ADVISORY OPINION OF THE COURT

24 November 1998*

(Free movement of goods – copyright – disguised restriction on trade)

In Case E-1/98

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by Borgarting Court of Appeal (Borgarting lagmannsrett) for an Advisory Opinion in the case pending before it between

The Norwegian Government, represented by the Royal Ministry of Social Affairs and Health

and

Astra Norge AS

on the interpretation of Articles 11 and 13 of the Agreement on the European Economic Area (hereinafter "EEA") and Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No. 22, 9.2.1965, p. 369), as amended by Directives 75/318/EEC, 75/319/EEC and 83/570/EEC (hereinafter the "Directive"), referred to in point 1 of Chapter XIII of Annex II to the EEA Agreement.

THE COURT,

composed of: Bjørn Haug, President, Thór Vilhjálmsson and Carl Baudenbacher (Judge-Rapporteur), Judges,

Registrar: Gunnar Selvik,

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* Language of the Request for an Advisory Opinion: Norwegian.

after considering the written observations submitted on behalf of:

– the appellant, the Norwegian Government, Royal Ministry of Social Affairs and Health, represented by Ingvald Falch, Advocate, Office of the Attorney General (Civil Affairs);

– the respondent, Astra Norge AS, represented by Counsel Wilhelm Matheson, Advokatfirma Wiersholm Mellbye & Bech ANS;

– the intervener, Paranova AS, represented by Counsel Jonas W. Myhre, Advokatfirma Hjort DA;

– the EFTA Surveillance Authority, represented by Bjarnveig Eiríksdóttir, Officer, Legal & Executive Affairs Department, acting as Agent;

– the Commission of the European Communities, represented by Richard B. Wainright, Principal Legal Adviser and Hans Støvlbæk, Member of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of the appellant, the respondent, the intervener, the EFTA Surveillance Authority and the Commission of the European Communities at the hearing on 11 November 1998,

gives the following

Advisory Opinion

Facts and procedure

1 By an order dated 13 February 1998, registered at the Court on 19 February 1998, Borgarting lagmannsrett, a Norwegian court of appeal, made a Request for an Advisory Opinion in a case brought before it by the Norwegian Government (hereinafter the "appellant") against Astra Norge AS (hereinafter the "respondent"). Paranova AS (hereinafter the "intervener") takes part in the national proceedings as an intervener supporting the standpoint of the appellant. The case before the national court concerns the issue whether Summaries of Product Characteristics (hereinafter "SPCs") for medicinal products, as laid down by the Norwegian Medicines Control Authority (*Statens legemiddelkontroll*, hereinafter "MCA"), are protected by copyright to the benefit of the respondent.

2 According to Act No. 132 of 4 December 1992 on medicinal products (*Legemiddelloven* – hereinafter the "Medicinal Products Act"), an SPC is a simple description of the product in a brief, factual form, done according to a standard layout. The onus is on the applicant to send in a proposal for an SPC. The proposal is then reviewed by MCA, which can make changes itself or direct the applicant to make changes and corrections. After this process the SPC is approved/laid down by MCA as part of the product being given marketing authorization.

3 In a letter of 29 September 1995, MCA informed all operators who reported medicinal products imported by way of parallel import to it that it would henceforth apply the following practice regarding SPCs for medicinal products imported by way of parallel import:

> *"The same Summary of Product Characteristics will apply for parallel imports and direct imports of medicinal products because, from a therapeutic point of view, they describe the same medical product. Upon issuance of a marketing authorization for medicinal products imported by the way of parallel import, the Summary of Product Characteristics will be included as an attachment to the marketing authorization letter. There is no requirement that the company name of the direct importer must be linked to the name of the medicinal product. If the medicinal product imported by way of parallel import has another product name than the one imported by way of direct import, this is to be indicated. Any different compositions of medicinal products will be indicated on the Summary of Product Characteristics submitted.*
> *(…)*
> *For medicinal products imported by way of parallel import and for which a marketing authorization has already been granted, the Norwegian Medicines Control Authority will now send out the latest approved Summaries of Product Characteristics to the relevant parallel importers. We ask the parallel importers to modify the relevant Summaries of Products Characteristics in keeping with the above-mentioned practice."*

4 In 1996, the respondent brought proceedings against the appellant before Oslo City Court ("Oslo byrett"), asking for the Norwegian medicinal product authorities to be forbidden from giving out and/or approving SPCs for products which are imported by way of parallel import and which are identical to the SPCs which have been approved earlier for the respondent's products, which are imported directly. The respondent argued that it had a national copyright in the SPCs. Oslo byrett ruled in favour of the respondent and held that the SPCs approved by MCA as part of the process of granting a marketing authorization for a product are protected by copyright to the benefit of the respondent. The appellant appealed the judgment to Borgarting lagmannsrett, which decided to refer a Request for an Advisory Opinion to the EFTA Court.

5 The questions referred by the national court concern the interpretation of Articles 11 and 13 EEA and various Articles of the Directive.

Legal background

1. EEA law

6 Article 11 EEA reads:

> *"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties."*

7 Article 13 EEA reads:

> *"The provisions of Article 11 and 12 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 the Contracting Parties."*

8 Articles 3 to 5 of the Directive read:

"Article 3

No proprietary medicinal product may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State.

Article 4

In order to obtain an authorisation to place a proprietary medicinal product on the market as provided for in Article 3, the person responsible for placing that product on the market shall make application to the competent authority of the Member State concerned.

The application shall be accompanied by the following particulars and documents:

1. Name or corporate name and permanent address of the person responsible for placing the proprietary product on the market and, where applicable, of the manufacturer.

2. Name of the proprietary product (brand name, or common name together with a trade mark or name of the manufacturer, or scientific name together with a trade mark or name of the manufacturer).

3. Qualitative and quantitative particulars of all the constituents of the proprietary product in usual terminology, but excluding empirical chemical formulae, with mention of the international non-proprietary

name recommended by the World Health Organisation where such name exists.

4. *Brief description of the method of preparation.*

5. *Therapeutic indications, contra-indications and side-effects.*

6. *Posology, pharmaceutical form, method and route of administration and expected shelf life.*

7. *Control methods employed by the manufacturer (analysis and assay of the constituents and of the finished product, special tests, e.g. sterility tests, tests for the presence of pyrogenic substances, the presence of heavy metals, stability tests, biological and toxicity tests).*

8. *Results of:*

   - *physico-chemical, biological or microbiological tests;*
   - *pharmacological and toxicological tests;*
   - *clinical trials.*

   However:

   a) *A bibliography relating to the pharmacological tests, toxicological tests and clinical trials may be substituted for the relevant test results in the case of:*

      i) *a proprietary product with an established use, which has been adequately tested on human beings so that its effects, including side-effects, are already known and are included in the published references;*

      ii) *a new proprietary product, in which the combination of active constituents is identical with that of a known proprietary product with an established use;*

      iii) *a new proprietary product consisting solely of known constituents that have been used in combination in comparable proportions in adequately tested medicinal products with an established use;*

   b) *In the case of a new proprietary product containing known constituents not hitherto used in combination for therapeutic purposes, references to published data may be substituted for the tests of such constituents.*

9. *A summary, in accordance with Article 4a, of the product characteristics, one or more specimens or mock-ups of the sales presentation of the proprietary product, together with a package leaflet where one is to be enclosed.*

10. A document showing that the manufacturer is authorised in his own country to produce proprietary products.

11. Any authorisation obtained in another Member State or in a third country to place the relevant proprietary product on the market.

Article 4a

The summary of the product characteristics referred to in point 9 of the second paragraph of Article 4 shall contain the following information:

1. Name of the proprietary product.

2. Qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product; the international non-proprietary names recommended by the World Health Organization shall be used, where such names exist, or failing this, the usual common name or chemical description.

3. Pharmaceutical form.

4. Pharmacological properties and, in so far as this information is useful for therapeutic purposes, pharmacokinetic particulars.

5. Clinical particulars:

5.1. therapeutic indications,
5.2. contra-indications,
5.3. undesirable effects (frequency and seriousness),
5.4. special precautions for use,
5.5. use during pregnancy and lactation,
5.6. interaction with other medicaments and other forms of interaction,
5.7. posology and method of administration for adults and, where necessary, for children,
5.8. overdose (symptoms, emergency procedures, antidotes)
5.9. special warnings,
5.10. effects on ability to drive and to use machines.

6. Pharmaceutical particulars:

6.1. incompatibilities (major),
6.2. shelf life, when necessary after reconstitution of the product or when the container is opened for the first time,
6.3. special precautions for storage,
6.4. nature and contents of container,
6.5. name or style and permanent address or registered place of business of the holder of the marketing authorization.

Article 4b

> *When the marketing authorization referred to in Article 3 is issued, the person responsible for placing that product on the market shall be informed, by the competent authorities of the Member State concerned, of the summary of the product characteristics as approved by them. 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 authorization is issued or subsequently.*

Article 5

> *The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the proprietary medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.*
>
> *Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4."*

2. National law

9 The Directive is incorporated into Norwegian law through the Medicinal Products Act.

10 As a prerequisite to being put on the market in Norway, all proprietary medicinal products must have been the subject of a marketing authorization granted by MCA. The first, second and third paragraphs of Section 8 of the Medicinal Products Act read:

> *"No proprietary medicinal product may be sold or placed on the market without first being approved by the Ministry.*
>
> *Approval is granted on the basis of an assessment of the quality, safety and effects of the product.*
>
> *Before approval is granted, approval must also be granted for the name of the product, summary of product characteristics, labelling, packaging, package leaflet, etc."*

11 Sections 8 and 9 of the related Regulation No. 951 of 22 October 1993 concerning proprietary medicinal products (*Forskrift om farmasøytiske spesialpreparater*) read:

> *"Section 8 Decisions of the Norwegian Medicines Control Authority*

When the MCA has made its decision, the applicant will be notified in writing. If approval is refused, the applicant must be notified of the reasons for this at the same time.

If the product is approved, the marketing authorization will be issued when any special conditions have been met.

Section 9 Conditions for marketing authorization

When the MCA has approved a product as regards its quality, safety and efficacy, the following shall be approved before marketing authorization may be given:

1. The name of the product, package size, accessory equipment, package, labelling, package leaflet and summary of product characteristics."

Questions

12 The following questions were referred to the EFTA Court:

1. Is there a measure present having effect equivalent to import restrictions contrary to Article 11 EEA which cannot be justified by reference to industrial or commercial property in Article 13 EEA

if

a Summary of Product Characteristics which is approved/laid down by the competent medicinal product authority in accordance with Council Directive 65/65/EEC, amended inter alia by Article 4, point 9 of Council Directive 83/570/EEC, is protected by the importer's (direct importer's) national copyright law (recte: national copyright), with the consequence that the medicinal products authority may not give out/approve/lay down the same Summary of Product Characteristics for a product imported by way of parallel import without the consent of the direct importer?

2. Does Council Directive 65/65/EEC, as amended, primarily Article 4a and 5 of the Directive, allow national legislation to provide copyright protection for a Summary of Product Characteristics which is approved/laid down by the medicinal products authority in that manner and with the consequences described in question 1?

13 Reference is made to the Report for the Hearing for a more complete account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

Findings of the Court

14 The national court seeks in essence to know whether a possible copyright in the SPCs would conflict with the principle of free movement of goods and the Directive.

15 In the view of the *appellant*, the *intervener*, the *EFTA Surveillance Authority* and the *Commission of the European Communities*, a copyright of the direct importer in the SPC would constitute a measure having an effect equivalent to a quantitative restriction within the meaning of Article 11 EEA that cannot be justified under Article 13 EEA. The *respondent* is of the opinion that the SPC is an important tool for the marketing of medicinal products and that copyright protection does not restrict trade within the meaning of Article 11 EEA. The respondent concludes that, in any case, an eventual restriction would be justifiable under Article 13 EEA.

16 One of the basic aims of the rules on free movement of goods in the EEA Agreement is to avoid artificial partitioning of the EEA market. This aim is reflected in the general obligation of the Contracting Parties in Article 1(2) of Protocol 28 to the EEA Agreement to adjust national legislation on intellectual property so as to make it compatible with the principles of free circulation of goods and services and with the level of protection of intellectual property attained in Community law, including the level of enforcement of those rights.

17 The Directive does not address the issue of whether copyright protection of the SPC is possible or not. Furthermore, it does not seek to harmonize rules governing copyright protection. The aim of the Directive is to harmonize rules concerning the production and distribution of medicinal products in order to safeguard public health.

18 According to the Preamble to Directive 83/570/EEC, the main purpose of introducing the SPC is to safeguard public health. The other central element is to further the free movement of medicinal products. To achieve those goals, the competent authorities may make the marketing of such products dependent on an authorization. In order to carry out this task, they have to have at their disposal all useful information on authorized proprietary medicinal products, based in particular on SPCs adopted in the other Member States.

19 The SPC is a cornerstone of the marketing authorization. It is initially drafted by the applicant, but its contents are defined by the Directive. It is the competent authority and not the applicant who approves and has the final responsibility for the SPC. According to the submissions of the Commission of the European Communities before the Court, the SPC may even be substantially written by the authority in certain cases. The SPC is not a joint product manufactured by the applicant and the national authority, but rather a product that is controlled and

finally determined by the national authority. It is not, however, for the Court to decide whether a copyright in an SPC may be granted to the applicant.

20 The argument of the respondent, according to which the SPC is an important tool for the marketing and promotion of medicinal products, must be rejected. The SPC may very well be used as an advertising instrument. Its main function, however, is to describe the product and inform consumers in an objective manner. Since parallel imports are, by definition, identical or at least very similar to the products sold by the direct importer, no significant difference should exist between the original SPC and the SPC of the parallel importer. On the contrary, from a public health standpoint, it is desirable that identical products are accompanied by identical SPCs. It is also necessary that all relevant information available is included in the SPC so as to avoid any confusion as to the identity of the product.

21 These findings about the nature of the SPCs are confirmed by the wording of Article 4b of the Directive, as applicable within the Community (after amendments by Council Directive 93/39/EEC, not yet incorporated into the EEA Agreement). According to this provision, the competent authorities shall forward to the European Agency for the Evaluation of Medicinal Products a copy of the authorization together with the SPC.

22 If the competent national authority were to be prevented from giving out, laying down or approving, in respect of a product imported by way of parallel import, an SPC that was part of a marketing authorization already issued unless the direct importer gave its permission, the parallel importer would be required to prepare and to propose its own SPC. A restriction of this kind would complicate the authorization procedure and make it more costly. It would, therefore, amount to a measure having an effect equivalent to a quantitative restriction on imports in medicinal products. The respondent has stated that the parallel importer would have to hire a qualified pharmacist in order to carry out this task. The Court notes that, in certain circumstances, it might even be impossible for the parallel importer to draw up a comprehensive SPC that is new and different. But even if carrying out the necessary tests or gathering the necessary information as well as drafting the SPC should prove to be a relatively easy exercise, for instance, because relevant data are publicly available, this would still constitute a measure having an effect equivalent to a quantitative restriction within the meaning of Article 11 EEA. A national law which makes it possible for a direct importer to prevent the competent national authority from attaching the original SPC to the market authorization letter would therefore be incompatible with EEA law.

23 The Court notes that there is no *de minimis* rule under Article 11 EEA. This follows already from the judgment of the Court of Justice of the European Communities (hereinafter “ECJ”) in *Dassonville* (Case 8/74 *Procureur du Roi* v *Dassonville* [1974] ECR 837) which, by virtue of Article 6 EEA, is relevant for the interpretation of Article 11 EEA.

24 The respondent asserts that, should the Court find that copyright constitutes a measure covered by Article 11 EEA, one would have to assume that this measure falls within the exception provided by Article 13 EEA. The essence of the copyright in the SPC, the respondent asserts, is the right of the author, i.e. the direct importer, to reserve the SPC it has developed for the marketing of its products.

25 Article 13 EEA states *inter alia* that Article 11 EEA "shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of … the protection of industrial and commercial property." Copyright is covered by this definition (see, in particular, Joined Cases 55/80 and 57/80 *Musik-Vertrieb membran* v *GEMA* [1981] ECR 147).

26 The case at hand is not about trade in SPCs but trade in the medicinal products themselves. If the competent authority should be prevented from continuing its practice described above, trade in medicinal products between the Contracting Parties of the EEA Agreement would be restricted. In other words, the enforcement of a national copyright in an SPC, with the consequence that the competent national authority would be prevented from giving out/approving/laying down the same SPC for a product imported by way of parallel import as for a directly imported medicinal product, would lead to an artificial partitioning of the market in the European Economic Area. This would be disproportionate to the aim of protecting the copyright in the SPC. In addition, the Court finds that this would amount to a disguised restriction on trade between the Contracting Parties. A justification under Article 13 EEA is, therefore, not possible.

Costs

27 The costs incurred by the EFTA Surveillance Authority and the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, in so far as the parties to the main proceedings are concerned, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by Borgarting lagmannsrett by the order of 13 February 1998, hereby gives the following Advisory Opinion:

Articles 11 and 13 EEA, in combination with Directive 65/65/EEC, are to be interpreted as not permitting the protection of a direct importer's national copyright in a Summary of Product Characteristics, approved by the competent medicinal products authority, which would have the consequence that the medicinal products authority may not give out, approve or lay down the same Summary of Product Characteristics for a product imported by way of parallel import without the consent of the direct importer.

Bjørn Haug Thór Vilhjálmsson Carl Baudenbacher

Delivered in open court in Luxembourg on 24 November 1998.

Bjørn Haug
President

Gunnar Selvik
Registrar