OPINION OF ADVOCATE GENERAL MENGOZZI
delivered on 15 June 2010 [1]

I — Introduction

1. In this case, the Court is asked to clarify the scope of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('the Directive on electronic commerce'), [2] then to give effect once again to its *Keck and Mithouard* [3] case-law by ruling on whether a prohibition on Internet sales of contact lenses is compatible with the Treaty provisions on the free movement of goods.

II — Legal framework

A — *Primary European Union law*

2. Article 28 EC states that '[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.'

3. Article 30 EC provides that '[t]he provisions of Articles 28 [EC] and 29 [EC] shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

1 — Original language: French.
2 — OJ 2000 L 178, p. 1.
3 — Joined Cases C-267/91 and C-268/91 [1993] ECR I-6097.

B — *Secondary European Union law*

4. Article 1(2) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, [4] as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 [5] ('Directive 98/34'), defines Information Society services, as they are to be understood for the purposes of that directive, as follows:

"'service": any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

— "at a distance" means that the service is provided without the parties being simultaneously present,

— "by electronic means" means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,

— "at the individual request of a recipient of services" means that the service is provided through the transmission of data on individual request.

An indicative list of services not covered by this definition is set out in Annex V.

…'

5. Recital 18 in the preamble to the Directive on electronic commerce states inter alia that 'activities which by their very nature cannot be carried out at a distance and by electronic means, such as the statutory auditing of company accounts or medical advice requiring the physical examination of a patient are not information society services'.

4 — OJ 1998 L 204, p. 37.
5 — OJ 1998 L 217, p. 18.

6. Recital 21 states that 'the coordinated field covers only requirements relating to on-line activities such as on-line information, on-line advertising, on-line shopping, on-line contracting and does not concern Member States' legal requirements relating to goods such as safety standards, labelling obligations, or liability for goods, or Member States' requirements relating to the delivery or the transport of goods, including the distribution of medicinal products'.

7. Article 1(3) of the Directive on electronic commerce provides that '[t]his Directive complements Community law applicable to information society services without prejudice to the level of protection for, in particular, public health and consumer interests, as established by Community acts and national legislation implementing them in so far as this does not restrict the freedom to provide information society services'.

8. Article 2(a) of the Directive on electronic commerce defines information society services as 'services within the meaning of Article 1(2) of Directive 98/34/EC as amended by Directive 98/48/EC'.

9. Article 2(h) of the Directive on electronic commerce defines the coordinated field as 'requirements laid down in Member States' legal systems applicable to information society service providers or information society services, regardless of whether they are of a general nature or specifically designed for them.'

10. Article 2(h)(i) of that directive provides:

'The coordinated field concerns requirements with which the service provider has to comply in respect of:

— the taking up of the activity of an information society service, such as requirements concerning qualifications, authorisation or notification,

— the pursuit of the activity of an information society service, such as requirements concerning the behaviour of the service provider, requirements regarding the quality or content of the service including those applicable to advertising and contracts, or requirements concerning the liability of the service provider.'

11. Article 2(h)(ii) of the same directive continues:

'The coordinated field does not cover requirements such as:

— requirements applicable to goods as such,

— requirements applicable to the delivery of goods,

— requirements applicable to services not provided by electronic means.'

12. Article 4 of the Directive on electronic commerce first provides, in paragraph 1, that 'Member States shall ensure that the taking up and pursuit of the activity of an information society service provider may not be made subject to prior authorisation or any other requirement having equivalent effect', then states, in paragraph 2, that '[p]aragraph 1 shall be without prejudice to authorisation schemes which are not specifically and exclusively targeted at information society services'.

C — *Hungarian legislation*

13. Article 1(3) of Law CVIII of 2001 on electronic commerce and information society services (A elektronikus kereskedelmi szolgáltatások, valamint az információs társadalommal összefüggő szolgáltatásokról szóló 2001. évi CVIII. Törvény, 'Law CVIII of 2001') states that '[t]he scope of this Law shall not extend to information society services provided and used in any court or official proceedings, and shall not affect the application of legislation on the protection of personal data'. Article 1(4) continues: '[t]he scope of this Law shall not extend to communications made by a person for purposes outside their business or professional activities, or their public duties, using information society services, including contractual statements made in that way'.

14. Article 3(1) of that law states that '[n]o prior authorisation or official decision having equivalent effect shall be required in order to take up or pursue the activity of an information society services provider'.

15. Article 1 of Order 7/2004 (XI. 23.) of the Ministry of Health on the technical requirements relating to the sale, repair and hiring of medical devices (A gyógyászati segédeszközök forgalmazásának, javításának, kölcsönzésének szakmai követelményeiről szóló 7/2004 (XI. 23.) Egészségügyi Minisztériumi rendelet, 'Order 7/2004') provides that 'without prejudice to the requirements concerning the medical devices listed in Annex 1, this Order shall apply to pursuit of the activities of selling, repairing and hiring out any medical device, of delivering such device, and of manufacturing customised medical devices. … The sale, repair and hiring out of medical devices covered by this Order shall be deemed health services'.

16. Article 2 of the same order provides:

'For the purposes of this Order:

(a) "medical device" means a technical medical or care device held by a person who, temporarily or permanently, suffers from poor health, a handicap or a disability,

…'

17. Under Article 3(1) of Order 7/2004, '[m]edical devices may be sold, repaired and hired … in a specialist shop which has an operating licence under a separate provision and which satisfies the conditions laid down in points I.1 and I.2. of Annex 2 to this Order'.

18. Article 4(5) of Order 7/2004 governs home delivery as follows:

'The following may be delivered to the customer's home:

(a) a repaired mass-produced medical device,

(b) a medical device used for trial and/or fitting purposes, or custom-made solely in order to facilitate trial and familiarisation, for purposes of use by the final customer.'

19. Annex 1 to that order expressly states:

'The following medical devices are excluded from the scope of this Order:

…

— mass-produced optical products, with the exception of contact lenses;

…'

20. In addition, Annex 2 to Order 7/2004 lays down two of the specific conditions referred to in Article 3(1). Point I.1(d) of that annex provides, among the substantive conditions which must be satisfied, that '[a] shop covering at least 18 m^2 or premises separated from the workshop are necessary for the sale of contact lenses and custom-made spectacles'. For its part, point I.2(c) of that annex lays down one of the conditions relating to staff, since, in order to sell contact lenses, a person is required to 'practise as an optometrist or ophthalmologist qualified in the field of contact lenses'.

III — Main proceedings and questions referred for a preliminary ruling

21. Ker-Optika Bt. ('Ker-Optika' or 'the applicant in the main proceedings') is a limited partnership governed by Hungarian law, which, among other activities, sells contact lenses via its Internet site.

22. On 29 August 2008, Ker-Optika was the subject of an administrative decision adopted by the ÀNTSZ Pécsi, Sellyei, Siklósi Kistérségi Intézete, the district office of the ÀNTSZ, in other words the National Public Health and Duty Doctor Service, prohibiting it from selling contact lenses on the Internet.

23. Ker-Optika lodged an objection before the ÀNTSZ Dél-dunántúli Regionális Intézete, the regional office of the abovementioned service, which, in a decision dated 14 November 2008, dismissed the objection and upheld the prohibition imposed by the district establishment on Ker-Optika, basing its decision on Article 3(1) of Order 7/2004. Order 7/2004 was considered therefore to preclude the sale of contact lenses by electronic means, since it required, on the contrary, that contact lenses be sold in a specialist optical goods shop satisfying the conditions, both substantive and personal, to which Article 3(1) of that order refers.

24. Objecting to that interpretation, the effect of which is that part of its business was prohibited, Ker-Optika brought an action before the Baranya Megyei Bíróság (Baranya Regional Court) (Hungary) for annulment of the decision of the regional office of the National Public Health and Duty Doctor Service.

25. Before the referring court, the applicant in the main proceedings argued that, firstly, the sale of contact lenses constituted an information society service and that, in that regard, the decision at issue was therefore contrary to Article 3(1) of Law CVIII of 2001, under which no prior authorisation or official decision having equivalent effect is required in order to commence or continue the provision of information society services. Secondly, it argued that, since Order 7/2004 allows the home delivery of medical devices, the Internet sale of contact lenses should be permitted.

26. For its part, the defendant in the main proceedings relied on the Directive on electronic commerce, in particular Recital 18 in the preamble. In its view, the sale of contact lenses is an activity which cannot be carried out at a distance since it can be considered equivalent to medical advice which requires a physical examination of the patient, and therefore falls outside the scope of that directive. Accordingly, the provisions of Law CVIII of 2001, which transposes the Directive on electronic commerce into Hungarian law, cannot apply to the activity at issue in the main proceedings.

27. Faced with a difficulty in interpreting European Union law, the Baranya Megyei Bíróság decided to stay the proceedings and, by order for reference dated 10 February 2009, submitted to the Court, pursuant to Article 234 EC, the following three questions for a preliminary ruling:

'(1) Does the sale of contact lenses constitute medical advice requiring the physical examination of a patient and thus not fall within the scope of [the] Directive [on electronic commerce]?

(2) If the sale of contact lenses does not constitute medical advice requiring the physical examination of a patient, must Article 30 EC be interpreted as precluding legislation of a Member State under which contact lenses may be sold only in specialist medical device shops?

(3) Does the principle of the freedom of movement of goods laid down in Article 28 EC preclude the provision of Hungarian law which makes it possible to sell contact lenses solely in specialist medical device shops?'

28. In essence, the referring court is asking the Court first and foremost to consider whether the activity at issue in the main proceedings falls under the Directive on electronic commerce and only if the answer is in the negative does it then raise a question

concerning the interpretation of primary European Union law. It is particularly in the latter event that the issue of the application of the abovementioned *Keck and Mithouard* case-law could arise.

at issue is covered by the Directive on electronic commerce and whether, therefore, the compatibility of Order 7/2004 with European Union law must be determined in the light of that directive.

IV — Procedure before the Court

29. Written observations have been submitted by the Czech, Greek, Spanish, Hungarian and Netherlands Governments, and by the European Commission.

30. At the hearing held on 15 April 2010 the Greek, Spanish, Hungarian and Netherlands Governments and the Commission made their observations orally.

V — The first question referred for a preliminary ruling

31. In asking the Court to decide whether the sale of contact lenses constitutes medical advice requiring the physical presence of the patient, the referring court is seeking first and foremost to ascertain whether the activity

32. Order 7/2004, which is at issue in the main proceedings, allows the sale of contact lenses — regarded in Hungarian law as a medical device — only in specialist shops or premises separated from the workshop covering at least 18 m^2 and by persons practising as optometrists or ophthalmologists. Consequently, Internet sales of that type of product are prohibited. However, the referring court points out that home delivery for use by the final customer of medical devices covered by that order, which therefore include contact lenses, is permitted, subject to compliance with the conditions laid down by that order. [6]

33. Even before considering further whether the sale of contact lenses is equivalent to medical advice requiring the physical presence of the patient, the first question,

6 — In its reply to the written question, the Hungarian Government points out that 'it is possible to deliver [contact lenses] to the customer's home for purposes of use by the final customer only in order to facilitate trial and familiarisation', which gives grounds for assuming that delivery can be carried out only by qualified personnel (see point 7 of the reply to the question put to the Hungarian Government).

which must be read together with the second and third questions, seems to me designed to establish whether the compatibility with European Union law of national legislation which has the effect of excluding a particular category of goods from sale via the Internet must be determined solely in the light of the Directive on electronic commerce.

34. The Directive on electronic commerce seeks to contribute to the proper functioning of the internal market by creating, in that field, a legal framework designed to ensure the free movement of information society services between the Member States. As its title indicates, that directive concerns only 'certain' legal aspects of information society services, and, as Article 1(2) makes clear, the directive seeks to approximate only 'certain national provisions on information society services relating to the internal market, the establishment of service providers, commercial communications, electronic contracts, the liability of intermediaries, codes of conduct, out-of-court dispute settlements, court actions and cooperation between Member States'.

35. Thus, even though it is widely supposed that the Directive on electronic commerce is the one which has enabled intra-Community electronic commerce to develop, the directive itself merely regulates certain stages of that commerce by virtue of which it takes place, by providing a legal framework for those stages, but does not contemplate the potential conditions relating to the movement of goods to which it could give rise. Moreover, the emphasis in that directive is on 'services' and not 'goods'.

36. In other words, it would be wrong to consider that the Directive on electronic commerce is aimed at a general liberalisation of electronic trade in goods. No obligation may be inferred from any of its provisions for Member States to permit, on a general and systematic basis, the Internet sale of any type of goods. Moreover, my feeling seems to me to be borne out by an analysis of the field coordinated by that directive.

37. If the Court were nevertheless to decide to pursue further the analysis of the Directive on electronic commerce, there would, in my view, still be at least two reasons capable of substantiating the fact that the compatibility of Order 7/2004 with European Union law cannot be assessed in the light of the Directive on electronic commerce. On the one

hand, this can be inferred from the definition of the coordinated field given by that directive. On the other, the sale of contact lenses does not seem to me to be capable of being characterised, in all its aspects, as an 'information society service' within the meaning of the Directive on electronic commerce.

38. In the first place, with regard to the coordinated field, the objective pursued by that directive, mentioned in point 34 of this Opinion, does not permit the inference that a prohibition on Internet sales can be examined in the light of the Directive on electronic commerce.

39. Furthermore, by defining inter alia the circumstances in which contact lenses may be sold and distributed to final customers, and by incidentally prohibiting Internet sales, and therefore home delivery which, as a general rule, is characteristic of that method of marketing, where it does not arise in the circumstances laid down by Order 7/2004 (that is to say, solely in order to facilitate trial, fitting or familiarisation), that order does indeed organise the detailed arrangements for their delivery in the broad sense. The sale of contact lenses as organised by that order does not, therefore, seem to me, on any view, to form part of the field coordinated by the Directive on electronic commerce.

40. Even though, initially, Recital 18 provides that '[i]nformation society services span a wide range of economic activities which take place on-line' and that 'these activities can, in particular, consist of selling goods on-line', it immediately goes on to state that 'activities such as the delivery of goods as such or the provision of services off-line are not covered'. As for Recital 21, it clearly provides that 'the coordinated field covers only requirements relating to on-line activities such as on-line information, on-line advertising, on-line shopping, on-line contracting and does not concern Member States' legal requirements relating to goods such as safety standards, labelling obligations, or liability for goods, or Member States' requirements relating to the delivery or the transport of goods, including the distribution of medicinal products'.

41. As the Czech and Netherlands Governments pointed out in their written observations, the definition of the coordinated field, as set out in Article 2(h)(ii) of the Directive on electronic commerce, reiterates that fundamental exclusion from the scope of the directive of requirements applicable to goods as such and to their delivery. In so doing, it is also aimed at reiterating that, while that directive 'covers only requirements relating to

on-line activities such as on-line information, on-line advertising, on-line shopping, on-line contracting', it is therefore certainly the case that it is intended to govern certain aspects of commerce which may arise on-line, but not to determine whether such types of activity or transaction must be open to Internet commerce. The directive therefore does not lay down the circumstances in which Internet sales of a particular category of goods may legitimately be prohibited.

42. In the second place, and in addition to the analysis of the provisions on the coordinated field, the reference to the concept of 'information society service' is a further factor which supports my conclusion that the reliance on the Directive on electronic commerce in the case at issue in the main proceedings is inappropriate.

43. That directive is intended to apply, not to all services, but only to that particular category consisting of information society services. If, under the Hungarian legislation, the sale of contact lenses constitutes a health service — which, in any event, is only a purely national classification –, the definition, given by the European Union legislation, of an information society service does not in fact appear capable of being applied to that particular activity.

44. As defined in Directive 98/34, 'information society service' means 'any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services'.[7] The definition given further indicates that '"by electronic means" means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means'.

45. Contrary to what is maintained by the Hungarian Government, I think that the sale of contact lenses, in itself, is perfectly capable of being carried out at a distance or via the Internet. That finding clearly necessitates acceptance of the separation between the phase of medical advice, which may be required before contact lenses are issued, and the actual sale of those lenses.

46. However, even by separating the medical advice from the sale of contact lenses, it does not seem to me to be possible to consider that the sale of contact lenses constitutes, in itself and with respect to each of its stages,

7 — See point 4 of this Opinion.

a service 'entirely transmitted, conveyed and received' by the means stated in the Directive on electronic commerce, contrary to what the Commission maintains. Although the order for lenses, its acceptance and the creation of the resulting on-line purchase contract may possibly be transmitted by electronic means, the fact remains that the conveyance of the contact lenses to the final customer takes the form, not of an electronic, but of a physical operation. It is at this stage of the argument that the distinction drawn by Recital 18 in the preamble to that directive, between information society services and the activities organised by them, takes on its full significance.

47. Finally, I recall that, in *Dynamic Medien*, [8] concerning the prohibition on the sale in Germany via the Internet of image storage media that had not been examined and classified by a competent national authority for the purpose of protecting young persons, as required by the German rules, I referred to the Court's settled case-law according to which, where the national rules adopted in a particular field are the subject of exhaustive harmonisation at European Union level, they must be assessed in the light of the harmonising measure and not of primary law. [9] I inferred from this that, whilst it was acknowledged that some aspects of the sale of image storage media might fall within the scope of the Directive on electronic commerce, it was nevertheless legitimate to enquire which specific provision in the directive in question was deemed to implement the exhaustive harmonisation of domestic legislation on the protection of young persons that would preclude verification of the prohibition's compatibility with the relevant provisions of the Treaty. [10] The Court did in fact follow that approach. [11]

48. What enabled me to draw that conclusion, namely, that certain aspects of the activity in question might fall within the scope of the Directive on electronic commerce, was that, at an earlier stage, the national legislation accepted the principle of the Internet sale of image storage media. The situation in the present case is quite different.

8 — Case C-244/06 [2008] ECR I-505.

9 — See point 21 of my Opinion in *Dynamic Medien*, cited above, and judgments in Case 150/88 *Eau de Cologne & Parfümerie-Fabrik 4711* [1989] ECR 3891, paragraph 28; Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9; Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32; Case C-99/01 *Linhart and Biffl* [2002] ECR I-9375, paragraph 18; and Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 64.

10 — See point 24 of my Opinion in *Dynamic Medien*, cited above.

11 — See judgment in *Dynamic Medien*, cited above, paragraphs 22 and 23.

49. Consequently, in order to accept that certain aspects of the sale of contact lenses are covered by the Directive on electronic commerce, it would first be necessary for Internet sales of contact lenses to be permitted. However, as I have attempted to show, it is very difficult to identify, within that directive, any rules harmonising national provisions which would permit reliance on the provisions of that directive as the grounds for a review by the Court of the compatibility with European Union law of the national legislation at issue in the main proceedings, which, I reiterate, has the effect of prohibiting Internet sales of contact lenses.

50. Moreover, a similar finding is dictated by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, [12] a term which covers contact lenses, since it does not lay down any conditions relating to the method by which they are marketed, sold or delivered.

51. I therefore propose that the Court answer the first question raised by the referring court, as reinterpreted in point 33 of this Opinion, that the compatibility with European Union law of national legislation which has the effect of prohibiting the Internet sale of contact lenses cannot be determined in the light of the provisions of the Directive on electronic commerce. The question whether the sale of contact lenses is medical advice requiring the physical presence of the patient, for the purposes of Recital 18 in the preamble to that directive, is therefore irrelevant.

52. Consequently, in the absence of any harmonising measure relevant to the resolution of the dispute in the main proceedings, Order 7/2004 must be assessed by reference to primary European Union law, [13] which is precisely the subject of the subsequent two questions referred for a preliminary ruling.

VI — The second and third questions referred for a preliminary ruling

A — *Introductory remark*

53. As a preliminary point, if the logical sequence of the questions raised by the referring court is considered, it is necessary first and foremost to determine whether the

12 — OJ 1993 L 169, p. 1.

13 — *Dynamic Medien*, cited above, paragraph 23.

compatibility with European Union law of the national legislation must be assessed in the light of Article 28 EC, and then to establish whether that national legislation may possibly be justified under Article 30 EC.

B — *Legal analysis*

1. Preliminary remarks

54. Where a national measure relates to both the free movement of goods and freedom to provide services, the Court will in principle examine it in relation to one only of those two fundamental freedoms if it appears that one of them is entirely secondary in terms of its relevance in relation to the other and may be considered together with it. [14]

55. The Hungarian Government submits that the sale of contact lenses, as the Court pointed out in *LPO*, [15] is not a commercial activity like any other and cannot be considered separately from the health services which are provided at the time of its occurrence. It further infers from the judgment in *Dollond and Aitchison* [16] that the Court has already accepted that the services relating to contact lenses are inseparable from their sale.

56. However, I remain convinced that the two activities, namely the sale of contact lenses, on the one hand, and any consultations which may take place in connection with it, on the other, are entirely separable.

57. Reliance on the judgment in *Dollond and Aitchison* does not seem at all appropriate to me because the question which the Court had to consider in that case is profoundly different from that raised in this case. In that judgment, the Court was required to rule on the methods of accounting for value added tax on a supply offered by a Community undertaking, consisting in the supply of contact lenses and of services consisting inter alia of eye tests. The Court was not asked to rule on whether it was necessary to consider the two activities together as a matter of course.

14 — Case C-275/92 *Schindler* [1994] ECR I-1039, paragraph 22; Case C-71/02 *Karner* [2004] ECR I-3025, paragraph 46; and Case C-20/03 *Burmanjer and Others* [2005] ECR I-4133, paragraph 35.

15 — Case C-271/92 [1993] ECR I-2899, paragraph 11.

16 — Case C-491/04 [2006] ECR I-2129, paragraph 35.

Consequently, and contrary to what the Hungarian Government claims, the Court is not bound for the future as regards the inseparability of those activities in the context of that judgment.

58. Furthermore, the Hungarian Government was invited at the hearing to clarify the conditions under which the health service — which is what that government considers the sale of contact lenses to be — is in principle provided. While, invariably, a medical prescription must be obtained prior to the sale, the other health services do not necessarily accompany the sale, and the nature of any medical formalities which may accompany it varies considerably depending on the stages of the sale under consideration.

59. Once the separation of those operations is admitted, it becomes fairly clear that the compatibility of Order 7/2004 with European Union law must be examined by reference to the Treaty provisions relating to the free movement of goods. Moreover, the Hungarian Government does not appear to dispute the existence of restrictions on the sale of contact lenses to patients.[17] Furthermore, it should be pointed out that the Court, when it was required to assess the compatibility of a measure prohibiting the sale by mail order of image storage media,[18] or, even closer to this case, the Internet sale of medicinal products,[19] relied on the principle of the free movement of goods.

2. Existence of a measure having an effect equivalent to a quantitative restriction on imports

60. The question which then arises is whether the prohibition on the sale of contact lenses which results from the legislation at issue in the main proceedings is contrary to Article 28 EC.

61. Order 7/2004 does not impose any requirements to be met by contact lenses,[20] but merely states that sales must take place in a specialist shop complying with the requirements relating to minimum floor area and qualified staff, or, where appropriate, by home delivery for purposes of trial or fitting, but under no circumstances via the Internet. It does therefore specify the selling arrangements for that type of goods.

17 — See point 34 of the written observations submitted by the Hungarian Government.

18 — See *Dynamic Medien*, cited above, paragraph 26 et seq.

19 — *Deutscher Apothekerverband*, cited above, paragraph 64 et seq.

20 — Within the meaning of the *Cassis de Dijon* case-law, inter alia (see Case 120/78 *Rewe-Zentral* [1979] ECR 649, '*Cassis de Dijon*', and *Keck and Mithouard*, cited above, paragraph 15).

62. However, according to the rule established in *Keck and Mithouard*, [21] 'the application to products from other Member States of national provisions restricting or prohibiting certain selling arrangements is not such as to hinder directly or indirectly, actually or potentially, trade between Member States…, so long as those provisions apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States'. Only on those conditions is it possible for the national measure not to be caught by the prohibition laid down by Article 28 EC.

63. As regards the first condition, it is indisputable that the national measure at issue does in fact apply without distinction to all relevant traders operating within Hungarian territory, since each of the traders wishing to operate on the Hungarian market for contact lenses must comply with the requirements of Order 7/2004.

64. On the other hand, it seems to me that the requirements laid down by Hungarian law for the marketing of contact lenses affect to a greater degree the selling of products from other Member States.

65. Admittedly, there is nothing to prevent traders based in another Member State from opening a specialist shop satisfying the requirements laid down by Order 7/2004 in order to sell contact lenses. However, it is obvious that such trade is more restrictive and more costly. The advantage of selling on-line is precisely that the Internet offers traders a shop window with a visibility that transcends frontiers, without the trader bearing the costs and constraints associated with the possession of a 'real' shop. On-line selling is an alternative selling arrangement to trade as traditionally understood and represents an extra means whereby national traders can reach customers who are not confined, from a geographical point of view, to the population around the physical shop.

66. Consequently, as regards the German prohibition on selling medicinal products via the Internet, the Court has already held that '[a] prohibition such as that at issue in the main proceedings is more of an obstacle to pharmacies outside Germany than to those within it. Although there is little doubt that as a result of the prohibition, pharmacies in Germany cannot use the extra or alternative method of gaining access to the German market consisting of end consumers of medicinal products, they are still able to sell the products in their dispensaries. However, for pharmacies not established in Germany, the internet provides a more significant way to gain direct access to the German market. A prohibition which has a greater impact on pharmacies established outside [the national] territory could impede access to the market for products from other Member States more than it impedes access for domestic

21 — Cited above, paragraph 16.

products'.[22] The Court seems to have therefore clearly accepted that the prohibition on Internet sales of a category of goods penalises traders who do not operate within the national territory more than it penalises those who do. That reasoning is perfectly capable of being applied, in my view, to the present case, in so far as the Hungarian legislation requires not only that the sale of contact lenses be carried out exclusively in a physical shop, but that, moreover, the latter satisfy criteria in respect of floor area and staff qualifications.

67. Furthermore, the Hungarian Government acknowledged at the hearing that the number of Hungarian products likely to be sold in shops which specialise in medical devices, and more specifically shops specialising in contact lenses, is utterly insignificant, although it was unable to provide any statistical data. It is therefore obvious that the prohibition affects mainly products from other Member States of the European Union.

68. Finally, as regards the second cumulative condition laid down by Order 7/2004, namely the condition as to staff, the Court has already held that legislation reserving to specialist staff the sale of contact lenses was capable of affecting intra-Community trade.[23]

69. Consequently, a national prohibition on Internet sales of contact lenses, such as that laid down by Order 7/2004, does constitute a measure having an effect equivalent to a quantitative restriction within the meaning of Article 28 EC.

3. Possible justification for the measure having equivalent effect under Article 30 EC

70. The prohibition of measures having an effect equivalent to a quantitative restriction, laid down by Article 28 EC, is not absolute, however, since such measures may be justified by virtue of their necessity in order to satisfy public interest grounds listed in Article 30 EC or mandatory requirements. The Hungarian Government points to the fact that Order 7/2004 pursues a public interest objective which is that of the protection of public health.

71. It is in fact settled case-law that a measure having an effect equivalent to a quantitative

22 — *Deutscher Apothekerverband*, cited above, paragraph 74.

23 — *LPO*, cited above, paragraph 8.

restriction may be justified on the basis of the protection of health and life of humans. The Court has repeatedly pointed out that 'the health and life of humans rank foremost among the assets and interests protected by the Treaty'. [24]

72. While it is true to say that the Treaties have not conferred full and absolute competence on the European Union in that field, and such competence remains largely shared between the Union and its Member States, as attested by Article 152 EC, it is for the Member States to determine the level of protection which they wish to afford to public health and the means to be employed in order to achieve it. [25] It is fully accepted that levels of protection may vary from one Member State to the other, which presupposes that Member States are allowed a certain discretion. Consequently, Order 7/2004 cannot be considered unjustified, on the ground that it is disproportionate, under Article 30 EC, merely because, in other Member States, the sale of contact lenses does not require a medical prescription, a specialist shop or qualified personnel. [26] Nevertheless, that power retained by the Member States must be exercised in compliance with the provisions of the Treaty. [27]

73. Consequently, the proportionality per se of the set of rules established in the light of the objective pursued of protecting public health must be analysed.

74. According to the Hungarian Government, Order 7/2004 pursues a legitimate objective of protecting public health, consisting in the protection of patients' interests. In view of the fact that contact lenses are particularly invasive medical devices, in direct contact with the membrane of the eye, it is imperative to avoid deregulation of the selling of contact lenses, in order more effectively to prevent impairments of sight and ophthalmic diseases caused by misuse of contact lenses, which could result in irreparable damage to sight. That is the reason why the conditions of sale of contact lenses are governed by strict rules, and why the presence of the patient is necessary at each stage of that sale. The patient must be in contact with a professional capable of advising and monitoring him throughout his experience with contact lenses, that is to say, at the time of prescription, then of purchase, but also when the trials and the fitting take place. The follow-up performed on each visit by the patient requires the existence of

24 — Case 215/87 *Schumacher* [1989] ECR 617, paragraph 17; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26; Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 10; Case C-320/93 *Ortscheit* [1994] ECR I-5243, paragraph 16; *Deutscher Apothekerverband*, cited above, paragraph 103; Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 46; and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* [2009] ECR I-4171, paragraph 19.

25 — *Apothekerkammer des Saarlandes and Others*, cited above, paragraphs 18 and 19.

26 — *Commission* v *Germany* [2008], cited above, paragraph 51.

27 — Case C-108/96 *Mac Quen and Others* [2001] ECR I-837, paragraph 24, and *Commission* v *Germany* [2008], cited above, paragraph 23.

a specialist shop covering at least 18 m^2, or premises separated from the workshop, the minimum area requirement ensuring, in the Hungarian Government's view, that the shop has the necessary equipment and space for performing examinations, but also sufficient space for the presentation of products and instructions on their use. Each contact the professional has with the patient must be an opportunity to check, if necessary, the state of the latter's sight by performing examinations, and to give him all necessary advice and information. Consequently, since it is not possible to dispense with the presence of the patient, the Hungarian Government does not accept, in its written observations, that examinations and trials can take place at a distance. [28] Finally, the Hungarian Government considers Order 7/2004 to be necessary and proportionate. The objective of preserving eye health, set by the Republic of Hungary, can only be achieved by ensuring that the patient is present at each stage of the supply, under medical supervision, of contact lenses, and that he is put in contact, as a matter of course, with qualified staff. The requirements of that order are of a scope and effect necessary for the achievement of that objective in accordance with the requirements of European Union law.

75. Although the concerns of the Hungarian Government relating to eye health are entirely commendable, I cannot help thinking that a certain inconsistency, if not a contradiction, has crept into the national legislation on the matter.

76. With regard to the personal condition, the Court has already held that national legislation which reserves to qualified staff the right to sell medicinal products, justifying it inter alia by the fact that such staff can check the authenticity of prescriptions more satisfactorily, is compatible with European Union law. [29] A certain parallel may be drawn with the present case, in so far as the Hungarian State makes the issue of contact lenses subject to possession of a medical prescription. Notwithstanding that fact, it is impossible to ignore the fact that the two categories of goods concerned are different in nature, in that contact lenses are regarded, not as medicinal products subject to prescription, but as medical devices. In any event, the Court has already accepted, at least indirectly, the compatibility with European Union law of national legislation requiring the presence of qualified, salaried opticians or associates in each optician's shop. [30]

77. The right of the Republic of Hungary to maintain in force legislation which makes the

28 — See point 46 of the written observations submitted by the Hungarian Government.

29 — *Deutscher Apothekerverband*, cited above, paragraph 119.

30 — Case C-140/03 *Commission* v *Greece* [2005] ECR I-3177, paragraph 35.

supply of contact lenses subject to a medical prescription cannot be disputed. Nevertheless, because of the fact that the present case concerns medical devices — and not medicinal products — the extent to which the professional is under an obligation to inform and advise is reduced, in view of the difference in terms of risk. The Court has already held that, '[u]nlike optical products, medicinal products prescribed or used for therapeutic reasons may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly, without the consumer being in a position to realise that when they are administered.'[31] The parallel with the Court's case-law on medicinal products therefore ends here.

78. The concern for the protection and preservation of public health shown by the Hungarian Government is perfectly legitimate. The latter identifies serious consequences which would be associated with misuse of contact lenses. However, the substantive condition imposed by Order 7/2004 undeniably weakens the Hungarian Government's case.

79. The disproportionate character of the measure is, in my opinion, to be found above all in that substantive condition which has the effect of preventing qualified persons who practise within the territory of another Member State from having access to the Hungarian market, and from selling their goods there.

80. Indeed, prohibiting absolutely Internet sales of contact lenses does not take account of the situation where such selling is carried out by qualified staff, possibly established in another Member State.[32]

81. If the relationship between the minimum area fixed at 18 m^2 and the quality of the information or follow-up does not appear obvious, a point rightly raised by the Czech and Netherlands Governments and the Commission in their written observations, it must be said that it is even less obvious when one takes into consideration the fact that home delivery of contact lenses is permitted. Indeed, there is an intrinsic contradiction underlying Order 7/2004. At the same time as it requires a shop with a minimum floor area sufficient to have the necessary equipment available and to perform examinations, that order permits home delivery for purposes

31 — *Apothekerkammer des Saarlandes and Others*, cited above, paragraph 60.

32 — This was indeed the situation which was referred to the Court in *Deutscher Apothekerverband*, cited above, concerning, in that instance, pharmacists.

of trying out and fitting the contact lenses. This seems to me proof that the various operations, which the Hungarian Government seeks to demonstrate are inseparable, can be viewed completely separately.

82. As regards home delivery, the Hungarian Government seems to start from the premise that Internet selling would lead to contact lenses being delivered only by a messenger or postman, and not by a professional. However, in so far as the Hungarian Government seems to maintain, in its reply to the written question put by the Judge-Rapporteur, that qualified staff carry out home delivery of contact lenses for trial or fitting purposes in Hungary, there is no reason why a system of Internet selling in which delivery was again the responsibility of qualified staff could not be envisaged.

83. Moreover, and as a consequence of what has already been noted in point 77 of this Opinion, the Hungarian legislation can legitimately be criticised for not qualifying in any way the obligation for the patient and the professional to be present together in the specialist shop. Although it may be conceded that information and advice are of great importance at the time of the initial prescription and in the first stages of use of contact lenses, the needs are not the same for customers who have been using those medical devices for some time. It is in that sense that it is possible to envisage, when lenses are renewed, for example, a reduced obligation to inform and advise. It is then not obvious that the Internet operator is unable to check the authenticity of prescriptions, if that proves necessary, or to provide sufficient information and advice by appropriate means such as, for example, a warning on the Internet site drawing attention, where appropriate, to the need to consult in the event of a problem, or the insertion of instructions for use in parcels.

84. The absence of any qualification is also borne out by the fact that the Hungarian Government does not seem to draw any distinction either between 'rigid' contact lenses and 'soft' contact lenses or between contact lenses correcting a visual deficiency and those whose sole purpose is to colour the iris. The professional's intervention to fit rigid contact lenses to the patient's eyes can be considered a delicate operation because the professional, according to the Hungarian Government's statements at the hearing, intervenes in relation to the product. The issue of rigid contact lenses merits the particular follow-up consisting of the process of fitting and checking. However, that process is much less prominent where soft contact lenses are prescribed. Furthermore, certain lenses may

have only a cosmetic use, and although care instructions must be supplied, the follow-up in respect of their use will prove much less burdensome than in the case of contact lenses for therapeutic use.

85. In the light of the foregoing, it seems to me that, however legitimate the aim pursued by Order 7/2004 may be, the objective of protecting public health can be achieved by means of measures less restrictive of the free movement of goods.

86. I therefore propose that the Court's answer to the second and third questions, as reorganised, should be that Article 28 EC must be interpreted as meaning that national legislation which requires, for the sale of contact lenses, the possession of a shop specialising in medical devices covering at least 18 m^2 or premises separated from the workshop and the presence of qualified staff, and which has the effect of prohibiting Internet sales, constitutes a measure having an effect equivalent to a quantitative restriction on imports. Articles 28 EC and 30 EC must be interpreted as meaning that such legislation is not justified on grounds of the protection of health and life of humans, in so far as the same objective can be achieved by means of less restrictive measures.

VII — Conclusion

87. In the light of all the foregoing considerations, I propose that the questions referred by the Baranya Megyei Bíróság be answered as follows:

'(1) The compatibility, under European Union law, of national legislation which has the effect of prohibiting Internet sales of contact lenses cannot be assessed by

reference to the provisions of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market. The question whether the sale of contact lenses is medical advice requiring the physical presence of the patient, for the purposes of Recital 18 in the preamble to that directive, is therefore irrelevant.

(2) Article 28 EC must be interpreted as meaning that national legislation which requires, for the sale of contact lenses, the possession of a shop specialising in medical devices covering at least 18 m^2 or premises separated from the workshop and the presence of qualified staff, and which has the effect of prohibiting Internet sales, constitutes a measure having an effect equivalent to a quantitative restriction in imports.

(3) Articles 28 EC and 30 EC must be interpreted as meaning that such legislation is not justified on grounds of the protection of health and life of humans, in so far as the same objective can be achieved by means of less restrictive measures.'