HEALTHCARE & LIFE SCIENCES - AUSTRIA

Detox capsules

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The Supreme Court recently ruled on the advertising of a product which sits in the grey zone between medicinal products, medical devices and foodstuffs.

Facts

The plaintiffs were an association of entrepreneurs, including parties from the defendant's industry, which sought to safeguard and promote the interests of companies operating in Austria and combat unfair competition – in particular, by asserting injunctive relief.

The defendant marketed products containing the components zeolite (clinoptilolite) and bentonite – in particular:

- zeolite MED detox powder;
- zeolite MED detox capsules;
- bentonite MED detox powder; and
- bentonite MED detox capsules.

The defendant advertised zeolite MED detox powder and capsules on the Internet. According to his ads, these products could be used for "natural detoxification". Customers who ordered the capsules received "clinoptilolite zeolite in tested effective qualities in accordance with the high quality criteria of the European and German Pharmacopoeia" and were instructed to use the mineral only as marketed by the defendant. Zeolite MED detox capsules are ideal for travel because of their ease of use and practicality.

On the other hand, the bentonite MED detox powder and capsules were described as suitable for detoxification and gentler than zeolite. The capsules were advertised as "gentle detoxifiers on the go". The description of these products indicated that bentonite was authorised as a pharmaceutical excipient and food additive in the functional group 'mycotoxin contaminants' and for all animal species in the functional groups 'thickener', 'anti-caking agent' and 'substances controlling radionuclide contamination' in the European Union.

The defendant's website also contained a link to his Facebook page, featuring similar advertising. In addition, the defendant answered user requests on the Facebook page. He confirmed, for example, that his zeolite and bentonite products could be used for skin ailments such as eczema and – with reference to the tested pharmacopoeia and pharmacy qualities – that the products were suitable for human and animal use.

In a statement issued on 6 May 2004, the Austrian Federal Ministry of Health and Women highlighted that, among other things, foods – including dietary supplements – containing clinoptilolites are not marketable in terms of their novel food properties. The defendant's products (ie, zeolite MED detox powder, zeolite MED detox capsules, bentonite MED detox powder and bentonite MED detox capsules) were not approved as pharmaceuticals or medical devices, nor was the zeolite MED detox skin powder approved as a medical device. The plaintiffs thus requested that

the defendant be prohibited from:

- offering and distributing products containing zeolite (clinoptilolite) and bentonite as medical devices if they were not authorised as such;
- including disease-related information in the advertising of those products (eg, that they could be used for eczema or arthrosis);
- including health claims in the advertising of those products (eg, "for natural detoxification, for detoxification in the health sector and to reduce pathogenic factors"); and
- promoting the products as "vegan, lactose-free and gluten-free".

Further, the plaintiffs' requested that the verdict be published in a Sunday edition of the *Neue Kronenzeitung* or an alternative court-determined medium.

Decisions

First-instance decision

The first-instance court(1) granted the requested injunctive relief, except for the prohibition on promoting the products as "vegan, lactose free and gluten free". According to the court, the defendant's advertising gave the average consumer the impression that the products offered therapeutic benefits, as well as healing and health properties for humans and animals. This created an incorrect impression that the defendant was distributing medicines or medical devices.

The defendant appealed the decision.

Court of appeal decision

The court of appeal(2) dismissed the prohibition on advertising the products as medical devices, expressly limiting the injunction to the products cited by the applicants in their request and excluding the ordinary recourse.

According to the court, the defendant's advertising gave the average consumer the impression that the products were suitable for treating and preventing disease. On the other hand, it could not be concluded that the products' main mechanism of action was achieved by physical effects. Further, the intended intake of powders or capsules did not mean that the main effect of the products was predominately achieved by physical means. As the defendant did not advertise the products as medical devices, a violation of the Medical Devices Act was ruled out.

Since the defendant did not designate or specify his products as medical devices and such an understanding could not be derived from his advertising, the request for injunctive relief in this regard was dismissed. However, the court held that, based on the public's understanding, the defendant's products were 'food supplements' within the meaning of Section 3 Z 4 of the Food Safety and Consumer Protection Act. Pursuant to Section 5(3) of the act, it is prohibited to:

- market or advertise a foodstuff with properties of prevention, treatment or cure of a human disease; or
- give the impression of such characteristics.

The defendant had advertised his nutritional supplements on a disease-related basis by highlighting that "the volcanic minerals [could] be applied to skin symptoms" and by referring to the products' use on arthrosis for humans and animals. Thus, the applicants' claim for injunctive relief was partially upheld, with the proviso that:

- the cease and desist order apply only to the specific products highlighted in the applicants' claim; and
- the term 'natural cosmetics' be omitted, as cosmetic products are not covered by the definition of 'foodstuff' in the Food Safety and Consumer Protection Act.

As health claims are permitted only with an authorisation, and since the defendant in the case at hand had no such authorisation, the applicants' claim for injunctive relief in relation to the products specifically sold by the defendant was justified.

However, the court ruled that there was no reason to publish its findings in a Sunday edition of the *Neue Kronenzeitung* in addition to publication on the defendant's website, as the cease and desist order was not based on misleading information in print media or direct mail items and the type and number of media in which publication is required should not be disproportionate to the publicity of the unlawful act.

The plaintiffs' appealed the court of appeal's decision.

Supreme Court decision

The Supreme Court accepted the plaintiffs' extraordinary recourse and partially granted the claim as regards the health and disease-related advertising in its published verdict.(3)

Section 2(1)(1) of the Medical Devices Act defines 'medical devices' as all instruments, apparatuses, devices, software, substances or other objects used individually or interconnected, including those specifically intended by the manufacturer for diagnostic or therapeutic use and for use to support the proper functioning of a medical device. The mere fact that these properties are attributed to a product does not make it a medicinal product (by presentation). According to Section 2(1) of the Medical Devices Act, a product is considered to be a medical device if the manufacturer's intended main effect in or on the human body is met by neither pharmacological nor immunological agents. In essence, it depends on the effect objectively attributed to the product.

Section 1(1) of the Medicinal Products Act defines 'medicinal products' as substances or preparations of substances intended for:

- use in or on the human or animal body to cure, treat or prevent human or animal diseases or disorders; or
- use in or on the human or animal body or administered to a human or an animal in order to restore, correct or influence physiological functions through a pharmacological, immunological or metabolic action.

Therefore, there are two groups of medicine:

- those which, because of their actual function, are medicinal products; and
- those which have no such function but claim to have such function by presentation of the medicinal product.

The subjective purpose (RIS-Justiz RS0041450) is sufficient for the acceptance of a medicine. Presentation medicines are also subject to the Medicinal Products Act in their entirety.

According to Section 1(3)(11) of the Medicinal Products Act, medical devices are not drugs. If a product falls under both the definition of the 'medicinal product' pursuant to Sections 1(1) and 1(3) of the Medicinal Products Act and the definition of 'product' regulated by another federal law, only the Medicinal Products Act applies (Section 1(3a)). This corresponds to Section 4(1 Z 1) of the Medical Devices Act, according to which the act does not apply to medicinal products. The decision as to whether a product is covered by the Medicinal Products Act or the Medical Devices Act depends on the main mode of action of the product. Therefore, a product cannot be both a drug and a medical device.

The Supreme Court has previously stated that due to the legal equality of functional and presentation medicines, the priority of application provided for in Section 1(3a) of the Medicinal Products Act also applies. A foodstuff with special medical purposes or a dietary supplement to which a curative or treating effect has been attributed must therefore be assessed exclusively in accordance with the Medicinal Products Act.

The fact that the defendant's products were not devices did not preclude their qualification as a medical device, as Section 2(1) of the Medical Devices Act also covers substances in general. The attribution of curative or treatment properties is also not decisive for the delimitation. Instead, the court had to examine whether the defendant's products had a pharmacological, immunological or metabolic effect, as the demarcation of medicinal products as medical devices according to Section 4 (1)(1) of the Medical Devices Act must be based on the product's main mode of action.

According to the European Court of Justice's(4) and the German Federal Court's(5) case law, a pharmacological effect exists where there is any kind of direct or indirect interaction between the molecules of the active ingredient and a cellular component of the human body. Such an interaction will be deemed to exist if the molecules prevent other substances from interacting with cells in the body.

Both according to the defendant's attributions and the plaintiffs' allegations concerning the actual mode of action of the defendant's products, the court determined that the products were supposed to bind to and remove contaminants from the body and thereby prevent the contaminants from interacting with human cells. This is neither a purely physical nor mechanical effect. The defendant's products were therefore assessed as presentation medicines. Consequently, the applicability of the Medical Devices Act was excluded. The appellate court therefore correctly denied an infringement of the Medical Devices Act.

However, the Supreme Court found that the court of appeal had wrongly restricted the injunction issued in connection with the disease and health claims. An order to cease and desist must always be based on the specific violation of the law. However, a certain generalised version of the order in connection with individual prohibitions is usually necessary to ensure that the order is not easily circumvented. Further, it is virtually impossible to describe all conceivable intervention actions.

The court of appeal's decision, which restricted the ban to four specific products, was too narrow in accordance with the principles of case law. The defendant would only have to rename the products to circumvent the ban. Therefore, the Supreme Court found that the injunction imposed by the first-instance court should be restored in this regard.

The plaintiffs rightly continued to pursue the request for publication dismissed by the lower courts. While verdicts must generally be published in the same manner as the announcement in question, there may also be special reasons for further publication. For example, if a company's former customers with an objective interest in the information are unlikely to search the guilty company's website, an injunction is generally not only published there.

This was true in the case at hand. The Supreme Court held that – especially in health-related interventions – the need for education is particularly significant. As such, the court held that publication in a Sunday edition of the *Neue Kronenzeitung* was appropriate and upheld the request, finding that a half-page summary of the judgment was sufficient.

Comment

Although the qualification as a medicine clearly outweighs the qualification as a food or medical device for products that could qualify as each of these, the plaintiffs wrongly qualified the products as medical devices and therefore requested the cease and desist of the distribution of these products as medical devices. As the products qualified as medicinal products, the Supreme Court had to dismiss this request. However, the plaintiff partially succeeded, because the Supreme Court granted the claim insofar as advertising the health and disease-related claims were concerned. The court also clarified that a broadly defined verdict was necessary to avoid easy evasion of the cease and desist order.

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Endnotes

(1) Regional Court Salzburg 30 March 2017, 9 Cg 102/16t.

(2) Higher Regional Court Linz 3 August 2017, 4 R 79/17s.

(3) Supreme Court 21 December 2017, 4 Ob 190/17w.

(4) C-308/11, Chemische Fabrik Kreussler & Co GmbH.

(5) I ZR 90/08 = PharmR 2010, 641; I ZR 166/08 = PharmR 2010, 638; I ZR 204/09 = PharmR 2011, 299.
