4. Fourth plea in law, alleging that the contested Implementing Decisions are invalid due to abuse and infringement of Regulation (EC) No 507/2006

5. Fifth plea in law, alleging that the contested Implementing Decisions are invalid due to gross infringement of Articles 168 and 169 TFEU and of Articles 3, 35 and 38 of the EU Charter of Fundamental Rights

(1) C(2022)7163 (final).
(2) OJ 2001 L 311, p. 67.
(3) OJ 2009 L 242, p. 3.
(4) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).
(5) Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6).
(6) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ 2014 L 158, p. 1).

Action brought on 23 February 2023 — UY v Commission

(Case T-109/23)

(2023/C 155/82)

Language of the case: German

Parties

Applicant: UY (represented by: R. Holzeisen, lawyer)

Defendant: European Commission

Form of order sought

The applicant claims that the Court should annul:

— Commission Implementing Decision (1) of 10 October 2022 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Comirnaty — tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)', a medicinal product for human use, and repealing Decision C(2020) 9598(final), as amended and supplemented, and the previous Implementing Decisions required by that decision;

— 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 (2) as regards advanced therapy medicinal products — last sentence of point 2.1. of Part IV of Annex I;

— Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (3) — Annex concerning the last sentence of point 2.1. of Part IV.

Pleas in law and main arguments

The action is based on the following five pleas in law:

1. First plea in law, alleging the grossest infringement of Articles 8, 11, 26, 54, 58, 59, 86 et seq. and 101 et seq. of, and Part I, Part III and Part IV of Annex I to, Directive 2001/83/EC, of Articles 3 to 7, 10a, 12 and 14-a of Regulation (EC) No 726/2004, (4) and of the United Nations Declaration on the Human Genome and Human Rights, due to circumvention of the high testing standards envisaged for gene-based medicinal products

   — The application of the provisions governing marketing authorisation laid down in respect of advanced therapy medicinal products was precluded, even though the substances concerned, which were declared as vaccines against infectious diseases, in fact correspond to gene therapy medicinal products.

— There was, in any event, a failure to ensure the involvement in the marketing authorisation procedure of the EMA's Committee for Advanced Therapies, which was specifically required solely on the basis of the genetic structure and mode of action of the substance, regardless of its classification as a gene therapy medicinal product.

— The conditions for marketing authorisation laid down in respect of vaccines based on genetic engineering were, in any event, infringed.

2. Second plea in law, alleging the grossest infringement of Articles 8, 11, 26, 54, 58, 59, 86 et seq. and 101 et seq. of, and Part I, Part III and Part IV of Annex I to, Directive 2001/83/EC, of Articles 3 to 7, 10a, 12, 14, 14a, 20, 20a, 25a, 57, 81 and 84a of Regulation (EC) No 726/2004, and of Articles 5 and 7 of Regulation (EC) No 507/2006 ([5])

   The initial marketing authorisation for Comirnaty (BioNTech), which was only conditional, was converted by the European Commission, on the recommendation of the EMA's Committee for Medicinal Products for Human Use (CHMP), into a marketing authorisation which is no longer conditional, or a marketing authorisation not subject to specific obligations, notwithstanding the omission of the most fundamental studies.

3. Third plea in law, alleging infringement of Regulation (EU) No 536/2014 ([6])

   Since 2021, an illegal pharmacological-genetic experiment with criminal law implications has been carried out on the entire population of the European Union.

4. Fourth plea in law, alleging that the contested Implementing Decisions are invalid due to abuse and infringement of Regulation (EC) No 507/2006

5. Fifth plea in law, alleging that the contested Implementing Decisions are invalid due to gross infringement of Articles 168 and 169 TFEU and of Articles 3, 35 and 38 of the EU Charter of Fundamental Rights

([1]) C(2022)7342 (final).
([2]) OJ 2001 L 311, p. 67.
([3]) OJ 2009 L 242, p. 3.
([4]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).
([5]) Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ 2006 L 92, p. 6).
([6]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ 2014 L 158, p. 1).

Action brought on 3 March 2023 — Insider v EUIPO — Alaj (in Insajderi)

(Case T-119/23)

(2023/C 155/83)

Language in which the application was lodged: English

Parties

Applicant: Insider LLC (Prishtina, Republic of Kosovo) (represented by: M. Ketler, lawyer)

Defendant: European Union Intellectual Property Office (EUIPO)

Other party to the proceedings before the Board of Appeal: Florim Alaj (Zug, Switzerland)

Details of the proceedings before EUIPO

Applicant of the trade mark at issue: Other party to the proceedings before the Board of Appeal

Trade mark at issue: Application for European Union figurative mark in Insajderi — Application for registration No 18 255 587

Procedure before EUIPO: Opposition proceedings