Case C-60/89

Criminal proceedings against Jean Monteil and Daniel Samanni

(Reference for a preliminary ruling from the Cour d'Appel, Aix-en-Provence, France)

(Interpretation of Articles 30 and 36 of the EEC Treaty — Concepts of 'disease' or 'illness' and 'medicinal product' — Pharmacists' monopoly of the right to sell certain products)

Summary of the Judgment

1. *Approximation of laws — Proprietary medicinal products — Product fulfilling both the definition of medicinal product given in Directive 65/65 and that of cosmetic product given in Directive 76/768 — Covered by Directive 65/65*

   (Council Directive 65/65, Art. 1(2), and Council Directive 76/768, Art. 1(1))

2. *Approximation of laws — Proprietary medicinal products — Definition of medicinal product given in Directive 65/65 — Application by the national authorities to eosin of a strength of 2% and modified alcohol of a strength of 70% — Criteria*

   (Council Directive 65/65, Art. 1(2))

3. *Free movement of goods — Quantitative restrictions — Measures having equivalent effect — Pharmacists' monopoly — Extent — Medicinal products within the meaning of Directive 65/65 — Presumption of justification — Other products — Justification — Protection of public health or of consumers — Examination by national court*

   (EEC Treaty, Arts 30 and 36; Council Directive 65/65)

1. A given product, even if it falls within the definition of cosmetic products given in Article 1(1) of Directive 76/768, must nevertheless be treated as a 'medicinal product' referred to in Article 1(2) of Directive 65/65 on proprietary medicinal products and be made subject to the corresponding rules if it is presented as possessing properties for the treatment or prevention of illness or disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.

   That classification is necessary in view of the aim of protecting public health pursued by both directives, since the legal rules applicable to proprietary medicinal products are more rigorous than those applicable to cosmetic products, in view of the particular dangers which the former may present to public health and cosmetic products generally do not.

2. Eosin of a strength of 2% and modified alcohol of a strength of 70% are medicinal products within the meaning of the first subparagraph of Article 1(2) of Directive 65/65 on proprietary medicinal products, as medicinal products 'by virtue of their presentation', when they are presented for treating or preventing disease. That is so not only when they are expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question. The external form given to the product in question may provide persuasive evidence, but is not the sole or conclusive evidence.

   In classifying the abovementioned products in the light of the second definition of medicinal product given in the second subparagraph of Article 1(2) of Council Directive 65/65/EEC, that of medicinal products 'by virtue of their function', account must be taken of the adjuvants also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

3. Under Community law as it now stands, the determination of the rules governing the distribution of pharmaceutical products remains a matter for the Member States, provided that the provisions of the Treaty, and in particular those relating to the free movement of goods, are respected.

   A monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation.

   If a Member State chooses to restrict to pharmacists the right to distribute products of that kind, such a barrier is, in principle and in the absence of any evidence to the contrary, justified in so far as it concerns medicinal products within the meaning of Council Directive 65/65/EEC on proprietary medicinal products.

Where other products are concerned, however they may be classified in national law, it is for the national court to determine whether a monopoly of the right to market such products granted to pharmacists is necessary for the protection of public health or of consumers and whether those two aims cannot be achieved by measures less restrictive of intra-Community trade.

REPORT FOR THE HEARING
in Case C-60/89 *

I — Legal background and facts of the case

A — *Legal background*

(a) *The French legislation on the distribution of medicinal products*

Article L.511 of the Code de la Santé Publique (Public Health Code) defines medicinal products as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals and any product which may be administered to humans or animals with a view to making a medical diagnosis or to restoring, correcting or modifying their physiological functions'. Medicinal products are to be distinguished, in particular, from cosmetic and bodily hygiene products, which are defined by Article L.658-1 of the same code as 'all substances or products other than medicinal products intended to be brought into contact with various parts of the human body or teeth or mucous membrane, with a view to cleaning them, protecting them, keeping them in good condition, changing their appearance, perfuming them or correcting their odours'.

Pursuant to Article L.511, cosmetic products are not to be regarded as medicinal products unless they contain certain substances. The same applies to dietetic products.

Trade in medicinal products is strictly regulated. Under Article L.601 of the Code de la Santé Publique, proprietary medicinal products, namely 'any ready-prepared medicinal product, presented in a particular packaging and under a special name', may be marketed only after a marketing authorization for them has been issued by the Ministre des Affaires Sociales (Minister for Social Affairs).

Pursuant to Article L.512 of the code, the marketing of medicinal products and proprietary medicinal products (as well as the sale of other products such as medicinal plants appearing in the pharmacopoeia) *may be undertaken only by pharmacists* who fulfil

* Language of the case: French.