ADVERTISING OF MEDICINAL PRODUCTS IN GERMANY

Roger Mann reviews relevant case law and highlights the growing influence of EC legislation

German advertising law (known for its tough standards) is falling more and more under the influence of European Community (EC) legislation and this is resulting in a slow but steady liberalisation. This is not so much as a result of the efforts of the German legislators to implement EC Directives but more because of the influence of precedents set by the highest German Court competent for Civil Law (*Bundesgerichtshof*) and the Court of Appeals (*Oberlandesgerichte*).

Unlike most areas of law in Germany (which is a civil law jurisdiction), general advertising law mainly consists of case law based on some rudimentary statutory rules in the *Act Against Unfair Competition* (*Gesetz gegen den unlauteren Wettbewerb* - UWG[1]), as interpreted by the courts. The main Sections of this Act read as follows:

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> 'Any person who, in the course of business activity for purposes of competition, commits acts contrary to honest practices, may be enjoined from these acts and held for damages' (Section 1). *And*
>
> 'Any person who, in the course of business activity for purposes of competition, makes deceptive statements concerning business matters ... may be enjoined from making such statements.' (Section 3).

German courts, and especially the *Bundesgerichtshof*, in the past tended to be very restrictive in interpreting these regulations. The best known example of this tendency is the '10% test' for misleading advertising (Section 3, UWG). An advertisement is already considered to be misleading by German courts if only 10 to 15% of the addressed average casual (passing) consumers would be mislead. In most cases, the courts make a decision on this test without an opinion poll or other expert opinion, because the sitting judges consider themselves to be part of the class of addressed consumers.

The 10% test for misleading advertising is outlined

Important judgments delivered by the *Bundesgerichtshof* during 1998, which affect case law and which are therefore relevant to the advertising of medicinal products in Germany, are detailed *below*.

Comparative advertising

In February 1998, the *Bundesgerichtshof* decided a case where a dealer in tennis rackets advertised his products with the statement: 'We do not expect you to buy cheap composite rackets.'[2] The Court considered this statement as comparative advertising along the lines of its own precedents. Until this decision, the Court had always decided that comparative advertising in principle violated Section 1 of the UWG, which provides generally that whoever commits 'acts contrary to honest practices' may be enjoined from these acts and held for damages.

The *Bundesgerichtshof* decided to overrule its own precedents and to implement EC Directive 97/55/EC[3] on comparative advertising itself by interpreting the general clause of Section 1 of the UWG on the basis of the standards and requirements laid down by the Directive.

New precedent set for comparative advertising

In this case, this did not lead to a different result because the general discrediting of composite rackets was also a violation of Article 3a Section 1 paragraph e of EC Directive 84/450/EEC[4] concerning misleading advertising as amended by the Directive on comparative advertising. However, a new principle of the admissibility of comparative advertising was established.

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The fact that the Court did not wait for the legislator demonstrates its determination to draw consequences from legal developments at the EC level. It is interesting to see how the Court justified its decision to implement the comparative advertising Directive itself.

MSs may decide the means of implementation of EC Directives

According to Article 5 of the EC Treaty[5], it is not only legislative authorities that are obliged to implement EC Directives, but all public authorities including the courts. However, according to Article 189, Section 3 of the EC Treaty (under the old numbering), the means by which a Directive is implemented is within the discretion of the Member States (MSs), and therefore their legislative bodies. As a consequence, in principle, the courts may only implement a Directive by applying it directly, if and when it has not been implemented within the implementation period. Though this period had not run out for the comparative advertising Directive when the *Bundesgerichtshof* reached its decision, it nevertheless felt authorised to implement the Directive by applying it directly. One reason given was that the 'open' character of the general clause of Section 1 of the UWG enables the courts to take into account changes in 'honest practices'. This also applies to changes on the EC level. The Court held that:

> 'behaviour which the European legislator has described as permissible in principle cannot - irrespective of the implementation period - be considered a violation of honest practices' (by the German courts).

The Bundesgerichtshof's judgment took into account an unimplemented Directive

According to the jurisdiction of the European Court of Justice (ECJ), even before formal implementation, MSs have to refrain from any actions which would not be in accordance with a Directive[6,7]. A judgment that did not take into account the contents of an (as yet) unimplemented Directive might not be in accordance with such a Directive. In the case of the comparative advertising Directive and the contrary German precedents, the *Bundesgerichtshof* held that only the direct application of the Directive ensured that its goals were achieved in time.

Although the comparative advertising Directive is rather restrictive itself and will therefore not have a revolutionary effect on German advertising law, the judgment reveals the influence of EC legislation on this area of German law.

Misleading advertising

In 1998, the ECJ confirmed that its standard for misleading material is an 'average consumer who is reasonably well-informed and reasonably observant and circumspect'[8]. In this decision the ECJ had to deal with a case referred by the German Federal Supreme Court for Administration Law (*Bundesverwaltungsgericht*) where the competent German foodstuffs monitoring authority had objected to the labelling of packaging for eggs claiming '6 corn - 10 fresh eggs'. In fact the poultry was only fed with 60 percent of '6 corn' food, which the German foodstuffs authority considered as misleading. The decision was taken on the basis of Section 17, Subsection 1, No 5 of the *Act on Foodstuffs and Goods in Daily Use* (*Lebensmittel und Bedarfsgegenständegesetz*[9]) because in light of such claim consumers would expect that the poultry would be fed exclusively with such food. The German Federal Supreme Court for Administration Law considered Article 10, Section 2(e) of Council Regulation (EEC) No 1907/90[10] on certain marketing standards for eggs applicable. This, in principle, allows statements designed to promote sales on packaging, provided that such statements and the manner in which they are made are not likely to mislead the purchaser.

Promotion statements on packaging are permitted, providing they are not misleading

The ECJ was asked to give opinions on suitable consumer tests

The German court referred three questions on the interpretation of Council Regulation (EEC) No 1907/90 to the ECJ under Article 177 of the EC Treaty requesting its opinion about the applicable consumer test. The feature 'reasonably observant and circumspect' used by the ECJ in this decision differs in particular from the 'casual' German consumer ('10% test', *see above*). The ECJ explicitly did not rule out that under certain circumstances, a national court might decide, in accordance with its own national law, to order a consumer research poll in order to clarify whether a statement is misleading. In the absence of any Community provision, the national court may determine, in accordance with its own national law, the percentage of consumers misled

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which would be sufficiently significant to ban the use of a statement. However, the ECJ will examine decisions of national courts on the basis of its attentive consumer standard.

Already one of the most important *Oberlandesgericht* (OLG) as far as unfair competition is concerned, the OLG Hamburg has adopted the 'attentive consumer test' as its new standard to examine whether an advertisement is misleading[11]. The Court has even gone so far to compare the ECJ decision of 16 July 1998[8] with an amendment of the German *Act Against Unfair Competition*. As such, it allows parties which have signed a negative covenant on the basis of the tougher 'casual consumer standard' ('10% test') to terminate such undertakings with immediate effect. This is even more remarkable as the decision of the ECJ did not set new standards but just confirmed earlier precedents[12] and has not been held in the area of unfair competition law but in the area of administrative law. It will be interesting to see how other *Oberlandesgerichte* will decide this question. Hopefully this question of law will soon be brought before the *Bundesgerichtshof*.

Exaggerated enticement

A further interesting set of decisions was handed down last year, when the *Bundesgerichtshof* had to decide about two advertisements for mobile phones. In this case, the mobile phone was offered free of charge in one case[13] and for DM30.00 in another case[14], but only in conjunction with a telephone contract.

On the basis of its previous decisions, one would have expected that the *Bundesgerichtshof* would have considered this kind of advertising to be a so-called 'exaggerated enticement' violating Section 1 of the UWG. According to this group of case law, the combination of a very cheap or even free product with another is 'exaggerated enticement' if the free/cheap product is only intended to entice customers to buy the other product. Under this rule the issuing of vouchers for free hamburgers has been considered to be a violation of honest practices, because customers may feel obliged to buy additional goods when cashing in the voucher[15].

Application of a consumer test ruled out exaggerated enticement

The *Bundesgerichtshof* denied an exaggerated enticement in the case of the mobile phone advertisements, using the remarkable reasoning that the addressed consumers are aware of the fact that mobile phones of a significant value are usually not just given away. Consumers realise that the mobile phone has to be financed and is therefore subsidised by the telephone contract. Therefore such an advertisement is permissible, as long as the conditions of the telephone contract are set out clearly in connection with the offered mobile phone.

Despite the fact that the court did not refer to any European standards of consumer protection, these decisions of the *Bundesgerichtshof* clearly reveal a turnaround in the consumer image of the court. Although it was not a misleading advertising case in the first instance, the court applied a consumer test based on an average informed and attentive consumer. One may look forward with interest to the next decision of the *Bundesgerichtshof* in the area of misleading advertising.

Act on premiums

In another field of advertising law, the highest German Court will soon have the opportunity to demonstrate its new liberalised line. A well-known US mail order house has advertised its lifelong unlimited guarantee for its products in Germany. On 21 October 1998, the Court of Appeal in Saarbrücken[16] considered this to be a violation of the *Act on Premiums* (*Zugabeverordnung*[17]). Based on existing precedents, the Court decided that such a guarantee, which may be triggered at any time for any reason, has a value of its own and therefore may not be given in addition to the sold goods. The US retailer has already announced that it will appeal against this decision. German experts believe that there is a good chance that the *Bundesgerichtshof* may depart from another of its long-standing principles.

In the future, a new precedent may be set for Act on Premiums

Advertising of medicinal products

Two EC Directives cover the labelling and advertising of medicinal products for human use...

On an EC level, the advertising of medicinal products is regulated by Council Directive 92/27/EEC[18] on the labelling of medicinal products for human use and on package leaflets and by Council Directive 92/28/EEC[19] on the advertising of medicinal products for human use.

...implemented in Germany by amending the Advertising of Medicaments Act

Both Directives have been implemented in Germany (in 1994) by an amendment of the *Act on the Advertising of Medicaments* (*Heilmittelwerbegesetz*, HWG[20]), which contains additional regulations for the advertising of medicinal products.

Section 3 of the *Act on the Advertising of Medicaments* prohibits the misleading advertising of medicinal products in general, and mentions a number of exemplary cases. In addition, intentional deceit is a criminal offence with up to one year imprisonment (Section 14 of the *Act on the Advertising of Medicaments*) or an administrative offence in cases of negligent behaviour with a fine of up to DM25 000.

While the *Act against Unfair Competition* protects fair competition in general, the *Act on the Advertising of Medicaments* is designed to protect public health. However, as far as the standard for misleading advertising is concerned, it has been considered the same. Therefore the '10% test' has also been used when Section 3 of the *Act on the Advertising of Medicaments* has been applied[21]. Consequently, a more liberal 'attentive consumer test' should now also be applied by the German courts in the field of advertising of medicinal products. This is of particular relevance as the decision of the ECJ resulting in the reconsideration of the standards by the Court of Appeal Hamburg was based on a Council Regulation in the field of food and drug law[8].

A more liberal consumer test should now be applied for advertising of medicinal products

Also with a view to comparative advertising, the implementation of the EC Directive on comparative advertising by the German Federal Supreme Court will have immediate effect on the advertising of medicinal products, as far as the general permissibility of comparative advertising is concerned. However, because under Article 7, Section 3 of Directive 84/450/EEC (as amended) the provisions of this Directive shall apply without prejudice to EC provisions on advertising for specific products, the additional requirements of the EC advertising and labelling Directives as implemented in the *Act on the Advertising of Medicaments* have to be observed. This applies especially to the advertising with expert opinions and scientific works regulated in Article 7 of Directive 92/28/EEC, as implemented in Section 6 of the *Act on the Advertising of Medicaments*.

As far as premiums are concerned, the *Act on the Advertising of Medicaments* contains a specific regulation in Section 7 which is based on Article 9 of Council Directive 92/28/EEC. Section 7 of the Act is even stricter than the *Act on Premiums* as gifts or other benefits in kind may not be supplied regardless of any connected purchase[22]. However, the expected change in the consideration of unlimited guarantees will not have a major impact on the marketing of medicinal products, as this type of advertising does not play an important role in the advertising of medicinal products.

Summary

Changes to German unfair competition law affect advertising of medicinal products

The information given *above* shows that German unfair competition law is currently 'on the move'. The courts in Germany have implemented the EC Directive on comparative advertising, are applying a more liberal consumer image in cases of misleading and enticing advertising, and have started to liberalise their attitude to discounts and premiums.

The advertising of medicinal products is also partly affected by this liberalisation because the same standards for misleading advertising are applicable in general unfair competition law and the advertising of medicinal products. However, stricter regulations in this area have to be borne in mind in the field of comparative advertising.

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References

1. *Gesetz gegen den Unlauteren Wettbewerb* (UWG), as amended 1998; *Bundesgesetzblatt*, III/FNA 43-1.
2. Bundesgerichtshof, 5 February 1998; *Gewerblicher Rechtsschutz und Urheberrecht*, 1998, 824 - '*Testpreis-Angebot*'.
3. *Official Journal of the European Communities*, 1997, **L290**, 18.
4. *Official Journal of the European Communities*, 1984, **L250**, 17.
5. EC Treaty, *Official Journal of the European Communities*, 1997, **C340**.
6. Article 191 Section 2 of the EC Treaty.
7. ECJ, 18 December 1997; *Wettbewerb in Recht und Praxis*, 1998, 290.
8. ECJ, 16 July 1998, C-210/96; *Wettbewerb in Recht und Praxis*, 1998, 848.
9. *Lebensmittel und Bedarfsgegenständegesetz*, as amended 1998; *Bundesgesetzblatt*, III/FNA 2125-40-1-2.
10. *Official Journal of the European Communities*, 1990, **L173**, 5.
11. OLG Hamburg, 28 January 1999 - 3 U 65/98.
12. *See* for example, ECJ cases: C-362/88 'GB-INNO-BM'; C-126/91 '*Yves Rocher*'; C-315/92 '*Verband Sozialer Wettbewerb*'; C-470/93 'Mars'.
13. *Bundesgerichtshof*, 8 October 1998; *Wettbewerb in Recht und Praxis*, 1999, 90.
14. *Bundesgerichtshof*, 18 October 1998; *Wettbewerb in Recht und Praxis*, 1999, 94.
15. OLG Munich, 25 October 1990; *Wettbewerb in Recht und Praxis*, 1991, 511.
16. OLG Saarbrücken, 21 October 1999; *Wettbewerb in Recht und Praxis*, 1999, 224 - 'Lands' End'.
17. *Zugabeverordnung* - Zugabe VO, as amended 1994; *Bundesgesetzblatt*, III/42-4-1.
18. *Official Journal of the European Communities*, 1992, **L113**, 8.
19. *Official Journal of the European Communities*, 1992, **L113**, 13.
20. *Heilmittelwerbegesetz* (HWG), as amended 1994; *Bundesgesetzblatt*, III/FNA 2121-20.
21. *See* Bülow/Ring, *Commentary on the Act on the Advertising of Medicaments*, 1996, Section 3, Margin note 18 *et seq.*
22. Bülow/Ring, *Commentary on the Act on the Advertising of Medicaments*, 1996, Section 7, Margin note 8.

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