REPORT FOR THE HEARING
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,[1] as amended (hereinafter the "Directive"), referred to in point 1 of Chapter XIII of Annex II to the EEA Agreement.

I. Introduction

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 "appellant") against Astra Norge AS (hereinafter "respondent"). Paranova AS takes part in the national proceedings as an intervener supporting the standpoint of the Norwegian Government. 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 "SLK"), are protected by copyright to the benefit of the respondent.

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[1] OJ No. 22, 9.2.1965, p. 369.

II. Legal background

2. The questions referred by the national court concern the interpretation of Articles 11 and 13 EEA and various Articles of the Directive as amended by Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.[2]

3. Article 11 EEA reads:

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

4. 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."*

5. Article 3 of the Directive reads:

> *"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."*

6. Article 4 of the Directive, as amended by Council Directive 83/570/EEC, reads:

> *"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.*
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> *The application shall be accompanied by the following particulars and documents:*
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> *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.*

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[2] OJ No. L 332, 28.11.1983, p. 1.

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."

7. Article 4a of the Directive, as inserted by Council Directive 83/570/EEC, reads:

"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."

8. Article 4b of the Directive, as inserted by Council Directive 83/570/EEC, reads:

> *"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."*

9. Article 5 of the Directive reads:

> *"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."*
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> *Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4."*

III. Facts and Procedure

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 SLK. The Directive is incorporated into Norwegian law through Act No. 132 of 4 December 1992 on medicinal products (*Legemiddelloven* – hereinafter the "Medicinal Products Act").

11. 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.*
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> *Before approval is granted, approval must also be granted for the name of the product, summary of product characteristics, labelling, packaging, package leaflet, etc."*

12. 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*
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> *When the SLK 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 SLK 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."*

13. According to 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 proposals for the marketing authorization. The proposal is then reviewed by SLK, which can make changes itself or direct the applicant to make changes and corrections. After this process the SPC is approved/laid down by SLK as part of the product being given marketing authorization.

14. In a letter of 29 September 1995, SLK informed all parties who reported medicinal products imported by way of parallel import 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."

15. In 1996, Astra brought proceedings against the Norwegian Government before Oslo City Court ("Oslo byrett"), asking for the Norwegian medicinal product authorities to be forbidden from granting authorization 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 Astra's products, which are imported directly. Astra argued that it had a national copyright on the SPCs. Oslo byrett ruled in favour of Astra and held that the SPCs approved by the SLK as part of the process of granting a marketing authorization for a product are protected by copyright to the benefit of Astra. The Norwegian Government appealed against the judgment. Borgarting lagmannsrett decided to submit a Request for an Advisory Opinion to the EFTA Court.

IV. Questions

16. 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, 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?

V. Written observations

17. Pursuant to Article 20 of the Statute of the EFTA Court and Article 97 of the Rules of Procedure, written observations have been received from:

– 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.

The Norwegian Government, Royal Ministry of Social Affairs and Health

18. Referring to the case law of the ECJ,[3] the *appellant* argues that property rights relating to documents associated with the imported product may be exhausted once the product is put on the market by the proprietor itself or with its consent. Furthermore, the ECJ has not restricted itself to finding fault with national legislation that directly hinders the import and reselling of a given product. Hindrance of a more indirect character is also included.

19. According to the judgments in *de Peijper*,[4] *Eurim-Pharm*[5] and *Smith & Nephew*,[6] a national rule that makes the grant of a marketing authorization to a

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[3] Case 15/74 *Centrafarm BV et Adriaan de Peijper* v *Sterling Drug Inc.* [1974] ECR 1147; Case 16/74 *Centrapharm et Adriaan de Peijper* v *Sterling Drug Inc.* v *Winthrop BV* [1974] ECR 1183; Cases 55/80 and 57/*80 Musik-Vertrieb membran GmbH et K-tel International* v *GEMA Gesellschaft für musikalische Aufführungs- und mechanische Vervielfältigungsrechte* [1981] ECR 147; Case 187/80 *Merck & Co. Inc.* v *Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063; Case 19/84 *Pharmon BV* v *Hoechst Ag* [1985] ECR 2281; Case C-10/89 *SA CNL-SUCAL NV* v *HAG GF AG* [1990] ECR I-3711; Case 158/86 *Warner Brothers Inc. and Metronome Video ApS* v *Erik Viuff Christiansen* [1988] ECR 2605*; Case* C-337/95 *Parfums Christian Dior SA and Parfums Christian Dior BV* v *Evora BV* [1997] ECR I-6013; and Case C-373/90 *Criminal proceedings against X* [1992] ECR I-131.

[4] Case 104/75 *Adrian de Peijper, Managing Director of Centrafarm BV* [1976] ECR 613.

[5] Case C-207/91 *Eurim-Pharm GmbH* v *Bundesgesundheitsamt* [1993] ECR I-3723.

[6] Case C-201/94 *The Queen* v *The Medicines Control Agency, ex parte Smith & Nephew Pharmaceuticals Ltd and Primecrown Ltd* v *The Medicine Control Agency* [1996] ECR I-5819.

parallel importer subject to the production of documents which Astra has already supplied to the SLK is prohibited under Articles 11 and 13 EEA.

20. According to a Communication of the Commission,[7] which was delivered after the *de Peijper* judgment, there is no requirement for parallel importers to submit a draft SPC to the competent authority in the State of import. In particular there is no requirement to submit a draft that differs from the SPC already submitted by the manufacturer or its appointed representative. The Communication indicates that the competent authority in the State of import shall not approve a new SPC for products imported by way of parallel import.

21. To support this argument, reference is made to the practice in the UK, where the competent authorities do not require a new, different draft SPC from parallel importers.

22. Referring to the purpose of the Directive, the Norwegian Government argues that, on the basis of the Directive, the procedure for granting a marketing authorization has been harmonized in cases of parallel import as well. The harmonization is to the effect that a new marketing authorization shall not be issued to products subject to parallel import.

23. In *Smith and Nephew*,[8] the ECJ stated that the objective of safeguarding public health pursued by the Directive justifies the application of the stringent measure laid down in Article 4 of the Directive only with regard to products which are put on the market for the first time.

24. Thus, the competent authority in the State of import is obliged to grant a marketing authorization to a person seeking to market a medicinal product being imported by way of parallel import, provided that (1) the product being imported by way of parallel import is covered by a marketing authorization in the European Economic Area State from which it is exported; (2) the product being imported by way of parallel import is effectively covered by a marketing authorization already granted in the State into which it is being imported; and (3) no countervailing considerations relating to the effective protection of the life and health of humans are revealed.

25. The SPC, as part of the marketing authorization, constitutes the basis and condition under which the product is marketed. According to Article 2(2) of Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use,[9] all parts of the advertising of a medicinal product must comply with the particulars listed in the SPC. Different SPCs for two identical products would force the competent national authority to stipulate different

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7 OJ No. C 115, 6.5.1982, p. 209.

8 See footnote 6.

9 OJ No. L 113, 30.4.1992, p.13.

conditions regarding the marketing and advertising for the same product. This would affect competition on the medicinal market, depending on the parts of the SPC affected and on the priority given to copyright protection.

26. The burden of drafting the SPC is placed on the first applicant for a marketing authorization for a given product. From an economical standpoint, this is reasonable because the first applicant for the product will be the manufacturer or someone deriving its rights from the manufacturer. Drafting an adequate SPC must be seen as being part of the development and manufacturing process. The costs related to the development of the product are generally returned when the manufacturer puts the product on the market and retails copies of it. The parallel importer has already paid its part of the development and production costs, including the costs relating to the drafting of the SPC, when it has purchased the product in the State of export.

27. The appellant submits that the existence in national law of copyright protection preventing the competent authority in that State from approving or giving out an SPC relating to a medicinal product being imported by way of parallel import, which is similar to an SPC already approved for that product, constitutes a quantitative restriction and is thus prohibited under Article 11 EEA.

28. To prepare a new, distinct SPC would be impracticable and costly for the parallel importer. The parallel importer does not have a complete set of information and documents relating to the medicinal products in question. Furthermore, according to the *de Peijper*[10] and *Eurim-Pharm*[11] judgments, the parallel importer is exempted from submitting this information to the competent authorities. If the parallel importer is required to submit a separate SPC to the authority, it will then be required to submit such information. Even if the parallel importer succeeds in establishing itself on the market in the State of import, it will be in a different position than the direct importer or the manufacturer, because its advertising must comply with the SPC it has prepared. If the competent authorities are precluded from requiring identical SPCs for all competitors trading identical medicinal products on the market, this will affect competition on the medicinal products market.

29. Furthermore, under Article 5(1) of the Berne Convention, parallel importers are precluded from using the SPC approved in the State of export to the same extent as they are precluded from using the SPC approved in the State of import.

30. The appellant submits that the exclusive right of reproduction is not affected by the practice instituted by SLK. A notification by the competent authority expressing that the SPC already approved for a particular medicinal

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10 See footnote 4.

11 See footnote 5.

product is in effect and applies to that product, including the situation where another person is granted an authorization to market it, does not affect the exclusive right of reproduction of the person first authorized.

31. The protection of industrial and commercial property does not justify a restriction enabling the owner of a copyright for a given SPC to deny the competent authority the approval and application of that SPC in cases of parallel import of the medicinal product in question.

32. The appellant states that the Directive also harmonizes the procedure for granting a marketing authorization in cases of parallel import of proprietary medicinal products. Article 4 of the Directive requires that the proposal for an SPC must be included in the application in order to obtain a marketing authorization. Under Article 4b of the Directive, the SPC must be approved by the competent authority. Thus, the SPC may be characterized as an intrinsic and integral part of the marketing authorization. According to the *Smith & Nephew* judgment, the SPC is one of the elements which must be identical in cases of parallel import.

33. The appellant submits that a practice by the competent authority under which the same SPC applies for identical medicinal products is supported by public health considerations, i.e. eliminating the risk of confusion among doctors and patients. No countervailing considerations relating to the effective protection of the life and health of humans exist.

34. Furthermore, it follows from Article 4b of the Directive that a person to whom a marketing authorization is granted shall be informed by the competent authority of the SPC approved by them. Copyright protection that precludes the competent authority from giving out the approved SPC to the applicant will be in conflict with the Directive.

35. The appellant suggests answering the questions as follows:

> *"A national rule which confers copyright protection on the Summary of the Product's Characteristics (SPC) approved by the competent national authority in accordance with Council Directive 65/65/EEC, as amended, for a particular proprietary medicinal product, to the effect that the competent national authority is precluded from approving or giving out the same SPC when the proprietary medicinal product is subject to parallel import into that State, is prohibited by*
> – *Articles 11 EEA, and cannot be justified under Article 13 EEA, and*
>
> – *Council Directive 65/65/EEC, as amended."*

Astra Norge AS

36. The *respondent* opposes the view that the approved SPC is an intrinsic and integral part of the marketing authorization. In Norway there exists a system which favours parallel imports of medicinal products in relation to direct imports. SLK charges direct importers a higher fee for registration than it levies on parallel importers. Furthermore, through a system of profit-sharing, pharmacists are encouraged to market and give out products imported by way of parallel import. The national authority has also accepted that the patient may claim for a product imported by way of parallel import, even if this contradicts the prescription. Concerning this situation, the respondent refers to the case law of the ECJ according to which it is incompatible with Article 11 EEA to favour certain trade channels in relation to others.[12]

37. The respondent states that the parallel importer benefits without cost from the effects of a fine-tuned SPC, elaborated at the national level by the direct importer's trained employees.

38. The respondent argues that the SPC is an extremely important remedy for the marketing and promotion of pharmaceutical products. It is not only a catalogue, but also a balance between medicine and adaptation to the market. The respondent refers to the fact that SPCs for identical products may differ substantially, even if the products are marketed under identical names. The norm applied by the market operator is a question of confidence in the market and of the market reliance on the description rendered by the market operator as appropriate and adequate for the safety of the product.

39. The function of the SPC is to give the competent authorities access to useful information on authorized medicinal products, and to serve as a vehicle of communication between the holder of the marketing authorization and the professionals in the health sectors. This is in line with Directive 92/28/EEC.

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12 Case 155/73 *Guiseppe Sacchi* [1974] ECR 409.

Without an SPC, it would, in practice, be impossible to exploit the product commercially because a distilled position of the product is required to be able to communicate with the market.

40. With respect to a general interpretation of Articles 11 and 13 EEA, the respondent refers to the case law of the ECJ.[13] The respondent rejects the argument that copyright protection of the direct importer's SPCs is a measure covered by Article 11 EEA because a parallel importer may prepare its own SPCs on the basis of information easily available in the public domain and general pharmaceutical knowledge. There are currently alternative SPCs on the market which fully substitute direct importers' formally approved SPCs. Reference is made to several extracts from the *Norsk legemiddelhåndbok* (Norwegian Pharmaceuticals Handbook). The alternative characteristics are based on information which is in the public domain.

41. With respect to new products and products which may have a long time remaining in their protection period, the respondent points out the feature of the parallel import business in general. The nature of this business leads to a certain time lag between the award of a marketing authorization to the direct importer and the time the parallel importer decides to enter the market. The parallel importer will generally wait with its decision to enter the market with a product until it is clear which price is adopted for the product by the competent authority and what is the reimbursement status for the product imported directly. In any case, the parallel importer must make sure that there is an appropriate price difference in the export and import market. Furthermore, the parallel importer is *per se* the second party to enter the national market. Prior to the import, a marketing authorization with a public SPC exists in another Member State. During this time, the parallel importer has the opportunity to exploit the SPCs and product information published in the export markets, the different medical authorities' and producers' information about products and all other kinds of information available.

42. The respondent concludes that the protection of the SPC by way of national copyright does not restrict trade within the meaning of Article 11 EEA. Furthermore, the case at hand must be distinguished from the *de Peijper*,[14]

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13 Case 8/74 *Procureur de Roi* v *Benoît and Gustave Dassonville* [1974] ECR 837; Case 120/78 *Rewe-Zentral AG* v *Bundesmonopolverwaltung für Branntwein* [1979] ECR 649; Case 104/75 *Adrian de Peijper, Managing Director of Centrafarm BV* [1976] ECR 613; Cases 55/80 and 57/80 *Musik-Vertrieb membran GmbH et K-tel Internat* v *GEMA Gesellschaft für musikalische Aufführungs- und mechanische Vervielfältigungsrechte* [1981] ECR 147; Cases 56/64 and 58/64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH* v *Commission of the European Economic Community* [1966] ECR 429; Case C-30/90 *Commission of the European Communities* v *United Kingdom of Great Britain and Northern Ireland* [1992] ECR I-829; Case C-10/89 *SA CNL-SUCAL NV* v *HAG GF AG* [1990] ECR I-3711; Case 187/80 *Merck & Co. Inc.* v *Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063; Case 16/74 *Centrapharm et Adriaan de Peijper* v *Sterling Drug Inc.* v *Winthrop BV* [1974] ECR 1183.

14 See footnote 4.

Eurim-Pharm[15] and *Smith & Nephew*[16] cases. The decisive question in the present case is whether the protection of the way the market operator presents its product to the potential buyer contradicts the essence of Article 11 EEA.

43. In the event the EFTA Court finds that copyright constitutes a measure covered by Article 11 EEA, there are grounds for accepting the view that this measure falls within the exception provided by Article 13 EEA. The essence of the copyright for an SPC is the right of the author, i.e. the direct importer, to reserve the SPC it has developed to the marketing of its products.

44. The respondent is of the opinion that the copyright protection for an SPC is not covered by the principle of exhaustion because the SPC is not subject to trade or licensing for which the holder of the copyright receives any royalty or fees. Therefore, no right can be exhausted. Furthermore, the SPC is neither imported nor re-imported to Norway but created within the jurisdiction of Norway. Should the EFTA Court consider the SPC to be an intrinsic part of the medicinal product imported to Norway, then the SPC in the exporting State of origin is subject to exhaustion.

45. The respondent states that the Directive does not prevent the protection of the direct importer's SPC copyright. The purpose of the Directive is the elimination of barriers to trade by the adoption of harmonized registration requirements. The intellectual property right that may be connected to the information produced and which is subject to such registration is not thereby eliminated. The Directive was not designed with parallel imports in mind, but rather was intended to harmonize the registration procedure and urge the Member States to take into account a marketing authorization already granted in other Member States. The fact that the ECJ, in the *Smith & Nephew*[17] judgment, declared the requirements set out in the Directive inapplicable to the import of parallel products does not prevent the national authorities from requiring documents in so far as national copyright law so directs. It follows from Article 13 EEA that the protection of intellectual property rights may also serve as a justification.

Paranova AS

46. The *intervener* refers to the Preamble to the Directive and to the Preamble to the acts amending the Directive. In that light, the harmonized regime is based on the SPC constituting a key source of information, *inter alia* between medicinal products authorities in the various States. The Directive contains no provisions which make reservations for the possibility that national copyright law might hinder such use of the SPC as set out in the Directive. On the contrary, the

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15 See footnote 5.

16 See footnote 6.

17 See footnote 6.

provisions state that the exchange/sending of SPCs between medicinal product authorities in various States and between such authorities and distributors of medicinal products shall take place, and no provision is made for hindrances due to national copyright law. Accordingly, enforcement of national copyright law concerning SPCs is contrary to Articles 4a and 4b of the Directive.

47. Furthermore, it follows from Directive 92/28/EEC that the parallel importer has access to SPCs. Corresponding conclusions may be drawn from the case law of the ECJ[18] and a Communication of the Commission on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted.[19]

48. It is submitted that the application of national copyright law, with the consequence that the competent medicinal products authorities may not give out/approve/lay down the same SPC for a product imported by way of parallel import without the consent of the direct importer, is a measure contrary to Article 11 EEA. If a parallel importer must draw up a separate SPC, it is dependent on all information required under Article 4a of the Directive being available through public sources. This would create problems, especially for products which are relatively new on the market and which may have a long time remaining in their protection period. Therefore it is submitted that such a practice may affect trade in that the actual opportunity for parallel imports of medicinal products may be made much more difficult and possibly even have to cease.

49. Furthermore it is not possible for the parallel importer to gain access to the information which is required by Article 4a of the Directive. Information such as therapeutic particulars are only published in medicinal pharmaceutical literature to the extent that the test show results which differ sufficiently from previously - published material or is otherwise of general and/or research related interest. The information published on the product in the Norwegian Pharmaceutical Product Compendium, which contains extracts of essential information submitted in connection with applications for marketing authorizations, is not sufficiently detailed to provide a basis for anything other than conjectures as to the clinical profile of the product. Such a practice will be able to affect trade, both directly and indirectly.

50. National copyright protection for SPCs may not be justified based on protection of industrial and commercial property rights within the meaning of Article 13 EEA. Reference is made to the case law of the ECJ,[20] in which copyright protection was upheld because of differences between various States' legislation. Such considerations do not apply in the case at hand.

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18 See footnote 6 and footnote 4.

19 See footnote 7.

20 Cases 60/84 and 61/84 *Cinéthèque SA and others* v *Fédération nationale des cinémas français* [1985] ECR 2605.

51. Furthermore, there is no room for applying Article 13 EEA in the present case because there exists a harmonized system for SPCs and the significance of those SPCs for the issuance of marketing authorization.

52. It is submitted that any rights by virtue of national copyright on the part of medicinal products manufacturer are exhausted when the medicinal product is put on the market by the manufacturer or by another party with the manufacturer's consent. The potential protection of the SPC cannot be more extensive than the rights granted for trade marks. The function of the SPC is only to serve as formalized, standardized information to authorities and users in the individual State. The SPC cannot be seen in isolation from the medicinal product itself.

53. Enforcement of any national copyright rights with a view to stopping parallel imports would lead to an unjustified partitioning of the market and would thus be contrary to the rules on the free movement of goods.

54. Enforcement of any national copyright rights with the consequence that the competent medicinal products authority may not give out/approve/lay down the same SPC for a product imported by way of parallel import as for a directly imported medicinal product, without the consent of direct importer, both aims at and leads to artificial partitioning of the market in the European Economic Area. This constitutes a disguised restriction on trade. Consequently, a justification under Article 13 EEA is impossible.

55. The intervener suggests answering the questions as follows:

> *"Question 2: Council Directive 65/65/EEC, as amended, prevents national legislation from allowing the exercise of copyright protection for a Summary of Product Characteristics which is approved/laid down by medicinal products authority in accordance with that Directive and which would lead to the medicinal products authority not being able to 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.*
>
> *Question 1: There is a measure with effect equivalent to a restriction on imports contrary to Article 11 EEA, which cannot be upheld by reference to the industrial or commercial property rights in Article 13 EEA, if a Summary of Product Characteristics which is approved/laid down by the competent medicinal products authority in accordance with Council Directive 65/65, as amended inter alia by Article 4(9) of Council Directive 83/570/EEC, is protected by the importer's (direct importer's) rights under 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 medicinal product imported by way of parallel import as for a medicinal product imported by way of direct import, without the consent of the direct importer."*

The EFTA Surveillance Authority

56. With respect to the interpretation of Article 11 EEA in relation to parallel imports of medicinal products, the *EFTA Surveillance Authority* refers to the case law of the ECJ[21] and the EFTA Court.[22]

57. The exercise of the copyright in the present case prevents the competent authority from giving out, laying down, or approving, in respect of a product imported by way of parallel import, an SPC which is a part of a licence already issued unless the direct importer gives its permission to do so. Restrictions of this kind, i.e. in the use of, or access to, the officially approved description of the kind of product the parallel importer seeks to put on the market, complicate the authorization procedure. Thus, the exercise of such copyright leads to at least a potential hindrance on parallel imports. A national law which makes it possible for a direct importer to exercise the copyright in such a way constitutes a measure having effect equivalent to a quantitative restriction contrary to Article 11 EEA.

58. According to established case law of the ECJ, the grounds of protection of industrial and commercial property referred to in Article 36 EC include the protection conferred by copyright.[23]

59. However, the exercise of an intellectual property right in a manner not corresponding to the essential function of that right cannot be justified by a reference to Article 36 EC.[24] When a copyright is exercised in such a way and circumstances as in fact to pursue an aim manifestly contrary to the objectives of Article 36 EC, such a right cannot be considered to be exercised in a manner which corresponds to its essential function within the meaning of Article 36 EC.[25]

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21 Case 8/74 *Procureur du Roi* v *Benoît and Gustave Dassonville* [1974] ECR 837; Case 104/75 *Adrian de Peijper, Managing Director of Centrafarm BV* [1976] ECR 613; Case 201/94 *The Queen* v *The Medicines Control Agency, ex parte Smith & Nephew Pharmaceuticals Ltd and Primecrown Ltd* v *The Medicine Control Agency* [1996] ECR I-5819.

22 Case E-5/96 *Ullensaker kommune and others* v *Nille* [1997] EFTA Court Report 32; and Case E-6/96 *Tore Wilhelmsen AS* v *Oslo kommune* [1997] EFTA Court Report 56.

23 Cases 55/80 and 57/80 *Musik-Vertrieb membran GmbH et K-tel Internat* v *GEMA Gesellschaft für musikalische Aufführungs- und mechanische Vervielfältigungsrechte* [1981] ECR 147; Case C-337/95 *Parfums Christian Dior SA and Parfums Christian Dior BV* v *Evora BV* [1997] ECR I-6013; Case 78/70 *Deutsche Grammophon Gesellschaft mbH* v *Metro-SB-Großmärkte GmbH & Co.KG* [1971] ECR 487; Case 102/77 *Hoffman-La Roche & Co.AG* v *Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH.* [1978] ECR 1139; Joined Cases C-92/92 and 326/92 *Phil Collins* v *Imtrat Handelsgesellschaft mbH and Patricia Im- und Export Verwaltungsgesellschaft mbH and Leif Emmanuel Kraul* v *EMI Electrola GmbH* [1993] ECR I-5145; and Case 158/86 *Warner Brothers Inc. and Metronome Video ApS* v *Erik Viuff Christiansen* [1988] ECR 2605.

24 Case 187/80 *Merck & Co. Inc.* v *Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063; Case 19/84 *Pharmon BV* v *Hoechst Ag* [1985] ECR 2281.

25 Case T-76/89 *Independent Television Publications Ltd* v *Commission of the European Communities* [1991] ECR II-575.

60. The EFTA Surveillance Authority argues that Astra is in principle entitled to reserve the exclusive right to reproduce the SPC. However, the restrictions on its use have the effect of hindering parallel imports of medicinal products and thus the potential of bringing about the partitioning of the market, which is contrary to the aims of the EEA Agreement.[26]

61. The EFTA Surveillance Authority concludes that national legislation which makes it possible to exercise a copyright in respect of an SPC in such a way as to oppose the use of the same SPC by the competent authority in respect of a product imported by way of parallel import, cannot be justified under Article 13 EEA.

62. According to the EFTA Surveillance Authority, in light of the given arguments, it is not necessary to answer the question whether it is contrary to Articles 4a and 5 of the Directive for national legislation to provide copyright protection for the SPC.

63. Should the EFTA Court give an answer to this question, the EFTA Surveillance Authority puts forward the following arguments: the Directive does not address the issue of prohibiting copyright protection for the SPC. The Directive 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.

64. Reference is made to the Preamble to Directive 83/570/EEC, which introduces the SPC into the Directive. The main purpose of introducing the SPC is to safeguard public health. The other main element is to ensure the free movement of medicinal products.

65. The content of the SPC must be easily accessible to the competent authorities. Affording copyright protection to the SPC would result in a situation where the information contained in it would not be easily accessible to or at the disposal of the competent authority.

66. There is an element of dialogue between the applicant and the authorities when the competent authority approves the SPC and issues the authorization. This element is reflected in Article 4b of the Directive. Therefore, the final version of the SPC may be different from the proposal submitted by the applicant. The direct importer is not necessarily the author of the SPC.

67. Furthermore, the SPC is integrally and intrinsically linked to marketing authorization, which is not only intended to apply with regard to the first marketing of the product. According to the case law of the ECJ,[27] the marketing

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[26] This aim is reflected in Article 1(2) of Protocol 28 to the EEA Agreement.

[27] See footnote 6.

authorization serves as an authorization issued on a once-and-for-all basis with regard to the relevant product.

68. Since the SPC is an integral part of the marketing authorization, the competent authority is merely checking whether the product is already covered by the earlier marketing authorization/SPC. The administrative decision that follows is not be regarded as new marketing authorization, but merely a confirmation that the product is covered by an earlier decision.

69. If the SPC attached to the earlier decision were to be given copyright protection, one would accept that the direct importer could successfully invoke copyright protection against an administrative decision.

70. In light of the foregoing, copyright protection for the SPC would be in conflict with the purpose of the Directive/SPC and the nature of the SPC. Any conclusion to the contrary would mean that the competent authorities run the risk of being in breach of copyright while simply performing their duties under the Directive.

71. The EFTA Surveillance Authority proposes answering the questions as follows:

> *"National legislation which renders it possible to exercise a copyright to a Summary of Product Characteristics issued in accordance with Council Directive 65/65/EEC, as amended, with the consequence that the competent medicinal products authority may not, without the consent of the direct importer, give out, approve or lay down the same Summary for a product imported by way of parallel import, constitutes a measure having equivalent effect to quantitative restrictions in the meaning of Article 11 EEA which cannot be justified under Article 13 EEA.*
>
> *This being so, there is no need to answer the second question."*

Commission of the European Communities

72. The *Commission of the European Communities*, referring to the provisions of the Directive, points out that it is always the competent authority and not the applicant who approves and takes responsibility for the SPC. It follows from Article 7a, paragraph 2 of the Directive that the SPC constitutes an integral and inseparable part of the marketing authorization itself. The administrative act which allows a parallel importer to place products imported by way of parallel import on the market merely confirms that a product which is subject to parallel import is covered by a marketing authorization already granted in the State of import.

73. With respect to the interpretation of Articles 11 and 13 EEA, the Commission refers to the case law of the ECJ[28] and to Article 5 of Protocol 28 to the EEA Agreement on Intellectual Property. Under the latter provision, the States in the European Economic Area are obliged to adhere to a number of multilateral conventions on industrial and intellectual property, including the Berne Convention for the Protection of Literary and Artistic Works. Under Article 2(4) of the Convention, it is for the national legislation to determine the protection to be granted to official texts of legislative, administrative and legal nature. Article 9(2) of the Convention permits contracting parties to allow copying in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.

74. The Commission submits that a national rule, the effect of which is to oblige a parallel importer to draw up its own SPC and not allow it to use the SPC of the holder of the marketing authorization, constitutes a measure of equivalent effect to a quantitative restriction on imports under Article 11 EEA which cannot be justified under Article 13 EEA. For the parallel importer it will be difficult and, in some cases, impossible to draw up a comprehensive new and different SPC because it will often not have information and documentation on the nature and effect of the product.

75. Articles 4a and 5 of the Directive must be interpreted as requiring Member States to approve the same SPC for the same product regardless of who the importer might be.

76. As a general rule, a product imported by way of parallel import must have the same SPC as the product authorized in accordance with the Directive. Otherwise, the product imported by way of parallel import would not be covered by the existing marketing authorization. If one applies copyright protection to the SPC, this would constitute a significant barrier to parallel imports of medicinal products.

77. The case at hand should be distinguished from the judgments of the ECJ according to which the EC Treaty does not prevent Member States from determining the conditions under which intellectual property rights are granted. The Commission suggests adopting an interpretation of the combined effects of the Directive and Articles 11 and 13 EEA which would not allow copyright protection to prevent the Norwegian authorities attaching the SPC to the parallel import authorization.

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[28] Case 144/81 *Keurkoop BV* v *Nancy Kean Gifts BV* [1982] ECR 2853; Case 53/87 *Consorzio italiano della componentistica di ricambio per autoveicoli and Maxicar* v *Régie national des usines Renault* [1988] ECR 6039; Case C-317/91 *Deutsche Renault AG* v *AUDI AG* [1993] ECR I-6227; Case 104/75 *Adrian de Peijper, Managing Director of Centrafarm BV* [1976] ECR 613; Case 201/94 *The Queen* v *The Medicines Control Agency, ex parte Smith & Nephew Pharmaceuticals Ltd and Primecrown Ltd* v *The Medicine Control Agency* [1996] ECR I-5819; Case C-207/91 *Eurim-Pharm GmbH* v *Bundesgesundheitsamt* [1993] ECR I-3723.

78. Reference is made to the case law of the ECJ concerning the specific subject-matter of copyright. In the present case, it is not the SPC itself in connection with the marketing authorization that is of value to the holder of the marketing authorization. Copyright protection for the SPC is useful to the extent that its exercise would impede parallel imports of the medicinal products to which it refers. In principle, Community law respects the existence of copyright in the SPC, if that is granted by national law. In the circumstances of the case, however, the exercise of copyright in the SPC need not and should not be permitted under Community law. Its protection would therefore be disproportionate to the objective pursued by the copyright and could be considered as constituting a disguised restriction on trade within the second sentence of Article 36 EC.[29]

79. The Commission proposes answering the questions as follows:

> *"Articles 11 and 13 EEA in combination with Directive 65/65/EEC are to be interpreted as not permitting the protection by the direct importer's national copyright law of a Summary of Product Characteristics which is approved by the competent medicinal products authority, to the extent 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."*

Carl Baudenbacher
Judge-Rapporteur

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[29] Case 34/79 *Regina* v *Maurice Donald Henn and John Frederick Ernest Darby* [1979] ECR 3795.