

Pleas in law and main arguments

1. The General Court erred in dismissing Appellant's non-contractual liability case as inadmissible by distorting both the nature of his claims and his pleas in law. As a result of such distortion, the Court failed to consider unlawfulness in the context of the Commission's capricious and disingenuous pretexts for refusing to act — which inaction eviscerated the Uniform Health Safety Standards for the protections of workers and the public in cases of radiological accidents caused by the military use of nuclear energy.

2. Failure to Apply Legal Principles Common to Member States
The Court failed to assess the unlawfulness of the Commission's lack of care, diligence and sound administration with reference to legal principles common to member state systems for determining administrative accountability for damage caused to individuals, as required under Article 188 of the EAEC Treaty.

3. Inappropriate Application of Commission's Unique Competition Law Exemption- Powers To Admissibility of Health Standards Complaint
The Court further erred by considering the Commission's military exemption of the radiological accident at Thule from the Directive's health protections, in the light of the Commission's wide and unique discretion to formulate EU competition policy by discretionary exemptions of unlawful trade agreements. This ignored admissibility decisions of this Court in other EU areas where the Commission does not possess such a unique discretion and where allegations of the Commission's failure to act did not deem a claim manifestly inadmissible.

The Court overlooked the fact that Commission does not have a unique and unfettered discretion to enforce the Uniform Health Safety Standards since the EAEC Treaty narrowly defines its exemption- power and specifically provides mechanisms for individuals to complain of its administrative failures to act in areas where protections have been conferred on them. This includes situations where the refusal to act has been addressed to another party.

4. Failure to Consider Whether Commission's Refusal to Act Violated EAEC Treaty's Designated Object of Protecting the Health of Workers and the Public.

The Court also erred by failing to enquire into whether the Commission's refusal to act violated the EAEC Treaty's objectives of establishing and ensuring the application of Uniform Health Safety Standards to protect workers and the public from the long term effects of ionizing radiation.

In doing so it overlooked the Commission's peremptory duty under the EAEC Treaty to ensure that the provisions of the Treaty are properly applied, including its embodied precautionary principle.

(¹) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation
OJ L 159, p. 1

Appeal brought on 7 May 2010 by Artegodan GmbH against the judgment of the General Court (Sixth Chamber) delivered on 3 March 2010 in Case T-429/05 Artegodan GmbH v European Commission, other party to the proceedings: Federal Republic of Germany

(Case C-221/10 P)

(2010/C 195/14)

Language of the case: German

Parties

Appellant: Artegodan GmbH (represented by: U. Reese and A. Meyer-Sandrock, lawyers)

Other parties to the proceedings: European Commission, Federal Republic of Germany

Form of order sought

— Annulment of the judgment of the General Court of the European Union of 3 March 2010 in Case T-429/05;

— Order that the defendant pay the applicant the sum of EUR 1 430 821,36 plus interest at 8 % per annum in respect of the period from the delivery of judgment until payment in full; alternatively that the dispute as to quantum be referred back to the General Court of the European Union;

— Declare the defendant liable to compensate the applicant for all damage arising in the future from the marketing efforts necessary to restore the market position of the medicinal product Tenuate Retard to that which it had prior to the withdrawal of authorisation;

— Order that the defendant pay the costs

Pleas in law and main arguments

By judgment of 3 March 2010, the General Court of the European Union dismissed the appellant's claim for compensation in respect of the unlawful withdrawal of marketing authorisations for medicinal products. The dismissal was based on arguments that there was an insufficiently serious breach of provisions of Union law by the Commission, and that the infringement of rules on the delimitation of competence does not give rise to liability on the part of Union institutions because such rules are not designed to protect the economic interests of undertakings. The General Court also held that the relevant provision in Article 11 of Directive 65/65 was imprecise. There was hitherto no precedent for the situation which had arisen, which might logically explain the legal error which the Commission is alleged to have committed. It was also necessary to take account of the complexity of examining the expert medical and scientific report. Viewed as a whole, the legal and factual assessments to be undertaken were so complex that the infringement of Article 11 of Directive 65/65 could not be regarded as a sufficiently serious breach.

In its appeal, the appellant argues that rules on the delimitation of competence, which limit the power of European sovereign bodies to remove existing legal positions, are designed to protect citizens and undertakings in their rights. Therefore, in the appellant's submission, infringement of the rules on the delimitation of competence should have been taken into account in the assessment as to whether a sufficiently serious breach had taken place.

It should also be noted that the Commission had no margin of discretion in taking its decision. Moreover, the Commission did not merely enact an abstract rule, but purposely removed an existing legal position from the appellant by means of administrative action. Thus, the appellant's losses were not merely the indirect result of an abstract rule but the purpose and content of the concrete administrative measure itself. In the appellant's submission, the Commission should therefore have examined with particular thoroughness whether there was a sufficient basis for the withdrawal of the authorisation.

That is not prevented by the priority of protecting health and the particular significance of the precautionary principle. The appellant acknowledges that those principles can justify taking and implementing immediately invasive measures against undertakings, but argues that, in order to restore balance in a State governed by the rule of law and to safeguard the proportionality principle, the possibility of appropriate compensation must be given by way of secondary legal protection.

Nor can it be objected that it is necessary for secondary legal protection to be refused in order to enable the precautionary

principle to be effectively implemented. That is because, in the circumstances of this case, the Commission had no margin for discretion. In such cases, there is no danger at the outset that implementation of the precautionary principle could be hindered by possible liability consequences.

Nor can the lack of precision of Article 11 of Directive 65/65 be relied upon in order to deny the claim for liability. That is because, in the appellant's submission, the onus of such imprecision must be borne not by the undertaking in question but by the Community as a whole. The Community should not be allowed to defend itself against claims for compensation on the ground that it itself failed, in dereliction of its duty, to enact sufficiently clear and unambiguous rules.

The lack of precedent cannot have an exculpatory effect either. In compensation matters, the Community organs have no privilege in the form of a 'right to a first error'. Moreover, the General Court had already legally determined that the Commission's decision was unlawful in form and substance. Thus, at the time the Commission's decision was implemented, there was already a decision by way of precedent.

The complexity of the factual and legal position is also not sufficient on its own to prevent there being a sufficiently serious breach. That will in any event apply in the case of a purely administrative measure, without any margin for discretion, whereby deliberate incursion is made into existing legal positions and significant material damage is thereby directly and foreseeably caused.

Moreover, the authorities having competence for questions arising in the law of medicinal products have suitable factual and legal competence. Thus merely average complexity, which is typically inherent in disputes concerning the safety and effectiveness of medicinal products, is not sufficient to prevent there being a sufficiently serious breach.

Appeal brought on 7 May 2010 by Brigit Lind against the order of the General Court (Fourth Chamber) delivered on 24 March 2010 in Case T-5/09: Brigit Lind v European Commission

(Case C-222/10 P)

(2010/C 195/15)

Language of the case: English

Parties

Appellant: Brigit Lind (represented by: I. Anderson, Advocate)

Other party to the proceedings: European Commission