3. Third plea in law, alleging a violation of Articles 2(5), 2(6) and the chapeau of Article 2(10) of Regulation (EU) 2016/1036 by double counting certain selling, general and administrative expenses for Isdemir domestic sales through Erdemir.

4. Fourth plea in law, alleging a violation of Article 2(6) of Regulation (EU) 2016/1036 and Article 2.2.2 of WTO Anti-Dumping Agreement by excluding foreign exchange gains and losses from the selling, general and administrative expenses.

(1) Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union (JO 2016 L 176, p. 21).

Action brought on 29 September 2021 — Çolakoğlu Metalurji and Çolakoğlu Dış Ticaret v Commission

(Case T-630/21)

(2021/C 471/85)

Language of the case: English

Parties

Applicants: Çolakoğlu Metalurji AŞ (Istanbul, Turkey), Çolakoğlu Dış Ticaret AŞ (Istanbul) (represented by: J. Cornelis and F. Graafsma, lawyers)

Defendant: European Commission

Form of order sought

The applicants claim that the Court should:

— annul Commission Implementing Regulation (EU) 2021/1100 of 5 July 2021 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in Turkey (OJ 2021 L 238, p. 32); and

— order the European Commission to pay the applicants' costs.

Pleas in law and main arguments

In support of the action, the applicants rely on four pleas in law.

1. First plea in law, alleging a violation of Article 2(10)(i) of Regulation (EU) 2016/1036 of the European Parliament and of the Council (1) by making an adjustment for a (notional) commission to the export price and, more specifically,

   — A violation of Article 2(10)(i)) of Regulation (EU) 2016/1036 to the extent the adjustment made for commissions exceeds the actual commission paid to Çolakoğlu Dış Ticaret AŞ;

   — A violation of Article 2(10)(i) of Regulation (EU) 2016/1036 as Çolakoğlu Dış Ticaret AŞ does not receive a mark-up; and

   — A manifest error of assessment in treating Çolakoğlu Dış Ticaret AŞ as an agent working on a commission basis and consequent violation of Article 2(10)(i) of Regulation (EU) 2016/1036.

2. Second plea in law, alleging a violation of Article 2(10)(b) of Regulation (EU) 2016/1036 by requiring payment of import duties for accepting a duty drawback adjustment.

3. Third plea in law, alleging a manifest error of assessment in refusing to carry out a quarterly dumping margin calculation and consequent violation of the chapeau of Article 2(10) of Regulation (EU) 2016/1036.

4. Fourth plea in law, alleging a violation of Article 2(10)(j) of Regulation (EU) 2016/1036 by refusing to adjust for hedging gains and losses.

(1) Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union (JO 2016 L 176, p. 21).

Action brought on 1 October 2021 — Agreiter and Others v Commission

(Case T-632/21)

(2021/C 471/86)

Language of the case: German

Parties

Applicants: Karin Agreiter (Merano, Italy) and 33 other applicants (represented by: R. Holzeisen, lawyer)

Defendant: European Commission

Form of order sought

The applicants claim that the Court should annul the contested implementing decision, as subsequently amended and supplemented.

Pleas in law and main arguments

In support of the action against European Commission Implementing Decision of 23 July 2021 amending the conditional marketing authorisation granted by Decision C(2021) 94(final) for 'Spikevax — COVID-19 mRNA Vaccine (nucleoside modified)', a medicinal product for human use, the applicants rely on the following pleas in law.

1. First plea in law, alleging that the contested implementing decision infringes Article 2(1) and (2) of Regulation (EC) No 507/2006. (1) If children become infected with SARS-CoV-2, they are at zero risk and, on that ground alone, there can be no positive risk-benefit balance for healthy children. The use of the experimental substance in question, which is based on genetic engineering, therefore constitutes a serious infringement of EU law. Furthermore, neither the WHO nor the EU has duly recognised an emergency situation in the sense of a public health threat.

2. Second plea in law, alleging that the contested implementing decision infringes Article 4 of Regulation (EC) No 507/2006 due to:

   — the absence of a positive risk-benefit balance, as defined in point 28a of Article 1 of Directive 2001/83/EC; (2)

   — the failure to meet the requirement under Article 4(1)(b) of Regulation (EC) No 507/2006, since the applicant is not in a position to provide the comprehensive clinical data;

   — the failure to meet the requirement under Article 4(1)(c) of Regulation (EC) No 507/2006, since there are no unmet medical needs that will be fulfilled by the authorised medicinal product;

   — the failure to meet the requirement under Article 4(1)(d) of Regulation (EC) No 507/2006.

3. Third plea in law, alleging infringement of Regulation (EC) No 1394/2007, (3) Directive 2001/83/EC and Regulation (EC) No 726/2004. (4) The contested implementing decision infringes, inter alia, the provisions of EU law on the authorisation of 'advanced therapy medicinal products' and on the correct designation of product characteristics and a correct package leaflet. The contested implementing decision is also vitiated by a misuse of power by the Commission concerning the infringement of the child protection rules for clinical trials.