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JUDGMENT OF THE COURT (Grand Chamber)
19 December 2019 (*)
(Appeal — Institutional law — Citizens' initiative 'One of us' — Communication from the European Commission setting out its conclusions and the reasons for not taking the action requested in the citizens' initiative)

In Case C-418/18 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 22 June 2018,

Patrick Grégor Puppinck, residing in Strasbourg (France),
Filippo Vari, residing in Rome (Italy),
Josephine Quintavalle, residing in London (United Kingdom),
Edith Frivaldszky, residing in Tata (Hungary),
Jakub Baltroszewicz, residing in Cracow (Poland),
Alicia Latorre Canizares, residing in Cuenca (Spain),
Manfred Liebner, residing in Zeitlofs (Germany),
represented by R. Kiska, Solicitor, and P. Diamond, Barrister,

appellants,

the other parties to the proceedings being:
European Citizens' Initiative One of Us,

applicant at first instance,

European Commission, represented by H. Krämer, acting as Agent,

defendant at first instance,

Republic of Poland,
European Parliament,
Council of the European Union,

interveners at first instance,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, R. Silva de Lapuerta, Vice-President, A. Prechal, M. Vilaras, E. Regan, S. Rodin (Rapporteur), P.G. Xuereb, L.S. Rossi and I. Jarukaitis, Presidents of Chambers, E. Juhász, M. Ilešič, J. Malenovský and N. Piçarra, Judges,
Advocate General: M. Bobek,
Registrar: M. Aleksejev, Head of Unit,
having regard to the written procedure and further to the hearing on 25 March 2019,
after hearing the Opinion of the Advocate General at the sitting on 29 July 2019,
gives the following

Judgment

By their appeal, Mr Patrick Grégor Puppinck, Mr Filippo Vari, Ms Josephine Quintavalle, Ms Edith Frivaldszky, Mr Jakub Baltroszewicz, Ms Alicia Latorre Canizares and Mr Manfred Liebner ask the Court to set aside the judgment of the General Court of the European Union of 23 April 2018, *One of Us and Others* v *Commission* (T-561/14; 'the judgment under appeal', EU:T:2018:210), whereby the General Court dismissed their action seeking the annulment of Communication COM(2014) 355 final from the Commission of 28 May 2014 on the European citizens' initiative 'One of us' ('the contested communication').

Legal context

Recital 1 of Regulation (EU) No 211/2011 of the European Parliament and of the Council of 16 February 2011 on the citizens' initiative (OJ 2011 L 65, p. 1, and corrigendum OJ 2012 L 94, p. 49), is worded as follows:

'The Treaty on European Union (TEU) reinforces citizenship of the Union and enhances further the democratic functioning of the Union by providing, inter alia, that every citizen is to have the right to participate in the democratic life of the Union by way of a European citizens' initiative. That procedure affords citizens the possibility of directly approaching the Commission with a request inviting it to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties similar to the right conferred on the European Parliament under Article 225 of the Treaty on the Functioning of the European Union (TFEU) and on the Council under Article 241 TFEU.'

Recital 20 of that regulation states:

'The Commission should examine a citizens' initiative and set out its legal and political conclusions separately. It should also set out the action it intends to take in response to it, within a period of three months. In order to demonstrate

that a citizens' initiative supported by at least one million Union citizens and its possible follow-up are carefully examined, the Commission should explain in a clear, comprehensible and detailed manner the reasons for its intended action, and should likewise give its reasons if it does not intend to take any action. When the Commission has received a citizens' initiative supported by the requisite number of signatories which fulfils the other requirements of this Regulation, the organisers should be entitled to present that initiative at a public hearing at Union level.'

Article 2(1) of that regulation provides:

'For the purpose of this Regulation the following definitions shall apply:

"citizens' initiative" means an initiative submitted to the Commission in accordance with this Regulation, inviting the Commission, within the framework of its powers, to submit any appropriate proposal on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties, which has received the support of at least one million eligible signatories coming from at least one quarter of all Member States.'

Article 4(1) and (2) of Regulation No 211/2011 states:

'1. Prior to initiating the collection of statements of support from signatories for a proposed citizens' initiative, the organisers shall be required to register it with the Commission, providing the information set out in Annex II, in particular on the subject matter and objectives of the proposed citizens' initiative.

That information shall be provided in one of the official languages of the Union, in an online register made available for that purpose by the Commission ("the register").

The organisers shall provide, for the register and where appropriate on their website, regularly updated information on the sources of support and funding for the proposed citizens' initiative.

After the registration is confirmed in accordance with paragraph 2, the organisers may provide the proposed citizens' initiative in other official languages of the Union for inclusion in the register. The translation of the proposed citizens' initiative into other official languages of the Union shall be the responsibility of the organisers.

The Commission shall establish a point of contact which provides information and assistance.

2. Within two months from the receipt of the information set out in Annex II, the Commission shall register a proposed citizens' initiative under a unique registration number and send a confirmation to the organisers, provided that the following conditions are fulfilled:

the citizens' committee has been formed and the contact persons have been designated in accordance with Article 3(2);

the proposed citizens' initiative does not manifestly fall outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties;

the proposed citizens' initiative is not manifestly abusive, frivolous or vexatious; and

the proposed citizens' initiative is not manifestly contrary to the values of the Union as set out in Article 2 TEU.'

The first paragraph of Article 9 of that regulation, that article being headed 'Submission of a citizens' initiative to the Commission', provides:

'After obtaining the certificates provided for in Article 8(2), and provided that all relevant procedures and conditions set out in this Regulation have been complied with, the organisers may submit the citizens' initiative to the Commission, accompanied by information regarding any support and funding received for that initiative. That information shall be published in the register.'

Article 10 of that regulation provides:

'1. Where the Commission receives a citizens' initiative in accordance with Article 9 it shall:

publish the citizens' initiative without delay in the register;

receive the organisers at an appropriate level to allow them to explain in detail the matters raised by the citizens' initiative;

within three months, set out in a communication its legal and political conclusions on the citizens' initiative, the action it intends to take, if any, and its reasons for taking or not taking that action.

2. The communication referred to in paragraph 1(c) shall be notified to the organisers as well as to the European Parliament and the Council and shall be made public.'

Article 11 of Regulation No 211/2011, headed 'Public hearing', states:

'Where the conditions of Article 10(1)(a) and (b) are fulfilled, and within the deadline laid down in Article 10(1)(c), the organisers shall be given the opportunity to present the citizens' initiative at a public hearing. The Commission and the European Parliament shall ensure that this hearing is organised at the European Parliament, if appropriate together with such other institutions and bodies of the Union as may wish to participate, and that the Commission is represented at an appropriate level.'

Annex II to that regulation, headed 'Required information for registering a proposed citizens' initiative', is worded as follows :

'The following information shall be provided in order to register a proposed citizens' initiative on the Commission's online register:

The title of the proposed citizens' initiative, in no more than 100 characters;

The subject matter, in no more than 200 characters;

A description of the objectives of the proposed citizens' initiative on which the Commission is invited to act, in no more than 500 characters;

The provisions of the Treaties considered relevant by the organisers for the proposed action;

…

Organisers may provide more detailed information on the subject, objectives and background to the proposed citizens' initiative in an annex. They may also, if they wish, submit a draft legal act.'

Background to the dispute

The background to the dispute is set out in paragraphs 1 to 30 of the judgment under appeal and may be summarised as follows.

On 11 May 2012 the Commission, in accordance with Article 4(2) of Regulation No 211/2011, registered the proposed European citizens' initiative with the title 'One of us' ('the ECI at issue').

The subject matter of the ECI at issue was 'the juridical protection of the dignity, the right to life and of the integrity of every human being from conception in the areas of EU competence in which such protection is of particular importance'.

The objectives of that ECI were described as follows:

'The human embryo deserves respect to its dignity and integrity. This is [stated] by the [Court of Justice of the European Union] in the *Brüstle* case, which defines the human embryo as the beginning of the development of the human being. To ensure consistency in areas of its competence where the life of the human embryo is at stake, the [Union] should establish a ban and end the financing of activities which presuppose the destruction of human embryos, in particular in the areas of research, development aid and public health.'

In an annex to the application for registration of the ECI at issue, three amendments to EU acts, existing or in prospect, were proposed. First, the organisers of that ECI requested that there be inserted a new article into Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ 2002 L 248, p. 1), prohibiting any European Union budget allocation being made for the funding of activities that destroy human embryos, or that presume their destruction. Second, they proposed the insertion of a new subparagraph in Article 16(3) of the Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020 — The Framework Programme for Research and Innovation (2014-2020) (COM(2011) 809 final), excluding from all funding under that framework programme research activities that destroyed human embryos, including those aimed at obtaining stem cells, and research involving the use of human embryonic stem cells in subsequent steps to obtain them. Third, they proposed the addition of a paragraph 5 to Article 2 of Regulation (EC) No 1905/2006 of the European Parliament and of the Council of 18 December 2006 establishing a financing instrument for development cooperation (OJ 2006 L 378 p. 41), providing, in essence, that EU financial assistance should not be used, directly or indirectly, to fund abortions.

The provisions of the Treaties deemed relevant by the organisers of the ECI at issue were Articles 2 and 17 TEU and to Article 4(3) and (4) and Articles 168, 180, 182, 209, 210 and 322 TFEU.

On 28 February 2014, pursuant to Article 9 of Regulation No 211/2011, the organisers of the ECI at issue submitted it to the Commission.

On 9 April 2014, pursuant to Article 10(1)(b) of Regulation No 211/2011, the Commission's representatives received the organisers of the ECI at issue. On 10 April 2014, pursuant to Article 11 of that regulation, the organisers of the ECI at issue were given the opportunity to present it at a public hearing organised at the European Parliament.

On 28 May 2014 the Commission, on the basis of Article 10(1)(c) of that regulation, adopted the contested communication, which has four parts, and in which the Commission stated that it would take no action on the ECI at issue.

In Section 1 of that communication, headed 'Introduction', the Commission set out, inter alia, the subject matter and objectives of the ECI at issue and the three proposed legislative amendments.

In Section 2 of that communication, headed 'State of play', the Commission, first, described the current state of EU legislation in relation to the protection of human dignity and specified the competences of the Union in that regard and stated, inter alia, that whether scientific research making use of human embryos may be carried out and funded by the European Union is an issue that has not been addressed by the Court's case-law.

Second, the Commission set out the state of human embryonic stem cell research ('hESC research'), the competences and activities of the EU Member States in that field, and the mechanisms put in place by the Union to ensure respect for human dignity in the funding of that research. In that regard, with respect to the competences of the Union, the Commission stated that hESC research operates within a strict ethical framework comprising a 'triple lock' system which entails that (i) EU projects must follow the laws of the country in which the research is carried out; (ii) all projects must be scientifically validated by peer review and must undergo rigorous ethical review; and (iii) EU funds may not be used for derivation of new stem cell lines, or for research that involves the destruction of human embryos.

Last, the Commission set out the competences and activities of the Member States and of the Union with respect to maternal and child health in the context of development cooperation.

In Section 3 of the contested communication, headed 'Assessment of the [ECI] Requests', the Commission set out the reasons why it did not intend to take any of the actions proposed by the organisers of that ECI.

First, the Commission stated that the Financial Regulation already ensured that all EU expenditure, including that in the areas of research, development cooperation and public health, must respect human dignity, the right to life, and the right to the integrity of the person.

Second, the Commission stated that the provisions of the Horizon 2020 framework programme on hESC research already addressed a number of important requests of the organisers of the ECI at issue, notably the request that the European Union should not fund the destruction of human embryos and that appropriate controls be put in place.

Last, the Commission stated that a prohibition on the funding of abortions in developing countries, as advocated by the organisers of the ECI at issue, would constrain the Union's ability to achieve the objectives set in the area of development cooperation.

Section 4 of the contested communication, headed 'Conclusions', contains a summary of the arguments set out in the preceding sections of that communication.

The procedure before the General Court and the judgment under appeal

By application lodged at the Registry of the General Court on 25 July 2014, the entity known as 'European Citizens' Initiative One of Us' and the seven natural persons who are the organisers of the ECI at issue and who form its citizens' committee brought an action seeking the annulment of the contested communication and, in the alternative, the annulment of Article 10(1)(c) of Regulation No 211/2011.

By order of 26 November 2015, *One of Us and Others* v *Commission* (T-561/14, not published, EU:T:2015:917), the General Court dismissed that action as being inadmissible in so far as it was directed against Article 10(1)(c) of that regulation. The Parliament and the Council, since they could no longer be considered to be defendants in the proceedings, were, as they requested, granted leave to intervene by decision of the President of the First Chamber of the General Court of 30 November 2015.

By the judgment under appeal the General Court dismissed the action.

After the General Court held, in paragraphs 53 to 65 of that judgment, that the action was inadmissible in so far as it had been brought by the entity known as European Citizens' Initiative One of Us, that court examined, in paragraphs 68 to 101 of that judgment, the question whether the contested communication could be challenged under Article 263 TFEU. The General Court held, in paragraph 77 of that judgment, that that communication produced binding legal effects such as to affect the interests of the appellants, by bringing about a distinct change in their legal position. The General Court stated in that regard that, under Article 10(1)(c) of Regulation No 211/2011, the Commission was obliged to set out in a communication, such as the contested communication, its legal and political conclusions on the citizens' initiative submitted. The General Court accordingly held that the action directed against that communication was admissible.

As regards examination of the substance of the action, the General Court rejected, in paragraphs 105 to 118 of the judgment under appeal, the first plea in law, claiming an infringement of Article 10(1)(c) of Regulation No 211/2011 on account of a failure to submit a proposal for a legal act in response to the ECI at issue, on the ground that the Commission has, by virtue of both that provision and Articles 11 TEU and 24 TFEU, the power to take action in response to an ECI. The General Court stated in that regard that the Treaties confer on the Commission a near-monopoly of legislative initiative.

For the same reasons the General Court rejected, in paragraphs 122 to 125 of the judgment under appeal, the second plea in law, claiming an infringement of Article 11(4) TEU.

The General Court rejected, in paragraphs 128 to 132 of that judgment, the third plea in law, claiming that the Commission had infringed Article 10(1)(c) of Regulation No 211/2011, read in the light of recital 20 of that regulation, by reason of failing to set out, separately, its legal and political conclusions on the ECI at issue. In that regard, the General Court stated that, while that recital states that the Commission is to set out separately its legal and political conclusions, that recital cannot be understood as imposing such an obligation on the Commission, since the preamble of an EU act has no binding legal force. Accordingly, since it is not stated in the wording of Article 10 of that regulation that the Commission is subject to such an obligation, the Commission cannot be criticised for not having set out its conclusions separately. For the sake of completeness, the General Court added that, even if such an obligation existed, a breach of that obligation could not have entailed the annulment of the contested communication.

The General Court also rejected, in paragraphs 141 to 158 of the judgment under appeal, the fourth plea in law, claiming an infringement of the obligation to state reasons, on the ground that the information provided in the contested communication was sufficient to enable the appellants to understand why the Commission declined to take any action in response to the ECI at issue. Further, the General Court held that the argument that the Commission had infringed the obligation to state reasons by failing to define or clarify the legal status of the human embryo in the contested communication was ineffective and had to be rejected, since the sufficiency of the statement of reasons had to be assessed solely in relation to the objective of the ECI at issue.

Last, the General Court rejected, in paragraphs 168 to 183 of the judgment under appeal, the fifth plea in law, concerning errors of assessment made by the Commission in the contested communication.

The General Court held in that regard that, given the broad discretion enjoyed by the Commission in the exercise of its power of legislative initiative, the Commission's decision not to submit a proposal for a legal act to the legislature had to be subject to limited review.

The General Court held, first, in paragraphs 172 to 175 of the judgment under appeal, that the Commission had not committed a manifest error of assessment, considering that the judgment of the Court of Justice of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669), was irrelevant for the purposes of assessing the lawfulness of the contested communication, since that judgment concerns only the question whether biotechnological inventions are patentable and does not deal with the issue of the funding of research activities involving or presupposing the destruction of human embryos.

The General Court held, second, in paragraph 176 of the judgment under appeal, that the appellants had not demonstrated the existence of a manifest error of assessment in relation to the ethical approach of the Commission to the subject of hESC research. The General Court also rejected, on the ground that it was insufficiently substantiated, the appellants' claim that that research was unnecessary.

Third, the General Court held, in paragraph 180 of the judgment under appeal, that the Commission had again not committed a manifest error of assessment in relying on a publication of the World Health Organisation, which states that there is a link between unsafe abortions and maternal mortality, to support the conclusion that a prohibition on funding abortions would constrain the Union's ability to attain the objective of reducing maternal mortality.

Fourth and last, the General Court held, in paragraph 182 of the judgment under appeal, that the Commission had not committed any manifest error of assessment in deciding not to submit to the EU legislature a proposed amendment to

the Financial Regulation designed to prohibit the funding of activities that are contrary to human dignity and human rights.

Forms of order sought by the parties before the Court of Justice

The appellants claim that the Court should:

set aside the judgment under appeal;

annul the contested communication, and

order the Commission to pay the costs.

The Commission contends that the Court should:

dismiss the appeal; and

order the appellants to pay the costs.

The appeal

In support of their appeal, the appellants put forward five grounds of appeal.

The first ground of appeal

Arguments of the parties

By their first ground of appeal, the appellants claim that the General Court erred in law when it rejected, in paragraphs 118 and 125 of the judgment under appeal, their argument in relation to the interpretation of Article 11(4) TEU and Regulation No 211/2011. They consider that the General Court, in holding, in paragraphs 111 and 113 of the judgment under appeal, that the near-monopoly of legislative initiative enjoyed by the Commission was not affected by the introduction of the ECI mechanism, failed to appreciate the specific character of that mechanism.

The appellants consider that, while Article 17(2) TEU provides that Union legislative acts may only be adopted on the basis of a Commission proposal, that provision cannot however be interpreted as conferring on the Commission an unlimited discretion with respect to proposals for legislation relating to a matter forming the subject of a citizens' initiative that has obtained the required support, within the meaning of Article 2(l) of Regulation No 211/2011. The appellants infer from the judgment of 14 April 2015, *Council* v *Commission* (C-409/13, EU:C:2015:217), that the Commission's discretionary power of legislative initiative has to reach its limits where the Commission decides not to submit a proposal for a legislative act in response to an ECI, and the exercise of its discretion in order to impede the objective of an ECI must then be considered to be unlawful.

The appellants maintain that, first, reasons must be stated for the Commission's decision not to submit a proposal for legislation in response to an ECI, and those reasons must be supported by cogent evidence and must not be contrary to the objective of the ECI concerned. Second, they consider that the Commission's discretion must be exercised with due regard for general policies and public policy objectives, subject to judicial review. According to the appellants, the General Court did not either address or identify the public policy objectives of the ECI at issue and the interdependence of Title III of the EU Treaty and Article 24 TFEU stemming from Regulation No 211/2011.

The appellants consider that the General Court erred in law when it found, in paragraph 124 of the judgment under appeal, that the sole objective of the ECI mechanism was to 'invite' the Commission to submit a proposal. Since Article 11(4) TEU does not provide that only those who have collected at least one million signatures are allowed to 'invite' the Commission to take appropriate measures, the appellants consider that any person or any group can 'invite' the Commission to take such measures. In the view of the appellants, given the nature of an ECI, and the costs and organisational difficulties involved, an ECI cannot be treated as no more than a mere 'invitation' to the Commission to take appropriate measures.

The appellants claim that the interpretation of the ECI mechanism adopted by the General Court in paragraphs 111, 113 and 124 of the judgment under appeal deprives the ECI mechanism of any effectiveness and results in its failing to address the democratic deficit of the European Union.

The appellants consider that, taking into consideration the power of the Council and Parliament to influence the Commission, the General Court ought to have recognised that a group of at least one million citizens who have supported an ECI have parity with those institutions. They consider that the Commission's power to take action or not take action in response to an ECI must depend on assessment criteria compliance with which must be subject to judicial review. In the view of the appellants, the findings made by the General Court in the judgment under appeal are incoherent, since the very existence of review of the lawfulness of the contested communication, carried out by the General Court in that judgment, supports their argument that the Commission is not free to take action or not take action in response to an ECI.

Last, the appellants maintain that the General Court erred in law in considering that Regulation No 211/2011 was to be interpreted as permitting the Commission to deprive citizens of their right, within the framework of an ECI, to have their proposals for legislative acts examined by the Parliament.

The Commission states that it claimed before the General Court that the contested communication did not constitute a challengeable act, under Article 263 TFEU. The Commission considers that, as regards the substance, the first ground of appeal should be rejected.

Findings of the Court

Article 11(4) TEU, introduced by the Treaty of Lisbon, provides that Union citizens may, subject to certain conditions, take the initiative of inviting the Commission, within the framework of its powers, to submit any appropriate proposal on matters where those citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties (judgment of 12 September 2017, *Anagnostakis* v *Commission*, C-589/15 P, EU:C:2017:663, paragraph 23).

The right to undertake an ECI constitutes, as does, in particular, the right to petition the Parliament, an instrument concerning the right of citizens to participate in the democratic life of the Union, provided for in Article 10(3) TEU, in that it allows them to apply directly to the Commission in order to submit to it a request inviting it to submit a proposal

for a legal act of the Union, for the purposes of the application of the Treaties (judgment of 12 September 2017, *Anagnostakis* v *Commission*, C-589/15 P, EU:C:2017:663, paragraph 24).

In accordance with the first paragraph of Article 24 TFEU, the procedures and conditions for submitting an ECI have been specified in Regulation No 211/2011.

By their first ground of appeal, the appellants maintain that the General Court erred in law in holding that the Commission was not obliged, under Article 11(4) TEU and Regulation No 211/2011, to submit a proposal for a legislative act in response to the ECI at issue.

In that regard, it must, in the first place, be noted that it is clear from the very wording of Article 11(4) TEU that an ECI is designed to 'invite' the Commission to submit an appropriate proposal for the purpose of implementing the Treaties, and not, as claimed by the appellants, to oblige that institution to take the action or actions envisaged by the ECI concerned. That textual interpretation is confirmed by the wording of Article 2(1) of Regulation No 211/2011, which defines a 'citizens' initiative' as an initiative submitted to the Commission, in accordance with that regulation, 'inviting' the Commission to submit a proposal such as that specified in Article 11(4) TEU. It is clear moreover from the wording of Article 10(1)(c) and from recital 20 of that regulation that, when the Commission receives an ECI, it is to set out the action that it intends to take, if any, and its reasons for taking or not taking action, which confirms that the submission by the Commission of a proposal for an EU act in response to an ECI is optional.

As regards, in the second place, the background to the ECI mechanism, it cannot, as argued by the Commission, be inferred from the judgment of 14 April 2015, *Council* v *Commission* (C-409/13, EU:C:2015:217), which concerned the withdrawal, by the Commission, of a proposal for an EU act during the legislative process, that the Commission is compelled to submit a proposal for an EU act in response to an ECI.

On the contrary, as the Court stated in that judgment, both Article 17(2) TEU and Article 289 TFEU confer on the Commission the power of legislative initiative, which means that it is for the Commission to decide whether or not to submit a proposal for a legislative act, except in the situation where it has an obligation under EU law to submit such a proposal. By virtue of that power, if a proposal for a legislative act is submitted, it is also for the Commission, which, in accordance with Article 17(1) TEU, is to promote the general interest of the European Union and take appropriate initiatives to that end, to determine the subject matter, objective and content of that proposal (judgment of 14 April 2015, *Council* v *Commission*, C-409/13, EU:C:2015:217, paragraph 70).

That power of legislative initiative conferred on the Commission is one of the expressions of the principle of institutional balance, characteristic of the institutional structure of the European Union, which means that each of the institutions must exercise its powers with due regard for the powers of the other institutions (see, to that effect, judgment of 14 April 2015, *Council* v *Commission*, C-409/13, EU:C:2015:217, paragraph 64 and the case-law cited).

In that regard, it must be observed that, as stated in recital 1 of Regulation No 211/2011, the ECI is intended to confer on Union citizens a right comparable to that held, pursuant to Articles 225 and 241 TFEU respectively, by the Parliament and the Council, to request the Commission to submit any appropriate proposal for the purpose of implementing the Treaties. It is apparent from those two articles that the right thus conferred on the Parliament and the Council does not undermine the Commission's power of legislative initiative, and the Commission remains free not to submit a proposal provided that it informs the institution concerned of the reasons. Consequently, an ECI submitted on the basis of Article 11(4) TEU and Regulation No 211/2011 can likewise not affect that power.

In addition, the appellants' argument that the Commission is obliged, in all cases, to take action in response to proposals in an ECI that has been registered and that has obtained the required support cannot be reconciled with the discretion enjoyed by the Commission, under Article 17(1) TEU, in its task of promoting the general interest of the Union and taking appropriate initiatives to that end, and with the general obligation incumbent on the Commission, under Article 17(3) TEU, to be completely independent in the exercise of its power of initiative.

Accordingly, the General Court was correct in holding, in paragraph 111 of the judgment under appeal, that the near-monopoly of legislative initiative conferred by the Treaties on the Commission is not affected by the right to an ECI provided for in Article 11(4) TEU.

In the third place, as regards the appellants' argument that the interpretation of the ECI mechanism by the General Court in the judgment under appeal deprives that mechanism of any effectiveness, it must be recalled that, as stated in Article 10(1) TEU, the functioning of the Union is to be based on representative democracy, which gives concrete expression to democracy as a value. Democracy is, under Article 2 TEU, one of the values on which the Union is founded.

That system of representative democracy was complemented, with the Treaty of Lisbon, by instruments of participatory democracy, such as the ECI mechanism, the objective of which is to encourage the participation of citizens in the democratic process and to promote dialogue between citizens and the EU institutions. However, as stated, in essence, by the Advocate General in point 71 of his Opinion, that objective fits within the pre-existing institutional balance and is pursued within the limits of the powers attributed to each EU institution by the Treaties, the authors of which did not intend, by means of the introduction of that mechanism, to deprive the Commission of the power of legislative initiative conferred on it by Article 17 TEU.

That said, the fact that the Commission is not obliged to take action in response to an ECI does not mean that such an initiative lacks any effectiveness.

An ECI which has been registered in accordance with Article 4(2) of Regulation No 211/2011 and which complies with all the procedures and conditions laid down in that regulation imposes a series of specific obligations on the Commission, as set out in Articles 10 and 11 of that regulation.

First, as soon as it receives an ECI, the Commission must, pursuant to Article 10(1)(a) of that regulation, publish it without delay in the prescribed register, in order to inform the public of the matters appearing in that ECI with respect

to which the citizens consider that an EU legal act is required. Second, under Article 10(1)(b), the Commission is obliged to receive, at an appropriate level, the organisers of an ECI that has collected the support of at least a million signatories, in order to allow them to explain in detail the matters raised by that ECI. Last, Article 10(1)(c) provides that the Commission is to set out in a communication its legal and political conclusions on the ECI, the action it intends to take, if any, and its reasons for taking or not taking that action.

It is stated also in Article 11 of Regulation No 211/2011 that the organisers of an ECI which satisfies the conditions laid down in Article 10(1)(a) and (b) of that regulation have the opportunity to present that initiative at a public hearing, organised at the Parliament, if appropriate together with other institutions and bodies of the Union that may wish to participate, at which the Commission is represented, which ensures that they have privileged access to the EU institutions.

The General Court was therefore correct in holding, in paragraph 124 of the judgment under appeal, that a rejection of the appellants' argument that the Commission is obliged to take action in response to the ECI at issue does not deprive the ECI mechanism of all effectiveness. As the Advocate General observed, in point 78 of his Opinion, the particular added value of the ECI mechanism resides not in certainty of outcome, but in the possibilities and opportunities that it creates for Union citizens to initiate debate on policy within the EU institutions without having to wait for the commencement of a legislative procedure.

In the light of the foregoing, the General Court was justified in holding, in paragraphs 105 to 118 of the judgment under appeal, that the interpretation of Article 10(1)(c) of Regulation No 211/2011 advocated by the appellants is wrong in law. The General Court was also correct to reject, in paragraphs 122 to 125 of the judgment under appeal, the appellants' arguments that Article 11(4) TEU imposes an obligation on the Commission to initiate a legislative procedure in response to an ECI that has been registered and that has the required support.

It follows that the first ground of appeal must be rejected as being unfounded.

The second ground of appeal

Arguments of the parties

By their second ground of appeal, the appellants claim that the General Court erred in law in holding, in paragraphs 128 and 132 of the judgment under appeal, that the Commission was not obliged, under Article 10(1)(c) of Regulation No 211/2011, to set out separately its legal and political conclusions on the ECIs submitted to it. The appellants maintain that that provision must be read in the light of recital 20 of that regulation, where it is stated that the Commission should set out its 'legal' and 'political' conclusions separately.

The Commission considers, expressing its support for the finding of the General Court that the preamble of an EU act has no binding legal force and cannot be relied on as a ground for derogating from a provision or for interpreting that provision in a manner that is clearly contrary to its wording, that the second ground of appeal must be rejected.

Findings of the Court

The preamble of an EU act may explain the content of the provisions of that act (see, to that effect, judgment of 10 January 2006, *IATA and ELFAA*, C-344/04, EU:C:2006:10, paragraph 76). As stated by the Advocate General in point 93 of his Opinion, the recitals of an EU act constitute important elements for the purposes of interpretation, which may clarify the intentions of the author of that act.

However, the preamble to an EU act has no binding legal force and cannot be relied on as a ground either for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner that is clearly contrary to their wording (see, to that effect, judgment of 24 November 2005, *Deutsches Milch-Kontor*, C-136/04, EU:C:2005:716, paragraph 32 and the case-law cited).

In this case, the General Court recalled, in paragraph 128 of the judgment under appeal, the settled case-law on the legal force of a preamble, and then, in paragraphs 129 and 130 of that judgment, held that the Commission was not subject to an obligation to set out separately its legal and political conclusions, since that obligation, which appears in recital 20 of Regulation No 211/2011, is not reproduced in Article 10(1)(c) of that regulation. For the sake of completeness, the General Court added, in paragraph 131 of the judgment under appeal, that, even if the Commission were obliged, under that provision, to set out separately its legal and political conclusions, that obligation would be purely formal, and consequently its breach would not result in the annulment of the contested communication.

It must be observed that the only respect in which the wording of Article 10(1)(c) of Regulation No 211/2011 and that of recital 20 of that regulation differ is that the latter recital alone makes reference to the Commission setting out 'separately' its legal and political conclusions. That reference thus serves to clarify the obligation incumbent on the Commission under that provision.

In that regard, the word 'separately', used in recital 20 of that regulation, must be understood as meaning that both the legal conclusions and the political conclusions of the Commission must appear in the communication relating to the ECI at issue in such a way as to ensure that the legal and political nature of the reasons contained in that communication can be understood.

However, that word cannot be understood as imposing an obligation to make a formal separation of the legal conclusions, on the one hand, and the political conclusions, on the other, an obligation the breach of which would incur the penalty of annulment of the communication concerned.

In this case, as also stated by the Advocate General in point 104 of his Opinion, it is clear from paragraphs 13 to 30 of the judgment under appeal that the contested communication satisfies the requirement mentioned in paragraph 79 of the present judgment.

It follows that the argument pursued by the appellants in the second ground of appeal cannot, in any event, succeed.

Consequently, the second ground of appeal must be rejected as being ineffective.

The third ground of appeal

Arguments of the parties

By their third ground of appeal, the appellants claim that the General Court erred in law, in paragraph 170 of the judgment under appeal, in holding that the contested communication had to be subject to limited review by the General Court, restricted to manifest errors of assessment. They consider, first, that the General Court relied on case-law that is not applicable to the ECI mechanism and, second, that the General Court offered no criterion by which errors that are 'manifest' can be distinguished from errors that are not.

The appellants argue, more specifically, that the General Court erred in accepting that the Commission, when it submits a communication in response to an ECI, has a broad discretion comparable to that which it has in the area of socio-economic policy. They add that the General Court did not state the reasons why it relied, by analogy, on the judgment of 14 July 2005, *Rica Foods* v *Commission* (C-40/03 P, EU:C:2005:455), though that judgment is not transposable to the ECI mechanism.

The Commission contends that the third ground of appeal is unfounded.

Findings of the Court

The General Court held, in paragraph 169 of the judgment under appeal, that the Commission, in exercising its powers of legislative initiative, must be allowed broad discretion, in so far as, through that exercise, it is called upon, pursuant to Article 17(1) TEU, to promote the general interest of the Union, carrying out, as necessary, the difficult task of reconciling divergent interests. Consequently, the General Court considered, in paragraph 170 of that judgment, that the contested communication should be subject to limited judicial review.

In that regard, as has been stated in the examination of the first ground of appeal, the Commission's decision not to take action in response to an ECI which has been registered and which has collected the required support is part of the exercise, by that institution, of its power of legislative initiative conferred in Article 17 TEU.

Since, as rightly stated by the General Court in paragraph 169 of the judgment under appeal, the Commission has, in the exercise of that power, a broad discretion, the General Court was also correct to hold, in paragraph 170 of that judgment, that the contested communication was subject to limited judicial review, and not to full review as claimed by the appellants.

It must, moreover, be made clear in that regard that while it is true, as pointed out by the Commission, that the Court held, in the judgment of 9 December 2014, *Schönberger* v *Parliament* (C-261/13 P, EU:C:2014:2423, paragraph 24), that a decision of the Parliament concerning the action to be taken in response to a petition meeting the conditions laid down in Article 227 TFEU is not amenable to review by the EU Courts, a communication from the Commission adopted under Article 10(1)(c) of Regulation No 211/2011 is, however, to be distinguished from such a decision in various respects.

Unlike such a petition, an ECI that is registered on the basis of Article 4(2) of Regulation No 211/2011 is subject, in accordance with that regulation, to strict conditions and to specific procedural safeguards. Further, while a decision of the Parliament of the kind mentioned in the preceding paragraph falls within a discretion 'of a political nature' (judgment of 9 December 2014, *Schönberger* v *Parliament*, C-261/13 P, EU:C:2014:2423, paragraph 24), it is clear from Article 10(1)(c) of that regulation that the Commission is obliged to set out, in a communication, its conclusions, both legal and political, on the ECI concerned, the action it intends to take, if any, and its reasons for taking or not taking that action.

The aim of those requirements is not only to inform, in a clear, comprehensible and detailed manner, the organisers of an ECI of the Commission's position on their initiative, but, also to enable the EU Courts to review the communications of the Commission adopted in accordance with Article 10(1)(c) of Regulation No 211/2011.

As regards the extent of that review, the General Court held, in paragraph 170 of the judgment under appeal, that the aim of that review is to determine, not only whether the reasons stated in the contested communication are sufficient, but also whether that communication is vitiated by, inter alia, manifest errors of assessment.

In that regard, it must, first, be recalled that the obligation to state reasons must apply, as a general rule, to all EU acts that produce legal effects (see, to that effect, judgment of 25 October 2017, *Commission* v *Council (WRC-15)*, C-687/15, EU:C:2017:803, paragraph 52). The statement of reasons must disclose, clearly and unequivocally, the reasoning of the institution that is the author of the measure, in such a way as to enable, on the one hand, interested parties to ascertain the reasons for the measure in order to defend their rights, and, on the other hand, the EU Courts to exercise their power to review the legality of that decision (see, to that effect, judgment of 12 September 2017, *Anagnostakis* v *Commission*, C-589/15 P, EU:C:2017:663, paragraph 28).

Second, where the EU institutions enjoy, as the Commission does in this case, a broad discretion and, in particular, when they are required to make choices that are, in particular, of a political nature and to undertake complex assessments, judicial review of the assessments that underpin the exercise of that discretion must consist in determining the absence of manifest errors (see, to that effect, judgment of 6 September 2017, *Slovakia and Hungary* v *Council*, C-643/15 and C-647/15, EU:C:2017:631, paragraphs 123 and 124 and the case-law cited).

Accordingly, the General Court did not err in law in holding, in paragraphs 169 and 170 of the judgment under appeal, that the contested communication falls within the exercise by the Commission of its broad discretion and must, consequently, be subject to limited judicial review, with the aim of determining, inter alia, the sufficiency of its statement of reasons and the absence of manifest errors of assessment.

It follows that the third ground of appeal must be rejected as being unfounded.

The fourth ground of appeal

Arguments of the parties

By their fourth ground of appeal, the appellants claim that the General Court erred in law when it undertook a limited review of the Commission's discretion and, further, carried out an incomplete review of the contested communication.

More specifically, the appellants argue that the General Court, in paragraphs 159 to 165 of the judgment under appeal, identified the alleged errors of assessment, and restricted its review, in paragraphs 166 to 177 of that judgment, to determining whether such errors were manifest errors. However, according to the appellants, it is clear from paragraphs 172 to 183 of the judgment under appeal that the General Court carried out that review only with respect to some of the alleged errors of assessment.

In that regard, the appellants argue, in the first place, that the General Court erred in law by failing to identify an inconsistency between the prohibition, laid down in the judgment of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669), on patenting inventions which involve the destruction of human embryos and the funding of research in relation to such inventions and, in addition, by failing to conclude from that judgment that the human embryo should be recognised to be a human being. The appellants consider that paragraphs 33 and 34 of that judgment establish human dignity as a legal principle that takes precedence over the law of patents and that must also be 'taken into account in order to rule on the economic and financial contribution of the Union to the destruction of human embryos'.

In the second place, the appellants consider that the General Court failed to declare that the Commission was obliged to establish in advance the legal status of a human embryo, in order to be able to strike a balance between the interests of hESC research and the dignity of the human embryo. In their opinion, if the Commission had recognised the human dignity of the embryo, that would have precluded it from seeking to balance that dignity and any competing interest of society, since the very notion of human dignity prohibits such balancing.

In the third place, as regards hESC research, the appellants argue that the assertion that the 'triple lock' system constitutes an ethically sound criterion for the assessment of research projects is manifestly misconceived, since such a system does not prevent the funding of illegal research projects and even offers an incentive to the Member States to lower their ethical standards. The appellants maintain that the finding made by the General Court, in paragraph 176 of the judgment under appeal, that the ethical approach of the Commission, which is different from that of the ECI at issue, is not vitiated by a manifest error of assessment, constitutes an error of law. According to the appellants, it is not the role of the General Court to determine the merits of competing socio-ethical interests since such an exercise is political in nature, not a matter of law. The appellants add that the review carried out by the General Court is incomplete, in that it did not examine all the alleged errors of assessment. In that regard, they claim that the General Court failed to examine the manifestly erroneous assertions of the Commission concerning the 'triple lock' system, and did not offer any additional observations in relation to such assertions.

In the fourth place, the appellants claim that the assertion, unaccompanied by any evidence in that regard, that the provision of abortions through funding from the EU budget reduces abortions is manifestly paradoxical.

In the fifth place, the appellants claim that the General Court, in paragraph 164 of the judgment under appeal, misrepresented their arguments, since those arguments related, in reality, to the fact that the Commission had wrongly characterised the commitments made in the context of the objectives of the Millennium Development Goals ('MDGs') and the International Conference on Population and Development ('ICPD') Programme of Action as constituting binding legal obligations.

The Commission contends that the fourth ground of appeal should be rejected as being unfounded.

Findings of the Court

First, it is necessary to reject the appellants' argument that the General Court erred when it found, in paragraphs 173 to 175 of the judgment under appeal, that the issue whether scientific research involving the use of human embryos can be financed by EU funds is clearly distinct from the issue that led to the delivery of the judgment of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669).

As is clear from paragraph 40 of that judgment, the Court stated that it is not the purpose of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13), the interpretation of which was at issue in that judgment, to regulate the use of human embryos in the context of scientific research, the purpose of that directive being limited to the patentability of biotechnological inventions (see also, to that effect, judgment of 18 December 2014, *International Stem Cell*, C-364/13, EU:C:2014:2451, paragraph 22). The judgment of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669), moreover, contains no finding by the Court that scientific research making use of human embryos could under no circumstances be funded by the Union.

Accordingly, since that argument is based on a misreading of the judgment of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669), the General Court committed no error in law in holding that that judgment could not be relied on by the appellants to demonstrate an inconsistency in the approach of the Commission with respect to the use of human embryos in scientific research.

Second, the appellants' argument in relation to the obligation to clarify the legal status of a human embryo is directed, as stated by the Advocate General in point 136 of his Opinion, against paragraph 156 of the judgment under appeal, which concerns the fourth plea in law relied on before the General Court, claiming a breach of the Commission's obligation to state reasons.

That being the case, and besides the fact that that argument does no more than repeat an argument presented in the procedure before the General Court to challenge the contested communication, that argument cannot properly support the fourth ground of appeal, which concerns the General Court's failure to identify alleged manifest errors of assessment committed by the Commission in that communication.

In the third place, as regards the arguments in relation to hESC research, claiming that the General Court determined, in paragraphs 176 and 177 of the judgment under appeal, the merits of competing socio-ethical interests, it must be said that those arguments are based on a misreading of the judgment under appeal.

It is clear from paragraph 176 of the judgment under appeal that the General Court set out the ethical approaches in relation to hESC research respectively followed in the ECI at issue and by the Commission. The General Court held that the Commission's approach was not vitiated by a manifest error of assessment. Further, in paragraph 177 of that judgment, the General Court rejected as being insufficiently substantiated the appellants' argument that there are solutions other than hESC research which, they claim, render that research redundant.

In so proceeding, the General Court did not engage in an examination of the respective merits of competing socio-ethical approaches. The General Court merely determined that the Commission, in its choice of the approach it decided to adopt, had not committed a manifest error of assessment.

It follows that the appellants' arguments in relation to hESC research must be rejected as being unfounded.

In the fourth place, as regards the argument in relation to the alleged error committed by the General Court in paragraphs 179 and 180 of the judgment under appeal, where it is stated that the provision of abortion services funded from the EU budget reduces abortions, it is clear that that argument is based on a misreading of the judgment under appeal.

In paragraph 180 of the judgment under appeal, the General Court correctly stated that, in the contested communication, the Commission, relying on a World Health Organisation publication, had mentioned the fact that improving the safety of health services associated with, inter alia, abortion helps to reduce maternal mortality and maternal illness, one causal factor being the practice of unsafe abortions.

Consequently, the General Court was correct to hold that the Commission had not committed any manifest error of assessment in considering that EU funding of a number of safe and effective health services, including abortion services, contributed to a reduction in the number of unsafe abortions and, therefore, in the risk of maternal mortality and maternal illness. It follows that the appellants' argument must be rejected as being manifestly unfounded.

In the fifth place, as regards the contention that the arguments of the appellants as stated in paragraph 164 of the judgment under appeal, in relation to the MDGs and the IPCD Programme of Action, were misrepresented, suffice it to state, as observed by the Advocate General in point 146 of his Opinion, that that argument cannot, in any event, succeed when there is no assertion in the contested communication that the MDGs and the IPCD Programme of Action contain binding legal obligations.

It follows from all the foregoing considerations that the fourth ground of appeal must be rejected.

The fifth ground of appeal

Arguments of the parties

By their fifth ground of appeal, the appellants claim that the General Court erred in law in stating, in paragraph 156 of the judgment under appeal, that there was no need to clarify the legal status of the human embryo for the purpose of rejecting the three proposals for the amendment of EU acts, existing or in prospect, suggested by the ECI at issue. According to the appellants, the objective of the ECI at issue did not concern solely the adoption of the three measures suggested to Commission, but primarily concerned the legal protection of the dignity, right to life and right to integrity of every human being from the moment of conception. The appellants consider that the Commission was obliged to cooperate with the organisers of the ECI at issue and to submit a proposal for a legislative act in response to it. The General Court erred in law in failing to take into account the specific subject matter of that ECI where it held that the Commission was not obliged to take action in response to that ECI.

The Commission contends that the fifth ground of appeal must be rejected.

Findings of the Court

By the fifth ground of appeal, the appellants claim, in essence, that, in paragraph 156 of the judgment under appeal, the General Court was wrong to hold that the Commission was justified in understanding the objective of the ECI at issue to be solely that the Commission submit the three proposals for legislation that had been described in that ECI and not also that it produce a definition or clarification of the legal status of the human embryo.

In that regard, it is clear from Article 4(1) of Regulation No 211/2011 that the organisers of an ECI, if it is to be registered, must provide the information set out in Annex II to that regulation. The requirements set out in that annex include the title of the proposal for an ECI, the subject matter of that ECI, a description of its objectives, and the provisions of the Treaties considered relevant by the organisers for the proposed action. Further, the organisers may annex to their request for registration more detailed information on the subject and objectives of and background to that ECI, or a draft legal act.

In this case, it is clear from paragraphs 2 to 4 of the judgment under appeal that, on the basis of what was recorded in the Commission's online register for the purposes of the registration of ECIs, first, the subject matter of the ECI at issue consisted in the legal protection of the dignity, right to life and right to integrity of every human being from conception, in the areas of EU competence in which such protection is of particular importance.

Second, that ECI had as an objective the protection of the dignity and integrity of the human embryo further to the judgment of 18 October 2011, *Brüstle* (C-34/10, EU:C:2011:669), which, according to the organisers, defines the human embryo as the beginning of the process of development of a human being. The organisers stated, in that regard, that, in order to ensure consistency in the exercise of its competences, the European Union should prohibit and put an end to the funding of activities that involve the destruction of human embryos, particularly in the fields of research, development aid and public health.

Third, the organisers made reference to Articles 2 and 17 TEU, and to Article 4(3) and (4) and Articles 168, 180, 182, 209, 210 and 322 TFEU as relevant provisions.

The organisers of the ECI at issue had annexed to their request for registration three proposals for amendments to existing or proposed EU acts.

More specifically, as stated in paragraph 14 of the present judgment, the organisers requested (i) the insertion, in the Financial Regulation applicable to the EU budget, of a provision prohibiting the funding by the Union of activities that destroy human embryos or presuppose their destruction; (ii) the addition, in a proposed EU regulation on the establishment of a framework programme for research and innovation, of a provision excluding from all funding under that programme research activities that destroy human embryos, including those aimed at obtaining stem cells, and research involving the use of human embryonic stem cells in subsequent steps to obtain them; and (iii) the addition, in the EU legislation establishing a financing instrument for development cooperation, of a provision stating, in essence, that EU financial assistance should not be used, directly or indirectly, to finance abortions.

It follows from the foregoing that the General Court was right, in paragraph 156 of the judgment under appeal, to hold that the objective of the ECI at issue was to invite the Commission to submit three proposals for legislation consisting in amending existing or proposed EU acts, relating respectively to the EU budget, to research and innovation, and to development cooperation, and not to submit, in addition, a proposal aimed at the definition or clarification of the legal status of the human embryo.

Consequently, the fifth ground of appeal must be rejected and, therefore, the appeal must be dismissed.

Costs

In accordance with Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to costs.

Under Article 138(1) of those rules, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

Since the Commission has applied for costs and the appellants have been unsuccessful, the latter must be ordered to pay the costs of the Commission and to bear their own costs.

On those grounds, the Court (Grand Chamber) hereby:

Dismisses the appeal;

Orders Mr Patrick Grégor Puppinck, Mr Filippo Vari, Ms Josephine Quintavalle, Ms Edith Frivaldszky, Mr Jakub Baltroszewicz, Ms Alicia Latorre Canizares and Mr Manfred Liebner to bear their own costs and to pay those incurred by the European Commission.

Lenaerts Silva de Lapuerta Prechal

Vilaras Regan Rodin

Xuereb Rossi Jarukaitis

Juhász Ilešič

Malenovský Piçarra

Delivered in open court in Luxembourg on 19 December 2019.

A. Calot Escobar K. Lenaerts

Registrar President

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* Language of the case: English.