HEALTHCARE & LIFE SCIENCES - AUSTRIA

Ascertainment of (dis)conformity of *in vitro* diagnostics

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The Supreme Court of Justice classes the infringement of a general norm as an unfair business practice or another unfair act in the sense of Section 1(1)(1) of the Unfair Competition Act unless the norm can be interpreted in such a way that it does not prohibit the queried conduct. This is also true for norms of secondary EU law, such as EU Directive 98/79/EC.

Facts

The parties were competitors in the marketing of rapid diagnostics (*in vitro* diagnostics and pregnancy and ovulation tests). The defendant's products were subject to internal and external regulatory assessments. On 15 December 2017 the defendant obtained a European Commission (EC) declaration of conformity for the products in question. The products were marked with the CE mark and the number of the notified body in the United Kingdom.

The plaintiff requested that the defendant be prohibited from placing on the market certain medical devices without including sufficient information on their safe application on the packaging and in the usage instructions, particularly if the packaging and usage instructions did not contain certain information as described in more detail by the plaintiff.

All three instances dismissed the claim.

Supreme Court of Justice decision

In its 22 September 2020 judgment, the Supreme Court of Justice first summarised the EU and Austrian legislation on the marketing of medical devices and *in vitro* diagnostics.(1)

According to Article 3 of EU Directive 98/79/EC on *in vitro* diagnostics, devices must meet the requirements set out in Annex I, taking into account their intended purpose. Member states must not prevent parties from placing devices that bear the CE mark on the market or putting them into service if they have undergone a conformity assessment in accordance with Article 9.

According to Article 8 of the directive, where a member state ascertains that *in vitro* diagnostics which are correctly installed, maintained and used for the intended purpose may compromise, among other things, patients' health or safety, they must take all appropriate interim measures to withdraw the devices from the market or prohibit or restrict parties from placing them on the market or putting them into service. The member state must immediately inform the EC of any such measures, indicating the reasons for its decision. For a non-compliant device that bears the CE mark, the member state must take appropriate action against whichever party affixed the mark and inform the EC and the other member states thereof.

Where a member state establishes that a CE mark has been wrongly affixed, the manufacturer or its authorised representative must cease the infringement under conditions imposed by the member state. Where non-compliance continues, the member state must take all appropriate measures to restrict or prohibit the party from placing the product in question on the market, or ensure that it is withdrawn from the market, in accordance with Article 8.

According to Annex I of the directive, manufacturers must supply information needed to:

- use the product safely and correctly, taking account of the training and knowledge of the potential users; and

- identify the manufacturer.

The label must include the following details, among others, which may take the form of symbols, as appropriate:

- the date by which the device or part thereof should be used, in safety, without degradation of performance, expressed as the year, the month and – where relevant – the day, in that order;
- a statement indicating that the device is to be used *in vitro*, where appropriate;
- any particular storage or handling conditions;
- any particular operating instructions;
- appropriate warnings or precautions to take; and
- a statement that the device is intended for self-testing, where applicable.

According to Annex III of the directive, to obtain an EC declaration of conformity, the manufacturer or its authorised representative must ensure and declare that the products concerned meet all applicable provisions of the directive. The manufacturer must affix the CE mark in accordance with Article 16.

The directive on *in vitro* diagnostics and EU Directive 93/42/EEC on medical devices were implemented in Austria by the Act on Medical Devices (MPG).(2) Section 6 of the MPG prohibits parties from placing medical devices(3) on the market if there is a substantiated suspicion that they do not comply with the two directives. The MPG also provides that medical devices must be accompanied by information specified in Annex III of EU Directive 98/791/EC.

Medicinal products may be placed on the market and put into service if they bear the CE mark. Medical devices may bear the CE mark only if they provably comply with the MPG (and the two directives) and have undergone the necessary conformity assessment which entitles them to bear the CE mark. Medical devices which bear the CE mark are considered compliant until this presumption is invalidated.

In *Medipac-Kazantzidis* (C-6/05), the European Court of Justice (ECJ) held that medical devices that conform with the provisions of EU Directive 93/42/EEC and are certified according to the procedure which it specifies fulfil the general requirements and are appropriate for the use for which they are intended. If a medical device does not comply with the directive even though it bears the CE mark, the relevant member state must take measures according to Article 8(3) of the directive and inform the EC and the other member states. The manufacturer or its authorised representative must cease the infringement under conditions imposed by the member state. To reconcile the free movement of products with the protection of patients' health, member states must take appropriate measures according to Article 8. Bodies which are not empowered to do so may not unilaterally decide on the action to be taken in such circumstances.

In *Servoprax (*C-277/15), the ECJ held that EU Directive 98/79/EC harmonises the essential requirements for *in vitro* diagnostics. If products correspond to these norms and are certified under the directive, it must be presumed that they fulfil the essential requirements and are appropriate for their intended use. According to Article 4(1) of EU Directive 98/79/EC, member states must not prevent parties from placing products which bear a CE mark on the market or putting them into service if they have undergone a conformity assessment according to Article 9 of the directive. Article 9 must be interpreted in the sense that a parallel importer of a device which bears a CE-mark is not obliged to undertake a new assessment.

The Supreme Court of Justice held that the presumption under EU Directives 98/79/EC and 93/42/EEC and the corresponding jurisdiction of the ECJ is implemented in Section 22(1) of the MPG. According to the MPG, a CE mark may be affixed only by those authorised to conduct a conformity assessment. This presumption is disprovable, since devices must not be placed on the market if there is a substantiated suspicion that they do not comply with the requirements. However, the fact that the presumption is disprovable is different from the question of how the disproof can be demonstrated. Does it require a proceeding according to Article 8 of the directive, which is conducted by the Federal Office for Safety in Healthcare (with the involvement of the EC), or can the presumption be disproved without this?

The ECJ's decision in *Medipac-Kazantzidis* covers the first alternative. On the other hand, certain precedents by German courts of appeal hold that a prohibition under the Unfair Competition Act is not excluded. In the present case, the plaintiff's argument that there was no Austrian Supreme Court of Justice precedent spoke for the tenability of the defendant's point of view that it may rely on the CE mark. Considering the EU and Austrian legislation, the jurisdiction of the ECJ and the absence of Austrian case law on the effects of the CE mark, the defendant's opinion that she could rely on the CE mark to assume that the products corresponded to the requirements of the MPG was at least tenable. With regard to Clause 6.1 of Annex III of EU Directive 98/79/EC, this aligns with the view that the information provided on the device's label and its instructions for use had been approved in the course of the EC conformity declaration. The final clarification of the legal situation was

not necessary since the defendant's position was so tenable that a request for a preliminary ruling by the ECJ was superfluous.

Comment

The Supreme Court of Justice has become a kind of alternative administrative court, since its case law deems the infringement of general (administrative) provisions to be acts of unfair competition unless there is a good argument that the challenged conduct complies with the allegedly infringed provision. In the present case, the plaintiff objected to the defendant's information on the safe application of the products in the instructions for use. The incomplete instructions for use would have infringed both the MPG and Annex I of EU Directive 98/79/EC.

Nevertheless, the Supreme Court of Justice refrained from ruling on this question with the argument that the CE mark indicates conformity and that only the regulatory authority – in Austria, the Federal Office for Safety in Healthcare – is competent to ascertain whether a CE mark has been affixed correctly. Therefore, the distributor in question could rely on the CE mark unless the mark was withdrawn by the competent authority. The decision clarifies that in Austria, only the Federal Office for Safety in Healthcare can make this determination. When a market participant deems a device which bears a CE mark to be non-compliant, the only possibility is to notify the Austrian Federal Office for Safety in Healthcare of the alleged infringement.

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Endnotes

(1) 4 Ob 135/20m, WBL 2021, 54.

(2) BGBl 657/1996, as amended.

(3) The definition of 'medical devices' in the MPG also comprises *in vitro* diagnostics.