



**Request for a preliminary ruling from the Østre Landsret (Denmark) lodged on 5 December 2025 –  
Stada Arzneimittel AG v Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceutical Company Ltd.**

**(Case C-794/25, Stada Arzneimittel)**

(C/2026/938)

*Language of the case: Danish*

**Referring court**

Østre Landsret

**Parties to the main proceedings**

*Applicant/Appellant:* Stada Arzneimittel AG

*Defendant/Respondent:* Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceutical Company Ltd.

**Questions referred**

1. Must a derivative, such as lisdexamfetamine, of an active ingredient, such as dexamfetamine, in accordance with the Opinion of Advocate General Henrik Saugmandsgaard Øe of 13 December 2018 in Case C-443/17, <sup>(1)</sup> *Abraxis Bioscience LLC v Comptroller General of Patents*, footnote 76, be considered to be an independent active ingredient, which thus comes within the concept of ‘product’ within the meaning of Article 1(b) of Regulation (EC) No 469/2009 <sup>(2)</sup> of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (SPC Regulation), if:
  - (a) the derivative itself is protected by a patent or
  - (b) the derivative in connection with the grant of a marketing authorisation is considered to be a new active substance within the meaning of Article 10(2)(b) of Directive 2001/83/EC <sup>(3)</sup> of the European Parliament and of the Council of 6 November 2001 (consolidated version) on the Community code relating to medicinal products for human use (Medicinal Products Directive)?If the fact that a derivative such as lisdexamfetamine enjoys independent patent protection or is classified as a new active substance under Article 10(2)(b) of the Medicinal Products Directive does not mean that it must be considered to be an independent active ingredient, what conditions must a derivative, such as lisdexamfetamine, of an active ingredient satisfy in order to be considered to be an independent active ingredient coming within the concept of ‘product’ within the meaning of Article 1(b) of the SPC Regulation?
2. Are there any limitations on judicial review by a court of a Member State in a case such as the present case concerning the alleged invalidity of a supplementary protection certificate, including limitations similar to those referred to in the judgment of the General Court of 5 May 2021 in Case T-611/18, <sup>(4)</sup> *Pharmaceutical Works Polpharma S.A v European Medicines Agency (EMA)* ECLI:EU:T:2021:241, paragraphs 164 to 172, which concerned judicial review by the General Court and the Court of Justice in cases regarding applications for marketing authorisation for medicinal products?

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<sup>(1)</sup> EU:C:2018:1020.

<sup>(2)</sup> OJ 2009 L 152, p. 1.

<sup>(3)</sup> OJ 2001 L 311, p. 67.

<sup>(4)</sup> EU:T:2021:241.