Questions referred

- 1. Is the second paragraph of Article 176 of Directive 2006/112/EC (¹) to be interpreted as precluding an amendment to the ZDDS (Law on VAT) as at 1 January 2007, which provides for the compulsory removal of a person from the VAT register, and the loss of the court-appointed liquidator's right to decide that the legal person whose dissolution has been ordered by a court decision is to continue to be registered under the ZDDS until its deletion from the companies register, and which instead makes dissolution of a commercially active legal person, by reason of liquidation or otherwise, a ground for compulsory removal from the VAT register?
- 2. Is the second paragraph of Article 176 of Directive 2006/112/EC to be interpreted as precluding compulsory removal from the VAT register under an amendment to the ZDDS (Law on VAT) as at 1 January 2007 where, at the time of compulsory removal from the VAT register, the taxable person meets the conditions for compulsory re-registration for VAT, the taxable person is party to current contracts and states that it has not ceased business and continues to carry on an economic activity, and where the taxable person must actually pay the tax calculated and payable upon the compulsory removal in order to retain entitlement to deduct VAT input tax on assets taxed upon removal from the register and available on subsequent registration? If compulsory removal from the register under the circumstances set out is permissible, may entitlement to deduct input tax on assets taxed upon removal from the register, which are available on the subsequent registration for VAT and with which the person effects or will effect taxable transactions, be made dependent on the actual payment of the tax to the exchequer or may the tax calculated upon removal from the register be set off against the amount of tax credit determined on subsequent registration for VAT, in particular where the tax is payable by a person in respect of whom entitlement to deduct input tax arises ...?
- (1) Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax OJ 2006 L 347, p. 1.

Request for a preliminary ruling from the Varhoven administrativen sad (Bulgaria) lodged on 2 November 2016 — 'TTL' EOOD v Direktor na Direktsia 'Obzhalvane i danachno-osiguritelna praktika' — Sofia

(Case C-553/16)

(2017/C 022/15)

Language of the case: Bulgarian

Referring court

Varhoven administrativen sad

Parties to the main proceedings

Appellant: 'TTL' EOOD

Respondent: Direktor na Direktsia 'Obzhalvane i danachno-osiguritelna praktika' — Sofia

Questions referred

1. Is a provision of national law such as Article 175(2), point 3, DOPK, which requires domestic companies which pay out income subject to withholding tax to pay interest for the period from the point at which the time limit laid down for the payment of the tax on such income expires until the day on which a non-resident company established in another Member State furnishes evidence that the requirements for the application of a double taxation convention have been fulfilled, including in cases in which, pursuant to the convention, no such tax or a lower amount thereof is to be paid, compatible with Articles 5(4) TEU and 12(b) TEU?

2. Are a provision of law such as Article 175(2), point 3, DOPK and a tax practice in accordance with which companies which pay out income subject to withholding tax are charged interest for the period from the point at which the time limit laid down for the payment of the tax on such income expires until the day on which a non-resident company established in another Member State furnishes evidence that the requirements for the application of a double taxation convention entered into with the Republic of Bulgaria have been fulfilled, which is charged also in cases in which, pursuant to the convention, no such tax or a lower amount thereof is to be paid, compatible with Articles 49 TFEU, 54 TFEU, 63 TFEU and 65(1) and (3) TFEU?

Request for a preliminary ruling from the Korkein hallinto-oikeus (Finland) lodged on 4 November 2016 — Astellas Pharma GmbH

(Case C-557/16)

(2017/C 022/16)

Language of the case: Finnish

Referring court

Korkein hallinto-oikeus

Parties to the main proceedings

Applicant: Astellas Pharma GmbH

Other parties: Helm AG, Lääkealan turvallisuus- ja kehittämiskeskus (Fimea)

Questions referred

- 1. Are Articles 28(5) and 29(1) of Directive 2001/83/EC (¹) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use to be as interpreted as meaning that the competent authorities of the concerned Member State in the decentralised procedure for marketing authorisations for generic medicinal products in accordance with Article 28(3) of that directive are not themselves competent when issuing a national marketing authorisation to determine the time from which the data exclusivity period for the reference medicinal product begins to run?
- 2. If the answer to the first question is that, when issuing a national marketing authorisation, the competent authorities of a Member State are not competent to determine the time from which the period of data exclusivity of the reference medicinal product starts to run:
 - is the court of that Member State when dealing with an appeal by the holder of the marketing authorisation for the reference medicinal product required to determine the time from which the period of data exclusivity starts to run, or is it subject to the same limit as the national authorities of that Member State?
 - in those circumstances, how is the national court to give effect to the right of the holder of the marketing authorisation of the reference medicinal product under Article 47 of the Charter of Fundamental Rights of the European Union and Article 10 of Directive 2001/83 to effective legal protection with regard to data exclusivity?
 - does the claim for effective legal protection require the national court to examine whether the original marketing authorisation granted in another Member State was issued in accordance with the rules laid down by Directive 2001/ 83?

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).