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Two Interesting Court Decisions Concerning Health Claims made on Foods

"BACH flower remedies", Judgment of the ECJ, Case C-177/15

On November 23, 2016, the Court of Justice of the European Union (ECJ) issued a Decision on a request for a preliminary ruling brought before it by the German Federal Supreme Court ("Bundesgerichtshof – FSC"), concerning the interpretation of EU provisions dealing with nutrition and health claims made on foods in the *Nutrition and Health Claims Regulation (EC) No. 1924/2006 ("HCR")*.

The decided case concerned products sold in small dropper bottles or as sprays, and distributed in Germany as BACH Flower Preparations ("Bach-Blüten-Präparate") under the designations "RESCUE drops" ("RESCUE TROPFEN") and "RESCUE NIGHT SPRAY", respectively. The bottles contained liquids with an alcohol content of 27% by volume to be consumed after diluting the drops in water or by spraying the liquid directly on the tongue. Originally, i.e. since before January 1, 2005, the manufacturer marketed these products *as medicinal products*, while in 2008 it switched for legal reasons to marketing them *as foodstuffs*, without making any actual changes to the products.

The German FSC had decided that the terms "RESCUE TROPFEN" and "RESCUE NIGHT SPRAY" constituted *health claims* within the meaning of the HCR, which provides that beverages containing more than 1.2% by volume of alcohol shall not bear health claims. The Regulation also provides, in its Article 28, that *"products bearing trademarks or brand names existing before January 1, 2005 which do not comply with this Regulation may continue to be marketed until January 19, 2022 after which time the provisions of this Regulation shall apply"*. One of the questions to be decided by the ECJ was whether the Regulation, and in particular its Article 28, are applicable, considering that before January 1, 2005 the same products had been marketed as medicinal products which were later marketed as foodstuffs.

According to the ECJ, the identical product, the composition of which has not been changed, cannot be or have been both, foodstuffs *and* medicinal products, but in the relevant case the preparations were *objectively foodstuffs* within the meaning of the Health Claims Regulation, according to the findings of the German FSC, with the result that Article 28 of the Regulation was applicable.

Since products which fall under Article 28 may continue to be marketed until January 19, 2022, the competitor who had applied for an injunction against the manufacturer may now expect problems in obtaining the injunction it had applied for in the pending German court proceedings.

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"Repair Capsules", Judgment of the German Federal Supreme Court, Case I ZR 81/15

Already on April 7, 2016, the FSC had issued a decision which had also dealt with the topic of health claims used in advertising, but the complete decision was only made available to the legal public in November 2016. The decision concerned two different products.

Leaflets distributed by the Defendant to interested customers via e-mail advertised so-called "Premium Repair Capsules" ("Repair-Kapseln Premium"), claiming: *"with an improved formula and containing new valuable ingredients our new Premium Repair Capsules make for fantastic skin, full-bodied hair and firm fingernails – even more effectively than previously …"*. The Defendant's website, to which a link in the leaflet referred, indicated that the Premium Repair Capsules contained Vitamin C, Zinc, Vitamin B1 and B2, Niacin, Pantothenic Acid, Vitamin B6, Folate, Biotin, Selenium, Cilicic Acid, and further substances made from plants and algae.

The Defendant also advertised another product called "Ace of Hearts Capsules" ("Herz-Ass-Kapseln"), claiming that certain *"vital substances" were required to keep the heart muscle cells "in good humour"*, listing, *i.a.*, Omega salmon oil, Vitamin C, Magnesium and Vitamin E, as well as various B Vitamins, hawthorn, apple skin and rooibos tea.

The Defendant's capsules were intended for human consumption and therefore constituted food, regardless of whether they were food supplements, which are considered as being "special food" in the applicable provisions.

The Federal Supreme Court held that the claims referring to the "Premium Repair Capsules" were health-related in the sense of the HCR. A health claim which will be understood by the consumers addressed to say that a certain product may remove damage to skin, hair or fingernails, is not identical to the health claims permitted by the *Commission Regulation (EU) No. 432/2012 of May 16, 2012 establishing a list of permitted health claims made on foods* according to which a certain nutrient *"contributes to the maintenance of normal skin, hair or nails"*, and the Defendant's claim is therefore *not* permitted.

As to the "Ace of Hearts Capsules", the Court held that a health claim which is not clear as to *which* of the nutrients, substances, foods, or food categories among the claims which are permitted according to the Annex to the above-mentioned Regulation of May 16, 2012, is responsible for the claimed effect of a product, is *not* identical to the permitted claims, and therefore *not* permitted.

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