2009/01/08 - II. ÚS 1009/08: PRELIMINARY QUESTION TO ECJ

HEADNOTES

The constitutional complaint thus represents a specific procedural means, the purpose of which is to ensure the respect of, alternatively afford protection to, the fundamental rights and freedoms guaranteed by the constitutional order. The complaint does not qualify as an ordinary or extraordinary remedial procedure relating to the subject of the specific proceeding before ordinary courts. The differentiation of the functions of ordinary and administrative courts, on the one hand, and the Constitutional Court on the other, is entirely within the competence of the national legislature. According to the provisions of the Treaties on the European Community and on the European Union relating to the division of competences, as well as the ECJ jurisprudence, it is in principle a matter for the Member States to lay down detailed procedural rules (cf. ECJ judgment of 13 March 2007, C-432/05, headnote, marginal number 39-42).

Although the referral of a preliminary question is a Community law matter, the failure, in conflict with Community law, to make a reference may, in certain circumstances, also entrain a violation of the constitutionally-guaranteed right to one's statutory judge. After all, one must bear in mind the fact that the prerequisite for the entitlement to submit a constitutional complaint is the exhaustion of all procedures afforded him by law for the protection of rights. A violation of the right to one's statutory judge comes about in the case where a Czech court (the decision of which may no longer be contested through further remedial procedures afforded by sub-constitutional law) applies Community law but fails, in an arbitrary manner, that is, in conflict with the principle of the law-based state (Art. 1 para. 1 of the Constitution of the Czech Republic), to refer a preliminary question to the ECJ.

The Constitutional Court asserts that it deems as arbitrary action such conduct by a court of last instance applying a norm of Community law where that court has entirely omitted to deal with the issue whether it should refer a preliminary question to the ECJ and has not duly substantiated its failure to refer, including the assessment of the exceptions which the ECJ has elaborated in its jurisprudence. In other words, it is a case where the court entirely fails to take into consideration the existence of the peremptory rule, which is binding on it, contained in Article 234 of the Treaty establishing the European Community.

CZECH REPUBLIC
CONSTITUTIONAL COURT
JUDGMENT

IN THE NAME OF THE CZECH REPUBLIC

On 8 January 2009, a panel of the Constitutional Court, composed of its Chairwoman, Dagmar Lastovecká, and Justices František Duchoň and Eliška Wagnerová (Justice Rapporteur), in the matter of the constitutional complaint of the commercial company, Pfizer, spol. s r. o., whose headquarters is at Stroupežnický 17, 150 00 Prague 5, represented by JUDr. Jan Matějka, an attorney of the law offices of Čermák, Hořejší, Matějka a spol., with its headquarters at Národní 32, 110 00, Prague 1, against the 6 October 2005 decision of the Ministry of Health of the Czech Republic, No. FAR - 165/1656, 32397/2005, the 28 March 2007 judgment of the Prague Municipal Court, No. 12 Ca 144/2005-137, and the 23 January 2008 judgment of the Supreme Administrative Court, No. 3 Ads 71/2007-183, decided as follows:

I. By proceeding in a manner violative of Art. 2 para. 3 of the Constitution of the Czech Republic in conjunction with Art. 4 para. 4 of the Charter of Fundamental Rights and Freedoms, the 23 January 2008 judgment of the Supreme Administrative Court, No. 3 Ads 71/2007-183, resulted in the violation of the complainant's fundamental right guaranteed by Art. 38 para. 1 of the Charter of Fundamental Rights and Freedoms.

II. Accordingly, that decision is quashed.

III. In other respects, the constitutional complaint is rejected on preliminary grounds.

REASONING

I.

1. In its constitutional complaint, consigned for postal delivery on 21 April 2008 and supplemented by a submission on 1 September 2008, the complainant has asked that the above-mentioned decisions be quashed, as they resulted in a violation of its fundamental rights guaranteed by Art. 11 para. 1 and Art. 36 para. 1 of the Charter of Fundamental Rights and Freedoms (hereinafter „Charter").

2. The constitutional complaint is admissible (§ 75 para. 1 a contrario of Act No. 182/1993 Sb., on the Constitutional Court, as subsequently amended, (hereinafter "Act on the Constitutional Court")), was timely submitted and, following the curing of defects as so requested, fulfills the other requirements demanded by law [§ 30 para. 1, § 72 para. 1, lit. a) Act on the Constitutional Court].

3. In its constitutional complaint, the complainant objects that several of its fundamental rights have been violated, in particular, its right to fair process under Art. 36 para. 1 of the Charter. This violation consisted in the fact that it was denied the opportunity to be a party to the administrative proceeding on the registration of the medicinal product, TORVACARD 40 por. tbl. flm., of the firm Zentiva, which was registered pursuant to a decision of the State Institute for the Supervision of Medications, File No. 5260/04, Reg. No. 31/206/04-C. This medicinal product was registered by making reference to the complainant's registration data for the medicinal product SORTIS 40. In the complainant's view, the denial of the opportunity to be a party to the administrative proceeding constituted a denial of the right to fair process, which can be effectuated only and solely in the case where a person claiming her rights is given the opportunity to take part in a proceeding to assert and defend her rights. In the complainant's view, sincethe Supreme Administrative Court (hereinafter „SAC"), in contrast to the Municipal Court, reached the conclusion that the Act on Medications valid at that time (No. 79/1997 Sb., which regulated the process of the registration of medicinal products) did not define a special class of parties to that proceeding, meaning that the issue of participation had to be assessed according to § 14 para. 1 of the then valid Act No. 71/1969 Sb., the Administrative Procedure Code, the SAC should have quashed the contested judgment of the Municipal Court, in accord with Constitutional Court Judgment No. Pl. ÚS 547/02 (however, the complainant meant Judgment I. ÚS 547/02, N 170/35 SbNU 301), which provides that „in order for a legal or natural person to have the status as a party to an administrative proceeding, it is sufficient that there be a mere supposition that they have rights, legally protected interests or obligations which should be considered in the matter."

4. According to the complainant, the violation of its right to fair process also occurred in view of the 9th paragraph of the Preamble to Directive 2001/83/EC (hereinafter „the Directive"), which emphasized the protection of innovative firms from being disadvantaged. Nonetheless, it was not possible to effectuate this protection since the administrative office denied the innovative firm participation in the proceeding. While it is true that para. 10 of the Preamble to the Directive provides that it is in the public interest that tests on humans and animals not be performed repeatedly, unless it were urgently needed, the complainant's participation in the proceeding should not, however, lead to the necessity of repeating those tests.

5. That the complainant should be a party to the administrative proceeding follows from the fact that it is the owner of the information and data of pre-clinical and clinical tests which the complainant provided the registrar, thus it has an interest in seeing that its property is used in comformity with law. Since it was denied its right to fair process, its right to own property guaranteed by Art. 11 of the Charter was also restricted. The complainant was not able, within the registration proceeding, to ensure the proper use of its own registration and other data, and thus its property rights were restricted beyond the limits of the law, as the law does not restrict the protection of property in information provided and in pharmacological and toxicological tests. Its property rights were restricted entirely without respect for the principle of proportionality. Moreover, the SAC denied the complainant its right to the protection of acquired rights and the protection of property by the fact that the complainant was not able to effectuate the

protection of data for the duration of the protective period for data on medicinal products which were registered before the coming into effect of Act No. 149/2000 Sb. (and Act No. 129/2003 Sb.), which amended the Act on Medications that was at that time valid. In the complainant's view, this was a clear case of genuine retroactivity (the time period was shortened while it was still running), which is not permissible. In accord with Judgment Pl. ÚS 21/96 (63/1997 Sb., N 13/7 SbNU 87), the legal norm which is valid and in force at the time the claim came into being must be applied to the start and the running of the protective period for data on the product SORTIS 40.

6. Therefore, in view of what has been stated above, the petitioner proposed that, in its judgment, the Constitutional Court quash the decisions cited in the heading.

7. At the Constitutional Court's request, the Prague Municipal Court and the SAC gave their views on the constitutional complaint. One party, the Ministry of Health, did not gives its views on the petition. In relation to the secondary party, Zentiva, a.s., the Constitutional Court proceeded as required by the proposition of law expressed in its Judgment I. ÚS 642/03 and did not request the secondary party to give its views, as the protection of its rights and interests were not at stake in this proceeding on a constitutional complaint.

8. In its statement of views, the Prague Municipal Court, represented by Mgr. Jiří Tichý, panel chairman, referred to the reasoning of its 28 March 2007 judgment, No. 12 Ca 144/2005-137. In its view, in the complainant's matter, there was no denial of the right to its statutory judge consisting in the failure to refer a question to the European Court of Justice. There were no grounds for so doing, as Act No. 79/1997 Sb. speaks clearly to the point of participation in an administrative proceeding.

9. In the opinion of JUDr. Jaroslav Vlašín, Chairman of Panel 3 of the SAC, the arguments that the complainant makes in its constitutional complaint are essentially identical to those it made in its cassational complaint. The SAC points out that in the adjudicated case, it dealt only with the issue of participation by the firm, Zentiva, a.s., in the proceeding on the registration of medicinal products and not on the merits of matter itself. No grounds were adduced for referring a preliminary question. Panel 3 did not find any provision in EU Directive No. 2001/93/EC [Note of translator: correctly No. 2001/83/EC] which would be necessary to interpret for the purposes of adjudicating the complainant's participation in the registration proceeding. The Chairman of Panel 3 then analyzed Art. 10 of the Directive, which delineates the cases where the results of toxicological and pharmacological tests or the results of clinical assessments of the original medicinal products can be used for registration of generic products. The purpose of that article is to lay down which data the competent body is not obliged to demand within the framework of the proceeding for the registration of generic medicinal products. That provision does not serve to protect the rights of industrial and commercial property of the producers of the original medicinal products, which are not assessed within the framework of the registration proceeding. There is thus nothing establishing its right to participation.

10. According to § 44 para. 2 of the Act on the Constitutional Court, the

Constitutional Court may, with the consent of the parties, dispense with an oral hearing if further clarification of the matter cannot be expected from such a hearing. The parties granted their consent, and an oral hearing was dispensed with.

II.

11. In order to assess the complainant‘s objections and assertions, the Constitutional Court also requested from the Prague Municipal Court case file No. 12 Ca 144/2005, from which it ascertained the following facts.

12. On 13 December 2005 the complainant contested before the Prague Municipal Court the 6 October 2005 decision of the Ministry of Health, No. FAR-165/1656, 32397/2005, which had rejected as inadmissible the appeal against the 29 December 2004 decision of the State Institute for the Supervision of Medicines, No. 5260/04, on the registration of the medicinal product TORVACARD 40. The appeal was based on the complainant’s assertion that it should have been a party to the administrative proceeding, however, it was not dealt with in the proceeding on registration, even though the decision on registration significantly affected both its rights and its commercial interests. According to the opinion of the Ministry of Health, this appeal cannot be considered as an ordinary remedial procedure against this decision, as it was not submitted by a person who was a party to this proceeding according to § 30 para. 2 of the Act on Medications, which is lex specialis in relation to the general regulation in the Administrative Procedure Code. The purpose of this provision is to exclude the possibility that some person other than the applicant for registration could be a party to the proceeding. There is another reason why the complainant cannot be considered a party to the administrative proceeding, namely that in a proceeding on registration only the rights of holders are founded in the decision on registration.

13. It appears from the 28 March 2007 decision of the Prague Municipal Court, No. 12 Ca 144/2005, that the court concerned itself primarily with the issue of whether the complainant was a party to the registration proceeding (which the complainant substantiated with reference to Art. 10 of the Treaty establishing the European Community and Art. 234 of the same Treaty, laying down the principle of legal protection, which would be violated were the complainant not to be admitted as a party to the proceeding). In the Municipal Court’s view, the group of parties is specially defined in § 30 para. 2 of Act No. 79/1997 Sb., on Medications, the purpose of which is to restrict the possibility that any other legal subject which sought participation in the registration proceeding would gain access to all data relating to the medicinal products submitted by the applicant for registration within the framework of the registration proceeding. The rejection of the appeal on the merits was thus well-founded because the fact that the complainant could not be a party to the proceeding also results in the outcomes that neither could it submit an appeal against the registration of the medicinal product. According to the court’s view, the complainant’s rights are in no way affected by the registration. If the complainant makes arguments based on EU Directive No. 2001/83/EC, it is solely the laying down of a protective period which serves to protect the producers of original medications, after which cannot be registered derivative, „generic“ medicinal products, but it does not follow from any

enactment that the holder of a decision on the registration of medicinal products would be a party to the proceeding on the registration of other medicinal products, albeit generic ones. On the contrary, according to the Municipal Court, Art. 19 of the Directive provides (sic!) that it is unacceptable for one competitor on the market to be entitled to adjudicate the products and performances of another competitor, alternatively for it to be entitled to participate in a proceeding in which the rights, legally protected interests, and obligations of another competitor are decided. The Municipal Court is then in no way bound by the decisions of the Supreme Administrative Court in Stockholm (according to whose opinion the producer of the original medicinal product has such an interest in the issue of registration that it has the right to appeal from the registration of generic copies) or those of the Supreme Administrative Court in Sweden, to which the complainant referred. That case concerned the registration of a „generic“ medicinal product, and that medicinal product was registered only after the statutory protective period had expired.

14. In its 14 May 2007 cassational complaint, the complainant contested the Municipal Court's judgment before the SAC. Although the SAC did not concur with the Municipal Court's opinion that § 30 para. 2 of the Act on Medications does not specially define the parties to the registration proceeding, it did concur with it on the point that the registration procedure concerns solely the rights and obligations of the registration. The fact that the State Institute for the Supervision of Medicines is authorized to make use of data submitted by the producer of the original product (and the applicant is thus not obliged to submit the results of pharmacological and toxicological tests) does not affect the rights to the protection of industrial and commercial property. It is only the applicant for registration who is a party to the proceeding, as the subject of the proceeding is not the protection of data or the protection of the holder's industrial and commercial property (for the protection of its rights, the holder is referred to civil judicial proceedings). The SAC gave its views only obiter dictum on the issue of the length of the protective period for the data on medicinal products. It was entirely correct that the Municipal Court did not adjudicate the issue whether the conditions were fulfilled for the registration of the medicinal product (the issue of the similarity or dissimilarity of the intended medical use), as the crucial issue was that of participation in the proceeding.

III.

15. The Constitutional Court has reached the conclusion that the constitutional complaint is well-founded.

16. As follows from the Constitutional Court's constant jurisprudence, the Constitutional Court is bound only by the petit [requested relief] in a submitted petition and not by its legal reasoning. The Constitutional Court can entertain the possibility of reviewing even in terms of other fundamental rights and freedoms than those which are mentioned in the petition. In this case what appears crucial is the issue whether the complainant's right to its statutory judge, guaranteed by Art. 38 para. 1 of the Charter, was violated. The primary, not however the sole, purpose of the right to one's statutory judge is to exclude arbitrary manipulation in

the assignment of cases to individual judges. In other words, the purpose of this right is to ensure impartial decision-making by an independent judge. As the Constitutional Court has already ruled, it is fitting that the constitutional imperative that no one may be removed from the jurisdiction of his statutory judge (Art. 38 para. 1, first sentence, of the Charter), „be deemed an entirely indispensable condition of the due performance of that part of public power which has been constitutionally entrusted to courts; after all, on the one hand it completes and strengthens judicial independence, and on the other hand it represents for each party to a proceeding the equally valuable guarantee that courts and judges have been enlisted to decide in his matter in accordance with principles (procedural rules) that have been previously laid down, so as to preserve the principle of the fixed assignment of the court's business and so as to exclude – for various reasons and sundry aims – the selection of courts and judges „ad hoc". Accordingly, the constitutional principle of the statutory judge cannot be circumvented, whatever be the grounds therefor; even less can its circumvention be masked with reference to a decision issued in conflict therewith being „otherwise correct on the merits", as not only historical experience, but even experience from the recent period of the totalitarian regime persuasively demonstrate how dangerous it is for the individual and damaging to the entire society to enlist courts and judges in the administration of justice in accordance with opportunistic perspectives or through selection" (III. ÚS 232/95, N 15/5 SbNU 101).

17. Whereas the purpose of the manipulative assignment of cases distinctive for totalitarianism is to carry out the will of the assignor (generally party organs), in a liberal democracy the purpose of the right to one's statutory judge is to ensure impartial and independent decision-making, that is, the discovery of the intent and purpose of the legal norm, or of the statute, which should be applied, such that it would be possible to decide fairly. Further, where a Community law component is present, the purpose of the right to one's statutory judge is to ensure the unitary interpretation of legal norms of Community law so as to make it possible, throughout the entire European Union, to fulfill the maxim of equality before the law through individual interpretations of the objective of legal norms contained in Community law. At the same time, the requirement of the foreseeability of the law (see, for ex., I.ÚS 287/04, N 174/35 SbNU 331, I.ÚS 431/04, N 31/36 SbNU 347, IV.ÚS 167/05, N 94/37 SbNU 277, Pl.ÚS 38/04, 409/2006 Sb., N 125/41 SbNU 551), which makes up a component of the demands arising from the requirement of the principle of a law-based state, is thereby ensured.

18. In consequence of the Czech Republic's accession to the European Union, Czech courts acquired the entitlement, and in certain circumstances also become subject to the obligation, to address the European Court of Justice (hereinafter „ECJ") with preliminary questions. On the basis of the third sub-paragraph of Article 234 of the Treaty establishing the European Community, a Member State court, against whose decisions there is no judicial remedy under national law, is obliged to refer a preliminary question to the ECJ (the ECJ, in its decision C-283/81, Srl CILFIT and Lanificio di Tabardo SpA v. Ministry of Health, [1982] 3415, then elaborated the aggregate of exceptions to the obligation to refer a preliminary question). The purpose of the proceeding on a preliminary question is above all to ensure the uniform application of Community

norms by the national courts of Member States and [the purpose of the third paragraph of Article 234 is] „to prevent a body of national case-law not in accord with the rules of Community law from coming into existence“ (107/76 Hoffmann-La Roche v. Centrafarm, [1977]).

19. The Constitutional Court has repeatedly held that it does not form a part of the system of ordinary courts. The Constitutional Court’s yardstick is constitutionality, in other words the review of conformity with the normative and value categories of the Constitution (cf. Klokočka, V.: The Task of the Constitutional Court in the Supervision of the Constitutionality of Judicial Action, Legal Advisor, No. 9/1998, suppl., p. V). The constitutional complaint thus represents a specific procedural means, the purpose of which is to ensure the respect of, alternatively afford protection to, the fundamental rights and freedoms guaranteed by the constitutional order (cf. analogously Šimíček, V., The Constitutional Complaint, Prague, Linde, 2005, p. 76). The complaint does not qualify as an ordinary or extraordinary remedial procedure relating to the subject of the specific proceeding before ordinary courts. The differentiation of the functions of ordinary and administrative courts, on the one hand, and the Constitutional Court on the other, is entirely within the competence of the national legislature. According to the provisions of the Treaties on the European Community and on the European Union relating to the division of competences, as well as the ECJ jurisprudence, it is in principle a matter for the Member States to lay down detailed procedural rules (cf. ECJ judgment of 13 March 2007, C-432/05, headnote, marginal number 39-42).

20. The normative framework for Constitutional Court review remains, even after 1 May 2004, the norms of the constitutional order of the Czech Republic (Pl. ÚS 50/04, 154/2006 Sb., N 50/40 SbNU 443, Pl.ÚS 36/05, 57/2007 Sb.), as the function of the Constitutional Court is the protection of constitutionality (Art. 83 of the Constitution of the Czech Republic), moreover in both its aspects, that is, both the protection of objective constitutional law, and of individual, that is fundamental, rights. Community law does not form a part of the constitutional order, therefore, the Constitutional Court is not competent to interpret that law. Nonetheless, the Constitutional Court cannot entirely overlook the impact of Community law on the formation, application, and interpretation of national law, all the more so in a field of law where the creation, operation, and aim of its provisions is immediately bound up with Community law (Pl. ÚS 50/04, 154/2006 Sb., N50/40 SbNU 443). It is, however, both supreme courts belonging to the system of ordinary courts which ensure the unity of jurisprudence within the Czech Republic, moreover within the compass of their statutorily-defined jurisdiction (competence). Since, as declared above, Community law belongs among the mass of sub-constitutional law, it is in principle a matter for the ordinary courts to review the application of Community law and in certain cases falling within the purview of Art. 234 of the Treaty establishing the European Community to refer to the ECJ questions concerning the interpretation or validity of Community law. It is an obligation in the case of supreme courts, against the decisions of which the procedural enactments provide for no remedial procedures resolvable within the framework of the system of ordinary and administrative courts. A similar doctrine has been embraced, for ex., by the German Federal Constitutional Court (see BvR 2419/06).

21. Although the referral of a preliminary question is a Community law matter, the

failure, in conflict with Community law, to make a reference may, in certain circumstances, also entrain a violation of the constitutionally-guaranteed right to one's statutory judge. After all, one must bear in mind the fact that the prerequisite for the entitlement to submit a constitutional complaint is the exhaustion of all procedures afforded the complainant by law for the protection of rights (§ 75 para. 1 of the Act on the Constitutional Court, interpreted in the Constitutional Court's jurisprudence such that by, those „procedures", is meant any sort of procedure – that is, not only a court action, etc., not only a purely procedurally understood remedial means within the framework of a specific proceeding – see, for ex., II. ÚS 722/05, I. ÚS 575/06, II. ÚS 1036/07 accessible at http://nalus.usoud.cz). A violation of the right to one's statutory judge comes about in the case where a Czech court (against whose decision there is no longer any further remedy afforded by sub-constitutional law) applies Community law but fails, in an arbitrary manner, that is, in conflict with the principle of the law-based state (Art. 1 para. 1 of the Constitution of the Czech Republic), to refer a preliminary question to the ECJ. As follows from the conjunction of Art. 2 para. 3 of the Constitution and Art. 4 para. 4 of the Charter, state power must be asserted only in cases, within the bounds, and in the manner provided for by law, while at the same time preserving the essence and significance of the fundamental rights and freedoms. Should it be otherwise, then that action or act of state power would constitute arbitrary conduct. As the Constitutional Court has repeatedly emphasized, it is not every violation of the norms of ordinary law, in their application or interpretation, which entails a violation of an individual's fundamental rights. Nevertheless, the violation of certain of the norms of ordinary law in consequence of arbitrary conduct (carried out, for ex., by the failure to respect a peremptory norm) or in consequence of interpretation which is in extreme conflict with the principle of justice, might be capable of encroaching upon an individual‘s fundamental rights or freedoms (cf., for ex., III. ÚS 346/01, N 30/25 SbNU 237).

22. The Constitutional Court asserts that it deems as arbitrary action such conduct by a court of last instance applying a norm of Community law where that court has entirely omitted to deal with the issue whether it should refer a preliminary question to the ECJ and has not duly substantiated its failure to refer, including the assessment of the exceptions which the ECJ has elaborated in its jurisprudence. In other words, it is a case where the court entirely fails to take into consideration the existence of the peremptory rule, which is binding on it, contained in Article 234 of the Treaty establishing the European Community. The bare opinion of a court, that it considers the interpretation of the given problem to be obvious, cannot be considered as due substantiation; such an assertion does not suffice, particularly in a situation where the court's opinion has been contested by a party to the proceeding. The substantiation is insufficient also where it fails duly to explain how and why the solution chosen comports with the purpose of the Community legal norm. This is a case where the court omitted to construe the peremptory rule contained in Article 234 of the Treaty establishing the European Community, thereby denying specific parties the right to their statutory judge guaranteed by Art. 38 para. 1 of the Charter.

23. For the sake of comparison and information, the Constitutional Court would allude to the fact that the concept of arbitrariness leading to a violation of the

right to one's statutory judge was defined primarily in the jurisprudence of the German Federal Constitutional Court. In its conception „it constitutes arbitrary conduct, if: (1) a fundamental violation of the obligation to refer a preliminary question has occurred; one can speak of a fundamental violation in the moment when the deciding court of last instance itself had doubts concerning the correct interpretation of Community law, yet failed to bring the matter before the ECJ; (2) the deciding court intentionally departed from the ECJ's settled interpretation of a given issue, but it failed nonetheless to institute a proceeding on a preliminary question; and (3) there did not exist (or does not as yet exist) ECJ constant jurisprudence on the given issue or this jurisprudence does not cover the entire range of questions. The Federal Constitutional Court deduces the non-existence of constant jurisprudence from the fact that the given issue can be interpreted in a manner differing from the interpretation made by the court applying Community law in the given case" (Bobek, M.: The Violation of the Obligation to Institute a Proceeding on a Preliminary Question pursuant to Article 234 (3) of the EC Treaty, Prague, C.H. Beck, 2004, p. 49).

IV.

24. As follows from what is stated above, the pivotal issue appears to the Constitutional Court to be whether the final instance court has acted in an arbitrary manner, that is, the issue of whether and how the final instance court reasoned that it considered the interpretation of the given issue of Community law to be so obvious that there is no reason for applying the peremptory norm contained in Art. 234 of the Treaty establishing the European Community and it is, therefore, not necessary to refer a preliminary question to the ECJ.

25. By the Czech Republic's acceptance into the European Union, all rules contained in Community law thereby became binding, with all consequences, at the moment of its acceptance. Also Directive No. 2001/83/EC thereby became binding, and was implemented domestically, that is, transposed into a national enactment, specifically into the Act on Medications. The provisions of the Act on Medications are crucial in the given matter, in particular § 24 para. 6, lit. c), which provides, among other things, that [without the separate legal enactments on the protection of industrial and commercial property being affected] applicants seeking registration are not obliged to submit either the results of pharmacological and toxicological tests or the results of clinical evaluations, insofar as they can demonstrate that the medicinal product is essentially similar to a medicial product which has been registered in the Czech Republic for a period of at least 6 years; however, if such medicinal product had already, prior to the issuance of a decision on registration, been registered in certain Community Member States, than the six-year time period would begin to run on the day of such registration. This provision resulted from the transposition of the Directive into the national legal order, namely its Article 10, which reflects the principles expressed in paragraphs 9 and 10 of the Preamble to the Directive. The SAC was, after all, entirely aware of this, as it itself stated this fact in its decision. Nevertheless, in the Constitutional Court's opinion, the SAC did not deal in a sufficient manner with the interpretation of the aims pursued by the given Directive, an act of secondary Community law, the respect and implementation of which should also have actually been ensured

by the Czech Republic. The issue of the purposes of a Directive is otherwise pivotal for the given issue, as the teleological and systematic interpretation is far more common than grammatical interpretation in Community law and, as a rule, is of greater relevance (cf. Bobek, M., Komárek, J., Passer, J., Gillis, M., Preliminary References in Community Law, Prague, Linde, 2005, p. 230, and Tichý, L., Arnold, R., Svoboda, P., Zemánek, J., Král, R., European Law, Prague, C.H. Beck, 2006, p. 228 and the jurisprudence mentioned therein). It follows from the legal character of the Directive that the national measures implementing it must ensure the objectives pursued by the Directive, whereas the choice of means remains on the national level.

26. In the Constitutional Court's view, the SAC's fundamental error was the fact that, in interpreting Community law, it shed no light on the jurisprudence of the ECJ, that is, the body with the authority to make the final and unifying interpretation of Community law, as follows from the conjunction of Arts. 220, 234, and 292 of the Treaty establishing the European Community (cf., analogously, Bobek, M.: The Violation of the Obligation to Institute a Proceeding on a Preliminary Question pursuant to Article 234 (3) of the EC Treaty, Prague, C.H. Beck, 2004, p. 60). As is seen from the SAC's decision, it did not in any way ascertain whether or how the ECJ has held on the given issue. The SAC's decision does not have so much as a reference to any ECJ decision whatsoever which would relate to the given issue. The SAC did not concern itself in the least with ECJ jurisprudence, therefore the SAC's decision can scarcely be considered as properly substantiated. Despite the fact that the complainant did not, in its cassational complaint, propose that a preliminary question be referred, it nonetheless appears alone from its submission instituting cassational proceedings that, for the reason of preserving the principle of legal protection, the complainant was alluding to a preliminary question. The complainant stated in its submission, among other things, that „the State Institute for the Supervision of Medicines does not come within the term, 'court', in the sense of Article 234 of the Treaty of Rome, so that it could not itself refer to the ECJ a preliminary question on the interpretation of the relevant provisions of Directive No. 2001/83/EC." The subject of the dispute is connected with the issue of the proper interpretation of Community law, decision on which the ECJ alone is entitled to render, a fact which the SAC has entirely overlooked. On the one hand, the SAC was well aware of the importance of the issue of interpretation of Community law, nonetheless it resolved the issue of participation in the proceeding by the citation of the pertinent provisions of the Directive and their implementation, without attempting to interpret them, much less seek out their intent.

27. The SAC's decision contains no reference to the exceptions which the ECJ has elaborated on the obligation of courts of last instance to refer preliminary questions, if they must apply a norm of Community law, although that obligation is laid down for it in the peremptory norm of Art. 234 of the Treaty establishing the European Community. The decision does not contain a reference of any kind to the criterion laid down in the ECJ's decision C-283/81, Srl CILFIT and Lanificio di Tabardo SpA v. Ministry of Health, [1982] 3415, in which the ECJ laid down specific exceptions which relieve courts of last instance of the obligation to refer a preliminary question on the interpretation of legal norms of Community law which should be applied in a concrete case. As follows from the SAC's statement of views,

it found no grounds for referring a preliminary question to the ECJ, as it had no doubts concerning the interpretation of particular provisions. In other words, in its decision the SAC considered the interpretation of Community law to be obvious and clear (moreover, without the necessity of making reference to any ECJ precedents whatsoever). In making that finding, it did not even take into consideration the argument the complainant made before the Prague Municipal Court which drew attention to the fact that the jurisprudence of the Swedish Supreme Court in Stockholm resolving the issue of participation speaks in favor of the complainant's interpretation. Namely, the Swedish court came to the conclusion that producer of the original medicinal product had such an interest in the issue of registration as to entitle it to appeal the registration of generic copies. The SAC's conviction, that its interpretation of the Community law norm is entirely clear and obvious, is not persuasive also for the reason that is has not properly come to terms with the objection that in other Members States the given enactment is interpreted and applied in a divergent fashion. If the decisional practice of the Swedish Supreme Court is to remain different, the SAC's conviction would thus be founded on nothing that is well-founded, the undesirable variance in interpretation of the intent of the Community norm at issue within the EU area, which is in conflict with the principle of legal certainty, from which follows also the requirement of the foreseeability of law throughout the entire territory in which it should be applied. This fact should have been of interest to the SAC.

28. The fact, that the SAC cannot be considered to have made due substantiation, follows also from the fact that the SAC merely transcribed certain aims contained in the Directive‘s Preamble in conjunction with the Act on Medications, without embarking on a more in-depth interpretation of them, all the while ignoring the other aims to which the complainant drew its attention. The SAC did not ask in more depth what consequences are ushered in by the further aims pursued by para. 9 of the Directive's Preamble, that is, the requirement that innovative firms not be disadvantaged, and further contained in Art. 10 of the Directive, according to which the registration of generic products should not affect the legal protection of industrial and commercial property. Preferring only certain aims leads to the outcome that the SAC's conclusion [namely that „only the applicant for registration is a party to the registration proceeding. The rights or obligations of the holder of the decision on registration of the original medicinal product cannot be affected by the decision on the registration“] follows from its selective choice. The SAC has not dealt with the interpretive alternatives, which would be to take into account also the other above-designated aims. Acknowledged participation could thus be a preventive and effective protection against possible encroachments upon the rights of the holder of the decision on the registration of the original medicinal product, that is, participation would pursue, in the form of a preventive defense, a restriction in the intensity of a possible encroachment into the property rights of the holder of the decision on the registration of the original medicinal product. Since this interpretive alternative also suggests itself, supported by Swedish jurisprudence, it would be appropriate to become acquainted with the ECJ's jurisprudence, and should it not prove possible to find a response therein, it would be necessary to refer a preliminary question to the ECJ.

29. In this context, we must also pause to consider the practice of our courts, which have rarely addressed themselves to the ECJ with a preliminary question. As

appears from the statistics contained in the ECJ Annual Report for 2007 (p. 99nn.), neither the Supreme Court nor the Supreme Administrative Court have ever yet addressed itself to the ECJ with a preliminary question, although our limited experience with Communitary law should, on the contrary, make for a larger number of references. The Municipal Court's work in this matter is also indicative of our limited experience with Community law. This court is wholely mistaken on the content of Art. 19 of the Directive at issue if it asserts that this provision lays down that „it is unacceptable for one competitor on the market to be authorized to adjudicate the products and performance of another competitor, or for it to be authorized to take part in a proceeding in which the rights, legally protected interests, and obligations of other competitors are decided upon." This reference served the Municipal Court as a subsidiary argument for excluding the possibility for the complainant to participate in the proceeding, even though Article 19 lays down nothing of the kind. The court took the citation from an assertion made by the secondary party, without having checked it.

30. Since the complainant has the right to the exhaustion of all remedies which the legal order envisages for the protection of its rights, the SAC, as the court of last instance, has violated its right to its statutory judge, which is guaranteed by Art. 38 para. 1 of the Charter, when it arbitrarily (that is, in conflict with Art. 2 para. 3 of the Constitution of the Czech Republic in conjunction with Art. 4 para. 4 of the Charter) failed to address itself to the ECJ with a preliminary question regarding the complainant's participation in the given proceeding. The SAC also failed both to explain or to substantiate, with regard to the existence of the peremptory rule contained in Art. 234 of the Treaty establishing the European Community, why its interpretation of the pertinent norms of Community law is quite obvious and why its chosen solution, consisting in the refusal to accord participation in the registration proceeding, comports with the intent of the Community norm.

31. For the above-stated reasons, the Constitutional Court has granted the complaint and, in accordance with § 82 para. 3 of Act No. 182/1993 Sb., on the Constitutional Court, as subsequently amended, quashed the SAC's decision. In did so based upon the fact that the SAC, as a court of last instance, is obligated, in the sense of Article 234 of the Treaty establishing the European Community, to refer a preliminary question, whereas lower courts are merely given the possibility, however do not have that obligation, and administrative bodies do not have the possibility to refer a preliminary question. Accordingly, the Constitutional Court rejected, as an inadmissible petition (§ 43 para. 1 lit. e) of the Act on the Constitutional Court), the constitutional complaint against the decision of the Ministry of Health of the Czech Republic, as well as against the judgment of the Prague Municipal Court.

Notice: A Constitutional Court decision may not be appealed (§ 54 para. 2 of the Act on the Constitutional Court).

Brno, 8 January 2009

Dissenting Opinion
of Justice Dagmar Lastovecká

I have adopted this separate opinion in relation to the statement of judgment I and part of the reasoning of the judgment, that is, to the conclusion reached that the Supreme Administrative Court's „arbitrary" means of proceeding (described primarily in points 25 to 28 of the reasoning) resulted in a violation of the petitioner's right to his statutory judge, guaranteed in Art. 38 para. 1 of the Charter of Fundamental Rights and Freedoms.

In a situation where a court of last instance applying a norm of Community law has entirely omitted to deal with the question whether it should refer a preliminary question to the ECJ and has not duly substantiated its failure to refer (see point 22 of the reasoning), and where the issue of the statutory judge has, thus, not been duly answered by the court, one cannot at that point reach a conclusion on the violation of Art. 38 para. 1 of the Charter of Fundamental Rights and Freedoms. Such conduct by the court constitutes a violation of the rules of fair process, and thereby also an encroachment upon the right guaranteed by Art. 36 para. 1 of the Charter of Fundamental Rights and Freedoms (cf. analogously, for ex., also the decisions of the Constitutional Court in the matters No. I. ÚS 74/06, and No. III. ÚS 521/05).