured by a method involving an industrial process'.

22. First, as the German Government points out, the products in question are essentially the result of an exercise of individual craftsmanship, which is not akin to 'standardised production' and which is, moreover, subject to strict protocol requirements. [14]

23. Secondly, German law [15] limits production to 100 packages per day ready for dispensation. This is, in my view, no 'significant quantity'. In any event, this upper limit will rarely be attained, as the case at issue demonstrates. According to Hohenzollern Apotheke, in 2015 merely 213 packages were dispensed. A pharmacy selling this number of packages will, typically, not produce far more than that.

24. Thirdly, the fact that the manufacturing has to occur in the context of the regular running of the pharmacy points to the fact that it is limited in scope. It should not be forgotten that a pharmacy principally sells products manufactured elsewhere.

25. I do not, therefore, see the requirements of Article 2 of Directive 2001/83 as being fulfilled. Ergo, the medicinal products in question do not fall within the scope of the directive.

26. In my view, the case should end here and the referring court should be told that Directive 2001/83, in particular Article 2 thereof, does not preclude a pharmacy manufacturing medicinal products under the conditions of Paragraph 21(2), point 1, of the AMG.

27. Should the Court, however, be of the opinion that the requirements of Article 2 of Directive 2001/83 are fulfilled, then Article 3 of that directive needs to be examined. What follows is, therefore, offered on this hypothetical basis only.

28. Article 3 contains a number of exceptions to the applicability of the directive. The referring court is unclear as to whether points 1 or 2 of Article 3 of the directive are relevant for the case at issue.

12 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 51).

13 — Judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 52). Needless to add that the Court specified, as it tends to do, that this was a question of fact, the establishment of which ultimately fell to the referring court.

14 — See Paragraph 8(1) and (2) of the Verordnung über den Betrieb von Apotheken (Apothekenbetriebsordnung) (Regulation on the operation of pharmacies: 'the ApBetrO').

15 — Paragraph 21(2), point 1, of the AMG.

B – *On Article 3, point 1, of Directive 2001/83*

29. Pursuant to Article 3, point 1, of Directive 2001/83, the directive is not to apply to any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula). Those conditions are cumulative, so that the exception provided for in Article 3, point 1, of Directive 2001/83 cannot apply if one of them is not satisfied. [16] By virtue of Article 1(19) of Directive 2001/83, a 'medical prescription' is issued by a professional person qualified to do so.

30. Given the lack of such medical prescription and the unambiguous wording of Article 3, point 1, of Directive 2001/83, I would assume that this provision is not applicable in the case at issue. In this connection, I do note that neither Ireland or Finland considers that Article 3, point 1, requires the preparation of magistral formula only after a clinician has drawn up a prescription for an individual patient. However, as I have argued previously, I find the wording of Article 3, point 1, sufficiently clear to imply that a patient must be identified before the medicinal product is produced. [17]

31. Article 3, point 1, of Directive 2001/83 is, therefore, not applicable to the case at issue.

C – *On Article 3, point 2, of Directive 201/83*

32. Let us, therefore, turn to Article 3, point 2, of Directive 2001/83.

33. According to this provision, the directive is not to apply to any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula). Those conditions are also cumulative so that the exception provided for in that provision cannot be applied if one of them is not satisfied. [18]

34. The only requirement which merits closer examination is that of 'in accordance with the prescriptions of a pharmacopeia', for the other requirements of Article 3, point 2, are, in my view, clearly fulfilled.

35. The referring court is uncertain as to whether point 1 of Paragraph 21(2) of the AMG is compatible with EU law because the German provision does not require the medicinal product manufactured in a pharmacy to be prepared in accordance with a pharmacopoeia.

36. Yet, the German Government stresses that pursuant to Paragraph 21(2), point 1, of the AMG, manufacturing must take place within the framework of the existing pharmacy operating licence. In addition, while Paragraph 21(2), point 1, of the AMG does not require such medicinal products to be prepared in accordance with the requirements of a pharmacopoeia, Paragraph 6(1) of the ApBetrO specifies the following: medicinal products produced in a pharmacy must be produced in accordance with the quality of pharmaceutical science [19] and must be manufactured and checked according to recognised pharmaceutical rules, and if the pharmacopoeia contains rules, such rules have to be complied with. [20] Paragraph 55 of the AMG in turn stipulates that 'the Pharmacopoeia is a collection

16 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 59).

17 — See my Opinion in Joined Cases *Abcur* (C-544/13 and C-545/13, EU:C:2015:136, point 47).

18 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 66).

19 — See Paragraph 1 of the provision.

20 — See Paragraph 2 of the provision.

of recognised pharmaceutical rules regarding the quality, testing, storage, dispensing and designation of medicinal products and the substances used in their manufacture, published by the Federal Institute for Drugs and Medical Devices in agreement with the Paul Ehrlich Institute and the Federal Agency for Consumer Protection and Food Safety'. [21]

37. Moreover, as the German Government correctly points out, the term 'pharmacopoeia' is neither defined in Directive 2001/83 nor in other acts of secondary law. Nor, has it been, to my knowledge, defined by the Court. A pharmacopoeia (etymologically, 'drug-making'), in its modern technical sense, is, as is also reflected in the abovementioned Paragraph 55 of the AMG, a book containing directions for the identification of compound medicines, and published by the authority of a government or a medical or pharmaceutical society. [22] The most prominent one in Europe, which is also repeatedly referred to in the context of Directive 2001/83 is the European Pharmacopeia, administered by the European Directorate for the Quality of Medicines and Healthcare (EDQM), a directorate of the Council of Europe in Strasbourg. [23]

38. As regards the case at issue, Hohenzollern Apotheke stresses that there are relevant rules contained, inter alia, in the Council of Europe's European Pharmacopoeia which it complies with in the manufacturing of its incense capsules. Therefore, the requirements of Article 3, point 2, of Directive 2001/83 are complied with as far as the activities at issue of Hohenzollern Apotheke are concerned.

39. As regards the wider question whether the cited German provisions also comply with Article 3, point 2, in general, I should like to stress the following: given that since *Abcur* the Court seems to assume that Article 3, point 2, of Directive 2001/83 applies to medicinal products fulfilling the requirements of Article 2 of that directive ('prepared industrially or manufactured by a method involving an industrial process'), [24] then the requirement of the 'prescriptions of a pharmacopoeia' should be interpreted strictly in accordance with its literal meaning, in particular as Article 3 of Directive 2001/83 is an exception to a general rule. [25]

40. Therefore, the wording 'in accordance with the prescriptions of a pharmacopoeia' implies that if such prescriptions exist they imperatively need to be followed. If they do not exist, I would have difficulty in accepting that this requirement for products that are 'prepared industrially or manufactured by a method involving an industrial process' to be excepted from the directive, under Article 3, can be simply dispensed with.

41. It will be for the referring court to interpret the German provisions in light of this finding. The requirement of following the prescriptions of a pharmacopoeia cannot, however, be disregarded in the context of such interpretation.

42. Moreover, such an interpretation is fully in line with the overarching objective of Directive 2001/83, which is the protection of public health. [26] The German provisions have within them sufficient safeguards to protect that public health objective. Finally, the medicinal products in question are to be supplied directly to patients. Such local and direct supplies do not interfere with the internal market logic underpinning the directive. [27]

21 — See Paragraph 55(1), first sentence, of the AMG, in the form of the translation provided by the Language Service of the German Federal Ministry of Health, available at: https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1223.

22 — See https://en.wikipedia.org/wiki/Pharmacopoeia.

23 — See https://www.edqm.eu/.

24 — See point 17 of this Opinion and judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 39). As is known, I think matters are less straightforward than that, see my Opinion in Joined Cases *Abcur* (C-544/13 and C-545/13, EU:C:2015:136, points 23 to 29).

25 — See judgment of 16 July 2015 in *Abcur* (C-544/13 and C-545/13, EU:C:2015:481, paragraph 54 and the case-law cited).

26 — See recital 2 of the directive.

27 — See recital 3 of the directive.

43. In conclusion, Article 3, point 2, of Directive 2001/83 does not preclude a pharmacy manufacturing medicinal products under the conditions of Paragraph 21(2), point 1, of the AMG.

D – *On advertising*

44. The referring court is, in my view, correct in assuming that the provisions of Directive 2001/83 concerning the requirement of a marketing authorisation pursuant to Article 6(1) of the directive and the advertising prohibition pursuant to Article 87(1) of the directive apply only to medicinal products that satisfy the requirements of Article 2(1) of the directive and are not excepted from the scope of the directive by Article 3 of the directive.

45. Article 87(1) of Directive 2001/83, by virtue of which Member States are to prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted in accordance with Union law is immaterial to the case at issue, for it does not apply to medicinal products falling outside the scope of Directive 2001/83. In *Ludwigs-Apotheke*, the Court held that medicinal products covered by a provision of the AMG were excluded from the scope of Directive 2001/83 and that, accordingly, the provisions of Title VIII, on advertising, of that directive were not applicable to them. [28]

46. This finding is without prejudice to other possible restrictions stemming from EU law. In this context, I should, in particular like to stress that, in a situation, such as in the case at issue, where Directive 2001/83 is not applicable, the (general) Directive 2006/114/EC [29] is still applicable. [30]

V – Conclusion

47. In the light of the above considerations I propose that the Court should answer the questions of the Bundesgerichtshof (Federal Court of Justice) as follows:

(1) Article 2(1) 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 last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, does not preclude a national law such as Article 21(2), point 1, of the Arzneimittelgesetz (Law on medicinal products), according to which no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing up to one hundred packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence.

(2) Should the Court not follow the interpretation proposed under the previous point and consider the requirements of Article 2(1) of Directive 2001/83 to be fulfilled, then Article 3, point 2, of Directive 2001/83 does not preclude a national law such as Article 21(2), point 1, of the Arzneimittelgesetz (Law on medicinal products), according to which no marketing authorisation is required for medicinal products that are intended for administration to humans and, on account of the proven frequency with which they are the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy

28 — See judgment of 8 November 2007 in *Ludwigs-Apotheke* (C-143/06, EU:C:2007:656, paragraph 23). See also my Opinion in Joined Cases *Abcur* (C-544/13 and C-545/13, EU:C:2015:136, point 78).

29 — Directive of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (codified version) (OJ 2006 L 376, p. 21).

30 — See my Opinion in Joined Cases *Abcur* (C-544/13 and C-545/13, EU:C:2015:136, points 75 to 83).

as part of the normal pharmacy business producing up to one hundred packages per day ready for dispensation and intended for supply under the existing pharmacy operating licence, provided that the prescriptions of a pharmacopoeia are complied with.