# German Jurisprudence on '*Probiotic*' Claims on Baby Food, Trademarks as '*Health Claims*' and Transitional Use of Existing Trademarks

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*On 26 February 2014, the German Federal Court of Justice (Bundesgerichtshof, hereinafter, BGH) held, in the case Hipp v. Milupa*[1]*, that trademarks can be health claims under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (hereinafter the Nutrition and Health Claims Regulation, NHCR). The BGH, therefore, confirmed the broad interpretation of the term 'health claim' and remanded the case back to the Frankfurt/Main Higher Regional Court (hereinafter, OLG Frankfurt). Products bearing trademarks that existed before 1 January 2005 and that do not comply with the NHCR may continue to be marketed until 19 January 2022. On 15 January 2015, the OLG Frankfurt handed down a new judgment in the proceedings between Hipp and Milupa*[2]*, relating to the question as to whether a trademark had to be used with the identical and unchanged food product before January 2005 to fall under the transitional rule, or whether changes to the product were permissible.*

## I. Introduction

Both parties of the litigation, *Milupa* (of the Danone Group) and *Hipp* (a German group present in over 50 countries), are major baby food manufacturers. Until 2012, Hipp sold products containing *Galactooligasaccharides* as a prebiotic component and the bacterium *Lactobacillus fermentum hereditum* as a probiotic component, with the label '*Praebiotik*® + *Probiotik*®'. Since 1999, *Praebiotik*® and *Probiotik*® are registered trademarks for Hipp, while Milupa or other producers of baby food are not permitted to use the terms Praebiotik and Probiotik for their products. On the products' labels, Hipp made the following statements (translated into English): '*Praebiotik*® + *Probiotik*® + *with natural lactic acid cultures* + *Praebiotik*® *for support of a healthy intestinal flora*'.

## II. Background

The NHCR defines a health claim in Article 2(2)(5) thereof as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents, and health. Food business operators are not free to make any health claim for marketing their food products. Only those health claims are permitted, which are listed in an EU list adopted by the EU Commission based on generally accepted scientific evidence. If a food business operator desires to use an unlisted health claim, it may apply for the inclusion of the claim on the approved list. Article 1(3) of the NHCR states that a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food, which may be construed as a nutrition or health claim, may be used without undergoing the authorisation procedures required under the NHCR, provided that it is accompanied by a related nutrition or health claim, which complies with the NHCR.[3]

*Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health* provides for a positive list of so-called general function claims.[4] After 14 December 2012, only health claims that are on this list are permitted. So

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1 Judgment of the BGH of 26 February 2014, I ZR 178/12.

2 Judgment of the OLG Frankfurt of 15 January 2015, 6 U 67/11.

3 In German, this is called the 'Kopplungsprinzip', i.e., the coupling principle.

4 OJ 2012 L 136/1.

far, not a single specific probiotic claim has received a favourable opinion from EFSA and a formal approval by the EU Commission, even though arguably substantial scientific evidence is available supporting probiotics' benefits.

## III. Comment

The '*probiotic*' baby food court litigation started in 2010 with proceedings between the competitors *Milupa* and *Hipp* before the Frankfurt/Main Regional Court (Landgericht Frankfurt, LG Frankfurt). In the judgment of 23 March 2011 (6 O 568/10), *Milupa* succeeded and the claims '*Praebiotik*® + *Probiotik*®' were considered unlawful claims under the NHCR. However, in the judgment of 9 August 2012 (6 U 67/11), *Hipp*'s appeal before the OLG Frankfurt was successful in that the terms *Praebiotik*® and *Probiotik*® were considered permissible as mere references to ingredients of the baby food (and not as health claims).

In the revision of 26 February 2014, the BGH ruled that both declarations (*i.e.*, the trademarks Praebiotik® and Probiotik®, as well as with the slogan '*Praebiotik*® + *Probiotik*® *with natural lactic acid cultures - Praebiotik*® *for the support of a healthy intestinal flora*') are health claims. Regarding the use of the trademarks *Praebiotik*® and *Probiotik*®, the BGH held that an average consumer would not simply understand this labelling as an objective description of quality or contents, as had been assumed by the OLG Frankfurt. The average consumer would interpret it rather as a reference to the prebiotic and probiotic characteristics (*i.e.*, the ability to stimulate natural intestinal function and the body's own defence system). Therefore, the BGH concluded that the terms 'Praebiotik® + Probiotik®' had to be considered as a health claims according to Article 2(2)(5) of the NHCR since they suggest that there is a relationship between the baby milk and a baby's health.

With this decision and its broad interpretation of the term '*health claim*', the BGH confirmed previous decisions on this topic. On 6 September 2012, in case C-544/10 *Deutsches Weintor e.G.*,[5] the Court of Justice of the European Union (hereinafter CJEU) ruled that it is apparent from the wording of Article 2(2)(5) of the NHCR that the starting-point for the definition of a '*health claim*' is the relationship that must exist between a food or one of its constituents and health. The CJEU noted that the definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration. In those circumstances, the CJEU concluded that the term '*relationship*' must be understood in a broad sense.[6]

Concerning the entire statement '*Praebiotik*®*+Probiotik*® *+ with natural lactic acid cultures + Praebiotik*® *for support of a healthy intestinal flora*', the BGH ruled that this claim was not permitted and ordered Hipp to stop using it. As regards the claim '*Praebiotik*® *+ Probiotik*®', the BGH remanded the matter to the previous instance (OLG Frankfurt) in order to verify whether the claim was already in use before January 2005. According to Article 28(2) of the NHCR, products bearing trademarks or brand names existing before 1 January 2005, which do not comply with the NHCR, may continue to be marketed until 2022. As the CJEU stated on 18 July 2013 in its judgement in case C-299/12 '*Green-Swan Pharmaceuticals*'[7], the trademark has to be used with the particular food product in question in that form before January 2005 to justify the application of the transitional provision. It is not sufficient that the trademark only existed[8]. The CJEU thereby dismissed *Green-Swan*'s literal understanding that the transitional period of Article 28(2) NHCR applies generally to all products bearing a trademark.[9]

In the revision of 26 February 2014, the BGH also raised the additional question as to whether the trademark had to be in use with the identical and unchanged food product before January 2005, or whether changes to the product (*e.g.* changes corresponding to a normal life cycle management) were permissible. The BGH ruling also appears to be in

5 Judgment of the Court of 6 September 2012. Deutsches Weintor eG v Land Rheinland-Pfalz. Reference for a preliminary ruling: Bundesverwaltungsgericht - Germany. Case C-544/10, European Court Reports 2012.

6 *Supra*, paragraph 34.

7 Judgment of the Court of 18 July 2013. Green - Swan Pharmaceuticals CR, a.s. v Státní zemědělská a potravinářská inspekce, ústřední inspektorát. Reference for a preliminary ruling: Nejvyšší správní soud - Czech Republic. Case C-299/12. European Court Reports 2013.

8 *Supra*, at paragraph 37.

9 Leonie Evans, Recent Judgments on the Health Claims Regulation: A Journey through the Colourful World of Health Claims Made on Food Stopping at Luxembourg and Karlsruhe, European Food and Feed Law Review (2014), p. 233 (237); Florence Verhoestraete, The Court of Justice of the European Union Confirms the Obvious and Clarifies the Trade Marks and brand names derogation, European Food and Feed Law Review (2013), p. 338 (342 et seq.).

line with the EU Commission's interpretation given in section III.1. of the '*Guidance on the implementation of Regulation (EC) No 1924/2006*'[10], where the statement '*contains probiotics/prebiotics*' is classified as a health claim in that the reference to '*probiotic*' and/or '*prebiotic*' implies a health benefit.

After revision and referral, on 15 January 2015, the OLG Frankfurt cancelled its previous judgment and ruled that the illegal health claims *Praebiotik*® and *Probiotik*® may not be exceptionally used for baby food as part of a continued use under Article 28(2) of the NHCR. For a continued use to exist, these designations needed to have been used "*in that form*" before 1 January 2005 for a food that essentially corresponds to the product marketed today. This was not the case with food supplements for adults on the one hand and baby food on the other side. On the other hand, the OLG Frankfurt held that this does not mean that any change and adaptation of the product and its presentation would be excluded. Considering the unusual length of the transitional period until 2022, it cannot be required that small changes in the recipe, the package layout, the dosage form, etc., are not covered by the scope of the transitional arrangements. It must always be asked whether the original, even modified, product is further distributed or whether it is a new product.[11]

The OLG Frankfurt again permitted a revision to the BGH because the questions concerning the interpretation of the transitional provision of Article 28(2) NHCR have fundamental importance.[12] This applies particularly to the question of whether the privilege applies only to labelled foods that are sold unchanged since 1 January 2005 and which deviations are still covered. The BGH may request a new preliminary ruling from the CJEU which may give further guidance on the transitional period under Article 28(2) NHCR.

Besides the dispute before German courts, the term '*probiotic*' could make a re-appearance on certain products, if Italy is successful in getting approval for its use as a '*generic descriptor*' according to its application of 20 June 2014 to the EU Commission. Pursuant to Article 1(4) of the NHCR, specific generic descriptors that have traditionally been used to indicate a particular class of foods or beverages, which could imply an effect on health, may be exempted from the application of the NHCR following a request by the food business operators concerned. On 20 September 2013, the EU Commission adopted *Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations)*.[13] The Yoghurt & Live Fermented Milks Association (YLFA), together with the Italian Dairy Association (Assolatte) and the Italian Food Supplements Association (AIIPA), are behind the Italian application of 20 June 2014 for approval of the term '*probiotic*' as a generic descriptor based on the fact that the general descriptive term '*probiotic*' had been used in Italy for over 20 years.[14] The application involve discussions in the EU's Standing Committee on the Food Chain and Animal Health (SCoFCAH). There is no formal deadline for issuing a final opinion. The relation between generic descriptors and trademarks appears to be another potentially contentious matter.

## IV. Conclusions

Two main conclusions arise (so far) from the German *probiotic* baby food battle. For claims related to trademarks, a consistently broad interpretation of the term '*health claim*' appears to emerge in the courts of the EU and its Member States. Second, for a continued use of a trademark as health claim until January 2022, under Article 28(2) of the NHCR, these designations need to have been effectively in use before 1 January 2005 "in that form" which could mean for a food that essentially corresponds to the product being marketed today. Arguably, small changes in the recipe, the package layout, the dosage form, etc., should be permitted. However, in relation to the second point, the OLG Frankfurt permitted a new revision to the BGH. It remains to be seen whether a revision against the judgment of the OLG Frankfurt has been filed in time (*i.e.*, one month after notification). The BGH may re-

10 Guidance on the implementation of Regulation (EC) No 1924/2006 of 14 December 2007. Available on the Internet at: http://ec.europa.eu/food/safety/docs/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf (last accessed on 6 May 2015).

11 Judgment of the OLG Frankfurt of 15 January 2015, 6 U 67/11, marginals 35-37.

12 Fundamental importance is a requirement for a revision under § 543 para. 2 no. 1 of the German Civil Process Code (Zivilprozessordnung, ZPO).

13 OJ 2013 L 251/7. See also: Blanca Salas, "Specific Rules on Derogations for Generic Descriptors under the Nutrition and Health Claims Regulation Entered into Force", European Journal of Risk Regulation Issue 1/2014, March 2014.

14 Application for Probiotics as Generic Descriptors. Available on the Internet at: http://www.ylfa.org/images/file/YLFA-pr-release-probiotics.pdf (last accessed on 6 May 2015).

quest a new preliminary ruling from the CJEU which may give further guidance on the transitional period under Article 28(2) NHCR. In preparation for the end of the transitional period, trademark owners should use the time to add related approved nutrition or health claims on labels or to apply for new supporting claims with appropriate substantiation for approval by the EFSA. Certain trademarks and brand names may not be permitted to remain in use after the 2022 deadline. When such an outcome appears likely, food business operators should start introducing additional trademarks and brands in parallel with the established ones to provide alternatives for any trademarks or brands that are likely phased-out.[15] Given the substantial commercial interests at stake, aside from the legal and systemic interpretative issues, interested operators should monitor the state-of-play at EU and relevant Member States' level so as to timely take the appropriate administrative and industrial actions that may be required.

15 Michael Rafter, Trademarks That Make Health and Nutrition Claims Under US and EU Food-Labeling Regulations, 15 March 2013, Vol. 68 No. 6 INTA Bulletin.