

In support of this appeal, the appellant claims that the General Court made an error in law in that it incorrectly interpreted Article 6(1) of Directive 2001/83/EC, which lays down the concept of the global marketing authorisation, and because the General Court failed to provide an adequate statement of reasons in the judgment under appeal.

In this respect the appellant claims first that the judgment under appeal is based on a misunderstanding of the wording and purpose of Article 6(1) of Directive 2001/83/EC and of the legal framework for the authorisation of new therapeutic indications and on the incorrect assumption that the appellant's interpretation of the Article 6(1) of Directive 2001/83/EC would facilitate manipulation and circumvention of data protection and indefinite extension of data protection for reference medicinal products.

Second, the appellant claims that the General Court's conclusion that Article 6(1) of Directive 2001/83/EC applies to Aclasta because this medicinal product could have been authorised as variation or extension of the medicinal product Zometa runs counter to the principle of legal certainty and would take away the incentive for pharmaceutical companies to invest in research and development of new treatments and is therefore not in the interest of public health.

It is on the basis of this incorrect interpretation of Article 6(1) of Directive 2001/83 that the General Court failed to recognize that the Commission Implementing Decision constitutes an infringement of Novartis data protection rights for Aclasta under Article 13(4) of Regulation 2309/93, read in conjunction with Article 14(11) and Article 89 of Regulation 726/2004, and that, for this reason, the Commission Implementing Decision had to be annulled.

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- ⁽¹⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
OJ L 136, p. 1
- ⁽²⁾ Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products
OJ L 214, p. 1
- ⁽³⁾ 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 L 311, p. 67

Action brought on 2 December 2015 — Slovak Republic v Council of the European Union

(Case C-643/15)

(2016/C 038/55)

Language of the case: Slovak

Parties

Applicant: Slovak Republic (represented by: Ministerstvo spravodlivosti Slovenskej republiky)

Defendant: Council of the European Union

Form of order sought

— annul Council Decision (EU) 2015/1601 of 22 September 2015 establishing provisional measures in the area of international protection for the benefit of Italy and Greece; ⁽¹⁾

— order the Council of the European Union to pay the costs.

Pleas in law and main arguments

The Slovak Republic puts forward six pleas in law in support of its action:

1. First plea in law: infringement of Article 68 TFEU and of Article 13(2) TEU and the principle of institutional balance

By adopting the contested decision going beyond the preceding guidelines of the European Council, and hence contrary to its mandate, the Council infringed Article 68 TFEU as well as Article 13(2) TEU and the principle of institutional balance.

2. Second plea in law: infringement of Article 10(1) and (2) TEU, Article 13(2) TEU, Article 78(3) TFEU, Articles 3 and 4 of Protocol No 1 and Articles 6 and 7 of Protocol No 2, and the principles of legal certainty, representative democracy and institutional balance

An act such as the contested decision cannot be adopted on the basis of Article 78(3) TFEU. In the light of its content, the contested decision has the character of a legislative act, and should therefore have been adopted by the legislative process, which is not however provided for in Article 78(3) TFEU. By adopting the contested decision on the basis of Article 78(3) TFEU, the Council not only infringed that provision but also encroached on the rights of national parliaments and the European Parliament.

3. Third plea in law: breach of essential procedural requirements governing the legislative process, and infringement of Article 10(1) and (2) TEU, Article 13(2) TEU, and the principles of representative democracy, institutional balance and sound administration

Should the Court of Justice, contrary to the submissions of the Slovak Republic in the second plea in law, reach the conclusion that the contested decision was adopted by the legislative process (*quod non*), the Slovak Republic pleads, in the alternative, infringement of essential procedural requirements laid down in Article 16(8) TEU, Article 15(2) TFEU, Article 78(3) TFEU, Articles 3 and 4 of Protocol No 1, Articles 6 and 7(1) and (2) of Protocol No 2, and also infringement of Article 10(1) and (2) TEU, Article 13(2) TEU, and the principles of representative democracy, institutional balance and sound administration. Specifically, there was a failure to comply with the requirement of publicity of negotiating and voting in the Council, a restriction of the participation of national parliaments in the process of adopting the contested decision, and a breach of the condition of consultation of the European Parliament.

4. Fourth plea in law: breach of essential procedural requirements laid down in Article 78(3) TFEU and Article 293 TFEU, and infringement of Article 10(1) and (2) TEU, Article 13(2) TEU, and the principles of representative democracy, institutional balance and sound administration

Before adopting the contested decision, the Council made several amendments and additions to the Commission's proposal. It thereby breached essential procedural requirements laid down in Article 78(3) TFEU and Article 293 TFEU, and infringed Article 10(1) and (2) TEU, Article 13(2) TEU, and the principles of representative democracy, institutional balance and sound administration. The European Parliament was not properly consulted and the Council did not decide unanimously on the amendments and additions to the Commission's proposal.

5. Fifth plea in law: infringement of Article 78(3) TFEU because of the non-fulfilment of the conditions of its applicability

In the alternative to the second plea in law, the Slovak Republic pleads an infringement of Article 78(3) TFEU on the ground of non-fulfilment of the conditions for its applicability, relating to the temporary nature of the measures adopted and to the existence of an emergency situation as a result of the sudden arrival of nationals of third countries.

6. Sixth plea in law: breach of the principle of proportionality

The contested decision is manifestly contrary to the principle of proportionality, since it is manifestly neither appropriate nor necessary for attaining the aim pursued.

⁽¹⁾ OJ 2015 L 248, p. 80.

Action brought on 3 December 2015 — Hungary v Council of the European Union

(Case C-647/15)

(2016/C 038/56)

Language of the case: Hungarian

Parties

Applicant: Hungary (represented by: M.Z. Fehér, Agent)

Defendant: Council of the European Union

Form of order sought

In its application, Hungary claims that the Court should:

- annul Council Decision (EU) 2015/1601 of 22 September 2015 establishing provisional measures in the area of international protection for the benefit of Italy and Greece ⁽¹⁾ ('the contested decision');
- in the alternative, in the event that the first head of claim is not upheld, annul the contested decision in so far as it refers to Hungary;
- order the Council to pay the costs.

Pleas in law and main arguments

1. The Hungarian Government submits that Article 78(3) TFEU does not provide the Council with an adequate legal basis for the adoption of the contested decision. Article 78(3) TFEU does not empower the Council to adopt a legislative act, nor, therefore, to adopt the measures established in the contested decision, specifically those which involve a binding exception in respect of a legislative act, in the present case Regulation (EU) No 604/2013. ⁽²⁾ In view of its content, the contested decision constitutes a legislative act — given that it establishes an exception in respect of Regulation No 604/2013 — with the result it could not be adopted on the basis of Article 78(3) TFEU, which solely empowers the Council to adopt acts through a non-legislative procedure, that is to say, non-legislative acts. In the event that, despite the foregoing, it is held that Article 78(3) TFEU may constitute the basis for the adoption of a legal act which entails an exception in respect of a legislative act, the Hungarian Government submits that that exception cannot go so far as to affect the essence of that legislative act and render nugatory its fundamental provisions, as the contested decision does.
2. A measure established for a period of 24 months — and in certain cases, 36 months — the effects of which, moreover, go beyond even that period, is not compatible with the concept of 'provisional measures' referred to in Article 78(3) TFEU. The contested decision exceeds the power granted to the Council by Article 78(3) TFEU, since, in determining its period of validity, account was not taken of the period necessary for the adoption of a legislative act on the basis of Article 78(2) TFEU.
3. In adopting the contested decision, the Council infringed Article 293(1) TFEU, since it departed from the Commission's proposal without reaching unanimity.