Unofficial Translation

Jurisprudence of the Lower Saxony judiciary

Document view

Health; General decree; Marketing of a cigarette; Flavor capsule

There are compelling reasons of health protection that prevent the requested general decree because the cigarette with a capsule embedded in the filter, such that the menthol flavoring can be released whenever wanted by crushing the capsule, makes smoking more attractive and thus violates the WHO Framework Convention on Tobacco Control (FCTC).

VG Braunschweig 5th Chamber, judgment of 26 Sept 2012, 5 A 206/11
Art 9 TabakRÜbk, Art 3 Para 1 GG, § 3 LMG 1974, § 47 Para 1 S 1 LMG 1974, § 47a Para 1 S 1 LMG 1974, § 47a Para 2 S 1 LMG 1974, § 47a Para 1 S 2 Nr 2 LMG 1974

Operative Part

The case is dismissed.
The Plaintiff shall pay the costs for the proceedings.
The judgement is provisionally enforceable due to the costs.
The Plaintiff can avoid the enforcement by paying a security in the amount of the reimbursement of costs to be set, if the Defendant does not pay a security in the same amount before the enforcement.
The appeal is permitted.
The value of the matter in dispute is set at 4,000,000.00 EUR.

Statement of Facts

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The Plaintiff requests the issuance of a general decree under § 47a of the Preliminary Tobacco Act (VTabakG) for the import and marketing of cigarettes, the filters of which contain a capsule filled with menthol and which are legally manufactured and marketed in other EU countries, in the Federal Republic of Germany. The flavor capsule is composed of substances, some of which are not approved for use in filters in Germany.

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The Plaintiff belongs to the "F." corporation and manufactures tobacco products, primarily cigarettes, which it distributes in Germany. The Plaintiff intends to market a cigarette in Germany under the brand name "G. H.", which contains menthol flavoring in the capsule embedded in the cigarette filter.

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With a letter dated 08/06/2010, the Plaintiff petitioned for, by enclosing the numerous documents with the Defendant, the issuance of a general decree according to § 47a VTabakG for cigarettes with filters that contain a flavor capsule. This capsule can be opened by the smoker by crushing it, which results in the release of menthol, which is then inhaled together with the smoke. The capsule consists of, among other things, gelatin, gellan gum, sorbitol, glycerin, sodium citrate, brilliant blue FCF, tartrazine and medium-chain triglycerides. According to Annex 1 to the German Preliminary Tobacco Act, these substances are not approved as additives for cigarette filters. Menthol, however, is generally permitted as a flavor for the manufacture of tobacco products. With traditional menthol cigarettes, which are available on the German market, the menthol is either added to the tobacco, the cigarette paper or the packaging material. The Plaintiff stated that there are already filter cigarettes with flavor capsules, which its subsidiaries in France would like to legally put on the market and, beginning in November 2010, also in Spain.

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On 11/25/2010, the Defendant submitted to the Federal Institute for Risk Assessment (BfR) the petition documents to check whether compelling reasons of health protection prevent the issuance of the general decree according to § 47a para. 2 VTabakG. With its letter of 12/22/2010, the Federal Office for Economic Affairs and Export Control explained to the Defendant the agreement required by § 47a para. 2 clause 1 VTabakG, provided the BfR has no objections.

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The BfR explained in its opinion of 01/28/2011, that it could not support the petition due to a possible additional health risk to smokers. An issuance of the requested general decree should definitely be connected with the establishment of a limit for menthol in the tobacco smoke, to exclude concentrations that are higher than those in traditional menthol cigarettes, as an additional health risk. The BfR further explained that it could be a health concern if physiological reactions to cigarette smoke, such as the urge to cough or irritation of the throat, have been suppressed by the addition of pharmacologically active concentrations of menthol. This results in an increased heath risk to smokers. The use of flavor capsules "could lead to a modified release of the added substance, when in the beginning particularly high, pharmacologically active concentrations could be present in mainstream smoke". As an additional aspect, the BfR stated that, in contrast to flavored tobacco, the encapsulated flavorings would not have been burned and under certain circumstances could strongly impact body odor and indoor air. That would result in a wide range of possible uses with which tobacco smoking would not have to be the main one.

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On 02/23/2011, the Defendant informed the Plaintiff that the filters of the cigarettes that are the object of the petition would gain a function, due to the embedding of the flavor capsule in the filter mouthpiece, which would go significantly beyond the task of filtering pollutants from the mainstream smoke. In order to be able to evaluate the health effects of filters that, in addition to their filter function, add flavor to the smoke, information and consent would be required. With its letter of the same day, the Defendant asked the BfR for additional information on answers to questions about the differences in the inhalation depth and in the nicotine content between traditional menthol cigarettes and the new type of flavoring and also whether the flavor capsule, through the heating of the filter during the smoking process, experiences a substantial change, whether the targeted release of the flavoring at a time specified by the smoker himself would lead to greater attractiveness of the new type of cigarette, whether they present an increased health risk compared to traditional menthol cigarettes, and whether the effect of suppressing the physiological reactions to cigarette smoke is to be evaluated differently in cigarettes with flavor capsules than in traditional menthol cigarettes.

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The BfR explained on 04/01/2011 that what is problematic is that, through the use of menthol there is a cooling effect in the area of the tongue and oral cavity. Menthol could also increase the nicotine dependence of smokers and at the same time inhibit the breakdown of nicotine. It must also be considered that the potential risk of menthol is that it makes the introduction to smoking easier for non-smokers. Data collected in the U.S. show an especially high risk of this among youth. The BfR did not have studies on the release of menthol, inhalation depth and nicotine intake through cigarettes that contain flavor capsules. However, the potential danger results from the fact that increasing new or young smokers would find an entry point to tobacco smoking. Therefore, it is not in the interest of consumer health protection to promote this trend further through new products. The question of whether there is an increased health risk for cigarettes with flavor capsules compared to traditional menthol cigarettes, could not be answered based on current knowledge. If menthol is limited to 14 mg/cigarette, this substance would no longer have any physiological effect and an increased health risk could be ruled out for both forms of application.

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With its decision of 05/12/2011, the Defendant rejected the petition for the issuance of a general decree and gave as its reason that compelling reasons of health protection/consumer health protection/// prevent it. The product should be considered in its entirety and not only with regard to the prohibited substances that are used for the manufacture of the flavor capsule. The cooling effect of menthol on the respiratory tracts can also result in symptoms of respiratory diseases, especially of lung diseases, being noticed much later. An additional health risk for smokers can therefore not be ruled out. The flavoring of cigarette smoke with menthol can also soften unpleasant properties of tobacco smoke and thus lead to increased cigarette consumption or it could completely lower the psychological barrier to smoking. The risk lies in the fact that young people in particular would get used to smoking and the risk of getting cancer would increase for them. The rejection of the requested general decree also does not interfere unlawfully with the free movement of goods according to Art. 34 AEUV, because health protection has priority, particularly in this case where a particularly sensitive consumer group is affected. An earlier introduction to smoking already as an adolescent or teenager would pose an increased health risk compared to the smoking itself and lead to a particular need to protect this consumer group.

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Against this decision, the Plaintiff objected on 05/25/2011 and justified it with the pleading of 06/17/2011. It explained: the Defendant's decision to reject is based on incorrect basic assumptions. The remarks on the novelty or differentness of the menthol supply via the flavor capsule in the cigarette filter are not applicable. Studies were conducted to determine whether and how the particular menthol application technology, and thereby also the menthol distribution within the cigarette, influences the menthol content in the mainstream smoke. They listed the substances contained in the mainstream smoke -- condensate, nicotine, carbon monoxide and menthol -- for three traditional menthol cigarettes found on the German market and the associated number of drags and the values for cigarettes with flavor capsules containing menthol first when the capsule is broken open before the first drag, second, when it is broken before the last two drags. The largest independent laboratory in the world for tobacco and tobacco product analysis, "Labstat" in Canada, measured the values. In order to be able to make a clear statement about whether the type of menthol application has an influence on the amount of menthol in the mainstream smoke, the menthol transfer efficiency (MTE) was also considered. That is the quotient of menthol in the mainstream smoke (mg) and the total content of menthol on the cigarette (mg). With cigarettes with the same condensate level, similar MTE values have been measured. As a result, filter retention and filter ventilation, which determined the condensate level in the mainstream smoke, also regulated the amount of menthol in the mainstream smoke. This also means that, due to the crushing of the capsule not until before the last two drags, there would be no change in the menthol content per drag because the resistance of each filter is set on the product side. This means that the way menthol arrives in the mainstream smoke is not relevant to the amount of the substances contained in the smoke. In contrast to traditional menthol cigarettes, smokers of cigarettes of the "G. I." type also have the option of completely foregoing the supply of menthol in the mainstream smoke because, due to the encapsulation of the flavoring, the migration of menthol particularly through the entire cigarette is prevented. Also there is no evidence that the burning of menthol that is added to the tobacco or cigarette paper significantly affects the quality of the menthol that then gets into the mainstream smoke. A study by Baker et al. from 2004 -- mentioned in the opinion of the BfR in Annex 2 to the opinion of 01/28/2011 -- showed that in any case a type of distillation and not a true pyrolysis occurred. The technical studies on different types of mentholated cigarettes would show that no differences in the type of intake, the effect or the associated health effects compared to a cigarette with a menthol capsule and a classic menthol cigarette were to be expected. Since there are already cigarettes on the German market that have used menthol in the filters, with "G. H." it has to do with the fact that, contrary to the Defendant's view, it is also not a novelty, rather a further development of menthol cigarettes already on the German market. Since

the regulations of § 47a VTabakG exist, the general decree would have to be issued. It was not an arbitrary decision of the Defendant in which consumer protection or health policy aspects could be considered but rather only opposing "compelling" reasons of health protection. They are not substantiated. According to the Tobacco Act, the substances contained in the capsule are, with the exception of the gellan gum and medium-chained triglycerides, only not permitted expressly for filters, but are permitted for other purposes. Due to their use in the filter as components of the menthol capsule, there is an increase in the health risk potential of the cigarette as such. The general view of the authorities mainly on the effect of menthol in the tobacco smoke is suppressed. However, these effects have been known for a long time and had not led to a change in the German Preliminary Tobacco Act.

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The BfR objected to the Plaintiff on 07/29/2011 and explained that the flavor capsule poses the risk of including additional permitted substances because there are no regulatory limitations, neither for the dimension of the capsule nor for the type and quantity of the included substances. The associated health risks were compelling reasons of health protection. The flavor capsule increases the risk potential compared to cigarettes without menthol. It is irrelevant that comparable risks could be posed by traditional menthol cigarettes, which could comply with the regulations of the Preliminary Tobacco Act.

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With the ruling on the objection of 10/06/2011 - delivered on 10/12/2011 - the Defendant rejected the Plaintiff's objection as unfounded. Therein, the Defendant explained that the smoker of a cigarette with a menthol capsule is exposed to a higher menthol concentration than the smoker of a traditional menthol cigarette, in which the flavoring occurs through the tobacco, the paper, the filter or the packaging material and has decreased due to the high volatility of the menthol content during storage. So according to the Plaintiff's study results, the menthol concentration is, at 5 mg per cigarette, approx. 25% higher than the concentration in comparable cigarettes and the MTE, at 20%, is 5 to 10% over the value of traditional cigarettes. The contents measured by the Labstat laboratory in Canada, human smoking behavior has not been described in its various manifestations because it involved a mechanical vaporizing procedure. The results would also not explain the subjectively perceived surge of menthol immediately after the crushing of the capsule. In contrast to the studies by Gordon et al. (Chemical Research in Toxicology, publ. 09/02/2011), which had found significantly elevated smoke gas concentrations for the compounds acetaldehyde, acetonitrile, acrylonitrile, benzene, 1,3-Butadien, 2,5-Dimethylfuran and isoprene, they were taken after the capsule of the study cigarette is crushed before it has been vaporized. The results of the study by the Spanish Ministry of Health, which were submitted with the petition referred solely to the values for TNCO and are not representative due to a small sample of the product; the information on the supplement of the Romanian law on the individual substances contained in the capsule would neither give information on whether the approval was based on a health evaluation nor whether, with the approval of the individual substances, the capsule itself had also been approved. The ADI status, which was also submitted with the petition, referred to studies from 1961 to 1979. The essential effectiveness of menthol, which lies in the stimulation of cold receptors, was not considered in the Plaintiff's observations. An additional risk to the smoker due to the cooling effect of the menthol on the respiratory tracts cannot be ruled out. The psychological barrier to smoking could be lowered due to the flavoring and youth would be introduced to smoking earlier. When evaluating the health risks of a product, the findings according to the state of the art of the international research must be considered. Since there would be no documents from other member states for the health evaluation of the capsule or its contents, only the findings of the BfR, DKFZ and the Food and Drug Administration (FDA) on the mode of action of menthol can be drawn upon. These would require a re-assessment of the addition of menthol to tobacco products and basically call into question the risk assessment underlying the approval in the TabakVO. The refusal of the

general decree does not violate the Plaintiff's subjective rights. As long as the Plaintiff has taken steps for the preparation of the product start, this does not fall under the protection of fundamental rights under Art. 14 GG. Based on the Plaintiff's calculation that tax revenue lost due to evasion by the general public amounts to 42 million EUR in the 2nd half of 2011 and 77 million EUR in 2012 because such products have been privately and illegally imported from the neighboring states; because of that more than 536 million additional cigarettes must be sold in Germany each year. With a cigarette consumption of 20 cigarettes per day, this means that around 73,500 new smokers should be appealed to each year.

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With the decision of 12/15/2011 (5 B 184/11), the adjudicating chamber has rejected the petition filed on 10/20/2011 by the plaintiff, as an interim measure, to temporarily allow the marketing of cigarettes with a flavor capsule because the Plaintiff had not sufficiently explained an adjudicatory basis (urgency).

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Previously, on 11/10/2011, the Plaintiff had already filed suit for the issuance of the requested general decree under reversal of the rejecting decisions. It points out that:

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The fact that the menthol concentration in the "G. H." cigarette was higher than in comparable cigarettes with no menthol capsules is not evidence of any greater health risk. Menthol in and of itself is not harmful which is also why no there are no limits to menthol additives to tobacco products. Even the differences in the MTE of 5 to 10% were low and could not alone justify an increased health risk. As long as the Defendant questions the validity of the data collected from the mechanical vaporizing procedure, it will be pointed out to it that it expressly requested the additional submission of the studies according to the Health Canada vaporizing conditions and also values transmitted are comparable anyway. Unlike the studies cited by the Defendant by Gordon et al. (2011) on a cigarette with a menthol capsule ("J.") offered on the American market, its product did not have the effect of delivering higher quantities of volatile compounds in the mainstream smoke as soon as the capsule is crushed in the filter, but due to the crushing of the capsule there would have been no increases in its studies. At the time of the measurements it ordered there was still no valid ISO standard for determining the level of menthol in mainstream smoke but a draft of the provisional ISO/DIS 13110 has been published. The total menthol in the mainstream smoke is determined according to the draft of the ISO standards. Apart from that, the study methods of Gordon et al. have also not been validated, the authors of the study themselves would acknowledge that, due to the established facts, certain smoke substance concentrations in the "J." cigarette would be increased, do not allow it to be concluded that the product is more harmful than traditional menthol cigarettes without additional studies. It is also not its intention and objectively not noticeable that cigarettes with menthol capsules would be particularly oriented toward youth or would be preferred by them. The situation of the U.S. market, in which approx. 1/3 of all products are mentholated, could not be transferred to the situation in Germany, where the market share of menthol cigarettes is below 3%. It also does not include an increase of 73,500 new smokers, but hopes that smokers of other brands would be won over, those who related to comparable products from the other countries in the EU until now. They also accepted that smokers would switch from their own products to the new product. There is no intention whatsoever of giving the disputed cigarettes to young people; rather it has worked closely with the retail market for years to promote protection of youth. With the tax revenue it calculated, it does not represent additional net tax revenue for the tax authorities, but additional taxes, which it had to pay. The Defendant bears the burden of proof for the existence of compelling reasons of health protection that oppose the requested general decree. The arguments cited are only conjunctures. The Defendant made their rejection decision solely out of political motives. In numerous other member states in the European Union, cigarettes with menthol capsules are legal on the market. In the meantime, the Czech

Republic has also decided to change its tobacco law so that the substances required for the manufacture of a menthol capsule for a cigarette filter are expressly permitted. In February 2012, the Hungarian National Institute for Food and Nutrition Science granted its (the Plaintiff) Hungarian subsidiary permission to market cigarettes with menthol capsules in the filter in Hungary ("K.").

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The Plaintiff is requesting that

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1. the refusal decision of the Defendant of 05/12/2011 in the framing of the objecting decision of 10/06/2011 be reversed and

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2. the Defendant be required to issue the requested general decree, to allow the import and marketing of cigarettes with filters, to which a capsule composed of, among other things, the substances gelatin, gellan gum, sorbitol, glycerin, sodium citrate, brilliant blue FCF, tartrazine and medium-chain triglycerides and filled with menthol (max. diameter 3.5 mm placed in the middle of the filter) is added, and which are legally manufactured in other EU member states and can be marketed there, in the Federal Republic of Germany.

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The Defendant is requesting that

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the case be dismissed.

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The Plaintiff replied:

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The free movement of goods is qualified/not w/o restrictions/// for tobacco products. The member states still have some discretion in the determination of the extent to which they want to ensure the health protection of the individual. The member states could provide stronger regulations individually in this not completely harmonized area. They also refer to the publications of the German Cancer Research Center (DKFZ) from the Red Series "Tobacco Prevention and Tobacco Control": "Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product" (Volume 17) and "Cigarette Marketing in Germany - Marketing for a Harmful Product“ (Volume 18) and on the article that appeared in the Federal Health Bulletin (Bundesgesundheitsblatt) of the DFKZ "Effects of Menthol as an Additive in Tobacco Products and the Need for Regulation" (Vol. 55, Issue 3, March 2012, p. 409-415).

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For further details, reference is made to the court records and the administrative procedures of the Defendant.

Grounds for the ruling

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The admissible claim to have the general decree issued is unfounded.

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The Plaintiff has no claim to the issuance of a general decree under § 47a Para. 2 Clause 1 in conjunction with Para. 1 Clause 2 No. 2 of the Preliminary Tobacco Act (VTabakG) of 09/09/2007 (BGBl. I S. 2296) for the import and marketing of cigarettes with filters, to which a capsule composed of, among other things, the substances gelatin, gellan gum, sorbitol, glycerin, sodium citrate, brilliant blue FCF, tartrazine and medium-chain triglyceride and filled with menthol, is added (G. H.). The refusal decision of the Defendant of 05/15/2011 and its objecting decision of 10/06/2011 are legitimate (§ 113 Abs. 5 VwGO). There are compelling reasons of health protection that conflict with the issuance of the requested general decree.

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The issuance of general decree under § 47a Para. 1 and 2 VTabakG stands in the regulatory context with the "movement ban" from § 47 para. 1 VTabakG. Thereafter "products within the meaning of this law", which do not comply with the German "food law" provisions, may not as a rule be brought into the country (§ 47 para. 1 clause 1 VTabakG). Something else applies under § 47a Para. 1 Clause 1 VTabakG for products that are legally manufactured and marketed in another member state of the European Union. They may be imported and sold here even if they do not comply with the applicable "food law" regulations in the Federal Republic of Germany unless they do not comply with other legal regulations issued for health protection (§ 47a Para. 1 Clause 2 No. 2 VTabakG). Under § 47 a Para. 1 Clause 2 No. 2 in conjunction with Para. 2 Clause 1 VTabakG, these products may only be marketed in the country if their marketability in the Federal Republic of Germany has been made public, through a general decree by the Federal Office for Consumer Protection and Food Safety - the Defendant – published in the Federal Gazette. The Defendant must issue this general decree in agreement with the Federal Office for Economic Affairs and Export Control if there are no compelling reasons of health protection barring it (§ 47a Para. 2 Clause 1 VTabakG).

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Indeed, the scope of application of § 47a Para. 2 in conjunction with para. 1 VTabakG is open here because with the capsule cigarette, for which the Plaintiff requested the general decree to market, is a tobacco product in accordance with § 3 VTabakG and thus a "product within the meaning of this law". The matter in dispute is not only the manufacture and marketing of non-permitted substances, which are used for the manufacture of the flavor capsule, rather the marketing of the cigarette with a menthol capsule in the filter in its entirety.

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The movement ban of § 47 Para. 1 Clause 1 VTabakG is also effective because the capsule cigarettes are products that do not comply with the tobacco regulations in Germany. To the extent § 47 Para. 1 Clause 1 VTabakG refers to "food law" provisions, this is factually incorrect because the regulations of the Preliminary Tobacco Act no longer fall under the food law and the legislature failed to adapt this term to tobacco products (see Zipfel/Rathke, Lebensmittelrecht (Food Law), Comments Vol. V, C 900 § 47 Recital 10; Recital 47a Recital 4). Since the flavor capsules are composed of substances, some of which are not approved as additives for cigarette filters according to Annex 1 to the Tobacco Act, the product as a whole does not comply with the current tobacco regulations in Germany.

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The requirement of § 47a para. 1 clause 1 VTabakG, that the product, among others, be legally marketed in another member state in the European Union is also met by the disputed cigarettes. In this respect, the Plaintiff submitted documents, from which it can be seen that this product, among others, is legally sold in France under the name "G. I.". Even the Defendant does not question this (any longer). Legal recognition does not depend on the fact emphasized by the Plaintiff, that in the meantime its product is legally marketed in numerous EU states in addition to France.

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The capsule cigarette also violates a regulation issued for the protection of health within the meaning of § 47a para. 1 clause 2 No. 2 VTabakG. The substances from which the flavor capsule is composed, are – at least partially – not approved for cigarette filters under Annex 1 to § 1 TabakVO. The tobacco act is a legal provision issued for the protection of health (see the reference to § 20 para. 3 VTabakG in the preamble of the tobacco act). As a result there is no exception to the movement ban of § 47 para. 1 in conjunction with § 47a para. 1 clause 1 VTabakG and the ability to market the Plaintiff's product can only be restored by a general decree in accordance with § 47a VTabakG.

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However, in the end the Defendant justifiably refused to issue the requested general decree. According to § 47a Para. 2 Clause 1 VTabakG, it can issue the general decree as long as there are no compelling reasons of health protection barring it, whereupon in accordance with § 47a Para. 2 Clause 3 VTabakG, the findings of the international research must be considered when evaluating the health risks of the product. The wording "general decrees…shall be…issued" reveals that in the decision about the issue, the Defendant has no discretion and that the material burden of proof that there are compelling reasons that bar marketing the product lies with the Defendant and the Plaintiff must not prove the harmlessness of the product (see under the term "Safety" in the identical § 54 LFGB, Wehlau, § 54 Recital 22 with further references; Meyer/Steinz, LFGB, § 54 Recital 20). The Defendant rightly contends that compelling reasons of health protection bar the issuance of the general decree.

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The European Court of Justice developed the criterion of the "compelling reasons of health protection" and the content and scope of this test criterion in its "Cassis" case (U. v. 20.2.1979 - Rs. 120/78) on the interpretation of the justifications of the previous Art. 30 EGV (now: Art. 36 AEUV) and further developed it particularly with the clarification of the use of additives (U. v. 5.2.1981 - Rs. 53/80 "Nisin"; U. v. 14.7.1983 - Rs. 174/82 "Sandoz"). Thereafter, the mandatory requirements are those objectives lying in the general interest that have priority over the free transport of goods. The "compelling" criterion expresses that, when assessing the health risks, the interests of health protection on the one hand and the obstruction of the free transport of goods on the other hand, there must be a comprehensive balancing of legal and other interests under consideration of the principle of proportionality. With this balancing, in cases in which harmonization is intended but not yet realized, and according to the particular status of the research, there is still uncertainty in the assessment of the harmfulness of substances and a degree of discretion of the member states in determining to what extent it wants to ensure health protection (see EUGH, U. v. 5.2.1981 – loco citato; U. v. 13.3.1986 - Rs. 54/85 "Pflanzenschutzmittel", NJW 1987, 565; U. v. 12.3.1987 - Rs. 178/84 "Reinheitsgebot Bier"; U. v. 28.10.2010 - C - 333/08 – "Verarbeitungshilfsstoffe").

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In the interpretation of the "compelling reasons of health protection" criterion, for tobacco products it must be considered that in contrast to food there is the fact that the smoking of each cigarette with or without a menthol additive is damaging to health and addictive. The free movement of goods for tobacco products has therefore also been qualified from the outset. That is roughly what is said in the recitals 4 for the Directive 2001/37/EG of 06/05/2001 for the alignment of the legal and administrative regulations of the member states regarding the manufacture, packaging and sale of tobacco products (- L194, 26 -), that in light of the particularly harmful effects of tobacco, in this context, priority should be given to health protection and all new findings supported by scientific results must be considered.

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According to these principles, in the present case there are compelling reasons of health protection considering the Defendant's degree of discretion.

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For this, the Defendant does not have to prove that the consumption of the Plaintiff product itself is more harmful than traditional menthol cigarettes permitted on the German market due to certain substances in the smoke. Rather, it is sufficient that there is information on this type of cigarette which shows significantly greater harmfulness and or risk of addiction compared to traditional cigarettes.

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Insofar as the Defendant cites the harmfulness of menthol in connection with the smoking of cigarettes, it does not however thereby give evidence of the compelling reasons of health protection. The fact that the additive menthol has a cooling, pain-relieving and slightly numbing

effect, which makes the inhalation of the severe and irritating tobacco smoke easier and according to American studies, an increased potential for addictiveness (see Kahnert et al., Effects of Menthol as an Additive in Tobacco Products and the Need for Regulation, Federal Health Bulletin (Bundesgesundheitsblatt) 2012, 409-415), is not sufficient to prohibit the marketing of a new cigarette with a menthol capsule, because these effects also arise when smoking the "traditional" menthol cigarettes that are allowed on the German market.

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It has not been clarified up to now whether the smoking of cigarettes with menthol capsules is more harmful than smoking traditional menthol cigarettes. The statements of the parties involved regarding the actual amount of menthol in the mainstream smoke of the disputed product, regarding the substances contained in the smoke when smoking these cigarettes and the associated health effects differ. The studies by Gordon et al., to which the Defendant makes reference, and the studies by the "Labstat" laboratory in Canada also do not yield clear results, due to different measuring methods. In the study by Gordon, increased concentrations of volatile organic compounds were measured in "J." cigarettes. The German Cancer Research Center (DKFZ) considers these study results alarming because they suggest that menthol in cigarettes embedded with capsules further increases the carcinogenicity and toxicity of cigarettes (DKFZ, "Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product, "Red Series", Volume 17, p. 7). However, the study by Gordon et al. ultimately results in no more than an "initial suspicion" because the study itself expressly states in its "abstract" and in the "conclusions" that additional studies are needed to be able to precisely determine and explain the differences in the smoke substance concentrations and the health effects between menthol capsule cigarettes and traditional menthol cigarettes.

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Whether such uncertainty after the judgment of the European Court of Justice then has the effect on the individual member states' freedom to take protective measures in the area of health protection in light of the precautionary principle, without having to wait until the existence and extent of this risk are clearly exposed (see EuGH, U. of 10/28/2010, loco citato, Recital 91) can ultimately remain unanswered here.

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In any case, the attractiveness of smoking is significantly increased by the marketing of the Plaintiff's cigarette with the novel capsule technology and thus violates the WHO Framework Convention on Tobacco Control (FCTC) of 05/21/2003.

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This framework agreement, which was signed by 174 countries, including Germany, documents a worldwide consensus that the attractiveness of tobacco products should be further increased by novel products. In Art. 9 FCTC, effective measures for the regulation of substances in tobacco products are called for and in the guidelines issued with it, it is explained that from the view of public health, there is no justification for allowing the use of flavorings to contribute to making tobacco products attractive. The framework agreement is an agreement under international law, which the EU und Germany, as parties to the agreement, have committed to implement. The regulations contained therein are based on objectively obtained results from international research. Therefore, it is logical if a member state takes them as a basis when exercising its degree of discretion of the health protection of citizens. That is why the Defendant also drew upon WHO objectives and regulations when assessing the harmfulness of the introduction of a capsule cigarette to health.

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The Defendant has clearly demonstrated that the menthol capsule makes the cigarettes more attractive for smokers and does not contribute to efforts to reduce cigarette consumption. It rightly referred to publications of the German Cancer Research Center (DKFZ, "Menthol Capsules in

Cigarette Filters – Increasing the Attractiveness of a Harmful Product, "Red Series", Volume 17), among others. There it is quoted from the U.S. patent on capsule technology by R. J. Reynolds from 2003: *"…cigarettes incorporating distinctive flavors that provide a pleasurable sensory experience are clearly of interest to smokers. Some smokers may prefer a cigarette that is capable of selectively providing a variety of different flavors, depending upon the smoker's immediate desire. The flavor of such a cigarette might be selected based on the smoker's desire for a particular flavor at that time, or a desire for a particular flavor at that time, or a desire to change flavors during the smoking experience. For example, changing flavors during the smoking experience may enable a smoker to end the cigarette with a breath freshening flavor, such as menthol or spearmint"* (quoted from DKFZ, Volume 17, p.11).

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This particular attractiveness especially for young smokers is confirmed through colorful, dynamic and innovative advertising ("Click. Switch. Refresh." (P. I. s), "Squeeze, Click, Change!"(J.). For one thing, the experience of freshness that menthol creates is emphasized, and for another, the opportunity to individually change and decide on the taste. The advertising addresses the need for individuality and "doing your own thing", which is particularly strong in young people (DKFZ, Volume 17, p. 13). Insofar as the Plaintiff denies appealing preferably to young people with its product, at least its general manager in Austria admits to appealing to the 20- to 35-year-olds and thus to young smokers. He is quoted by DKFZ as follows (Volume 17, p. 13; p. 29, Fn. 52): *"We are making large investments in market research. Our findings conclude that this innovation – S. – appeals to our customers. There is a tendency towards more freedom of decision, a tendency that can also be found in other consumer goods: I am doing what I want whenever I want it. It is my own decision whether I want more taste or less. S. address this very target group, which is a quite broad one and includes mainly 20-to-35 year-olds."*

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The WHO convention's goal of reducing the attractiveness of tobacco products is contravened by the menthol capsule cigarette. Even if it cannot be predicted with any certainty whether the capsule cigarette will lead to an increase in new smokers, it will definitely make it more difficult for current smokers to stop smoking. This type of cigarette contains a "technical" innovation, which distinguishes it significantly from traditional cigarettes (with and without menthol) since it offers completely different possibilities for only smoking a cigarette. Therefore, depending on personal preference, a totally "normal" cigarette can be smoked or, by crushing the capsule right after lighting the cigarette, a cigarette comparable with a "traditional" menthol cigarette. There is also the option of first smoking a totally "normal" cigarette and then by crushing the capsule, end with a breath-freshening menthol taste (which also makes it unnecessary to suck on a mint afterward). This makes this type of "capsule technology" so innovative and attractive that if it does not initially create an addiction, it can at least make it difficult to end one.

43

The adjudicating chamber considers the Defendant's observation (presented in the oral proceedings) that the target group of 20- to 35-year-old smokers still have no "established smoking behavior" but are rather in an "experimenting phase" relevant and therefore sees in this group a significantly increased interest in the capsule cigarette. There is also the increased risk that "occasional smokers", who only smoke a cigarette every now and then due to the harsh and unpleasant taste but don't reach for a cigarette on a regular basis, will become addicted to nicotine due to this new type of cigarette.

44

In this context, it is irrelevant that up to now in Germany menthol cigarettes only account for a small market share of less than 3%. That this can change in the short- and medium-term is shown by the development in Japan, where the market share of menthol cigarettes in 1980 was still less than 1%

and by 2008, according to the findings of the German Cancer Research Center, reached 20% (DKFZ, Volume 17, p. 22).

45

It can also remain an unanswered question in this proceeding that additional dangers could arise if not menthol but other capsule flavorings are added, which could be sweet, fruity or spicy (honey, licorice, lemon, etc.). Since a general decree is being requested here for a cigarette with a filter containing a capsule, filled exclusively with menthol, the flavoring by another additive would not be captured by the general decree and would not allow its marketing.

46

In light of the foregoing there are compelling reasons of health protection within the meaning of § 47a Para. 2 Clause 1 VTabakG, barring the requested general decree. They justify the resulting interference in the free transport of goods from Art. 34 of the Treaties of the European Union (AEUV), in the freedom to pursue an occupation from Art. 12 of the German Basic Constitutional Law (GG) and in the right of the Plaintiff to established and exercised from Art. 14 Para. 1 GG. Accordingly, reference is made to the avoidance of repetitions on the decision of the adjudicating chamber of 12/15/2011 in the summary proceedings (5 B 184/11 - juris).

47

Insofar as the Plaintiff contends that the refusal to issue a general decree for the disputed capsule cigarettes signifies unequal treatment compared to cigarettes traded on the market, for which the composition or the design of the package is changed to make them more attractive, does not represent a violation of Art. 3 GG (principle of equal treatment). The essential difference, which justifies unequal treatment here, is on the one hand that the capsule cigarette contains substances, some of which are not permitted as additives for cigarette filters according to Annex 1 of the German Tobacco Act so the cigarette as a whole does not meet the current regulations in Germany. In contrast, cigarettes whose composition is modified somewhat by removing a flavoring or whose packaging is redesigned, do not contradict the tobacco act a priori so that they can be marketed without a general decree and thus without checking the opposing compelling reasons of health protection. On the other hand, the introduction of a cigarette with flavor capsule is associated with a technical innovation, which represents such a significant difference from the changes referred to by the Plaintiff in the outer appearance of the product or by its change in taste, that an unequal treatment is justified.

48

The order for payment of costs is based on § 154 para. 1 VwGO. The decision on the Preliminary enforceability follows from § 167 VwGO in conjunction with §§ 708 No. 11, 711 ZPO.

49

The appeal is accepted according to § 124 Para. 2 No. 3 VwGO because the case has fundamental significance.

50

The setting of the value in dispute is based on § 52 Para. 1 GKG and corresponds with the Plaintiff's statements about the expected economic effects of a general decree not being issued in 2011.

The Federal Office of Consumer Protection and Food Safety denied a tobacco company's request to sell a cigarette that contained a menthol capsule that releases a burst of flavor whenever the smoker crushes the capsule during smoking. The tobacco company appealed the government decision. In this decision the court upheld the agency's denial. The court found that the effect of the releasing the refreshing flavor on demand encourages the smoker to remain dependent. Additionally, occasional smokers or young smokers may become addicted to cigarettes with the flavor capsule where they would otherwise be discouraged by the harsh and unpleasant tobacco taste. The court found that cigarettes with flavor capsules are most hazardous than conventional cigarettes.