TO THE PRESIDENT AND MEMBERS
OF THE GENERAL COURT OF THE EUROPEAN UNION

REPLY TO THE STATEMENT OF DEFENCE SUBMITTED BY THE COUNCIL OF THE EUROPEAN UNION ON 21 MAY 2024

IN CASE T-138/23
SEMMELWEIS EGYETEM V. COUNCIL OF THE EUROPEAN UNION

Lodged on 15 July 2024, pursuant to Article 83(1) of the Rules of Procedure of the General Court, by

SEMMELWEIS EGYETEM

Applicant

of 26 Üllői út, Budapest 1085, Hungary, represented by Dr. Péter P. Nagy ügyvéd of the Budapest Bar and by Dr. Balázs Karsai ügyvéd of the Budapest Bar, both of the law firm Nagy és Trócsányi registered with the Budapest Bar Association at 217, with an address at 4/B Ugocsa utca, Budapest 1126, telephone: +36 1 487-8700, email: nagy.peter@nt.hu (with service to be effected in these proceedings at the eCuria account associated with that email address)

v.

COUNCIL OF THE EUROPEAN UNION

Defendant

in proceedings brought for partial annulment in respect of Council Implementing Decision (EU) 2022/2506 of 15 December 2022 on measures for the protection of the Union Budget against breaches of the principles of the rule of law in Hungary, insofar as it concerns the Applicant.

I. Introduction

1. In its Statement of Defence dated 21 May 2024 (the "**Statement of Defence**"), Defendant laments the erosion of the rule of law in Hungary and that this verifies adoption of the Council Implementing Decision (EU) 2022/2506 on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary (the "**contested Decision**"). These allegations, correct or incorrect, are definitely beyond the scope of these proceedings[1].

2. In these proceedings, this Applicant only seeks the annulment of Article 2(2) of the contested Decision insofar as it applies to the Applicant for the sole reasons that, vis-à-vis the Applicant

   (a) this Article 2(2) lacks sufficiently solid basis (first plea),
   (b) the Applicant's right to be heard was infringed (second plea),
   (c) the contested Decision lacks legal basis (third plea) and
   (d) infringes the principle of proportionality (fourth plea), and, last but not least,
   (e) it distorts market (fifth plea).

3. We invite the Defendant to respect that the Applicant is a self-governing legal entity with precious traditions of autonomy. As the rector of the Applicant addressed the European Parliament on 7 June 2023:

   "*Just as our predecessors have done over the centuries, we cooperate with state leaders and the government, but more importantly, we believe in the autonomy of universities. Over the past 254 years, governments and even political regimes have come and gone, but our quest for autonomy has remained unchanged. Two years ago, we had the opportunity to take a further step away from the state towards university autonomy.*"[2]

4. The issue at hand is whether the concerns about rule of law raised by the Defendant against the Government of Hungary may lawfully serve as a pretext to denounce the integrity of the Applicant and punish the Applicant, in fact, its faculty and students.

5. Applicant Semmelweis Egyetem lodged an application (the "**Application**") against the Council of the European Union for the partial annulment of Article 2(2) contested Decision.

6. Defendant submitted a plea of inadmissibility on 30 May 2023 on which the Applicant submitted its observations on 18 July 2023.

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[1] See ¶28 Application
[2] https://semmelweis.hu/english/2023/06/dr-bela-merkely-speaks-up-for-semmelweis-university-in-brussels

7. In its order dated 5 April 2024, the General Court rejected the Defendant's plea of inadmissibility by concluding that the contested Decision is a regulatory act which is of direct concern to the Applicant and does not entail implementing measures. The General Court's rejection order and its findings generally support the arguments detailed in the Application, especially those emphasizing direct effects of the prohibition included in Article 2(2) contested Decision on the Applicant's legal situation[3] and those confirming that the implementation of the prohibition to enter into legal commitments with the Applicant is purely automatic and mandatory.[4]

8. Due to the General Court's rejection decision, the Defendant was called to submit its defence.

9. In its Statement of Defence dated 21 May 2024, Defendant requested the General Court to dismiss the Application in its entirety, as it considers that all pleas in law raised by the Applicant are unfounded.

10. Applicant emphasizes – as elaborated in detail below – that in its Statement of Defence, Defendant **(i)** fails to respond to or even to refer to most of the Applicant's arguments (presented either in the Application or in the observations on the plea of inadmissibility); **(ii)** disregards the evidence submitted by the Applicant, in particular in support of its exclusions from different projects; **(iii)** on a number of points - in particular as regards the failure to examine the Applicant's individual situation and the failure to guarantee the right to be heard - Defendant essentially makes the same findings as those set out in the Application; **(iv)** submits general arguments only; **(v)** often cites provisions and makes statements concerning not itself but the Commission and **(vi)** fails to support its arguments and statements by facts.

11. Applicant notes that the negative impacts of Article 2(2) contested Decision – as predicted in the Application submitted on 13 March 2023, ie. 16 months ago – are becoming more and more significant and diversified. On the one hand, exclusion of hundreds of students, teachers and researchers from the Erasmus+ Programme became undeniably certain since the submission of the Application. Their applications were initially conditionally supported for the period after 31 July 2024, but with respect to Article 2(2) contested Decision and the prohibition included therein, these conditionally supported applications will be rejected. Consequently, hundreds (or even thousands) of students are deprived from a once in a lifetime opportunity that is of particular importance for not just their professional development but for the Applicant and the whole healthcare sector as well. On the other hand, the exclusion of the Applicant from different projects falling under the scope of the Horizon Europe Programme is more automatic and prejudicial than earlier. As presented in the Application, Semmelweis Egyetem cannot receive any funding for its participation in different research projects due to the automatic prohibition laid down in the contested Decision, however, earlier it still had the chance to participate as an associated partner (who finances its own costs from its

[3] See, in particular, ¶¶65-66 order rejecting the Defendant's plea of inadmissibility
[4] See, in particular, ¶¶69-71 order rejecting the Defendant's plea of inadmissibility

own resources). This situation has detrimental effects on the Applicant's operation and finances but at least allowed it to have to opportunity to remain a member of the consortium doing the research project. However, one of the latest exclusion notification goes even further by automatically and explicitly rejecting the Applicant's proposal because it does not satisfy the minimum eligibility criteria set out in the call conditions. The respective admissibility and eligibility report enclosed to the rejection letter and signed by the Commission provides for the following brief explanation only: '*Hungarian entity applicant concerned by the measures set out in the Council Implementing Decision 2022/2506.*' The rejection letter and the eligibility report are attached hereto as Annex A.19.

12. Thus, the Applicant's situation became even more negatively affected by the contested Decision, as the proposals submitted by it are not even evaluated on the merits and it cannot participate in projects even as an associated partner any longer. As a result of this different evaluation process, even less institutions will be open to bear the risk of including the Applicant in their proposals submitted under the Horizon Europe Programme, since they understandably do not want to sabotage their own chance of being able to participate in different Union funded research projects. For a university that thrives on research and is full of accomplished professionals with great minds and with boundless curiosity, the scientific, reputational and financial consequences of such an exclusion are almost unbearable.

13. Applicant, in response to the Statement of Defence, submits the following reply pursuant to Article 83(1) of the Rules of Procedure of the General Court.

14. Applicant maintains its earlier submissions and arguments and does not wish to reproduce them in the present reply; thus, it reflects on the arguments put forward in Defendant's Statement of Defence only.

II. General observations on the Statement of Defence

15. Before replying to the Defendant's arguments made in respect of the five pleas of law raised in the Application respectively, Applicant puts forward a few general observations on the Statement of Defence as follows.

16. First of all, it shall be pointed out that the Statement of Defence rather appears to be a document seeking to justify the appropriateness of the legislative process preceding the adoption of the contested Decision and to justify the objective allegedly pursued by it (namely the protection of the financial interests of the Union), than a substantive response to the Application and the arguments presented therein. The general nature of the Defendant's arguments and the lack of individualization firmly supports the Applicant's pleas, particularly those establishing that the contested Decision lacks a sufficiently solid factual basis, that the Applicant has been denied the right to be heard as well as that the Defendant infringed the principle of proportionality.

17. One of the most striking example of this view of the Council ignoring the individual factors and details is that in spite of the fact that the Application and the observations on the plea of inadmissibility dedicate several paragraphs to the assessment of the programmes from which the Applicant is excluded from and the Applicant attached nine rejection letters in total to the aforementioned two submissions,[5] the Defendant fails to reply or at least refer to any of these assessments and annexes. Also, the Statement of Defence ignores the Applicant's arguments regarding the negative effects and detrimental consequences of Article 2(2) contested Decision on Semmelweis Egyetem's operation, reputation, and market position.

18. Having reviewed the main procedural documents of the case, it can be easily concluded that the Defendant fails to address or refute most of the arguments presented in the Applicant's submissions. The fact that the Defendant overlooks and omits to assess the specifics of the case at hand and Semmelweis Egyetem itself is harmful and prejudicial not just to the Applicant itself, but to its students, teachers, and researchers as well and also for those persons and entities, who wish to cooperate with the Applicant – a well-known and high-ranked university – in different projects. The lack of attention on the position and opportunities of these groups of persons became especially harmful recently, since hundreds (and if Article 2(2) contested Decision remains in effect, then potentially thousands) of students and researches are deprived of the opportunity to participate in the Erasmus+ Programme and to study and research abroad. In this respect, the Applicant wishes to highlight that participating in the Erasmus+ Programme and travelling abroad to prestigious universities to research and study while receiving a scholarship is a once in a lifetime opportunity for many. This Programme offers a unique chance to broaden the knowledge of the participants, from which knowledge first the Applicant, then the healthcare sector and thus the patients can profit. Given that a significant proportion of students apply in the final years of their studies, many of them are permanently denied the opportunity to participate in the programme because they will no longer study at Semmelweis Egyetem when the prohibition included in Article 2(2) contested Decision is annulled or lifted.

19. The negative effects on the Applicant caused by the prohibition are further substantiated by the latest rejection decision received by the University only a couple of weeks ago indicating that the proposal put together and submitted by the Applicant was rejected without any assessment due to the existence of Article 2(2) contested Decision and the fact that the Applicant falls under its personal scope.

20. Secondly, the Statement of Defence repeatedly argues that the measure challenged by the Applicant serves a high and honorable purpose, namely it protects the financial interests of the European Union. The importance of this goal as well as the protection of the Union funds is known to and acknowledged by the Applicant. However, the Defendant fails to verify or prove how this goal is achieved by banning Semmelweis Egyetem from participating in different research and study programmes financed by the European Union.

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[5] Annexes no. A.2., A.3., A.4., A.12., A.13., A.14., A.15. and A.16.

21. The references made to the violations of the rule of law cannot be interpreted in respect of the Applicant, a university, who is by definition unable to commit any of the violations listed in the Regulation (EU, Euratom) 2020/2092 on a general regime of conditionality for the protection of the Union budget (the "**Conditionality Regulation**"). Despite of this fact, the Council goes even further by repeatedly referring to breaches of the rule of law which are systematic in nature. In the Applicant's view, it requires no detailed explanation to draw the obvious conclusion, namely that in the absence of an individual infringement, there cannot be a systematic one, hence the Council's argumentations are unsubstantiated and misleading.

22. Moreover, the Applicant provided a detailed assessment of the control over it and highlighted that the National Foundation for Healthcare and Medical Education is not involved in the executive management of the University and that none of the curators of the Foundation is a member of the government and none of them is an active politician. These personal and asset management specifics of the Applicant refute those allegations of the Council (and earlier the Commission) that the measure included in Article 2(2) contested Decision is required due to the risk posed by the fact that top-level officials and senior political executives are present in the boards of public interest asset management foundations performing a public task (called as '*public interest trusts*' or '*PITs*' by the Defendant) or '*whose purpose it is to disburse large amounts of public funds*'.[6] None of these conditions are met in respect of the Applicant, therefore, the purpose of the prohibition cannot be justified.

23. Thirdly, as further detailed below, Defendant itself admits that the Applicant's situation was neither assessed during the preliminary procedure headed by the Commission leading to the adoption of the contested Decision, nor by the Defendant itself before and during the adoption of the contested Decision.[7] This admission carries a significant weight for a number of reasons, namely:

    - in November 2021, a communication process began between the Commission and Hungary raising - inter alia - '*issues related to public interest trusts*'.[8] The contested decision was adopted by the Defendant on 15 December 2022. Thus, during this rather long period, neither the Commission, nor the Council considered it important to assess the specificities of the Applicant or the potential effects of the prohibition thereon or to provide an opportunity to the Applicant to share its views on the measure at hand;

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[6] Communication from the Commission to the Council on the remedial measures notified by Hungary under Regulation (EU, Euratom) 2020/2092 for the protection of the Union budget, COM(2022) 687 final, 30.11.2022, ¶70.

[7] Defendant's Statement of Defence, ¶17: '*As regards systemic breaches, neither the Commission nor the Council needs to assess the situation of each of the entities that might be affected by an implementing decision such as the one under scrutiny in these proceedings.'*

[8] See Recital (2) contested Decision

- it could be assumed that the Defendant failed to assess the situation of the Applicant by the fact that in its plea of inadmissibility, the Defendant argued at length that Semmelweis Egyetem may or may not qualify as being maintained by a so-called public interest trust, since the interpretation of the word '*maintained'* is an '*autonomous concept of EU law*'[9] or an '*autonomous notion of EU law*'.[10] The Council also argued that the Applicant is not directly concerned by the contested Decision. These arguments indicated the lack of assessment of the Applicant's individual situation on the Defendant's part, which is expressly admitted in the Statement of Defence;

- the Defendant often relies on the documents and assessments made by the Commission, seemingly to mitigate its own liability for the devastating effects of Article 2(2) contested Decision. However, the Defendant's liability cannot be mitigated, let alone excluded as a result of that circumstance that the Commission failed to carry out a proper assessment in compliance with the basic lawmaking principles applicable to all Union bodies. Before the adoption of the contested Decision, the Defendant should have realized the Commission's omission and should have remedied it without delay;

- by this admission of the Defendant, many of the Applicant's arguments are verified, including that the contested Decision lacks a sufficiently solid factual basis, that the Applicant has been denied the right to be heard as well as that the Defendant infringed the principle of proportionality;

- the list of entities falling under the definition of '*any public interest trust established on the basis of the Hungarian Act IX of 2021 or any entity maintained by such a public interest trust*'[11] is not too long, when the contested Decision was adopted, Annex 1 of Act IX of 2021 contained 34 public interest asset management foundations performing a public task and clearly indicated the entities (mostly universities) maintained by them. Given the number of entities concerned and the fact that they can be easily identified from the annex to the aforementioned law, neither the search for these entities, nor the assessment of their characteristics, nor contacting them would have required significant capacities on the part of the Defendant.

24. Lastly, the Defendant notes in paragraph 10 of its Statement of Defence that the measure set out in Article 2(2) contested Decision was adopted because the changes made by Hungary were not sufficient to eliminate '*the risks for the EU budget deriving from the model of university governance based on PITs*'. Furthermore, the Defendant wishes the substantiate the appropriateness of the prohibition by arguing that the sole addressee of the contested Decision – that is Hungary – did not challenge the legality of the contested Decision, hence it is '*legally*

[9] See, in particular, ¶¶26-27 Defendant's plea of inadmissibility.
[10] See, in particular, ¶¶28-29 and ¶35 Defendant's plea of inadmissibility.
[11] See Article 2(2) contested Decision

final vis-á-vis Hungary as a Member State as regards both its factual and legal findings'.

25. The above statements are irrelevant in the present procedure and also somewhat misleading. The Applicant has neither the authorization nor the powers to influence the political decisions of the country where it is domiciled, hence it could not have a say either during the development of the changes implemented by Hungary before the adoption of the contested Decision or in connection with the decision-making process whether Hungary wishes to challenge the contested Decision or not. However, the fact that Hungary decided not to bring an action cannot be interpreted as meaning that, for that reason, the contested Decision is necessarily well-founded and lawful, in particular in relation to the Applicant. The disadvantages suffered by Semmelweis Egyetem cannot be considered non-existent only because Hungary decided not the challenge the contested Decision.

III. Specific observations on the Statement of Defence on a plea-by-plea basis

26. In the following sub-sections, the Applicant reflects on the Defendant's arguments put forward in respect of the five pleas in law raised in the Application.

A. First plea in law, the contested Decision lacks a sufficiently solid factual basis

(1) First sub-plea in law: Lack of a sufficiently solid factual basis

27. Defendant expressly admits that it did not assess the Applicant's situation before the adoption of the contested Decision, hence the Applicant's first plea in law is not refuted. However, the Defendant wishes to verify the lawfulness of its actions by making references to different provisions of the Conditionality Regulation. The core of Defendant's argumentation is that the procedural provisions and safeguards apply differently in case of '*generalised or systemic breaches*',[12] since in such cases there is no '*need to provide evidence of a breach of the principles of the rule of law affecting the Union budget for each and every individual entity concerned by a measure*'.[13] The Applicant's understanding is that the systemic breach referred to by the Defendant is the Hungarian legislation governing the PITs, that is an alleged breach to which the Applicant had and could not have had any influence on.

28. The Council's argumentation is based on the presumption that the legal framework under which PITs operate shall be considered as a systemic breach of the rule of law; therefore, cutting off the Applicant from the European research network and excluding it from European programs without assessing its situation and specifics is an appropriate, proportionate, and lawful measure.

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[12] ¶17 Statement of Defence
[13] ¶19 Statement of Defence

29. Applicant argues with the above logic for several reasons. First of all, as noted above, Semmelweis Egyetem has no power to influence the Hungarian lawmaking process and the different laws and acts adopted by the competent bodies, hence sanctioning it for laws not approved by the Commission and the Council cannot verify the appropriateness of a prohibition imposed on the Applicant.

30. As pointed out several times, the Applicant itself cannot violate the rule of law, it is a separate legal entity form the Foundation maintaining it, which has no powers to disburse the funds received by the Applicant and none of the curators of the Foundation is an active politician. Failure to assess these specifics as well as the potential effects before the adoption of the contested Decision cannot be verified by a presumption that the Hungarian legal framework governing the operation of PITs is problematic.

31. The fact that the Conditionality Regulation itself does not explicitly prescribe the assessment of the individual position and situation of the entities concerned by a future measure cannot be interpreted in a way that such assessment is unnecessary or let alone forbidden. In that regard, it shall be highlighted that the references made by the Defendant to different parts of the Conditionality Regulation are provisions applicable to and concerning the Commission and not the Defendant. Therefore, the Defendant cannot successfully rely on these provisions due to the fact that they concern a different Union body. The circumstance that the Commission may not be obliged to assess the individual situation of the potentially affected entities during its procedure cannot be understood as exempting the Council from the detailed assessment of the potential consequences of its actions, in particular where decisions involving serious adverse measures are taken.

32. Also, the Defendant wishes to support its argumentation by citing a special report of the Court of Auditors,[14] however, the citations included in the Statement of Defence only state that the Commission (and not the Council) and its proposal complied with the provisions of the Conditionality Regulation, meaning that the appropriateness and proportionality of the contested Decision as well as the lawfulness of the Council's procedure is not and cannot be verified by this special report either.

33. It is an undisputed fact that the contested Decision was adopted based on the authorization provided by the Conditionality Regulation. However, in the present case, special attention shall be paid to the fact that at the time of the adoption of the Conditionality Regulation, the Hungarian law governing the PITs has not yet existed. With respect to this timeline, it would be quite unusual if the Conditionality Regulation would prescribe an individual assessment obligation in respect of such entities (and the ones maintained by them) which did not even exist at the time of its adoption.

[14] ¶21 Statement of Defence

(2) Second sub-plea in law: Manifest errors of assessment

34. When responding to the Applicant's arguments on the manifest errors of assessment made, Defendant puts forward general arguments only, mostly referring to the concerns in connection with the Hungarian regulatory framework applicable to the PITs, the inadequacy of the remedial measures implemented by Hungary as a response to said concerns and the fact that the risk of conflict of interest poses a serious risk for the Union budget.

35. The above arguments cannot support the alleged unfoundedness of the Applicant's argumentation, on the contrary, they further indicate and prove that the Council failed to take into account the specific situation of the Applicant and builds its defence on general statements only concerning entities other than the Applicant.

36. In connection with manifest errors of assessment, the Court held, that: '*The EU institutions are under that duty when exercising their powers of assessment. Accordingly, where a party claims that the institution competent in the matter has committed a manifest error of assessment, the EU judicature must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case (judgments of 18 July 2007, Industrias Químicas del Vallés v Commission, C-326/05 P, EU:C:2007:443, paragraph 77, and of 22 November 2017, Commission v Bilbaína de Alquitranes and Others, C-691/15 P, EU:C:2017:882, paragraph 35).*
It follows from that case-law of the Court that pleas alleging breach of the duty of diligence frequently overlap with pleas alleging manifest error of assessment. Admittedly, the fact that all the relevant facts of the individual case have been taken into account carefully and impartially is not, of itself, sufficient to prevent the institution concerned from committing a manifest error of assessment. Nevertheless, a breach, by that institution, of its duty of diligence is the most common reason for such an error.'[15]

(3) Third sub-plea in law: Failure to comply with the duty to state reasons

37. The Defendant's brief response to this sub-plea indeed supports the Applicant's arguments, since the CJEU judgment cited in paragraph 29 of the Statement of Defence emphasizes that the interests of other parties to whom the measure is of direct concern may have in obtaining explanations must be appraised, thus it is indeed an important factor.

38. Applicant argues that since it is not the addressee of the contested Decision but directly concerned by it as the prohibition laid down in Article 2(2) has detrimental effects on its operation and reputation, the detailed statement of the reasons why it was affected by the prohibition is of particular importance and the failure to state adequate reasons is prejudicial to the Applicant.

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[15] Judgment of 16 June 2022, SGL Carbon v Commission, Joined Cases C-65/21 P and C-73/21 P to C-75/21 P, ECLI:EU:C:2022:470, ¶¶31-32

39. Defendant argues that the duty to state reasons is satisfied since the reasons underlying the adoption of the contested Decision have been exhaustively explained in the documents referenced by the Council.[16] Having reviewed once again the provisions indicated by the Defendant, the Applicant still argues that none of these contain any explanation and reasoning as to why Semmelweis Egyetem was included among the entities concerned by the contested Decision.

B. Second plea in law, the Applicant has been denied the opportunity to defend its rights; its right to be heard has been infringed

40. The importance of the right to be heard and the applicable case law on the interpretation of this fundamental principle is assessed in detail in the Application. The Defendant wishes to refute this assessment and the Applicant's line of argumentation by relying on two circumstances, namely that **(i)** the Applicant is not conferred with the right to take part in the procedure according to Article 6 Conditionality Regulation and **(ii)** the contested Decision is of general application, whereas the respective provisions of the Charter of Fundamental Rights of the Union can only be interpreted in case of individual measures.

41. As to the first argument, we submit that the right to take part in the procedure and the right to be heard are two different rights not to be confused or interchanged with one another. The fact that the Conditionality Regulation does not expressly state that the persons and entities directly concerned by the implementing decisions shall be heard before their adoption cannot be interpreted in a manner that the said persons are deprived of their right to be heard.

42. As to the second argument, the judgments cited by the Defendant in its Statement of Defence are not suitable to refute that the Applicant, as an entity directly concerned by the contested Decision, shall be denied exercising its right to be heard or that it may be deprived of that right, given that the contested Decision in question has more than one entity directly concerned by it. As indicated above, there are only a limited number of entities directly concerned by the prohibition laid down in Article 2(2) contested Decision and the fact that the inclusion of the statements and opinions of the entities concerned in the legislative process would somewhat lengthen the procedure cannot serve as a lawful basis for depriving these parties from exercising their right to be heard.

43. In addition to the fact that the Applicant is directly concerned by the contested Decision, we note the measure included in Article 2(2) is essentially a sanction with respect to its punitive nature. According to the settled case law, the principle of the right to be heard must necessarily be enforced in procedures, where sanctions may be imposed or a decision affecting the person's interest adversely may be adopted:

[16] See ¶31 Statement of Defence

'*Observance of the right to be heard is in all proceedings in which sanctions, in particular fines or penalty payments, may be imposed a fundamental principle of Community law which must be respected even if the proceedings in question are administrative proceedings.*'[17]

'*According to settled case-law, an integral part of respect for the rights of the defence is the right to be heard, which guarantees every person the opportunity to make known his or her view effectively during an administrative procedure and before the adoption of any decision liable to affect his or her interests adversely. In accordance with the case-law of the Court of Justice, the purpose of the rule that the addressee of an adverse decision must be placed in a position to submit his or her observations before that decision is taken is to put the competent authority in a position effectively to take all relevant information into account (see judgment of 16 October 2019, Glencore Agriculture Hungary, C-189/18, EU:C:2019:861, paragraph 41 and the case-law cited).*'[18]

'*The right to be heard therefore guarantees every person the opportunity to make known their views effectively during an administrative procedure and before the adoption of any decision liable to affect their interests adversely (judgment of 4 June 2020, EEAS v De Loecker, C-187/19 P, EU:C:2020:444, paragraph 68 and the case-law cited).*

It is also necessary to bear in mind that the right to be heard is one of the rights of the defence, a general principle of EU law which is applicable even in the absence of any specific rules in that regard. That principle requires that the addressees of decisions which significantly affect the interests of those addressees should be placed in a position in which they may effectively make known their views with regard to the evidence on which those decisions are based (see, to that effect, judgment of 14 June 2016, Marchiani v Parliament, C-566/14 P, EU:C:2016:437, paragraph 51 and the case-law cited).'[19]

'*It is apparent from the Court's case-law that respect for the rights of the defence is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they may effectively make known their views (see, inter alia, Case C-32/95 P Commission v Lisrestal and Others [1996] ECR I-5373, paragraph 21, and Case C-462/98 P Mediocurso v Commission [2000] ECR I-7183, paragraph 36).*'[20]

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[17] Judgment of 13 February 1979, Hoffmann-La Roche v Commission, C-85/76, EU:C:1979:36, ¶9.

[18] Judgment of 6 October 2021, Ukrselhosprom PCF and Versobank v ECB, T-351/18, ECLI:EU:T:2021:669, ¶371.

[19] Judgment of 28 October 2021, Vialto Consulting v Commission, C-650/19 P, ECLI:EU:C:2021:879, ¶¶121-122

[20] Judgment of 9 June 2005, Spain v Commission, C-287/02, ECLI:EU:C:2005:368, ¶37

C. Third plea in law, the lack of legal basis

44. Defendant argues that the Applicant failed to substantiate its arguments included in the third plea in law and also that the requirements of the Statute of the Court of Justice of the European Union and of the Rules of Procedure of the General Court are not met, since the Applicant only submitted a '*mere abstract statement of the grounds*'.[21] According to the Council, the third plea in law is therefore inadmissible or at least unfounded.

45. We submit that the relevant line of argument was set out over six pages in the Application supported by findings cited from the settled case law, thus it cannot be considered as a mere abstract statement only.

46. The Council wishes to verify the legality and the correctness of the contested Decision by stating that it was adopted in compliance with the procedural rules set forth by the Conditionality Regulation, which the Court of Justice deemed compatible with EU primary law and that the procedure was not intended to penalise single entities such as Semmelweis Egyetem but to protect the financial interests of the European Union.

47. As to the alleged compliance with the procedural rules during the adoption of the contested Decision, we submit that while the Applicant maintains that certain principles and provisions – such as granting the exercise of the right to be heard – were infringed, compliance with procedural rules does not necessarily result in the legality of the adopted legislation.

48. As to the achievement of legitimate objective, namely the protection of the Union budget, the Defendant has not demonstrated in any way how the Applicant violated those interests and how that violation was resolved by the adoption of the contested Decision. The arguments repeatedly put forward by the Defendant to the effect that the politicians on the PITs' boards may pose a threat to the use of EU funds, which leads to an infringement of the rule of law, cannot be interpreted or justified in relation to the Applicant, as has been stated on several occasions in our previous submissions as well as in the present reply above.

49. Defendant also argues that the Applicant failed to prove that the Decision was adopted for an end other than the protection of the Union budget. In our view, this argument can be easily refuted by the several annexes attached by the Applicant verifying that Semmelweis Egyetem has been excluded from a number of projects and therefore Article 2(2) Decision has detrimental and far-reaching consequences on the Applicant's business, position and reputation. These documents support that the Applicant is indeed sanctioned by the measure and the end achieved by the adoption of the measure is a completely different from the one repeatedly referred to by the Council.

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[21] See ¶41 Statement of Defence.

D. Fourth plea in law, infringement of the principle of proportionality

50. Defendant submits that contrary to the Applicant's reasoning, the principle of proportionality was not infringed by arguing that the contested Decision is appropriate for achieving its goal, which is the protection of the Union budget and it does not go beyond what is necessary to achieve said end. These arguments are not supported by facts.

51. First of all, the Defendant's admission of failing to analyse the individual situation of the Applicant in itself proves the occurrence of the infringement of the principle of proportionality, since without carrying out an individual assessment focusing on the specifics of the entity concerned as well as the potential effects of the planned measure imposed on said entity, the least onerous measure appropriate for attaining the legitimate objective pursued cannot be determined. However, the Court pointed out with reference to its settled case law that the disadvantages caused by a legislation must not be disproportionate to the goals pursued:

'*According to settled case-law, the principle of proportionality, which is one of the general principles of EU law, requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is necessary in order to achieve those objectives; when there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see judgment of 4 May 2016, Philip Morris Brands and Others, C-547/14, EU:C:2016:325, paragraph 165 and the case-law cited).*'[22]

52. Secondly, the case law cited in paragraph 46 of the Statement of Defence is essentially identical to the judgments cited in the Application and their findings highlighted by the Council indeed support the arguments put forward by the Applicant. Hence, the Defendant does not refute but further strengthens the Applicant's statements and its fourth plea in law.

53. As to the reference made to the judgment confirming the legality of the Conditionality Regulation, we refer to the fact that the Conditionality Regulation itself does not provide for any measures explicitly naming entities maintained by PITs, hence the legality of the Conditionality Regulation and the fact that budgetary corrective measures can be adopted under its provisions cannot verify the appropriateness and the proportionality of the prohibition measure challenged by the present lawsuit.

54. Defendant's reference to Recital (19) of the contested Decision is once again a shining example of the Council's omission to assess Semmelweis Egyetem's individual situation and also its willingness to invoke such malfunctions or wrongdoings which by definition cannot be committed or done by the Applicant itself. The cited section includes the following statement: '(…) *given that those breaches are intrinsically linked to the process under which Union funds are used by Hungary*

[22] Judgment of 8 July 2020, VQ v ECB, T-203/18, ECLI:EU:T:2020:313, ¶61

in that they consist in improper functioning of the public authorities deciding on the award of contracts financed through the Union budget. In addition, if the identified breaches are coupled with the limits and obstacles in the detection, investigation and correction of fraud, identified as additional grounds related to investigation, prosecution and the anti-corruption framework, the impact can be considered even more significant.'

55. The cited provision cannot be interpreted in a way that its subject or one of its subjects is the Applicant, since **(i)** it does not decide on the award of contracts financed through the Union budget, **(ii)** no breaches of the rule of law committed by the Applicant were identified or even suspected by the Council, **(iii)** the terms fraud and corruption as well as investigation and prosecution cannot be interpreted in connection with the Applicant, a university, which neither carries out such activities nor is in a position to act in such unlawful ways.

56. Defendant aims to further substantiate the appropriateness of the measure included in Article 2(2) contested Decision by citing the Commission's communication of 12 January 2024 stating that the prohibition of signing new legal commitments with PITs or entities maintained by them ensures full protection of the Union's financial interests from the conflict of interests risks identified.[23] Applicant argues that in this respect, the Commission cannot be considered as an entity being able to objectively assess the appropriateness of the measure due to its involvement in the process leading to the adoption of the contested Decision. On the other hand, it is not disputed by the Defendant that the individual situation of the Applicant was not considered during the lawmaking process, thus no such conflict of interest risks could have been identified in case of the Applicant. If the Defendant had carried out the proper assessment, it would have noticed that there is no conflict of interest arising in connection with any of the members of the Foundation's board and that the Foundation has no powers and competences over the distribution of the funds received through different Union programs, so that the measure cannot and should not be applied to the Applicant.

57. Defendant's statement noting that the contested measure has no definitive effects[24] is close to being offensive from the perspective of the Applicant suffering serious financial and reputational disadvantages as a result of said measure as well as from the perspective of its students, teachers and researchers being excluded from participating in different research projects and in the Erasmus+ Programme. The definitive effects can easily be identified in case of those who are not allowed to study and research abroad and to utilize the opportunity provided by the Erasmus+ Programme unlike their peers studying at universities not penalized by the Council.

58. Finally, contrary to the Defendant's allegations, we presented in detail how and why the Defendant exceeded the degree of discretion available to it, which statements

[23] See ¶50 Statement of Defence
[24] See ¶51 Statement of Defence

are further substantiated by the exclusion decisions attached by the Applicant during the course of the present procedure.

E. Fifth plea in law, the contested Decision distorts the market in which the Applicant is competing

59. By taking a look at the different rankings listing universities from all over the world as well as the importance of being seen and participating in different projects and how being a highly ranked university with great reputation can attract students and researchers from different countries, it is evident that the Applicant's exclusion from the Union projects and programmes have far reaching and detrimental consequences on its market position as well. To put it shortly: the Applicant suffers a significant competitive disadvantage. To support these statements, we refer to certain percentages already indicated in our Application, namely that the proportion of the Applicant's '*non-Hungarian students is 32% and 55% in the Faculty of Medicine*'[25] and 35.9% of Semmelweis Egyetem's income from tuition fees in 2022 was the tuition of non-Hungarian students.[26]

60. In spite of the above facts set out in detail in the Application, Defendant argues that the fifth plea in law is inadmissible or, in the alternative, unfounded, since Article 107 TFEU referred to by the Applicant is not addressed to the Union institutions. So, instead of assessing the arguments put forward within the context of this plea in law, Defendant opts for the easier path and due to the mentioned circumstance, it fails to submit a coherent line of arguments and defence in response to the Applicant's fifth plea in law.

61. Since the Council does not react to the Applicant's statements on the merits and relies on the scope of application of Article 107 TFEU only, Applicant considers that Defendant does not dispute the fifth plea in law and otherwise admits the market distorting effect of Article 2(2) contested Decision.

Budapest, 15 July 2024

Respectfully submitted,
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Dr. Balázs Karsai

[25] See ¶6 Application
[26] See ¶25 Application

Schedule of annexes

No.	short description of the annex	page numbers of the first and last pages of the annex	number of the paragraph in which the item is mentioned for the first time
A.19	Rejection of the Applicant's participation in the SMILE project and the related proposal evaluation form	pp. 1-5.	11.