Cranberry tablets – food or medicine?

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Defining the boundaries between medicines, food supplements, dietetic foods and foods is frequently difficult. A recent Supreme Court decision sheds some light on the differences between medicines and dietetic foods.

Facts

The defendant advertised cranberry tablets with claims including the following:

- "against urinary tract infection";
- "the substances present in cranberries reduce the adhesion of bacteria on the bladder mucosa, thus counteracting inflammation";
- "the bacteriostatic effect of special extracts from watercress and horseradish supplement the protective effect of cranberry on the bladder in an ideal way";
- "Vitamins C and D: these vitamins play a role in the proprioceptive defence, which is particularly challenged in case of a urinary tract infection"; and
- "prevents urinary tract infections... so in the best case a bladder infection can be avoided".

There was no indication that the tablets had any medicinal properties.

The plaintiff, a qualified institution for the protection of the interests of competitors, sued the defendant to cease and desist distribution of the tablets:

- as a medicinal product without marketing authorisation; and
- as a dietetic food with specific medicinal purposes (ie, the dietary treatment of urinary tract infections with extracts from cranberry, watercress and horseradish, as well as vitamins).

The appeal court ordered the defendant to cease and desist distribution of the tablets as a medicinal product, but declined to order it to cease and desist distribution of the tablets as a dietetic food. Both parties appealed to the Supreme Court.

Decision

The Supreme Court dismissed the plaintiff's appeal to grant the injunction in respect of distribution of the tablets as a dietetic food. It stated that the prerequisite for a cease-and-desist claim is the danger of either first infringement or reoffence, and clarified that danger of reoffence requires that an infringement have already been committed. The court further stated that the scope of a cease and desist order must be oriented to the specific infringement. Therefore, the justification of the cease and desist claim against distribution of the tablets as a dietetic food with specific medicinal purposes would require danger of reoffence. This would imply that the product was distributed both as a presentation medicine (because of its presentation) and as a dietetic food (because of its designation and function).

Supreme Court Decision 17 Ob 14/10y had already rejected this possibility, finding that under EU

law, medicinal products as defined by EU Directives 65/65/EEC and 92/73/EEC are expressly not food. Therefore, if a substance is marketed as a medicine in the sense of Section 1, Paragraph 1(1) of the Act on Medicines, it is subject only to the provisions of the legislation on medicinal products. Presentation medicines are also subject to the Act on Medicines.

The Supreme Court held that the appeal court had acted in line with the above guidelines when it decided that the tablets' qualification as a presentation medicine excluded them from qualification as a dietetic food with specific medicinal purposes (meaning that the defendant could not be charged with infringing the regulations for such foods). If the defendant could be charged with distributing the product as a presentation medicine in breach of the Act on Medicines (thus acting unfairly within the meaning of Section 1 of the Unfair Competition Act), then the cease-and-desist order could apply only to distribution of the product as a medicine.

The Supreme Court ruled that distribution of the product without indicating or advertising any of its medicinal properties was not unfair (and therefore did not infringe Section 1 of the Unfair Competition Act), because the plaintiff had based its cease-and-desist claim only on the marketing of the tablets as a presentation medicine, not on medicinal properties of the tablets thus qualifying them as a medicine by function.

The Supreme Court also dismissed the defendant's appeal, which was based on the argument that the appeal court's decision was self-contradictory. The Supreme Court stated that the appeal court's decision neither expressly nor impliedly permitted the tablets to be offered as dietetic food with specific medicinal purposes. It had dismissed the claim only because there was no danger of re-offence.

The Supreme Court stated that the defendant's claims alleging the medicinal properties of the tablets went far beyond what is permitted for a dietetic food with specific medicinal purposes. It agreed with the reasoning of the appeal court that the claims used in the advertisements for these tablets qualified as advertising medicinal properties (ie, they made multiple specific references to curative and preventive effects); it further agreed with the appeal court's consequent qualification of the tablets as a presentation medicine.

Comments

The Supreme Court's decision is in line with its established practice. Two prior decisions, cited by the Supreme Court, held that the marketing of medicinal products requires marketing authorisation and that products qualify as medicinal products due to their presentation as such, even in the absence of medicinal properties.

The wording in Section 1, Paragraph 1 of the Act on Medicines and the German version of Article 1(2) of the EU Directive on the Community Code Relating to Medicinal Products for Human Use (2001/83/EC) must be understood to reference presentation. This reference is clear in the English version of the EU directive, which refers to "any substance or combination of substances presented as having properties for treating or preventing disease in human beings". Originally, the German version was also worded "*Alle Stoffe oder Stoffzusammensetzungen, die... bezeichnet werden*" ("any substance or combination denoting..."); only in Directive 2004/27/EC was the wording amended to "*Zu Heilung oder Linderung... bestimmt*" ("for curing or alleviating determined..."). Since the English and French versions remained unchanged in this respect, and in the absence of an explanation in the recitals, there is no doubt that the EU legislature did not intend to renounce the concept of presentation medicine.

The decision clarifies that any product that qualifyies as a medicine (by function or presentation) is subject only to the laws regulating medicinal products. Food supplements, dietetic foods and ordinary foods presented as having medicinal properties are medicines by presentation and thus subject to marketing authorisation, which obviously cannot be obtained in the absence of functional medicinal properties.

In addition to the strict limits applicable to health and nutrition claims for foods under the EU Regulation on Nutrition and Health Claims Made on Foods (1924/2006), any reference to the treatment or prevention of diseases must also be avoided.

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