Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

12 May 2022 *

(Appeal – Article 265 TFEU – Action for failure to act – Directive 93/42/EEC – Medical devices – Article 8(1) and (2) – Safeguard clause procedure – Notification by a Member State of a decision prohibiting the placing on the market of a medical device – Prolonged lack of reaction on the part of the European Commission – No decision – Admissibility – *Locus standi* – Time limit for bringing proceedings – Request to act within a reasonable time – Principle of sound administration – Obligation to state reasons of the General Court of the European Union)

In Case C-430/20 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 11 September 2020,

Christoph Klein, residing in Großgmain (Austria), represented by H.-J. Ahlt, Rechtsanwalt,

appellant,

the other party to the proceedings being:

European Commission, represented initially by C. Hermes, F. Thiran and M. Jáuregui Gómez, and subsequently by C. Hermes and F. Thiran, acting as Agents,

defendant at first instance,

THE COURT (Second Chamber),

composed of A. Arabadjiev, President of the First Chamber, acting as President of the Second Chamber, I. Ziemele (Rapporteur), T. von Danwitz, P.G. Xuereb and A. Kumin, Judges,

Advocate General: P. Pikamäe,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: German.

Judgment

1 By his appeal, Mr Christoph Klein requests the Court of Justice to set aside the order of the General Court of the European Union of 2 July 2020, *Klein* v *Commission* (T-562/19, not published, EU:T:2020:300; 'the order under appeal'), by which the General Court dismissed as inadmissible his action under Article 265 TFEU seeking a declaration that the European Commission unlawfully failed to act in the context of the safeguard clause procedure initiated by the Federal Republic of Germany on 7 January 1998 and adopt a decision in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1) with regard to his inhalation-assisting device ('the Inhaler device').

Legal context

2 Article 8 of Directive 93/42, entitled 'Safeguard clause', provides:

'1. Where a Member State ascertains that the devices referred to in Article 4(1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

(c) shortcomings in the standards themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

– the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6,

– the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the [European Union].

3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.'

3 Article 18 of that directive, entitled 'Wrongly affixed CE marking', provides:

'Without prejudice to Article 8:

(a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the [Union] shall be obliged to end the infringement under conditions imposed by the Member State;

(b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8.

…'

Background to the dispute

4 The background to the dispute is set out as follows in paragraphs 1 to 30 of the order under appeal:

'1 … the appellant, is the director of atmed AG, a limited company incorporated under German law which is currently insolvent. He is also the inventor of an inhalation-assisting device for persons suffering from asthma, which he patented at the beginning of the 1990s.

Prohibition decision relating to the Inhaler device

2 From 1996 to 2001, manufacture of the [Inhaler device] was entrusted to Primed Halberstadt GmbH on behalf of Broncho-Air Medizintechnik AG. The latter company also distributed the device, under the name Inhaler Broncho Air® … When it was placed on the German market, the device bore the CE marking, indicating that it conformed to the essential requirements of [Directive 93/42].

3 In 1996, the German authorities sent Broncho-Air Medizintechnik a draft decision intended to prohibit the distribution of the Inhaler device. In that draft decision, the authorities stated that, due to the lack of an exhaustive clinical evaluation, they had doubts as to whether the device conformed to the essential requirements of Directive 93/42. They also expressed their intention to recall all instances of the device already placed on the market.

4 On 22 May 1997, Broncho-Air Medizintechnik sent the German authorities a letter informing them that the Inhaler device had not been placed on the market since 1 January 1997 and that its distribution would remain suspended until further trials and studies on the conformity of the product with Directive 93/42 were available. It also informed the German authorities that the device in question had not been distributed abroad.

5 On 23 September 1997, the German authorities adopted a decision prohibiting Primed Halberstadt from placing the Inhaler device on the market. In that decision, the German authorities essentially stated that, pursuant to the opinion of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products and Medical Devices, Germany), the Inhaler device did not meet the essential requirements laid down in Annex I to Directive 93/42 in so far as its safety had not been sufficiently established in a scientific manner in the light of information supplied by the manufacturer. An administrative action was brought against that prohibition decision under the [Verwaltungsgerichtsordnung (German Code of Administrative Court Procedure) of 21 January 1960 (BGBl. 1960 I, p. 17), in the version applicable to the present proceedings].

6 On 7 January 1998, the German authorities sent the … Commission a letter headed "Safeguard clause procedure under Article 8 of Directive 93/42 relating to [the Inhaler device]", in which it informed the Commission of its prohibition decision of 23 September 1997.

7 The Commission did not adopt any decision following that notification by the German authorities.

Prohibition decision relating to the effecto device

8 On 16 June 2000, the exclusive rights to the appellant's medical device were transferred to atmed. Following that transfer, that device was, from 2002, exclusively distributed by atmed under the name "effecto®" ("the effecto device"). In 2003, atmed also assumed responsibility for its manufacture. When it was placed on the German market, that device bore the CE marking, indicating that it conformed to the essential requirements of Directive 93/42.

9 On 18 May 2005, the German authorities adopted a decision prohibiting atmed from placing the effecto device on the market. In essence, they considered that the conformity assessment procedure, in particular the clinical evaluation, had not been carried out properly and, for that reason, the device could not be deemed to satisfy the essential requirements of Directive 93/42. That decision was not notified to the Commission by the German authorities pursuant to Article 8(1) of Directive 93/42.

10 On 16 January and 17 August 2006, atmed contacted the Commission to complain that the German authorities had not informed the Commission of the prohibition decision of 18 May 2005. According to atmed, a safeguard clause procedure should have been initiated under Article 8 of Directive 93/42.

11 On 6 October 2006, in the light of the information received from atmed, the Commission asked the German authorities whether, in their view, the conditions for a safeguard clause procedure under Article 8(1) of Directive 93/42 were met.

12 On 12 December 2006, the Federal Republic of Germany explained to the Commission that it believed the procedure initiated by the letter of 7 January 1998, in respect of the Inhaler device, constituted a safeguard clause procedure within the meaning of that provision and that initiation of a new procedure, for the same device under another name, was not justified. Moreover, the German authorities informed the Commission of their continuing doubts regarding the conformity of the effecto device with the essential requirements of Directive

93/42 and, therefore, asked the Commission to confirm their prohibition decision of 18 May 2005. On 13 December 2006, the Commission informed atmed of the German authorities' response.

13 On 18 December 2006, atmed asked the Commission to take proceedings against the Federal Republic of Germany for failure to fulfil an obligation under Article 226 EC and to pursue the safeguard clause procedure which, it said, had been activated in 1998.

14 On 27 January 2007, the appellant and Broncho-Air Medizintechnik concluded an agreement whereby the latter transferred to the appellant its rights in relation to the Inhaler device.

15 On 22 February 2007, the Commission proposed to the German authorities to assess the decision of 18 May 2005 in the context of the safeguard clause procedure of 1998 and handle it on the basis of the new information. According to the Commission, that would avoid the need for a new notification and improve efficiency.

16 On 18 July 2007, the Commission informed the German authorities [that] it had concluded that the situation they had brought before it was in fact a case of a wrongly affixed CE marking which therefore needed to be dealt with under Article 18 of Directive 93/42. In that regard, the Commission called into question the premiss that the effecto device was not capable of fulfilling the essential requirements laid down in that directive. On the other hand, it considered that further clinical data were necessary to prove that the effecto device complied with the said requirements and invited the German authorities to cooperate closely with atmed in order to establish what data were missing. The Commission provided the appellant with a copy of its letter to the German authorities in that regard.

17 In 2008, the appellant presented a petition to the European Parliament concerning the failure of the Commission to take sufficient action in his case. On 19 January 2011, the Parliament adopted resolution P7_ TA (2011) 0017.

18 On 9 March 2011, the appellant asked the Commission to pay compensation of EUR 170 million to atmed and EUR 130 million to him personally. On 11 March 2011, the Commission rejected that claim for compensation submitted by the appellant.

Proceedings before the General Court and the Court of Justice

19 By application lodged at the Registry of the General Court on 15 September 2011, the appellant brought an action seeking compensation on the basis of the combined provisions of Article 268 TFEU and the second paragraph of Article 340 TFEU.

20 By judgment of 21 January 2014, *Klein* v *Commission* (T-309/10, EU:T:2014:19), the General Court dismissed that action essentially on the ground that the Commission had not acted unlawfully under the provisions of Directive 93/42, both as regards the prohibition in relation to the Inhaler device and as regards the prohibition in relation to the effecto device.

21 By judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252), the Court of Justice set aside in part the judgment of 21 January 2014, *Klein* v *Commission* (T-309/10, EU:T:2014:19) and referred the case back to the General Court. First, as regards the prohibition on the placing on the market of the Inhaler device, the Court of Justice considered that the General Court had erred in law in holding that the Commission

had not been under an obligation to adopt a decision in accordance with Article 8(2) of Directive 93/42 following receipt of the letter of 7 January 1998. Secondly, as regards the prohibition in relation to the effecto device, the Court of Justice rejected as inadmissible the appellant's ground of appeal which sought to establish that the General Court had erred in that part of the judgment.

22 In the context of the appeal, the General Court, by judgment of 28 September 2016, *Klein* v *Commission* (T-309/10 RENV, not published, EU:T:2016:570), examined the rest of the conditions which must be met, according to settled case-law, in order for the … Union to incur non-contractual liability, and again dismissed the appellant's appeal.

23 From the outset, the General Court rejected as inadmissible the appellant's head of claim seeking compensation on grounds of the Commission's failure to act in relation to the effecto device. In that regard, the General Court relied on the fact that the judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252) made final the finding that the Commission could not be criticised for any failure to act as regards that device. Next, the General Court held that the breach of EU law committed, according to the Court of Justice, by the Commission, with regard to the prohibition on the placing on the market of the Inhaler device, had to be regarded as being sufficiently serious. Moreover, as regards the question whether Article 8 of Directive 93/42 was a provision that conferred on the appellant any rights, as required by settled case-law, the General Court held that the appellant could rely only on the rights to compensation that had been transferred to him by Broncho-Air Medizintechnik under the agreement of 27 January 2007, and could not rely on rights to compensation associated with his personal situation or atmed, since the standard of protection referred to in Article 8(2) of Directive 93/42 does not cover those rights. Lastly, as concerns the causal link, the General Court found that, even if all the damage the appellant claimed to have suffered were proven, the existence of a direct causal link could not, in any event, be established between that damage and the Commission's unlawful conduct.

24 Following the appellant's appeal, the Court of Justice, by judgment of 6 September 2018, *Klein* v *Commission* (C-346/17 P, EU:C:2018:679), set aside in part the judgment of 28 September 2016, *Klein* v *Commission* (T-309/10 RENV, not published, EU:T:2016:570), in so far as the General Court had dismissed the action on the grounds that the appellant had not established the existence of a direct and sufficient causal link capable of engaging the European Union's liability. However, the Court of Justice rejected the appellant's grounds which called into question the other findings of the General Court, in particular, first, the finding that the lack of unlawful conduct on the part of the Commission in relation to the effecto system had been finally established and, secondly, the finding that the appellant could not rely on rights to compensation associated with his personal situation or atmed, since the standard of protection referred to in Article 8(2) of Directive 93/42 did not cover those rights. Lastly, in accordance with the second sentence of the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, the Court decided to give final judgment in the matter and dismissed the action. In that regard, it found in essence that the appellant had not complied with the obligation on him to adduce conclusive proof as to the extent of the damage alleged.

Steps taken following the judgment of 6 September 2018, Klein v Commission (C-346/17 P)

25 On 28 September 2018, the appellant sent a letter to the Commission, making reference to the judgment of 6 September 2018, *Klein* v *Commission* (C-346/17 P, EU:C:2018:679). In that letter, he called on the Commission, first, to take a decision without delay under Article 8(2) of Directive 93/42, with regard to prohibition of the placing on the market of the Inhaler device and, secondly, to initiate infringement proceedings against the Federal Republic of Germany, on the grounds that it had not initiated the safeguard clause procedure, in accordance with Article 8(1) of that directive, with regard to the prohibition on the placing on the market of the effecto device.

26 On 21 November and 18 December 2018, the Commission sent two letters to the appellant in reply. In the first letter, the Commission told him, with regard to his first request, that it was under consideration and that he would be informed if the Commission resumed examination of the safeguard clause procedure initiated by the German authorities on 7 January 1998 and whether, in that connection, it was entering into consultations with the parties concerned, in accordance with Article 8(2) of Directive 93/42. With regard to his second request, the Commission informed the appellant that no measures would be taken against the Federal Republic of Germany. By the second letter, the Commission sent the appellant a detailed list of questions concerning factual and legal aspects of the prohibition on the placing on the market of the Inhaler device and the safeguard clause procedure initiated by the German authorities. The appellant replied to the Commission's list of questions on 14 January 2019.

27 On 6 February 2019, the appellant contacted the Commission and requested a personal meeting with the Commissioner for Internal Market and the Secretary-General of the Commission. That request was rejected by the Commission on 21 February 2019.

28 On 4 April 2019, the appellant sent another letter to the Secretary-General of the Commission asking the latter in essence to inform him whether a decision in accordance with Article 8(2) of Directive 93/42 would be adopted regarding the Inhaler device. In that letter, he also stated that if there was no reply from the Commission by 12 April 2019 he would bring an action before the General Court.

29 On 29 April 2019, the appellant contacted the President of the Commission by email, copying the email to the Secretary-General of the Council of the European Union and the President of the European Parliament. In that email, he asked the President of the Commission to take action against the competent Commissioner's refusal to act in respect of the Inhaler device, in order to put an end to persistent breaches of EU law. On 13 May 2019, the appellant contacted the President of the Commission one last time, seeking damages due to the absence of a decision with regard to the Inhaler device.

30 On 26 July 2019, the Commission sent the appellant a letter reiterating, in essence, the content of its letter of 21 November 2018.'

The action before the General Court and the order under appeal

5 By application lodged at the Registry of the General Court on 14 August 2019, the appellant brought an action under Article 265 TFEU seeking a declaration that the Commission had unlawfully failed to act in the context of the safeguard clause procedure initiated by the Federal Republic of Germany on 7 January 1998 and to take a decision in accordance with Directive 93/42 with regard to the Inhaler device.

6 By a separate document lodged at the Registry of the General Court on 24 October 2019, the Commission raised a plea of inadmissibility under Article 130 of the Rules of Procedure of the General Court, alleging, first, the appellant's partial lack of *locus standi*, secondly, the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act and, thirdly, the fact that the action at first instance had been brought out of time.

7 In the order under appeal, in the first place, the General Court held that the appellant's action for failure to act must be declared inadmissible since that action had been brought in order to rely on rights associated with his 'personal situation'. The General Court found, however, that the appellant did have *locus standi* since he had brought that action as a beneficiary of the transfer of rights that took place between himself and Broncho-Air Medizintechnik.

8 In the second place, the General Court held that, since, first, the time limit for bringing an action under Article 265 TFEU, following the request to act made by the appellant in the letter of 28 September 2018, expired on 13 February 2019 and, secondly, as the action had been brought on 14 August 2019, that action had been brought out of time and must therefore be rejected as inadmissible.

9 In the third place, with regard to the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act under the second paragraph of Article 265 TFEU, the General Court also, for the sake of completeness, upheld the Commission's complaint, so that the General Court held that the action at first instance must, in any event, be dismissed as inadmissible on that ground.

Forms of order sought by the parties to the appeal

10 The appellant claims that the Court of Justice should:

– set aside the order under appeal;

– declare that the action at first instance is admissible and that the Commission breached its obligations under the TFEU by failing to act in the safeguard procedure concerning the Inhaler device, initiated by the Federal Republic of Germany on 7 January 1998, and not issuing a decision in accordance with Article 8(2) of Directive 93/42, or, in the alternative, refer the case back to the General Court, and

– order the Commission to pay the costs.

11 The Commission contends that the Court should:

– dismiss the appeal in its entirety and

– order the appellant to pay the costs.

The appeal

12 In the context of the appeal, the appellant contests the grounds on which the General Court dismissed his action as inadmissible.

13 As regards, first, the appellant's partial lack of *locus standi*, the appellant puts forward three grounds of appeal: first, distortion of the evidence and the facts and an incorrect interpretation in law as regards the right claimed, second, distortion of the evidence and the facts as regards his position as authorised representative and, third, incorrect legal classification of his right and infringement of EU law.

14 As regards, secondly, whether the action at first instance was brought out of time, the appellant puts forward two grounds of appeal: first, incorrect determination of the starting point of the period within which an action may be brought as laid down in Article 265 TFEU and, second, distortion of the facts and breach of the principle of the protection of legitimate expectations.

15 As regards, thirdly, the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act, the appellant puts forward three grounds of appeal: first, distortion of the evidence and the facts and an incorrect interpretation in law, second, breach of the obligation to state reasons and, third, infringement of Article 8(2) of Directive 93/42, of Article 28 et seq. and Article 265 TFEU and of Article 47 of the Charter of Fundamental Rights of the European Union ('the Charter').

The appellant's partial lack of locus standi

First ground of appeal: distortion of the evidence and the facts and incorrect interpretation in law as regards the right claimed

– *Arguments of the parties*

16 The appellant disputes the finding, made in paragraph 53 of the order under appeal, that the action must be declared inadmissible in so far as it was brought in order to rely on rights to compensation associated with his personal situation. In that regard, it follows directly from that action, from the arguments put forward at first instance and from the documents submitted that the appellant did not bring the action in order to rely on rights to compensation. It follows from that that the General Court distorted the evidence and the facts and that it gave an incorrect interpretation in law as regards the right claimed.

17 The Commission disputes the appellant's arguments.

– *Findings of the Court of Justice*

18 It should be noted that paragraph 53 of the order under appeal contains a clerical error in the language of the case in so far as it states that the appellant brought the action 'in order to rely on rights to compensation associated with his personal situation'. It is clear, however, from the grounds of the order under appeal, in particular from paragraphs 41 to 52 thereof, that the General Court by no means considered that the appellant intended to rely on such rights to compensation in the present proceedings.

19 It is true that in paragraph 44 of the order under appeal, the General Court referred to certain findings made in the judgment of 28 September 2016, *Klein* v *Commission* (T-309/10 RENV, EU:T:2016:570), which stated that the appellant could not rely on rights 'to compensation' associated with his 'personal situation'. However, the General Court clarified this, in

paragraph 45 of that order, stating that, although those considerations were expressed in the context of an action to establish non-contractual liability based on a reading of Article 268 TFEU in conjunction with Article 340 TFEU, they were relevant as regards entities whose legal situation was to be regarded as being affected by Article 8(2) of Directive 93/42 and were therefore fully applicable in the present case.

20 In those circumstances, the first ground of appeal must be rejected.

Second ground of appeal: distortion of the evidence and the facts as regards the appellant's position as authorised representative

– *Arguments of the parties*

21 The appellant claims that, in paragraph 50 of the order under appeal, the General Court distorted the evidence and the facts as regards his position as authorised representative. As a result, the General Court failed to recognise that the appellant was the authorised representative of Broncho-Air Medizintechnik, within the meaning of Article 8(2) of Directive 93/42, and as such he was directly concerned by the Commission's failure to act and his legal situation was affected in a way that was personal to him.

22 The Commission disputes the appellant's arguments.

– *Findings of the Court*

23 It is settled case-law that, where an appellant alleges distortion of the evidence by the General Court, he must, under Article 256 TFEU, the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union and Article 168(1)(d) of the Rules of Procedure of the Court, indicate precisely the evidence alleged to have been distorted by the General Court and show the errors of appraisal which, in his view, led to such distortion. In addition, it is also settled case-law of the Court that distortion must be obvious from the documents in the Court's file, without there being any need to carry out a new assessment of the facts and the evidence (judgment of 8 March 2016, *Greece* v *Commission*, C-431/14 P, EU:C:2016:145, paragraph 32 and the case-law cited).

24 In the present case, the General Court held, in paragraph 40 of the order under appeal, that, in order to show that he was directly and individually concerned by the Commission's failure to act, the appellant had 'relied in particular on the fact that he was the inventor of the Inhaler device, and also that he was the licensor in relation to Broncho-Air Medizintechnik and the main shareholder of atmed' and that he was 'the person most affected economically'.

25 First, such a finding does not appear to be distorted. Indeed, in the application lodged with the General Court, the appellant merely stated that he had *locus standi* under the third paragraph of Article 265 TFEU 'by virtue of the power of attorney attached', that power of attorney establishing his capacity as authorised representative of Broncho-Air Medizintechnik. Moreover, in his observations on the plea that that application was inadmissible, the appellant added that he was 'also personally directly concerned by the [Commission's] failure to act'. In his words, he 'is not only the inventor of the Inhaler device at issue in the present case, he is also the licensor in relation to Broncho-Air Medizintechnik … and the main shareholder of atmed AG (in liquidation)'. He is therefore 'the person most affected economically', '[and that] economic

approach [should] be taken into consideration'. It does not therefore appear that the appellant had specifically mentioned before the General Court that he was directly affected as a result of his personal legal situation, in his capacity as authorised representative of Broncho-Air Medizintechnik.

26 Secondly, the General Court was right to recall, in paragraph 47 of the order under appeal, that it is clear from settled case-law relating to the fourth paragraph of Article 263 TFEU, applicable *mutatis mutandis* to Article 265 TFEU, that a measure is likely to be of direct concern to an appellant if his legal situation is affected. As the Commission contends, in his capacity as the authorised representative and consequently a person representing Broncho-Air Medizintechnik, the appellant's personal legal situation, unlike that of the manufacturer being represented, is not affected. Moreover, as the General Court pointed out in paragraph 49 of the order under appeal, the mere fact that a measure may have an influence on an appellant's economic situation is not enough for the view to be taken that that measure is of direct concern to him (see, to that effect, judgment of 28 February 2019, *Council* v *Marquis Energy*, C-466/16 P, EU:C:2019:156, paragraph 56 and the case-law cited).

27 The second ground of appeal must therefore be rejected.

Third ground of appeal: error in law in that the General Court held that the measure the Commission failed to adopt follows exclusively from the application of Article 8(2) of Directive 93/42

– *Arguments of the parties*

28 The appellant maintains that the General Court erred in stating, in paragraph 50 of the order under appeal, that the measure the Commission failed to adopt follows exclusively from the application of Article 8(2) of Directive 93/42. The Commission's failure to act infringes not only Article 8, but also Article 28 et seq. TFEU and the Charter. Moreover, the General Court's finding that that directive, being secondary law, precludes the application of EU primary law is incorrect. In that regard, Broncho-Air Medizintechnik still intends to place the Inhaler device on the market and such placing on the market would be precluded by the Commission's failure to adopt a decision. That entails infringement of Broncho-Air Medizintechnik's freedom to conduct business, discrimination in relation to its potential competitors and an obstacle to that company placing its device on the market.

29 The Commission disputes the appellant's arguments.

– *Findings of the Court of Justice*

30 It is apparent from the findings of the General Court in paragraph 50 of the order under appeal that:

'… The appellant claims that the Commission's alleged failure to act is based not only on Article 8(2) of Directive 93/42, but also on Article 28 et seq. TFEU and Articles 15, 17, 20, 21, 41 and 47 of the [Charter], which apply to him in a personal capacity as a citizen of the Union. However, apart from the fact that that assertion is unsubstantiated and should therefore be

rejected as inadmissible under Article 76(d) of the Rules of Procedure [of the General Court] …, it must be held that the measure which the Commission failed to adopt follows only from the application of Article 8(2) of Directive 93/42. …'

31 In that regard, it should be noted that the appellant does not dispute the General Court's finding that his assertion was in no way substantiated and should therefore be rejected as inadmissible. Moreover, it is only for the sake of completeness that the General Court added that the measure which the Commission failed to adopt follows only from the application of Article 8(2) of Directive 93/42.

32 It is settled case-law that pleas directed against grounds of the judgment included for the sake of completeness cannot as such lead to the annulment of that judgment and are therefore ineffective (see, to that effect, judgment of 10 March 2022, *Commission* v *Freistaat Bayern and Others*, C-167/19 P and C-171/19 P, EU:C:2022:176, paragraph 108 and the case-law cited).

33 Therefore, since the third ground of appeal is directed against a ground of the order under appeal included for the sake of completeness, that ground of appeal must be rejected as being ineffective.

34 In the light of all the above considerations, all the grounds of appeal relating to the appellant's partial lack of *locus standi* must be rejected.

The belated nature of the action at first instance

Arguments of the parties

35 The appellant disputes the finding, in paragraph 79 of the order under appeal, that the time limit for bringing an action under Article 265 TFEU began to run on 28 September 2018, the date of the appellant's letter to the Commission, and expired on 13 February 2019.

36 First, the General Court distorted the facts, made an incorrect legal classification of those facts and infringed Article 265 TFEU. In that regard, it was only through the 'threat of bringing an action' that it was it possible to exercise coercion, such that it must necessarily be mentioned in the request to act, so that the date of that request could constitute the starting point of the time limit for bringing the action provided for in Article 265 TFEU. By considering the binding nature of the appellant's letter to the Commission of 28 September 2018 as having been established, without it being clear from that letter that the appellant would bring an action for failure to act if two months passed without the Commission taking any action, the General Court infringed Article 265 TFEU. Moreover, that binding nature must be assessed objectively, so that the circumstance, mentioned in paragraph 70 of the order under appeal, that the Commission was allegedly unable to rule out that the possibility that the appellant would bring an action for failure to act cannot be decisive. Lastly, the Commission sought to ensure that, on the basis of the information it provided to him in its letters of 21 November and 18 December 2018, the appellant would not bring an action for failure to act.

37 Contrary to what the Commission contends, the first ground of appeal is not inadmissible. The assessment of that 'binding nature' is a matter of law which is subject, as such, to review by the Court of Justice in the context of an appeal.

38 The Commission contends that the General Court did not commit the errors in law alleged by the appellant. According to settled case-law, Article 265 TFEU presupposes that a 'letter of formal notice is manifestly binding'. If, as the appellant maintains, an express 'threat' to bring an action for failure to act were required, such formality would unduly delay the procedure laid down in Article 265 TFEU and would not be in the interests of legal certainty. Moreover, in so far as the appellant disputes the General Court's classification of the letter of 28 September 2018, his line of argument is inadmissible in that, by that line of argument, the appellant seeks in essence to call into question the General Court's assessment of the facts. After all, that classification appears to be correct, the General Court having established the binding nature of the letter of 28 September 2018 on the basis of the letter's content and context.

Findings of the Court of Justice

39 Regarding, in the first place, the admissibility of the first ground of appeal, it should be borne in mind that it follows from Article 256 TFEU and from the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union that the General Court has exclusive jurisdiction, first, to establish the facts, except where the substantive inaccuracy of its findings is apparent from the documents submitted to it, and, secondly, to assess those facts. That assessment does not constitute, save where the evidence produced before the General Court has been distorted, a question of law which is subject, as such, to review by the Court of Justice. When the General Court has established or assessed the facts, the Court of Justice has jurisdiction, under Article 256 TFEU, to review the legal characterisation of those facts by the General Court and the legal conclusions which it has drawn from them (judgments of 23 November 2017, *Bionorica and Diapharm* v *Commission*, C-596/15 P and C-597/15 P, EU:C:2017:886, paragraph 55, and of 4 February 2020, *Uniwersytet Wrocławski and Poland* v *REA*, C-515/17 P and C-561/17 P, EU:C:2020:73, paragraph 47).

40 In the present case, it is clear from the appeal that, by the first ground of appeal, which concerns specifically the assessment contained in paragraphs 62, 68, 70 and 79 of the order under appeal, the appellant calls into question, first, the legal criterion applied by the General Court in paragraph 62, since the case-law cited in the order under appeal does not, in his view, by any means concern a situation comparable to that at issue in the present case, and the 'binding nature' of a letter must be assessed objectively. Secondly, the appellant maintains that no such binding nature is evident from the letter of 28 September 2018.

41 In that regard, it must be borne in mind that the classification for legal purposes of an act by the General Court is a question of law which may be raised in an appeal (judgment of 23 November 2017, *Bionorica and Diapharm* v *Commission*, C-596/15 P and C-597/15 P, EU:C:2017:886, paragraph 55 and the case-law cited). That is true of the question whether a letter, such as the appellant's letter to the Commission of 28 September 2018, is of a 'binding nature' and must therefore be regarded as a request to act causing the time limit referred to in Article 265 TFEU to run (see, by analogy, judgment of 1 June 2006, *P & O European Ferries (Vizcaya) and Diputación Foral de Vizcaya* v *Commission*, C-442/03 P and C-471/03 P, EU:C:2006:356, paragraph 90 and the case-law cited).

42 The first ground of appeal is therefore admissible.

43 Regarding, in the second place, the merits of that ground of appeal, it should be noted that, in paragraphs 61 and 66 of the order under appeal, the General Court held, after noting that an action for failure to act may be brought only within two months of the expiry of an initial period

of two months from the date of such a request to act, that the action brought by the appellant was inadmissible, since his letter to the Commission of 28 September 2018 must be regarded, in the light of both its subject matter and content, as a 'request to act', under Article 265 TFEU, made both in his personal capacity and on behalf of Broncho-Air Medizintechnik.

44 In that regard, the General Court pointed out, first, in paragraph 67 of the order under appeal, that the letter of 28 September 2018 was sufficiently clear and precise to enable the Commission to ascertain in specific terms the content of the decision which it was being asked to adopt, namely a decision it was required to adopt under Article 8(2) of Directive 93/42, with regard to the measure decided upon by the German authorities to prohibit the placing on the market of the Inhaler device.

45 Secondly, the General Court held, in paragraph 68 of the order under appeal, that the use in that letter of expressions such as 'without delay' or 'any persistence by the Commission in its refusal [would be regarded by the appellant] as further intentional prevarication' was such as to make the Commission aware of the binding nature of the appellant's request. The General Court added that, in the letters sent to the appellant subsequently, including those of 21 November and 18 December 2018, the Commission again referred to the letter of 28 September 2018, making references to and identifying specifically the appellant's 'requests', which demonstrates the binding nature of those requests in the view of that institution. The General Court also stated that the binding nature of the letter of 28 September 2018 for the Commission could be inferred from the fact that, in its letter of 18 November 2018, the Commission gave a final answer to the appellant's request to instigate proceedings for failure to act against the Federal Republic of Germany, under Article 258 TFEU, in its refusal to do so.

46 Although the appellant does not dispute that his letter of 28 September 2018 is sufficiently clear and precise, he maintains that the General Court's assessment in paragraph 68 of the order under appeal – set out in paragraph 45 of the present judgment – that that letter was binding, is vitiated by errors of law.

47 It should be recalled that, according to the second paragraph of Article 265 TFEU, an action for failure to act is admissible only if the institution, body, office or agency concerned has first been called upon to act. If, within two months of being so called upon, the institution, body, office or agency concerned has not defined its position, the action may be brought within a further period of two months. Thus, an action for failure to act can be brought only if the institution, body, office or agency concerned has been 'called upon to act' and provided that that institution, body, office or agency has not 'defined its position' within a certain period. The requirement for the appellant to first call upon the institution, body, office or agency is a necessary requirement, not only because it constitutes the starting point for the time limits set for the person concerned, but also because it forces that institution, body, office or agency to define its position within a limited period regarding the legality or otherwise of its inaction (see, to that effect, judgment of 4 February 1959, *De Gezamenlijke Steenkolmijnen in Limburg* v *High Authority*, 17/57, EU:C:1959:3, p. 8).

48 As regards the characteristics which a request must possess in order to be classified as a 'request to act' for the purposes of Article 265 TFEU, it is clear from the case-law that, although an express reference to that article is sufficient to show that a request to act indicates an intention to pursue the matter (see, to that effect, judgment of 22 May 1985, *Parliament* v *Council*, 13/83, EU:C:1985:220, paragraph 24), such a reference is not essential provided that the request shows that it requires the institution, body, office or agency at issue to define its position (order of

18 November 1999, *Pescados Congelados Jogamar* v *Commission*, C-249/99 P, EU:C:1999:571, paragraph 18, and judgment of 23 November 2017, *Bionorica and Diapharm* v *Commission*, C-596/15 P and C-597/15 P, EU:C:2017:886, paragraph 54 and the case-law cited) or adopt a formal decision within a mandatory period (see, to that effect, judgment of 10 June 1986, *Usinor* v *Commission*, 81/85 and 119/85, EU:C:1986:234, paragraph 16).

49 The request must therefore, first, contain a 'formal request or indicate an intention to pursue the matter' (judgment of 13 July 1961, *Elz* v *High Authority*, 22/60 and 23/60, EU:C:1961:17, p. 188) and, secondly, make it clear that litigation may ensue in the event of persistent failure to act. Consequently, if it cannot be clearly inferred from that request that the author intends to bring an action under Article 265 TFEU if his 'requests' are not met, the request cannot be regarded as constituting a request for the purposes of that provision.

50 In the present case, it should be noted that, although the letter of 28 September 2018 was sufficiently clear and precise to enable the Commission to ascertain in specific terms the content of the decision which it was being asked to adopt, the evidence taken into consideration by the General Court in order to classify that letter as a 'request to act' does not make it possible to consider that the appellant announced in that letter his intention to bring an action if his 'requests' were not met.

51 In the first place, it must be held that the binding nature of a request to act must be assessed objectively. Thus, such a nature must be clear from the actual wording of the request of the person concerned, in other words, it must be revealed by that wording (see, to that effect, order of 18 November 1999, *Pescados Congelados Jogamar* v *Commission*, C-249/99 P, EU:C:1999:571, paragraph 19).

52 First, it is clear from paragraphs 68 and 70 of the order under appeal that, in classifying the letter of 28 September 2018 as a 'request to act', the General Court relied inter alia on evidence which is not clear from the wording of that letter, nor, moreover, from the appellant's conduct towards the institution at issue. In those paragraphs, the General Court stated that that letter 'was capable of making the Commission aware of the binding nature of the appellant's request' and that 'the Commission could not in any event rule out the appellant bringing an action for failure to act as it was a procedural instrument available to him'. In so doing, the General Court did not infer the binding nature of that letter from the wording of the letter, but from a subjective interpretation which the institution concerned was likely to put on it, and therefore failed to have regard to the case-law referred to in paragraphs 48, 49 and 51 of the present judgment.

53 Secondly, in paragraph 68 of the order under appeal, the General Court also, for the purpose of establishing the binding nature of the letter of 28 September 2018, relied on the content of the letters sent subsequently by the Commission to the appellant, in which the Commission referred to the letter of 28 September 2018 and identified specifically the appellant's 'requests', which demonstrated the binding nature of those requests 'in the view of that institution'. However, besides the fact that, as was stated in paragraph 51 of the present judgment, the binding nature of the request must be clear from the request itself, it must, in any event, be held that the fact that those 'requests' were specifically identified by the Commission merely leads to the conclusion that the letter of 28 September 2018 was sufficiently clear and precise to enable the Commission to ascertain the content of the decision which it was being asked to adopt, but not that the appellant would bring an action if those 'requests' were not met.

54 Thirdly, the General Court held that the binding nature of the letter of 28 September 2018 for the Commission could be inferred from the fact that that institution had, in its letter of 18 November 2018, given a final reply to the appellant's request to bring proceedings for failure to act against the Federal Republic of Germany, under Article 258 TFEU, and rejected that request. That is irrelevant, however, since the Commission's position regarding the appellant's first request does not enable the binding nature of his second request to be established.

55 In those circumstances, it must be held that the binding nature of the letter of 28 September 2018 is not objectively clear from the grounds of the order under appeal which are recalled in paragraphs 52 to 54 of the present judgment.

56 In the second place, notwithstanding the above considerations, it should be noted that, in paragraph 68 of the order under appeal, in order to establish the binding nature of the letter of 28 September 2018, the General Court relied on the use of expressions such as 'without delay' or 'any persistence by the Commission in its refusal [would be regarded by the appellant] as further intentional prevarication'.

57 First, in paragraph 64 of the order under appeal, the General Court itself stated that the request made to the Commission to adopt a decision under Article 8(2) of Directive 93/42 'without delay' should be viewed in the context of the judgments of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252, paragraph 79), and of 6 September 2018, *Klein* v *Commission* (C-346/17 P, EU:C:2018:679, paragraph 63), in which the Court of Justice held that the Commission was under an obligation to act following receipt of the letter from the German authorities of 7 January 1998. The binding nature of the invitation to act would therefore not result from the use by the appellant, in his request to act addressed to the Commission, of the words 'without delay'.

58 Secondly, the term 'prevarication', in its ordinary meaning, describes a serious failure by an official to comply with the duties of his office. The appellant's reference to such a failure cannot be interpreted as expressing his intention to bring an action if his 'requests' are not met.

59 Consequently, it cannot be held that the expressions referred to in paragraph 56 of the present judgment indicate the appellant's intention to bring an action for failure to act if his 'requests' are not met, so that the use of those expressions alone does not mean it can be classified as a request to act for the purposes of Article 265 TFEU.

60 In the light of all of the above considerations, it must be held that the General Court erred in law in ruling, in paragraph 69 of the order under appeal, that the Commission was justified in stating that the time limit for bringing an action under Article 265 TFEU, following the request to act received from the appellant by letter of 28 September 2018, expired on 13 February 2019.

61 Therefore, the first ground of appeal, alleging distortion of the facts, incorrect legal classification of those facts and infringement of Article 265 TFEU, must be upheld, without there being any need to consider the second ground of appeal, alleging a breach of the principle of protection of legitimate expectations.

62 That being so, since the General Court, for the sake of completeness, in paragraph 102 of the order under appeal, dismissed the appellant's action on the grounds that the length of time the latter took to call upon the Commission to act was unreasonable, it is also necessary to examine the lawfulness of that ground of appeal.

The unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act

63 Since the second ground of appeal concerning the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act concerns in particular the statement of reasons of the order under appeal, that ground will be examined first.

Arguments of the parties

64 The appellant claims that the General Court infringed Article 265 TFEU, the obligation to state reasons and his right to be heard, since it took no account the proceedings or the content of the judgment of 21 January 2014, *Klein* v *Commission* (T-309/10, EU:T:2014:19); or the judgments of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252); and of 6 September 2018, *Klein* v *Commission* (C-346/17 P, EU:C:2018:679). In particular, the General Court did not take into account, first, the fact that the appellant conducted those proceedings not only on his own behalf and on behalf of atmed, but also on behalf of Broncho-Air Medizintechnik, the company that originally held the rights to market the Inhaler device, and, secondly, the fact that although, according to the findings of the Court of Justice, the Commission was required to adopt a decision under Article 8 of Directive 93/42, it had not done so to date. Nor did the General Court take account of the fact that the appellant has been attempting to place his device on the market for 20 years and that the Commission alone, by adopting a decision under Article 8 of Directive 93/42, could make it possible to place that device on the market.

65 The Commission disputes the appellant's assertions. In that regard, the General Court referred several times to the judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252), and, in particular, to the finding that the Commission was required to adopt a decision under Article 8(2) of Directive 93/42 following the letter from the German authorities of 7 January 1998. When examining the plea of inadmissibility, alleging the unreasonableness of the length of time that elapsed before the person concerned called upon the Commission to act, the General Court did not disregard the existence of that requirement but rather relied on it in paragraphs 94 and 95 of the order under appeal when assessing whether that time was unreasonable.

Findings of the Court of Justice

66 According to settled case-law, in the context of an appeal it is necessary to bear in mind that the purpose of review by the Court of Justice is, primarily, to examine to what extent the General Court took into consideration, in a legally correct manner, all the arguments upon which the appellant relies. In that regard, the Court of Justice does not require the General Court to provide an account which follows exhaustively and one-by-one all the arguments put forward by the parties to the case. It is sufficient that the General Court's reasoning enables the persons concerned to know why it has not upheld their arguments and provides the Court of Justice with sufficient material for it to exercise its power of review (order of 10 December 2020, *AL* v *Commission*, C-356/20 P, not published, EU:C:2020:1021, paragraphs 38 and 39 and the case-law cited).

67 It should be noted that, in paragraph 99 of the order under appeal, the General Court stated that, in view of the length of time taken to submit a formal request to act to the Commission, in accordance with Article 8(2) of Directive 93/42 with regard to the Inhaler device, it must be held that the request of 28 September 2018 was not sent to the Commission within a reasonable time.

68 In reaching that finding, the General Court held, first of all, in paragraphs 94 and 95 of the order under appeal, that the safeguard clause procedure had been initiated by the German authorities on 7 January 1998 and that, although the obligation on the Commission to act was not established by the Court of Justice until the judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252), that obligation already existed on 7 January 1998.

69 Next, the General Court pointed out, in paragraph 96 of that order, that Broncho-Air Medizintechnik, the company that originally held the rights to market the Inhaler device, did not at any time contact the Commission to obtain information on how the safeguard clause procedure was being conducted in respect of the prohibition on placing that device on the market, or even to make a formal request for a decision to be adopted under Article 8(2) of Directive 93/42.

70 Lastly, in paragraphs 97 and 98 of the order under appeal, the General Court stated that, at the time of the transfer agreement, which was concluded between the appellant and Broncho-Air Medizintechnik some nine years after the notification of 7 January 1998, although both parties were aware of the fact that the Commission had taken no action following notification of the safeguard clause by the German authorities, no steps had been taken to make a formal request to it to act under Article 265 TFEU. It was only after the final rejection of the appellant's action for compensation, that is to say, more than 20 years after that notification, that the appellant, acting on behalf of the company Broncho-Air Medizintechnik inter alia, called upon the Commission to act.

71 In that context, in paragraph 100 of the order under appeal, the General Court rejected the argument, allegedly put forward by the appellant, that the period prior to the transfer agreement of 27 January 2007 should not be taken into account for the purpose of assessing whether the time taken for the Commission to be called upon to act was reasonable, in view of the fact that the appellant was entitled to bring an action for failure to act only as a beneficiary of the transfer of rights made by Broncho-Air Medizintechnik. The General Court added, in paragraph 101 of that order, that even though the appellant stated that he had prompted the Commission to 'revive' in 2007 the safeguard clause procedure initiated in 1998, the appellant's intention was that the Commission should adopt a decision with regard to the prohibition on the placing on the market of the effecto device and not that of the Inhaler device.

72 It should be observed that, according to the Court of Justice's settled case-law, the reasonableness of a period of time is to be appraised in the light of all of the circumstances specific to each case and, in particular, the importance of the case for the person concerned, its complexity, the various procedural stages which the EU institution followed and the conduct of the parties in the course of the procedure (see, to that effect, judgment of 14 June 2016, *Marchiani* v *Parliament*, C-566/14 P, EU:C:2016:437, paragraphs 99 and 100 and the case-law cited).

73 In that regard, in his observations on the plea of inadmissibility in Case T-562/19, the appellant specifically referred to a number of factors that may characterise the Commission's conduct in the light of the abovementioned case-law, including: continuation by the Commission itself, in 2007, of the safeguard clause procedure initiated in 1998; the fact that the Court of Justice had already established, in 2015, that the Commission was required to act; the fact that the

Commission itself, in its letter of 16 November 2018, had made express reference to the 'German notification of 7 January 1998', raising questions of a factual and legal nature about the device itself; the Commission's letter of 26 July 2019, in which the Commission informed the appellant that the information thus communicated was useful, and, the intentional nature of the Commission's conduct.

74 It must be held, however, that the reasoning provided by the General Court in paragraphs 94 to 98 of the order under appeal is inadequate in the light of the circumstances of the present case and the arguments put forward by the appellant. In particular, the General Court should have stated specifically the extent to which those circumstances might have affected the reasonableness of the length of time that elapsed before the appellant called upon the Commission to act.

75 In those circumstances, the second ground of appeal must be upheld in so far as it alleges a breach of the obligation to state reasons and the order under appeal must therefore be set aside, without there being any need to examine the first and third grounds of appeal.

The action before the General Court

76 In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, where a decision of the General Court is set aside, the Court of Justice may itself give final judgment in the matter, where the state of the proceedings so permits.

77 In the present case, the Court has the necessary information to give final judgment on the admissibility of the action brought by the appellant.

78 In the context of the plea of inadmissibility it raised before the General Court, the Commission put forward three grounds for the inadmissibility of the action at first instance, which were upheld by the General Court, alleging, first, the appellant's partial lack of *locus standi*, second, the fact that the action had been brought out of time and, third, the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act.

79 Since, as was held in paragraph 34 of the present judgment, all the grounds of appeal relating to the appellant's partial lack of *locus standi* must be rejected, it is necessary to examine only, first, the ground of inadmissibility alleging that the action at first instance was brought out of time and, secondly, the plea alleging the unreasonableness of the length of time that elapsed before the appellant called upon the Commission to act.

80 As regards, in the first place, the ground of inadmissibility put forward by the Commission alleging that the appellant failed to comply with the time limit laid down in the second paragraph of Article 265 TFEU for the lodging of an action for failure to act, the Commission contends that it is not the letter of 4 April 2019 that should be regarded as giving it formal notice for the purposes of the second paragraph of Article 265 TFEU but the letter of 28 September 2018, in view of the subject matter and content of that letter.

81 However, as is apparent from the considerations set out in paragraphs 43 to 61 of the present judgment, the letter of 28 September 2018 cannot, in view of its wording, be regarded as a request to act which triggered the time limit for bringing the action under Article 265 TFEU.

82 On the other hand, as is clear from paragraph 28 of the order under appeal, the appellant, in the letter of 4 April 2019, expressly requested the Commission to inform him whether a decision under Article 8(2) of Directive 93/42 would be taken in respect of the Inhaler device, and stated that, failing a reply from the Commission by 12 April 2019, he would bring an action before the General Court. It must therefore be held that that letter was sufficiently clear and precise not only to enable the Commission to ascertain in specific terms the content of the decision which it was being asked to adopt, but also to show that the purpose of the letter was to require it to define its position.

83 In the present case, the action was brought on 14 August 2019, that is to say within two months of the expiry of an initial period of two months from the request to act of 4 April 2019, plus the single period of 10 days on account of distance provided for in Article 60 of the Rules of Procedure of the General Court.

84 In those circumstances, the ground of inadmissibility alleging that the action at first instance was brought out of time must be rejected.

85 As regards, secondly, the ground of inadmissibility alleging that the length of time that elapsed before the appellant called upon the Commission to act was unreasonable, the Commission contends, in essence, that the German authorities informed it of the notification of the safeguard clause procedure concerning the Inhaler device on 7 January 1998, so that, even though the Commission's obligation to act was not established by the Court of Justice until 2015, it had existed for over 21 years, with the result that in any event the action at first instance was not brought within a reasonable time.

86 As the General Court rightly recalled, in essence, in paragraph 93 of the order under appeal, the reasonableness of the length of proceedings cannot be determined by reference to a precise maximum limit determined in an abstract manner. It must be assessed in the light of all of the circumstances specific to each case, in particular, the importance of the case for the person concerned, its complexity, the various procedural steps the EU institution has followed and the conduct of the parties during the proceedings. In that regard, the list of relevant criteria is not exhaustive and the assessment of the reasonableness of a period does not require a systematic examination, by the EU judicature, of the circumstances of the case in the light of each of those criteria (see, to that effect, judgments of 26 November 2013, *Groupe Gascogne* v *Commission*, C-58/12 P, EU:C:2013:770, paragraphs 85 and 86, and of 5 June 2018, *Kolev and Others*, C-612/15, EU:C:2018:392, paragraph 72).

87 As regards, in particular, the conduct of the institution concerned, it is necessary to recall that it is under a duty to exercise its powers in accordance with the general principles of EU law, in particular the principle of sound administration (see, by analogy, judgment of 10 March 2011, *Agencja Wydawnicza Technopol* v *OHIM*, C-51/10 P, EU:C:2011:139, paragraph 73), now expressly set out in Article 41 of the Charter, paragraph 1 of which provides specifically that every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the European Union.

88 As the Court has had occasion to note, that principle requires administrative authorities to conduct a diligent and impartial examination of all the relevant aspects of the requests submitted to them so as to ensure that, when adopting a decision, they have at their disposal the most complete and reliable information possible for that purpose. Furthermore, that obligation to act diligently, a corollary of which is the right of every person to have his or her affairs handled by

the administrative authorities impartially, fairly and within a reasonable period of time, essentially requires those authorities to examine, carefully and impartially, all the relevant facts of the case (see, to that effect and by analogy, judgments of 10 December 1957, *Société des usines à tubes de la Sarre* v *High Authority*, 1/57 and 14/57, EU:C:1957:13, p. 113; of 4 April 2017, *Ombudsman* v *Staelen*, C-337/15 P, EU:C:2017:256, paragraph 34; and of 14 May 2020, *Agrobet CZ*, C-446/18, EU:C:2020:369, paragraph 44 and the case-law cited).

89 In that context, the administrative authority concerned is required in particular to define its position, when it is supposed to do so, and to terminate within a reasonable period proceedings that have been instituted.

90 In the present case, in his observations on the plea of inadmissibility, the appellant argued, first, that the case-law, stemming from the judgment of 25 September 2003, *Schlüsselverlag J. S. Moser and Others* v *Commission* (C-170/02 P, EU:C:2003:501, paragraph 36), relied on by the Commission in order to contend that the request to act had been made to it after an unreasonable period of time had elapsed is not relevant since it concerns the application of Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings (OJ 1989 L 395, p. 1), as amended by Council Regulation (EC) No 1310/97 of 30 June 1997 (OJ 1997 L 180, p. 1), which included strict time limits for the purpose of limiting the duration of the proceedings concerned. Directive 93/42, however, does not contain such strict time limits.

91 That argument must be rejected, since it is clear from the settled case-law, rightly recalled in paragraph 91 of the order under appeal, that there is an obligation to act within a reasonable time in all cases where, in the absence of any statutory rule, the principles of legal certainty or protection of legitimate expectation preclude institutions, bodies, offices and agencies of the European Union and physical or legal persons from acting without any time limits, thereby threatening, inter alia, to undermine the stability of legal positions already acquired (see also, to that effect, judgment of 14 June 2016, *Marchiani* v *Parliament*, C-566/14 P, EU:C:2016:437, paragraph 96 and the case-law cited).

92 Secondly, the appellant relies on the fact that the Commission itself continued the safeguard clause procedure. In particular, in a letter of 22 February 2007, the Commission proposed to the appellant, and to the German authorities, that the appellant's device should be assessed 'in the context of the safeguard clause procedure of 1998 and examined on the basis of the new information', so that events prior to 2007 relating to that safeguard clause procedure would be irrelevant. The appellant also points out in his observations that the Commission itself, in its letter of 16 November 2018, referred expressly to the notification by the German authorities of 7 January 1998, stating that that institution was in the process of analysing his first request. Moreover, on 18 December 2018, the Commission sent the appellant a detailed list of questions concerning factual and legal aspects of the prohibition on the placing on the market of the Inhaler device and the safeguard clause procedure initiated by the German authorities.

93 In that regard, as was recalled in paragraphs 86 to 89 of the present judgment, the reasonableness of the length of proceedings must be assessed in the light of all of the circumstances specific to each case, in particular, the importance of the case for the person concerned, its complexity, the various procedural steps the EU institution has followed and the conduct of the parties during the procedure.

94 Regarding, first of all, the importance of the case for the person concerned, it should be noted that the Inhaler device was the subject of a decision prohibiting its placing on the market taken by the German authorities after the latter initiated the safeguard clause procedure under Article 8 of Directive 93/42. To date, however, the Commission has not adopted a decision following that notification from the German authorities, thereby precluding the placing on the market of that device.

95 Regarding, next, the various procedural steps the Commission has followed, it should be stated from the outset that it is that institution itself which, on 22 February 2007, proposed continuing the procedure concerning the Inhaler device initiated by the German authorities in 1998, so that the appellant was right to state that the period before 22 February 2007 should not be taken into account for the purpose of assessing whether the length of time that elapsed before the appellant called upon the Commission to act was reasonable.

96 Furthermore, it was also the Commission which, in its letter of 16 November 2018 to the appellant, made express reference to the notification from the German authorities of 7 January 1998, stating that it was in the process of considering the appellant's first request, in the following words:

'We are in the process of considering your first request. Before the end of November 2018, we shall inform you whether the Commission will resume examination of the notification of 7 January 1998 from the German authorities and whether, to that end, it will begin the relevant consultations with the parties concerned.'

97 Furthermore, on 18 December 2018, it was again the Commission which, referring to the abovementioned notification, sent the appellant a detailed list of questions concerning factual and legal aspects of the prohibition on the placing on the market of the Inhaler device and the safeguard clause procedure initiated by the German authorities.

98 Regarding, lastly, the conduct of the Commission during the procedure, in addition to the fact that that institution failed, in breach of the principles recalled in paragraphs 87 to 89 of the present judgment, to adopt any decision following the notification from the German authorities of 7 January 1998, despite, first, the Parliament's request to that effect in Resolution P7_TA (2011) 0017, referred to in paragraph 17 of the order under appeal and, secondly, the Court's finding in the judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, EU:C:2015:252), that the Commission was required to adopt a decision under Article 8(2) of Directive 93/42 following that notification, it is appropriate to take into account specifically the statements made by the Commission to the appellant following the judgment of 6 September 2018, *Klein* v *Commission* (C-346/17 P, EU:C:2018:67), and the appellant's letter of 28 September 2018.

99 It is apparent from the Commission's letters of 16 November and 18 December 2018, the contents of which are set out in paragraphs 96 and 97 of the present judgment, that it did not by any means rule out adopting the decision requested, despite the length of time that had elapsed since it was first approached, and those documents did not contain the slightest reservation as regards the unreasonableness of the period within which it was called upon to act.

100 In those circumstances, the ground of inadmissibility put forward by the Commission, alleging the unreasonableness of the length of time that elapsed before the appellant called upon it to act, must be rejected.

101 In the light of all the above considerations, the action brought by the appellant before the General Court under Article 265 TFEU seeking a declaration that the Commission unlawfully failed to act in the context of the safeguard clause procedure initiated by the Federal Republic of Germany on 7 January 1998, and to take a decision in accordance with Directive 93/42 with regard to the Inhaler device, is admissible in so far as the appellant brought that action in his capacity as the beneficiary of the transfer of rights that took place between himself and Broncho-Air Medizintechnik.

102 However, since the state of the proceedings is not such as to permit final judgment to be given on the merits, the case must be referred back to the General Court.

Costs

103 Since the case is referred back to the General Court, it is appropriate to reserve the costs.

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

1. **Sets aside the order of the General Court of the European Union of 2 July 2020, *Klein* v *Commission* (T-562/19, EU:T:2020:300), in so far as the General Court dismissed as inadmissible the action brought by Mr Christoph Klein under Article 265 TFEU seeking a declaration that the European Commission unlawfully failed to act in the context of the safeguard clause procedure initiated by the Federal Republic of Germany on 7 January 1998 and to adopt a decision in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, in respect of the Broncho Air® Inhaler device;**

2. **Refers the case back to the General Court of the European Union for judgment on the merits;**

3. **Reserves the costs.**

[Signatures]