PRODUCT REGULATION & LIABILITY - AUSTRIA

No outer packaging required?

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Occasionally, slipshod implementations of EU directives lead to unnecessary court proceedings. The Austrian courts recently dealt with the Austrian legislature's implementation of Article 54 of the Community Code.

Facts

Both parties marketed infusion solutions (namely, physiologic saline solutions) in Austria. The claimant sued the defendant to cease and desist marketing its solution in glass or plastic bottles without outer package showing the particulars in accordance with the labelling ordinance.(1) The claimant argued that according to Section 17(1) of the Act on Medicinal Products,(2) pharmaceuticals must not be marketed solely in an immediate package (in the present case, a glass bottle with saline solution), but requires an additional outer package (carton) showing the particulars set out in Section 17(1). By not packing the products in cartons, the defendant saved the cost of outer packaging and thus achieved an unfair competitive advantage.

Section 17(1) of the act provides that medicinal products requiring a marketing authorisation or subject to registration (unless there are radioactive medicinal products) may be put on the market only if the outer and immediate packages contain several particulars (listed in detail in the labelling ordinance).

Decisions

The first-instance regional court(3) dismissed the claim. The higher regional court(4) confirmed the decision, but admitted an appeal to the Supreme Court.

Notwithstanding the higher regional court's admission of an appeal, the Supreme Court considered the appeal as inadmissible and confirmed the lower courts' decisions.(5) The Supreme Court concurred with the appellate court's opinion that Section 17(1) of the act requires the labelling of certain particulars in the case of eventual outer packaging, but does not require outer packaging of medicinal products.

The Supreme Court held that the appellate court's interpretation was supported by Section 17(8) of the act, which provides that small immediate packages must contain only a limited number of the particulars according to Section 17(1), insofar as outer packaging exists. This interpretation conforms with Article 54 of EU Directive 2001/83/EC,(6) which provides that certain particulars (as listed in Section 17(1) of the act and the labelling ordinance) must appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging. Article 55(2) of the directive also provides for certain relief in connection with immediate packages placed in outer packaging, as implemented by Section 17(8) of the act. According to Article 1(24) of the directive, 'outer packaging' is defined as the packaging into which the immediate packaging is placed. Therefore, both provisions start from the premise that a medicinal product does not necessarily require outer packaging and immediate packaging.

The Supreme Court also considered the claimant's further argument that Section 17(5a) of the act was flawed: the requirement to have security markings and an appliance that can recognise possible manipulations to outer packaging aims to prevent the falsification of medicinal products by replacing original outer packaging with an imitation. If there is no outer packaging, such manipulations are impossible at the outset.

Comment

Although the wording of Section 17(1) of the act (ie, "if the outer packaging and the immediate packaging contains the following particulars in German language...") could be interpreted as the requirement of both immediate and outer packaging, the Supreme Court clearly backed an interpretation which falls in line with the Community Code. Contrary to the Austrian implementation of the Community Code, Article 54 of the Community Code undoubtedly provides that outer packaging is not mandatory. A review of the Community Code before the claimant initiated its claim would have saved it a disappointment.

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Endnotes

(1) Ordinance on the labelling of medicinal products (*Federal Law Gazette II* 174/2008).

(2) Act on Medicinal Products (*Federal Law Gazette* 185/1983), as amended.

(3) Regional Court Innsbruck, 69 Cg 133/16g, January 25 2017.

(4) Appellate Court Innsbruck, 2 R 20 17/h, February 23 2017.

(5) Supreme Court, 4 Ob 61/17z, July 27 2017.

(6) Community Code relating to medicinal products for human use.