Reports of Cases

JUDGMENT OF THE GENERAL COURT (First Chamber, Extended Composition)

21 February 2024*

(Public procurement – Negotiated procedure without prior publication of a contract notice – Supply of disinfection robots to European hospitals – Extreme urgency – COVID-19 – Non-participation of the applicants in the tendering procedure – Action for annulment – Lack of individual concern – Contractual nature of the dispute – Inadmissibility – Liability)

In Case T-38/21,

Inivos Ltd, established in London (United Kingdom),

Inivos BV, established in Rotterdam (Netherlands),

represented by R. Martens, L. Hoet and A. Van Laer, lawyers,

applicants,

v

European Commission, represented by L. André and M. Ilkova, acting as Agents,

defendant,

THE GENERAL COURT (First Chamber, Extended Composition),

composed, at the time of the deliberations, of D. Spielmann, President, V. Valančius, R. Mastroianni, M. Brkan (Rapporteur) and T. Tóth, Judges,

Registrar: P. Cullen, Administrator,

having regard to the order of 21 May 2021, *Inivos and Inivos* v *Commission* (T-38/21 R, not published, EU:T:2021:287),

having regard to the written part of the procedure,

further to the hearing on 28 February 2023,

having regard, following the cessation of Judge Valančius's duties on 26 September 2023, to Article 22 and Article 24(1) of the Rules of Procedure of the General Court,

* Language of the case: English.

gives the following

Judgment

1 By their action, the applicants, Inivos Ltd and Inivos BV, seek, first, on the basis of Article 263 TFEU, annulment of the decision of the European Commission of 18 September 2020 to use a negotiated procedure without prior publication of a contract notice for the acquisition of disinfection robots ('the decision to use the negotiated procedure without prior publication of a contract notice'), of the decision of 3 November 2020 to award that contract ('the contested award decision') and of the decision of 19 November 2020 to conclude the framework contracts with two operators, and a declaration that those framework contracts are null and void and, secondly, on the basis of Article 268 TFEU, compensation for the damage which they claim to have suffered as a result.

Background to the dispute

2 The applicants, established in the United Kingdom and the Netherlands, are companies active in the field of specialised medical technology in the prevention and control of infections.

3 In the context of the COVID-19 crisis, the Commission decided to assist Member States by supporting the deployment in their hospitals of robots for the disinfection of indoor areas, using the Emergency Support Instrument. After an analysis of available technologies, disinfection by autonomous robots using UV light was chosen.

4 On the basis of the urgency arising from the COVID-19 crisis, the Commission decided, on 18 September 2020, to use the negotiated procedure without prior publication of a contract notice, in accordance with point (c) of the second subparagraph of point 11.1 of Annex I to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ 2018 L 193, p. 1; 'the Financial Regulation').

5 In order to prepare the tendering procedure and gather information on the market concerned and on potential suppliers, the Commission carried out a preliminary market consultation pursuant to Article 166 of the Financial Regulation by sending a survey, inter alia, to associations and other entities grouping manufacturers of robots.

6 On the basis of that market consultation, the Commission drew up a large database of suppliers, which were then assessed using predefined criteria, namely CE marking (an essential requirement), production capacity (at least 20 units per month) and experience in the deployment of robots in hospitals (at least 10 robots).

7 Six suppliers which fulfilled those criteria were invited to submit a tender under a negotiated procedure without prior publication, with reference CNECT/LUX/2020/NP0084, but only three actually did so.

8 On 30 October 2020, an evaluation report was drawn up in accordance with Article 168(4) of the Financial Regulation with a view to awarding the contract. Two tenders were ranked, whereas the third was rejected since it did not fulfil the selection criteria.

9 On 3 November 2020, the authorising officer responsible adopted the contested award decision in line with the recommendation in the evaluation report.

10 On 19 November 2020, the Framework Contracts for Disinfection Robots for European Hospitals (COVID-19) were concluded with the two selected tenderers ('the framework contracts at issue') and their signature was announced in the *Official Journal of the European Union* on 9 December 2020 by contract award notice 2020/S 240-592299.

11 On 23 November 2020, the applicants became aware of a Commission press release announcing that it intended to purchase 200 disinfection robots under a dedicated budget from an Emergency Support Instrument.

12 In its press release, the Commission stated that hospitals from most Member States had expressed a need and an interest in receiving those robots, which could disinfect standard patient rooms using UV light in only 15 minutes and thus help to prevent and reduce the spread of the virus. The process is controlled by an operator, located outside of the space to be disinfected, in order to avoid any exposure to the UV light. For the purchase of those disinfection robots, a dedicated budget of up to EUR 12 million was made available from the Emergency Support Instrument.

13 On 3 December 2020, since no contract notice had been published for the award of the contracts in question in the online version of the Supplement to the *Official Journal of the European Union* concerning European public procurement contracts, and since no information had been published concerning a decision by the Commission to award the contracts at issue, the applicants sent a letter to the Commission in which they expressed the concern that the applicable public procurement rules, based on the Financial Regulation, had not been followed. They also asked the Commission to suspend or terminate the framework contracts at issue and to revoke any award decision taken, and asked the Commission to re-tender the contracts by means of a procurement procedure with prior publication of a contract notice.

14 On 9 December 2020, the applicants were informed, through the contract award notice (OJ 2020/S 240-592299), that the framework contracts at issue had already been concluded on 19 November 2020.

15 In that award notice, the use of the negotiated procedure without prior publication of a contract notice is justified as follows:

'Extreme urgency brought about by events unforeseeable for the contracting authority and in accordance with the strict conditions stated in the directive.

Explanation:

The COVID-19 pandemic has put under extreme stress the healthcare systems across the world and in Europe. In this context, in order to contribute to the efforts to ensure, as a matter of urgency, increased safety of staff and patients in selected European hospitals and similar healthcare facilities, the Commission decided to support the deployment of autonomous robots for disinfection of indoor spaces, using the Emergency Support Instrument [(C(2020) 5162

final)]. Disinfection robots are actually already being used for hospital disinfection and the Commission has collected a number of reports from hospitals using this technology during the COVID-19 crisis. However, the number of robots deployed is insufficient and by far does not cover all hospitals having to deal directly with the disease. The Commission is taking action to partially mitigate this problem.

Therefore the use of the exceptional negotiated procedure without prior publication of the contract notice is necessary since the action is extremely urgent, as at the time of writing the 2nd wave of COVID-19 is rapidly spreading as explained above. Figures in some Member States are currently higher than during the peak of the 1st wave and healthcare resources are reportedly under increasing pressure across the EU. Therefore, it is necessary to rapidly deploy disinfection robots to aid healthcare workers in their effort to combat the pandemic.'

16 On 24 December 2020, the Commission published a new notice (OJ 2020/S 251-626998) following the contract award notice of 9 December 2020, replacing, as the legal basis for the purchase of up to 200 disinfection robots, Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ 2014 L 94, p. 65) with the Financial Regulation.

Forms of order sought

17 The applicants claim that the Court should:

– annul the decision to use the negotiated procedure without prior publication of a contract notice;

– annul the contested award decision;

– annul the Commission's decision of 19 November 2020 to conclude the framework contracts at issue with two other operators;

– declare the framework contracts at issue null and void;

– order the Commission to disclose the tender specifications on the basis of which the framework contracts at issue were awarded;

– give an interlocutory ruling on the Commission's liability for unlawfully using the negotiated procedure without prior publication of a contract notice;

– in the alternative, order the Commission to pay them compensation of EUR 3 000 000, on the basis of loss of opportunity;

– order the Commission to pay the costs, including the costs incurred by the applicants.

18 The Commission contends that the Court should:

– dismiss the action as manifestly inadmissible;

– in the alternative, dismiss the action as manifestly unfounded;

– order the applicants to pay the costs.

Law

The applications for annulment

Admissibility of the first head of claim, seeking annulment of the decision to use the negotiated procedure without prior publication of a contract notice

19 In its statement of defence, the Commission contends that the first head of claim is inadmissible in that the applicants have no interest in the annulment of the decision to use the negotiated procedure without prior publication of a contract notice. According to the Commission, since the applicants did not participate in the tendering procedure, they have no interest in bringing proceedings. In that regard, the Commission submits that, if the decision to use the negotiated procedure without prior publication of a contract notice were to be annulled, it would be far from certain that the procedure would be reopened and there would be no guarantee that the applicants would be selected.

20 The applicants submit that the first head of claim is admissible. They claim that the fact that they were absent from the tendering procedure cannot be used to challenge the admissibility of that head of claim, since their absence was due to the Commission's failure to publish a contract notice. They submit that if the Court were to reject the first head of claim as inadmissible for that reason, it would be impossible for competitors to challenge the direct award of public contracts. According to the applicants, their absence from the procedure was due to the Commission's failure to publish a contract notice and their absence does not prevent them from having an interest in bringing proceedings.

21 It should be borne in mind that, according to settled case-law, only measures which produce binding legal effects and are capable of affecting the interests of third parties by bringing about a distinct change in their legal situation constitute measures in respect of which an action for annulment may be brought (see, to that effect, judgments of 31 March 1971, *Commission* v *Council*, 22/70, EU:C:1971:32, paragraph 42; of 2 March 1994, *Parliament* v *Council*, C-316/91, EU:C:1994:76, paragraph 8; and of 13 October 2011, *Deutsche Post and Germany* v *Commission*, C-463/10 P and C-475/10 P, EU:C:2011:656, paragraph 36).

22 In order to determine whether an act the annulment of which is sought produces such effects, it is necessary to look to its substance (judgment of 11 November 1981, *IBM* v *Commission*, 60/81, EU:C:1981:264, paragraph 9), the context in which it was drafted (see, to that effect, judgment of 17 February 2000, *Stork Amsterdam* v *Commission*, T-241/97, EU:T:2000:41, paragraph 62), and the intention of those who drafted it (judgment of 26 January 2010, *Internationaler Hilfsfonds* v *Commission*, C-362/08 P, EU:C:2010:40, paragraph 52; see also, to that effect, judgment of 17 July 2008, *Athinaïki Techniki* v *Commission*, C-521/06 P, EU:C:2008:422, paragraphs 42, 46 and 52). By contrast, the form in which an act is adopted is in principle irrelevant for assessing the admissibility of an action for annulment (judgments of 11 November 1981, *IBM* v *Commission*, 60/81, EU:C:1981:264, paragraph 9, and of 7 July 2005, *Le Pen* v *Parliament*, C-208/03 P, EU:C:2005:429, paragraph 46).

23 Only an act by which its author reaches an unequivocal and definitive position, in a form enabling its nature to be identified, constitutes a decision challengeable by an action for annulment (judgment of 13 December 2016, *IPSO* v *ECB*, T-713/14, EU:T:2016:727, paragraph 20; see also, to that effect, judgment of 26 May 1982, *Germany and Bundesanstalt für Arbeit* v *Commission*, 44/81, EU:C:1982:197, paragraph 12).

24 More specifically, acts or decisions adopted by a procedure involving several stages, in particular where they are the culmination of an internal procedure, are open to review only if they are measures definitively laying down the Commission's position on the conclusion of that procedure, and not provisional measures intended to pave the way for the final decision (judgments of 7 March 2002, *Satellimages TV5* v *Commission*, T-95/99, EU:T:2002:62, paragraph 32, and of 16 December 2020, *Balti Gaas* v *Commission and INEA*, T-236/17 and T-596/17, not published, EU:T:2020:612, paragraph 88).

25 It is in the light of the foregoing considerations that it is necessary to examine whether the decision to use the negotiated procedure without prior publication of a contract notice is an act which definitively lays down its position, adversely affects the applicants and is challengeable by an action for annulment.

26 In that regard, it is necessary to analyse the content of that decision. The decision was the first stage of the negotiated procedure without prior publication of a contract notice and took the form of a file note signed by the Director of the Artificial Intelligence and Digital Industry Directorate, dated 18 September 2020. The purpose of that document was to justify the use of such a procedure for the award of the contract entitled 'Disinfecting robots to help combat the COVID-19 crisis'.

27 In its reply to a written question put by the Court, the Commission maintained that the decision to use the negotiated procedure without prior publication of a contract notice was an internal act which did not produce any legal effects outside the sphere of the institution which had taken that decision. That decision can be considered to have legal effects only from the date on which the Commission sent out the individual calls for tenders. The decision to use the negotiated procedure without prior publication of a contract notice does not prejudge operators which are in a position to tender. The Commission added that only the successive acts of the tendering procedure could ultimately produce legal effects. The decision to use a tendering procedure does not in itself produce legal effects; such effects are produced only by the acts which implement that decision by actually carrying out the procedure, such as the award decision.

28 In a reply to a written question put by the Court, the applicants stated that the Commission's unlawful conduct resulted from multiple decisions, including the decision to use the negotiated procedure without prior publication of a contract notice, but that those decisions are inevitably interlinked since the decision to use that procedure led to the contested award decision and ultimately made it possible to conclude the framework contracts at issue. According to the applicants, the decision to use the negotiated procedure without prior publication of a contract notice should not be considered a preparatory act for the contested award decision, since it produces discernible legal effects, given that the parties which were not invited to submit a tender were *ipso facto* excluded from participating in the tender procedure and had no opportunity to secure the contract. In addition, operators which were not invited to participate in that procedure were not formally informed of the award of the framework contract until

9 December 2020 by the first contract award notice. Consequently, the applicants submit that the decision to use the negotiated procedure without prior publication of a contract notice should not be excluded from the Court's judicial review.

29 It should be pointed out that the decision to use the negotiated procedure without prior publication of a contract notice states the reasons for using that procedure. That document thus determines the choice of the procedure applicable to the contract award at issue. However, as the Commission stated in a reply to a written question put by the Court, that document is not addressed to any particular person and does not prejudge the economic operators which are invited to tender for that contract. Therefore, no operators were invited to tender at that stage of the procedure and, consequently, no operators could have been excluded.

30 Accordingly, the applicants are adversely affected by the decision not to invite them to tender, which in the present case took the form of the contested award decision. The applicants may therefore, provided that they were aware of it, bring an action against the last act available at the time when they brought their action, which excludes them from the procedure. The decision to use the negotiated procedure without prior publication of a contract notice does not constitute a decision affecting the applicants' interests since that decision did not exclude them from the tendering procedure at issue. When the action was brought, the Commission had already adopted, on 3 November 2020, the award decision which definitively awarded the contract and which resulted in the definitive exclusion of the applicants from the tendering procedure at issue.

31 Consequently, the decision to use the negotiated procedure without prior publication of a contract notice is preparatory in nature.

32 As regards the applicants' argument that the fact that they were absent from the tendering procedure cannot be used to challenge the admissibility of their action against the decision to use the negotiated procedure without prior publication of a contract notice, it must be borne in mind that any legal defects in measures of a purely preparatory nature may be relied upon in an action directed against the definitive act for which they represent a preparatory step (see judgment of 16 December 2020, *Balti Gaas* v *Commission and INEA*, T-236/17 and T-596/17, not published, EU:T:2020:612, paragraph 101 and the case-law cited). In the present case, by their second head of claim, the applicants seek annulment of the contested award decision, which in principle allows them to rely on any irregularity in the choice to use the negotiated procedure without prior publication of a contract notice, provided that the head of claim seeking annulment of the contested award decision is admissible.

33 Accordingly, the first head of claim, seeking annulment of the decision to use the negotiated procedure without prior publication of a contract notice, must be declared inadmissible.

Admissibility of the second head of claim, seeking annulment of the contested award decision

34 In its statement of defence, the Commission contends that the second head of claim is inadmissible in that the applicants have no interest in seeking the annulment of the contested award decision. According to the Commission, since the applicants did not participate in the tendering procedure, they have no interest in bringing proceedings. In that regard, the Commission submits that the annulment of the contested award decision would not mean that the applicants would be selected, since they were not among the tenderers.

35 The applicants submit that the second head of claim is admissible. First, the applicants claim that the fact that they were absent from the tendering procedure cannot be used to challenge the admissibility of their action, since their absence was due to the Commission's failure to publish a contract notice. They submit that if the Court were to reject the second head of claim as inadmissible for that reason, it would be impossible for competitors to challenge the direct award of public contracts. According to the applicants, the fact that they were absent from the procedure does not preclude them from having an interest in bringing proceedings. They submit that the annulment, in particular, of the contested award decision will restore a level playing field vis-à-vis their competitors.

36 Secondly, the applicants submit that they are directly and individually concerned by the contested award decision. They claim (i) that they operate on the same market as the tenderers which were awarded the contracts at issue and (ii) that they were able to provide robots in accordance with the description of the quality criteria set out in the award notice. They therefore claim that they were eligible to participate as candidates in the public tendering procedure organised by the Commission for the award of a framework contract.

37 As recalled in paragraph 21 above, only measures which produce binding legal effects and are capable of affecting the interests of third parties by bringing about a distinct change in their legal situation constitute measures in respect of which an action for annulment may be brought and which are open to review.

38 In addition, it should be borne in mind that an interest in bringing proceedings and *locus standi* are distinct conditions for admissibility which must be satisfied by a natural or legal person cumulatively in order to be admissible to bring an action for annulment under the fourth paragraph of Article 263 TFEU (see judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 62 and the case-law cited).

– *Whether an act is open to review*

39 As is apparent from paragraph 23 above, only an act by which its author reaches an unequivocal and definitive position, in a form enabling its nature to be identified, constitutes a decision challengeable by an action for annulment.

40 In the present case, as stated in paragraph 30 above, the applicants were not excluded from the negotiated procedure without prior publication due to the decision to use that procedure, dated 18 September 2020, which had not yet determined the operators invited to participate in that procedure and, consequently, the operators which had been excluded from it. The invitations to tender sent by the Commission to six operators determined which operators were invited to participate in that procedure and which were not. However, in the context of that procedure, the award notice announcing that the contract had been granted to two tenderers was the act which, by its publication, enabled the applicants to acquaint themselves with the use of that procedure for the award of that contract. Consequently, the contested award decision had the automatic effect of definitively depriving the applicants of the opportunity to participate in that procedure and thereby of excluding them from it. Thus, the contested award decision produced effects on the applicants' legal situation in that it definitively laid down their legal situation as an operator excluded from the negotiated procedure without prior publication of a contract notice at issue.

41 Consequently, the contested award decision is challengeable.

– *The applicants' legal interest in bringing proceedings*

42 According to the settled case-law, an action for annulment brought by a natural or legal person is admissible only in so far as that person has an interest in having the contested act annulled. Such an interest requires that the annulment of that act must be capable, in itself, of having legal consequences and that the action may therefore, through its outcome, procure an advantage to the party that brought it. The proof of such an interest, which is evaluated at the date on which the action is brought and which is an essential and fundamental prerequisite for any legal proceedings, must be adduced by the applicant (judgments of 18 October 2018, *Gul Ahmed Textile Mills* v *Council*, C-100/17 P, EU:C:2018:842, paragraph 37, and of 27 March 2019, *Canadian Solar Emea and Others* v *Council*, C-236/17 P, EU:C:2019:258, paragraph 91).

43 It must therefore be determined whether, in the present case, annulment of the contested award decision is likely to procure an advantage for the applicants.

44 The Commission contends that that is not the case, since such an annulment does not mean that the applicants would be selected, since they did not participate in the tendering procedure.

45 In that regard, it must be borne in mind that participation in a tendering procedure may, in principle, validly constitute a condition which must be fulfilled before the person concerned can show an interest in obtaining the contract at issue or that he or she risks suffering harm as a result of the allegedly unlawful nature of the decision to award that contract. However, where an undertaking has not submitted a tender in the context of a negotiated procedure without prior publication of a contract notice because it has not been invited to do so, it would be excessive and even contradictory to require it to have participated in that procedure, when participation in such a procedure requires it to have been invited by the contracting authority (see, to that effect and by analogy, judgment of 26 January 2022, *Leonardo* v *Frontex*, T-849/19, EU:T:2022:28, paragraphs 25 to 28).

46 In the present case, it must be stated that the applicants could not have been aware of the negotiated procedure without prior publication of a contract notice at issue and that they were not invited to tender in the context of that procedure. Accordingly, they cannot be criticised for not having participated in that procedure.

47 In addition, it must be ascertained whether the applicants are operators acting on the market subject to the negotiated procedure without prior publication at issue.

48 In that regard, it is apparent from the award notice of 24 December 2020 that the purpose of the contract award at issue was for the Commission to acquire 200 autonomous disinfection robots using UV rays as a disinfection method so that they could be deployed in European hospitals. The applicants stated in their application that they produced the 'portable disinfection robot "Ultra-V", an intelligent disinfection robot that uses UVC light ray technology for consistently effective decontamination'. The applicants have adduced evidence, in annex to their application, relating to the 'Ultra-V' robot and the scientific evaluations of that robot carried out for the United Kingdom National Health Service. It is apparent from those factors that the applicants produce a disinfection robot using UV rays.

49 Nevertheless, the Commission argued at the hearing that the applicants could not have been invited to participate in the tendering procedure at issue since the purpose of that procedure was to acquire self-driving autonomous robots, which is not the case with the 'Ultra-V' robot they produce.

50 In that regard, it should be pointed out that that requirement is not included in the criteria applied by the Commission to select the undertakings to be invited to tender or in the award criteria published in the contract award notice of 24 December 2020. However, according to the Commission, that requirement constitutes the very subject matter of the contract award at issue, given that the award notice states, under heading II.1.4 entitled 'Short description', that the Commission will purchase up to 200 easy-to-use self-driving UV disinfection robots.

51 It is apparent from the evidence produced by the applicants that the 'Ultra-V' robot they produce requires the intervention of an operator only in the preparation phase which precedes the disinfection process. That robot operates using six sensor-units called 'Spectromes' which are positioned in the room by the operator before disinfection. When questioned at the hearing, the applicants stated that the operator had only to position the sensor-units in the room before disinfection and that the robot then moved to those sensor-units on its own, which made it possible to adapt to each room and increased the effectiveness of the UV rays. In addition, the sensor-units are only positioned once and do not need to be moved every time the same room is disinfected. It follows that the 'Ultra-V' robot does not require any human intervention during the disinfection process itself.

52 In the light of the foregoing and given that the contract award notice of 24 December 2020 does not specify the degree of autonomy that the robots required, it must be held that the 'Ultra-V' robot produced by the applicants is an easy-to-use self-driving robot, as required by the award notice.

53 It follows that the applicants have adduced sufficient evidence to show that they were active on the market for autonomous disinfection robots using UV rays which were the subject of the negotiated procedure without prior publication of a contract notice.

54 Furthermore, it should be borne in mind that an applicant has an interest in seeking the annulment of an act in order to obtain a finding, by the EU Courts, that an unlawful act has been committed against him or her, so that such a finding can then be the basis for any action for damages aimed at properly restoring the damage caused by the contested act (see judgment of 5 September 2014, *Éditions Odile Jacob* v *Commission*, T-471/11, EU:T:2014:739, paragraph 44 and the case-law cited).

55 By their first plea, the applicants specifically challenge the choice to use that exceptional procedure and claim that the conditions for using that procedure, laid down in point (c) of the second subparagraph of point 11.1 of Annex I to the Financial Regulation, were not met.

56 It follows that the purpose of the applicants' actions for annulment is to obtain a finding that the Commission acted unlawfully in relation to them in the tendering procedure at issue, so that such a finding can serve as a basis for their claims for damages. During the hearing, the applicants confirmed that seeking redress from the Commission would help restore balance in the market.

57 It follows from all of the foregoing that the applicants have an interest in seeking the annulment of the contested award decision.

– *The applicants' standing to bring proceedings*

58 Pursuant to the fourth paragraph of Article 263 TFEU, any natural or legal person may institute proceedings against an act addressed to that person or which is of direct and individual concern to that person, and against a regulatory act which is of direct concern to that person and does not entail implementing measures.

59 Since it must be held that the addressees of the contested award decision are the successful tenderers for the contract at issue and not the applicants and that such an award decision does not constitute a regulatory act of general application, it is necessary to ascertain whether that decision is of direct and individual concern to the applicants.

60 In the first place, as regards the question whether the applicants are directly concerned by the contested award decision, it should be pointed out that the requirement laid down in the fourth paragraph of Article 263 TFEU, that a natural or legal person must be directly concerned by the measure which is the subject matter of the proceedings requires the fulfilment of two cumulative criteria, namely the contested measure should, first, directly affect the legal situation of the individual and, secondly, leave no discretion to the addressees who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from EU rules alone without the application of other intermediate rules (see judgment of 14 July 2022, *Italy and Comune di Milano* v *Council and Parliament (Seat of the European Medicines Agency)*, C-106/19 and C-232/19, EU:C:2022:568, paragraph 61 and the case-law cited).

61 It is necessary to examine in turn whether the applicants satisfy each of those two requirements.

62 First, it is appropriate to examine whether the contested award decision directly affects the applicants' legal situation.

63 In that regard, it is apparent from paragraph 40 above that the contested award decision had the effect of definitively depriving the applicants of the opportunity to participate in the negotiated procedure without prior publication of a contract notice at issue and thereby of excluding them from it. Thus, the contested award decision directly produced effects on the applicants' legal situation since it definitively laid down their legal situation as an operator excluded from the negotiated procedure without prior publication of a contract notice at issue.

64 However, the applicants' legal situation can be directly affected by the contested award decision only in so far as they are able to prove that they are operators acting on the relevant market.

65 In the present case, as is apparent from paragraphs 47 to 53 above, the applicants have adduced sufficient evidence to demonstrate that they were active on the market for autonomous disinfection robots using UV rays.

66 Secondly, the contested award decision definitively identified two operators as successful tenderers for the contract at issue with immediate and binding effect. Given that that award decision produces its legal effects in that regard without any additional measure being required, the second requirement, referred to in paragraph 60 above, is satisfied.

67 It follows that the contested award decision directly affected the applicants.

68 In the second place, as regards the question whether the contested award decision is of individual concern to the applicants, it is settled case-law that persons other than those to whom a decision is addressed may claim to be individually concerned only if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and, by virtue of those factors, distinguishes them individually just as in the case of the person addressed (judgment of 15 July 1963, *Plaumann* v *Commission*, 25/62, EU:C:1963:17, p. 107; see also, to that effect, judgment of 20 January 2022, *Deutsche Lufthansa* v *Commission*, C-594/19 P, EU:C:2022:40, paragraph 31 and the case-law cited).

69 It is therefore necessary to ascertain whether the contested award decision affects the applicants by reason either of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons.

70 In that regard, it is apparent from settled case-law that, where the decision affects a group of persons who were identified or identifiable when that measure was adopted by reason of criteria specific to the members of the group, those persons might be individually concerned by that measure inasmuch as they form part of a limited class of economic operators (judgment of 13 March 2008, *Commission* v *Infront WM*, C-125/06 P, EU:C:2008:159, paragraphs 71 and 72; see also, to that effect, judgment of 12 July 2022, *Nord Stream 2* v *Parliament and Council*, C-348/20 P, EU:C:2022:548, paragraph 158 and the case-law cited).

71 In the specific circumstances of the contracting authority's use of the negotiated procedure without prior publication of a contract notice, an operator which had not been invited to participate in that procedure, even though it was able to fulfil the criteria applied by the contracting authority to select the undertakings to be invited to tender, must be regarded as belonging to a limited class of competitors able to submit a tender if they had been invited to participate in the procedure.

72 In the present case, in its statement of defence, the Commission explained that the criteria used to determine which operators should be invited to participate in the procedure at issue were CE marking, a production capacity of at least 20 units per month and experience in deploying robots in hospitals involving at least 10 robots. When questioned at the hearing, the Commission confirmed that those criteria were also the selection criteria used in connection with the procedure at issue.

73 Consequently, the criteria used by the Commission to assess which operators should be invited to participate in the negotiated procedure without prior publication of a contract notice were made available to the applicants in the context of the judicial proceedings. In addition, when questioned at the hearing as to whether they fulfilled those criteria and whether they had adduced evidence in that regard, the applicants referred to Annex A.8 to their application.

74 First, as regards the criterion relating to CE marking, the applicants stated at the hearing that their 'Ultra-V' robot had the CE marking since one of them was a Dutch company that deployed its robots in the European Union. Furthermore, as the applicants submitted in the application, the user guide for the 'Ultra-V' robot shows the logo of the CE marking. Therefore, it must be held that that robot fulfilled that criterion.

75 Secondly, as regards the criterion relating to production capacity, the applicants stated at the hearing that they fulfilled that criterion and were even able to increase their production capacity. However, it should be pointed out that the applicants have not adduced any evidence, either in the application, including Annex A.8 thereto, or in the reply, establishing that their production capacity could reach 20 robots per month.

76 Thirdly, as regards the criterion relating to their experience in deploying robots in hospitals, it should be pointed out that the applicants have produced studies conducted by university hospitals in the United Kingdom and a report drawn up by two hygiene specialists of the North West Anglia NHS Foundation Trust, from which it is apparent in particular that they have been deploying robots in hospitals in the United Kingdom National Health Service since at least April 2015. However, that evidence does not make it possible to determine the exact number of robots deployed.

77 Accordingly, even if the applicants had deployed at least 10 robots in hospitals, the fact remains that they have not shown that the monthly volume of their production capacity for the 'Ultra-V' robot reached the value defined by the Commission for the purpose of selecting the operators invited to tender.

78 It follows that the applicants have not adduced sufficient evidence to show that they were able to fulfil the criteria used by the Commission to select the operators which had been invited to tender under a negotiated procedure without prior publication of a contract notice. Consequently, they have not proved that they formed part of a limited class of operators in a position to be invited to tender and to submit a tender. It follows that the contested award decision is not of individual concern to the applicants.

79 Accordingly, the second head of claim, seeking annulment of the contested award decision, is inadmissible.

Admissibility of the third and fourth heads of claim, seeking annulment of the Commission's decision to conclude the framework contracts at issue and to declare them null and void

80 The Commission submits that the third and fourth heads of claim are inadmissible in so far as they seek annulment of the Commission's decision to conclude the framework contracts at issue and a declaration by the Court that those framework contracts are null and void. The Commission maintains that the annulment of the contested award decision will not have the effect of rendering the contracts, already signed, null and void in so far as those contracts are subject only to the court having jurisdiction over the contract and cannot be annulled by the EU Courts in the context of an action for annulment brought under Article 263 TFEU.

81 As regards the question whether the decision to conclude framework contracts is an act open to review, it should be recalled that, under Article 263 TFEU, the EU Courts review only the legality of acts adopted by the institutions and bodies, offices or agencies of the Union intended to produce binding legal effects vis-à-vis third parties.

82 It is settled case-law that claims for annulment, in the context of Article 263 TFEU, of acts adopted by the institutions in a purely contractual context, from which they are inseparable, are inadmissible (see order of 3 October 2018, *Pracsis and Conceptexpo Project* v *Commission and EACEA*, T-33/18, not published, EU:T:2018:656, paragraph 62 and the case-law cited; see also, to

that effect, judgments of 17 June 2010, *CEVA* v *Commission*, T-428/07 and T-455/07, EU:T:2010:240, paragraph 52, and of 29 January 2013, *Cosepuri* v *EFSA*, T-339/10 and T-532/10, EU:T:2013:38, paragraph 26).

83 In the present case, the applicants seek annulment of the Commission's decision of 19 November 2020 to conclude the framework contracts at issue and to declare those framework contracts concluded between the Commission and the successful tenderers null and void. In that regard, it is sufficient to note, first, that the signing of framework contracts is, by definition, inherent in the contractual process, without it being possible, in that regard, to identify, in the present case, a decision separable from that process and, secondly, that those framework contracts produce and exhaust all their effects in the context of the contractual relationship between the parties in question to the contracts, in respect of which the applicants are third parties.

84 It follows from the foregoing considerations that the third and fourth heads of claim, in so far as they seek annulment of the decision to conclude the framework contracts and of the framework contracts concluded between the Commission and the successful tenderers, are inadmissible.

85 In the light of the foregoing, the claims for annulment must be rejected as inadmissible.

The claim for damages

86 The applicants seek compensation for the loss of an opportunity to tender for a public contract as a result of the Commission's unlawful use of the negotiated procedure without prior publication of a contract notice. According to the applicants, that damage must be regarded as real and certain because they definitively lost their opportunity to secure the contract. They claim that the Commission's refusal to disclose the technical and award criteria on the basis of which the contract was granted has made it impossible for them to prove that they could have actually won the contract. Accordingly, the applicants ask the Court, primarily, to order the Commission to communicate the market specifications on the basis of which the framework contracts at issue were awarded and to give an interlocutory ruling on the Commission's liability in so far as it unlawfully used the negotiated procedure without prior publication of a contract notice in order to determine the amount of damages at a later stage. In the alternative, they seek damages of EUR 3 000 000.

87 The Commission disputes those arguments.

88 It should be recalled from the outset that, pursuant to the second paragraph of Article 340 TFEU, in the case of non-contractual liability, the European Union, in accordance with the general principles common to the laws of the Member States, is to make good any damage caused by its institutions or by its servants in the performance of their duties.

89 According to settled case-law, in order for the European Union to incur non-contractual liability under the second paragraph of Article 340 TFEU for unlawful conduct on the part of its institutions, a set of conditions must be fulfilled, namely the unlawfulness of the acts alleged against the institutions, the fact of damage and the existence of a causal link between that conduct and the damage pleaded. Where one of those conditions is not satisfied, the action must be dismissed in its entirety and it is unnecessary to examine the other conditions (see judgment of 15 October 2013, *Evropaïki Dynamiki* v *Commission*, T-474/10, not published, EU:T:2013:528,

paragraph 215 and the case-law cited; see also, to that effect, judgment of 9 September 2008, *FIAMM and Others* v *Council and Commission*, C-120/06 P and C-121/06 P, EU:C:2008:476, paragraphs 106 and 164 to 166 and the case-law cited).

90 In the present case, it is appropriate, as a preliminary point, to examine the second condition for the non-contractual liability of the European Union to be incurred, set out in paragraph 89 above, namely whether the applicants have established the fact of the damage which they claim to have suffered.

91 As regards the condition requiring actual damage to have been suffered, the European Union will incur liability only if the applicant has actually suffered 'real and certain' loss. Consequently, it is for the applicant to produce to the EU Courts the evidence to establish the fact and the extent of such a loss (see judgment of 8 November 2011, *Idromacchine and Others* v *Commission*, T-88/09, EU:T:2011:641, paragraph 25 and the case-law cited).

92 In that regard, it should be pointed out that the damage alleged by the applicants is the loss of an opportunity to tender for a public contract. As the Commission argues, the fact of submitting a tender does not confer an advantage on the tenderer since it does not guarantee that it will be awarded the contract. Therefore, the loss of an opportunity to tender does not constitute real and certain loss for which compensation may be awarded, but hypothetical damage.

93 In so far as the applicants allege, in essence, damage arising from the loss of an opportunity to be awarded the contract, it should be borne in mind that it follows from the case-law that such a loss of an opportunity to secure a contract constitutes real and certain loss only if, in the absence of the improper conduct by the institution, there would be no doubt that the applicant would have been awarded that contract (see, to that effect, order of 22 June 2011, *Evropaïki Dynamiki* v *Commission*, T-409/09, EU:T:2011:299, paragraph 85 and the case-law cited).

94 The applicants themselves acknowledge that, in calculating their loss, account must be taken of the likelihood that they would have won the contract. In that regard, the amount of compensation which the applicants seek in the alternative corresponds to the net profit they would have made if they had been awarded the contract.

95 It is necessary to examine whether the applicants have adduced evidence to establish that they would have obtained the contract if they had been invited to the negotiated procedure without prior publication at issue.

96 In that regard, the applicants claim that they were not in possession of the technical and award criteria on the basis of which the contract was awarded and, moreover, in their fifth head of claim, asked the Court to order the Commission to communicate the contract specifications on the basis of which the framework contracts at issue were awarded. However, it should be pointed out that the applicants had at their disposal the award criteria used in connection with the contract award at issue and published in the award notice of 24 December 2020.

97 In the present case, the contract award notice of 24 December 2020 stated, under heading II.1.4, entitled 'Short description', that the purpose of the contract was for the Commission to purchase up to 200 easy-to-use self-driving UV disinfection robots. Under heading II.2.5, entitled 'Award criteria', that contract award notice contained a short description of the award criteria for the contract at issue. More specifically, there were three qualitative criteria, namely, first, the technical excellence and maturity of the disinfection robot (relating in particular to the quality of

the disinfection process, efficiency and speed of the disinfection process, robot autonomy, range, ease of use), secondly, the quality of the approach to ensure supply to the selected hospital within four weeks of the order and to ensure the subsequent training of hospital staff, support and maintenance and, thirdly, the response time in the provision of technical and maintenance support.

98 The applicants maintain that they are an international company in the field of medical technology and infection prevention and control, and that they produce a portable disinfection robot called 'Ultra-V' which uses UVC light ray technology. In addition, they claim that they could have given an appropriate response to each of the award criteria described in paragraph 97 above.

99 However, as regards the award criteria relating, first, to the quality and speed of supply to the selected hospital and to the subsequent training of hospital staff and, secondly, to the response time in the provision of technical and maintenance support, the applicants have not adduced any evidence to substantiate their assertion, in paragraph 20 of their application, that they were able to fulfil those criteria.

100 It follows from all of the foregoing that the applicants have not established that there would have been no doubt that they would have been awarded that contract if they had been invited to tender in the negotiated procedure without prior publication of a contract notice at issue.

101 Consequently, it is not necessary to order the Commission to disclose the tender specifications on the basis of which the framework contracts at issue were awarded.

102 It follows that the condition requiring actual damage to have been suffered has not been satisfied for the European Union to incur non-contractual liability under the second paragraph of Article 340 TFEU.

103 Given the cumulative nature of the conditions to which the non-contractual liability of the European Union, within the meaning of the second paragraph of Article 340 TFEU, is subject, there is no need to examine the other conditions required by the case-law in that regard.

104 In those circumstances, the claim for damages and the action must be dismissed in their entirety.

Costs

105 Under Article 134(1) of the Rules of Procedure of the General Court, 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 applicants have been unsuccessful, they must be ordered to pay the costs, including those relating to the interim proceedings, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (First Chamber, Extended Composition)

hereby:

1. Dismisses the action;

2. Orders Inivos Ltd and Inivos BV to pay the costs, including those relating to the interim proceedings.

Spielmann Mastroianni Brkan

Delivered in open court in Luxembourg on 21 February 2024.

V. Di Bucci S. Papasavvas
Registrar President