Reports of Cases

OPINION OF ADVOCATE GENERAL
BOT
delivered on 21 March 2018 [1]

Case C-346/17 P

Christoph Klein
v

European Commission

(Appeal — Non-contractual liability — Directive 93/42/EEC — Articles 8 and 18 — Medical devices — Inaction by the Commission following notification of a decision to prohibit placing on the market — Safeguard clause procedure — Sufficiently serious breach of a rule of law conferring rights on individuals — Causal link — Actual and certain damage)

1. By his appeal, Mr Christoph Klein seeks to have set aside the judgment of the General Court of the European Union of 28 September 2016, *Klein* v *Commission* (T-309/10 RENV, not published, 'the judgment under appeal', EU:T:2016:570), whereby the General Court dismissed his action for compensation for the harm alleged to have been sustained following a breach by the European Commission of its obligations under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. [2]

2. Examination of this appeal, limited to the fifth ground of appeal, in accordance with the Court's request, will lead me to explain the reasons why I consider that this ground of appeal is well founded and that, accordingly, the judgment under appeal must be set aside in part.

I. Legal framework

3. According to Article 1 of Directive 93/42, entitled 'Definitions, scope':

'1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.

2. For the purposes of this Directive, the following definitions shall apply:

(a) "medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

– diagnosis, prevention, monitoring, treatment or alleviation of disease,

1 Original language: French.

2 OJ 1993 L 169, p. 1.

– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

– investigation, replacement or modification of the anatomy or of a physiological process,

– control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

…'

4. Article 2 of that directive, entitled 'Placing on the market and putting into service', provides:

'Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.'

5. Article 3 of that directive, entitled 'Essential requirements', is worded as follows:

'The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.'

6. Article 4(1) of Directive 93/42 provides:

'Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11.'

7. Article 8 of that directive, entitled 'Safeguard clause', states:

'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 authorised 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.'

8. Article 9 of Directive 93/42, entitled 'Classification', provides for a classification of medical devices in accordance with Annex IX.

9. Article 11(5) of that directive states:

'In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.'

10. Article 17(1) of that directive provides:

'Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.'

11. Article 18 of Directive 93/42, 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 authorised representative established within the [European 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.'

12. Annex I to that directive, entitled 'Essential requirements', is worded as follows:

'1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

…

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a), as specified by the manufacturer.'

13. The particulars that must be included in the instructions for use accompanying the medical devices are set out in point 13.6 of Annex I to Directive 93/42.

II. Background to the dispute

A. The facts

14. Mr Klein 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-assistive medical device for persons suffering from asthma, which he patented in the early 1990s. According to Mr Klein, the device in question is the only inhalation-assistive medical device that can be used, in particular, by patients when they are lying down, which is particularly appropriate in the case of patients who are bedridden or suffer from a chronic obstructive pulmonary disease. It is common ground that this device came within Class I of the medical devices within the meaning of Article 9 of, and Annex IX to, Directive 93/42. [3]

15. Between 1996 and 2001 the manufacture of that medical device was entrusted to Primed Halberstadt GmbH on behalf of Broncho-Air Medizintechnik AG. The latter company was also the distributor of the device, under the name Inhaler Broncho Air® ('the Inhaler device'). [4]

16. When it was placed on the German market, the device bore the CE marking, in order to indicate that it conformed to the essential requirements referred to in Article 3 of Directive 93/42, which are set out in Annex I to that directive.

17. On 16 June 2000, the exclusive rights to exploit the inhalation-assistive medical device were transferred to atmed, which, from 2002, was the sole distributor of that medical device under the name 'effecto®' ('the effecto device'). In 2003, atmed also assumed responsibility for its manufacture. When it was placed on the German market, the device bore the CE marking.

B. The prohibition decisions

1. The decision prohibiting the Inhaler device

18. In the course of 1996, the German authorities informed the company distributing the Inhaler device, Broncho-Air Medizintechnik, that they proposed to ban its distribution on the ground that they were not satisfied that it conformed to the essential requirements laid down in Directive 93/42, as there had not been an exhaustive clinical evaluation.

3 See judgment of 21 January 2014, *Klein* v *Commission* (T-309/10, 'the judgment of the General Court of 2014', EU:T:2014:19, paragraph 73), and also European Parliament resolution P7_TA(2011)0017 of 19 January 2011 on Petition 0473/2008 by Christoph Klein (German), concerning the failure of the Commission to take action regarding a competition case and the harmful impact of this on the company concerned (OJ 2012 C 136 E, p. 44, paragraph A).

4 See judgment of the General Court of 2014 (paragraph 17), judgment of 22 April 2015, *Klein* v *Commission* (C-120/14 P, not published, 'the judgment of the Court of Justice' EU:C:2015:252, paragraph 12), and the judgment under appeal (paragraph 2).

19. By letter of 22 May 1997, Broncho-Air Medizintechnik informed the German authorities that the Inhaler device had no longer been placed on the market since 1 January 1997 and that its distribution would be suspended until additional trials and studies on the conformity of the product to the requirements of Directive 93/42 were available. It also informed the German authorities that the device in question had not been distributed abroad. [5]

20. On 23 September 1997, the German authorities adopted a decision prohibiting Primed Halberstadt from placing the Inhaler device on the market ('the decision prohibiting the placing of the Inhaler device on the market'). In that decision, the German authorities observed, in essence, that, in accordance with the opinion of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal institute for medicines products and medical devices, Germany), that device did not meet the essential requirements laid down in Annex I to Directive 93/42, since its safety had not been sufficiently established in a scientific manner in the light of the information supplied by the manufacturer.

21. By letter of 7 January 1998, entitled 'Safeguard clause procedure pursuant to Article 8 of Directive 93/42 … relating [to the Inhaler device]', the German authorities informed the Commission that they had adopted the decision prohibiting the placing of the Inhaler device on the market and provided the grounds for that decision.

22. The Commission did not adopt any decision following notification of the German authorities' letter of 7 January 1998.

2. The decision prohibiting the medical device distributed, from 2002, under the name 'effecto®'

23. By a decision of 18 May 2005, the German authorities prohibited atmed from placing the effecto device on the market ('the decision prohibiting the placing of the effecto device on the market'). They considered, in essence, that the conformity evaluation procedure, in particular the clinical evaluation, had not been carried out properly and that, for that reason, that device could not be regarded as satisfying the essential requirements laid down in Directive 93/42. That decision was not notified to the Commission by the German authorities pursuant to Article 8(1) of Directive 93/42.

24. On 16 January and 17 August 2006, atmed contacted the Commission's services and complained that the German authorities had not informed them of the decision prohibiting the placing of the effecto device on the market.

25. On 6 October 2006, in the light of the information communicated by atmed, the Commission asked the German authorities whether they considered that the conditions for implementing the safeguard clause procedure laid down in Article 8 of Directive 93/42 were satisfied.

26. On 12 December 2006, the German authorities explained to the Commission that the procedure initiated in 1998 concerning the Inhaler device constituted, from their viewpoint, a safeguard clause procedure within the meaning of Article 8 of Directive 93/42 and that the implementation of a new safeguard clause procedure for the same device bearing a different name was not justified. In addition, the German authorities informed the Commission of their continuing doubts as to whether the effecto device conformed to the essential requirements laid down in Directive 93/42 and therefore requested the Commission to confirm the decision prohibiting the placing of the effecto device on the market.

27. On 13 December 2006, the Commission informed atmed of the German authorities' response.

5 See judgment of the General Court of 2014 (paragraph 19) and judgment under appeal (paragraph 4).

28. On 18 December 2006, atmed requested the Commission to initiate infringement proceedings under Article 226 EC (now Article 258 TFEU) against the Federal Republic of Germany and also to pursue the safeguard clause procedure which, it said, had been activated in 1998.

29. On 22 February 2007, the Commission suggested that the German authorities assess the decision prohibiting the placing of the effecto device on the market in the context of the safeguard clause procedure which they had initiated in 1998 as regards the Inhaler device and deal with that decision on the basis of the new information.

30. On 18 July 2007, the Commission informed the German authorities that it had concluded that this was a case of a wrongly affixed CE marking and for that reason should be dealt with in the light of Article 18 of Directive 93/42. In that regard, the Commission queried the fact that the effecto device could not fulfil the essential requirements laid down in that directive and considered that further clinical data were necessary in order to give a definitive answer on that point. The Commission requested the German authorities to cooperate closely with atmed in order to ascertain what data were missing and sent the appellant a copy of its letter to the German authorities in that regard.

31. In 2008, the appellant presented a petition to the European Parliament complaining of the insufficient treatment of his case by the Commission and of the harmful effects resulting for atmed.

32. On 19 January 2011, the Parliament adopted resolution P7_TA(2011)0017.[6]

33. On 9 March 2011, the appellant requested the Commission to pay compensation of EUR 170 million to atmed and of EUR 130 million to the applicant.

C. Procedure before the General Court and the Court of Justice

34. By application lodged at the Registry of the General Court on 15 September 2011, the appellant brought an action for damages under Article 268 TFEU in conjunction with the second paragraph of Article 340 TFEU. By judgment of the General Court of 2014, the latter Court dismissed the action, after finding that the Commission had not acted unlawfully in the light of the provisions of Directive 93/42.

35. First of all, the General Court declared inadmissible, on the ground that it was out of time, the appellant's claim relating to the harm allegedly sustained before 15 September 2006. Next, as regards the decision prohibiting the placing on the market of the Inhaler device, the General Court considered that the Commission's failure to act was not unlawful, on the ground that, in spite of the title of the letter of 7 January 1998,[7] such a prohibition did not correspond to a case of a safeguard clause within the meaning of Article 8(2) of Directive 93/42, but to a case of wrongly affixed CE marking within the meaning of Article 18 of that directive. In that context, in accordance with Article 8(3) of that directive, the Commission was required only to be informed of the position by the Member State concerned and was not required to adopt any decision. Last, as regards the decision prohibiting the placing on the market of the effecto device, the General Court rejected the appellant's arguments that, in essence, the Commission ought to have initiated a safeguard clause procedure under Article 8(2) of Directive 93/42 of its own motion or, at least, to have initiated infringement proceedings under Article 226 EC (now Article 258 TFEU).

36. Following the appellant's appeal, the Court of Justice, by the judgment of the Court of Justice, set aside the judgment of the General Court of 2014 in part and referred the case back to the latter Court.

6 See footnote 3 to this Opinion.

7 See point 21 of this Opinion.

37. Thus, in the first place, the Court of Justice dismissed the appellant's appeal in that he sought damages in respect of the period before 15 September 2006. In the second place, as regards the decision prohibiting the placing of the Inhaler device on the market, the Court of Justice held that the General Court had misconstrued Articles 8 and 18 of Directive 93/42 when it considered that the Commission had not failed to fulfil its obligations under that directive. In particular, it considered that the General Court had erred in law in holding that the Commission was not required to initiate a safeguard clause procedure, in accordance with Article 8 of Directive 93/42, following receipt of the letter 7 January 1998. In addition, the Court of Justice considered that any application of Article 18 of Directive 93/42 to the Inhaler device did not release the Commission from the obligation to take action pursuant to Article 8(2) of that directive. As regards the decision prohibiting the placing on the market of the effecto device, the Court of Justice rejected as inadmissible the ground of appeal whereby the appellant sought to establish that the General Court had erred on that point.

38. By the judgment under appeal, the General Court, to which the matter had been referred, dismissed the appellant's action. It considered, in particular, that, in application of the second paragraph of Article 61 of the Statute of the Court of Justice of the European Union, the action was inadmissible in that it referred to an alleged unlawful failure to act on the part of the Commission in the procedure relating to the effecto device. As regards the substance, the General Court held that infringement of EU law by the Commission was sufficiently serious on the grounds that (i) the Commission did not have a discretion as regards the adoption of a decision following the safeguard clause procedure opened in 1998 in accordance with Article 8(2) of Directive 93/42 and that (ii) a normally prudent and diligent administration should not, in similar circumstances, have committed the irregularity found. The General Court also held that the appellant could not rely on the rights to compensation that had been transferred to him by Broncho-Air Medizintechnik, on whose behalf the Inhaler device had been manufactured. As regards the existence of a causal link between the Commission's wrongful failure to act and the alleged harm, the General Court, in the first place, found that Broncho-Air Medizintechnik, the distributor of the Inhaler device, had decided, before the decision of the German authorities, that it would no longer place that product on the market or sell it. The General Court considered, in the second place, that it was by no means certain that the Commission would have adopted a decision contrary to the finding of the German authorities and, in the third place, that as the purpose of the procedural costs incurred by the appellant had been to challenge the legality of the decisions of the German authorities, they could not be imputed to the Commission.

39. As the General Court found that the appellant had not established the existence of a direct and sufficient causal link capable of rendering the European Union liable, it considered that there was no need to examine the condition relating to the existence of harm, and then dismissed the action in its entirety.

III. Forms of order sought

40. The appellant claims that the Court should:

– set aside the judgment under appeal;

– order the respondent to pay the appellant the sum of EUR 1 562 662.30, plus interest at 8 percentage points over the basic interest rate from delivery of the judgment;

– establish the principle that the Commission is under an obligation to compensate the appellant for the harm caused to him from 15 September 2006 on which he continues to rely and which still remains to be quantified;

– order the Commission to pay the costs; and

– in the alternative, set aside the judgment under appeal and refer the case back to the General Court.

41. The Commission contends that the Court should dismiss the appeal and order Mr Klein to pay the costs.

IV. Examination of the appeal

42. The appeal consists of eight grounds of appeal. The appellant claims:

– by the first ground of appeal, incorrect application of the second paragraph of Article 61 of the Statute of the Court of Justice of the European Union, with the consequence that the second head of the form of order sought concerning the effecto device is admissible;

– by the second ground of appeal, infringement of the second paragraph of Article 61 of the Statute of the Court of Justice of the European Union, with the consequence that the examination of his action is flawed, as the General Court misconstrued the scope of the judgment of the Court of Justice which conferred on him rights to compensation linked with his personal situation and with the rights transferred by atmed;

– by the third ground of appeal, infringement of Article 84(1) of the Rules of Procedure of the General Court and of Article 41 of the Charter of Fundamental Rights of the European Union,[8] with the consequence that the head of the form of order whereby he sought a declaration that the Commission's failure to act constitutes an infringement of Article 41 of the Charter and breach of the principle of good administration is admissible;

– by the fourth ground of appeal, infringement, primarily, of Article 8 of Directive 93/42 and Article 28 et seq. TFEU, in that they confer rights on individuals;

– by the fifth ground of appeal, incorrect legal classification of the facts giving rise to the existence of a causal link between the act and the alleged damage;

– by the sixth ground of appeal, breach of the principle of a fair hearing and of the right to be heard and infringement of Article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms[9] and of Article 47 of the Charter, with the consequence that the General Court should have taken a proposal for a Commission decision (Annex COM RENV 1') into account; and

– by the seventh ground of appeal, infringement of Article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms and of Article 47 of the Charter, and of Article 63(3)(d) of the (former) Rules of Procedure of the General Court and of Article 24 of the Statute of the Court of Justice of the European Union, owing to the rejection of the claim that the Commission should be ordered to produce the entire file concerning the safeguard clause procedure.

43. The eighth ground of appeal, which is new, seeks to obtain, by way of interim measure in the context of this appeal, that the respondent be ordered, in accordance with Article 64(2)(b) of the Rules of Procedure of the Court of Justice, to produce before the Court the entire file concerning the safeguard clause procedure.

8 'The Charter'.

9 Signed at Rome on 4 November 1950.

A. Preliminary observations

44. Before setting out the details of my analysis of the fifth ground of appeal, criticising the reasoning in the judgment under appeal relating to the causal link, it seems to me to be essential to emphasise, as the Commission did at the hearing, the limits of the dispute, as resulting, first, from the principle of *res judicata* and, second, from the lack of foundation, in my view, of the first ground of appeal and the fourth ground of appeal,[10] which should entail their rejection by the Court.

45. First, it should be noted that it is not in dispute that, by the combined effect of the judgment of the General Court of 2014 (paragraph 54) and the rejection of the first ground of appeal in the earlier appeal on that point by the judgment of the Court of Justice (paragraph 48), the appellant's claim is limited to the harm allegedly sustained after 15 September 2006 (paragraph 98 of the judgment of the Court of Justice).

46. Second, the rejection of the first ground of appeal in the present appeal has the effect that any claim in connection with the effecto device is inadmissible. In fact, there can be no doubt, on reading paragraphs 82 to 88 of the judgment of the Court of Justice, under the heading 'Fourth plea: absence of a decision concerning the effecto device', that the rejection of that ground of appeal by the Court of Justice applies to all the complaints relating to that device.[11]

47. Third, Article 8(2) of Directive 93/42, the infringement of which is alleged by the fourth ground of appeal, refers to the manufacturer and not the inventor, contrary to the appellant's contention. Consequently, the appellant cannot rely on the rights to compensation transferred to him by Broncho-Air Medizintechnik.[12]

48. Fourth, as regards the harmful act, it should be borne in mind that the Court of Justice held that the General Court had erred in law in finding that the Commission was not required to act with regard to the decision prohibiting the placing on the market of the Inhaler device. It is also necessary to take into consideration the fact that, after the case had been referred back to it, the General Court held that, 'in so far as, first, the Commission had no discretion as regards the adoption of a decision following the safeguard clause procedure opened in 1998 in accordance with Article 8(2) of Directive 93/42 and as, second, a normally prudent and diligent administration should not, in similar circumstances, have committed the irregularity established, the infringement of EU law by the Commission must be regarded as being sufficiently serious'.[13]

10 The rejection of the other grounds of appeal does not call for any particular observations owing to their subject matter. I shall merely state, very briefly, that to my mind the second ground of appeal is based on flawed assertions based on the judgment of the Court of Justice concerning the rights conferred on the appellant, the third ground of appeal is new and the sixth ground of appeal is ineffective in that it relates to a proposal for a decision. The seventh and eighth grounds of appeal are also ineffective in the light of the finding by the General Court that the Commission had failed to fulfil its obligations.

11 In that regard, it is appropriate to bear in mind that, since the beginning of the proceedings, the appellant has put forward different pleas depending on the devices, which explains why the reasoning in the decisions distinguishes them. For the Inhaler device, his claims were based on the absence of a Commission decision, in spite of the fact that it had initiated the safeguard clause procedure, while, for the effecto device, the prohibition of which by the German authorities had not been notified to the Commission, the applicant maintained that the Commission ought to have had heard him and to have taken a decision in the context of that procedure (on the latter claim, see paragraph 83 of the judgment of the Court of Justice).

12 See paragraph 67 of the judgment under appeal.

13 See paragraph 57 of the judgment under appeal.

49. Consequently, it follows from all of those factors that the search for the existence of a causal link between the illegality of the Commission's failure to act concerning the Inhaler device and the harm alleged by the appellant,[14] which the General Court decided to carry out before having verified that the harm actually occurred,[15] had to be limited to the harm alleged to have been sustained, after 15 September 2006, by Broncho-Air Medizintechnik, whose rights to compensation had been transferred to the appellant.

50. It was in those circumstances that the General Court considered that 'the [appellant] [did] not establish the existence of a direct and sufficient causal link capable of rendering the European Union liable'[16] and held essentially that:

– the decision to cease placing the Inhaler device on the market and selling it had been taken by Broncho-Air Medizintechnik before the marketing of that device had been prohibited;

– there was no certainty that a decision favourable to the appellant would be taken by the Commission; and

– the costs incurred by the applicant were related to the challenge to the legality of the German decisions.

B. My assessment of the merits of the fifth ground of appeal

1. Arguments of the parties

51. By his fifth ground of appeal, which consists of five main parts, the appellant claims that the General Court's examination of causation was legally flawed.

52. The appellant begins by observing that the General Court considered that Broncho-Air Medizintechnik or Primed Halberstadt had voluntarily ceased to market the Inhaler device because Broncho-Air Medizintechnik stated in its letter of 22 May 1997 that it would no longer market the device for the time being. In the appellant's submission, there can be no question of a voluntary act, for reasons unconnected with the prohibition procedure in progress. In reality, Broncho-Air Medizintechnik had no objective other than the placing of the Inhaler device on the market. The German authorities left it no other choice, however, since in practice no one would buy a product which, admittedly, is not objectively dangerous but which is the subject of a pending prohibition procedure. As a matter of civil law, the appellant would be under an obligation to provide information to potential purchasers and no purchaser would then have bought the product.

53. The appellant maintains that the General Court distorted the facts. He submits that it follows from its findings that Broncho-Air Medizintechnik had not voluntarily withdrawn its device from the market and that, in any event, the decision to suspend the marketing of the Inhaler device on an interim basis had become obsolete by the effect of the decision prohibiting the placing on the market subsequently adopted and of the appeal lodged against that decision.

14 In paragraph 68 of the judgment under appeal, the General Court stated: 'The [appellant] maintains that the Commission's unlawful failure to act has a direct and sufficient causal link with the heads of damage he claims to have sustained, namely loss of profits on the inhalers that were not sold following the decision prohibiting the placing of the Inhaler device on the market, the procedural costs and lawyers' fees, and also the interest on the loans entered into in order to fund these proceedings, the depreciation in the shares in atmed, the loss of patents and similar rights, the loss of the [appellant's] income in his capacity as director of atmed, the [appellant's] other claims in connection with atmed and non-pecuniary damage'.

15 See paragraphs 40 and 84 of the judgment under appeal. It is also stated, in paragraph 73: 'even on the assumption that all the heads of claim that the [appellant] alleges in his written pleadings were established'.

16 Paragraph 83 of the judgment under appeal.

54. The appellant also claims that the General Court's reasoning in paragraph 74 of the judgment under appeal, according to which it followed from that 'voluntary' nature of that withdrawal decision that the harm alleged by the appellant is linked with the decision taken by Broncho-Air Medizintechnik on its own initiative and not with the Commission's alleged failure to act, is based on an incorrect legal characterisation of the facts. If, in the spring of 1998, the Commission, as it was required to do, had adopted without delay a favourable decision, Broncho-Air Medizintechnik could then have immediately sold its device again. It is therefore not the initial decision not to continue to place the Inhaler device on the market that is at the origin of, in particular, the costs linked with the formation of atmed and the evaluation of the effecto device, when they were the only solutions available to overcome the absence of a decision taken by the Commission.

55. In addition, the appellant maintains that the General Court, in paragraph 76 of the judgment under appeal, made an incorrect legal classification of atmed's email of 6 December 2006, since atmed could not make a declaration on behalf of Broncho-Air Medizintechnik and since that document is not of such a kind as to contradict the fact that the Commission's failure to act was the decisive cause of the device no longer being distributed after the date on which the Commission could and should have taken a decision.

56. Furthermore, the appellant observes that, in paragraphs 79 and 80 of the judgment under appeal, the General Court arrived at the conclusion that there is no causal link, because there is no certainty that the Commission would have adopted a decision favourable to the appellant and would have considered that the national measure was not justified. However, the General Court referred only to the information provided by the German authorities, without carrying out its own examination, although the German authorities considered, incorrectly, for example, that the device, with the active principle, constituted a medicinal product. In addition, the General Court ought to have found that, according to Article 8(2) of Directive 93/42, the Commission, after consultation with the parties concerned, ought to have found that the measure taken by the Member State, within the meaning of that provision, was justified or unjustified. In carrying out that examination, the Commission was required to take into account, inter alia, the principle of proportionality together with the fact that the device in question was a Class I device, the fact that the product bore the CE marking, and the decisions of the Court of Justice specifically applying the provisions of Directive 93/42.

57. Then, disputing the classification of its assertions concerning the outcome of the safeguard clause procedure as 'hypothetical', in paragraph 81 of the judgment under appeal, the appellant maintains that the Commission could have adopted a legally correct decision, since he produced a proposal for a decision, Annex COM RENV 1, finding that the measure adopted by the German authorities was 'not justified'. In the appellant's submission, that evidence was distorted by the General Court, which did not take it into consideration.

58. The appellant observes, last, that, in its examination, the General Court did not further examine the effecto device. If, after initiating the safeguard clause procedure in the spring of 1998, the Commission had adopted a decision, Broncho-Air Medizintechnik would, following that decision, have been able to market and sell the Inhaler device to this day. In the alternative, if the Court of Justice should consider that the Commission would not necessarily have classified the German authorities' prohibition as unjustified, the appellant claims that the consequences of the absence of a decision would be sufficiently direct, since the absence of a Commission decision was the principal, decisive and objectively foreseeable cause of the expenditure relied on connection with the formation and then the dissolution of atmed. [17]

17 See paragraph 90 of the appeal, under the heading '(e) Alternative causation'.

59. The Commission requests the Court to reject those complaints on the ground that the General Court correctly held that there is no certainty that the Commission would have adopted a decision along the lines alleged by the appellant and that the appellant has not proved the existence of a sufficiently direct causal link.

60. The Commission claims that there is no ground on which the appellant is entitled to maintain that its failure to act, from 7 January 1998, forced Broncho-Air Medizintechnik to cease distribution of the Inhaler device in the course of 1997, especially as that date does not correspond to the date stated at the first hearing, and that its failure to act gave rise to the formation of atmed.

61. It contends, as regards the ground relating to the voluntary nature of the cessation of marketing, that the complaint of distortion is not in any event sufficiently substantiated, that the General Court did not hold in paragraph 75 of its judgment that the safeguard procedure had become devoid of purpose and that the 2006 email corroborates the finding that Broncho-Air Medizintechnik had taken the initiative and decided that it would no longer place the device on the market.

62. As regards the criticism concerning the ground relating to the presumed outcome of the Commission decision, the Commission contends that the harm allegedly sustained by the appellant would be imputable to any unlawful conduct on its part only if it could be proved that the harm would not have arisen if the Commission's conduct had not been vitiated by illegality. The analysis of the causal link cannot proceed from the incorrect premiss that, in the absence of unlawful conduct, the Commission would have refrained from acting or would have adopted an act to the contrary, which could also constitute illegal conduct on its part. It claims that there must be a comparison between the situation generated, for the third party concerned, by the erroneous action and the situation that would have resulted for that third party if the Commission had acted in a way that respected the rule of law. In that regard, the Commission observes that the decision of the General Court is not based on the appellant's failure to produce documents, but on Broncho-Air Medizintechnik's recognition of the need to carry out further evaluations.

63. Furthermore, the Commission suggests that the Court should reject the complaint alleging that the General Court did not find that the German authorities had been wrong to consider in 2007 that the effecto device should be subject to the rules on medicinal products since that complaint is ineffective as regards the Inhaler device in 1997. It claims that the Federal Republic of Germany produced the evidence required by Article 8 of Directive 93/42 in the event of risks linked with medical devices and that the German authorities' decision ought in any event to have been upheld owing to the uncertainties as regards the effectiveness of the device, linked with the lack of clinical data.

64. As regards the criticism relating to the hypothetical nature of the appellant's arguments, the Commission observes that the complaint is not substantiated. In the interest of completeness, it states that the appellant had not relied on Annex COM RENV 1 in support of its arguments concerning the causal link and that that document contains confirmation of the German authorities' decision concerning the lack of sufficient clinical data.

65. As regards the argument based on the causal link with the marketing of the effecto device, the Commission contends, first, that the General Court was not required to respond to it owing to its decision excluding the appellant and atmed from the scope of Article 8 of Directive 93/42, as they were unable to claim the status of manufacturer, and second, that the formation of atmed was not obligatory. For the same reasons, it contends that the last complaint, setting out an 'alternative causation', must be rejected.

66. As regards the expenditure, the Commission claims that the costs declared related exclusively to atmed's activity since 2005.

2. My assessment

67. I shall set out below the complaints among those maintained by the appellant that justify the setting aside of the judgment under appeal.

68. First, the appellant correctly maintains that the General Court was not entitled to find, in paragraphs 74 to 76 of the judgment under appeal, that the causal link between the alleged harm and the Commission's failure to act, from 7 January 1998, was not established, owing to the decision which Broncho-Air Medizintechnik took to suspend the distribution and sale of the Inhaler device on an interim basis from 1 January 1997, without awaiting the decision of the German authorities.

69. I shall observe mainly that that legal characterisation of the facts,[18] on the basis of which the General Court found that there was no direct causal link, is inconsistent with the grounds of the judgment of the Court of Justice, which had acquired *res judicata*, and also, in the absence of a cross-appeal, with the grounds of the judgment under appeal relating to the Commission's breach of its obligations, based on its failure to act from 7 January 1998, the date of notification of the decision taken by the German authorities, from which the safeguard clause procedure should have been initiated.[19]

70. In those circumstances, it is immaterial that Broncho-Air Medizintechnik took the decision to suspend distribution of the Inhaler device, after the German authorities had informed it in 1996 of their doubts as to the conformity of the device, but before the decision prohibiting the placing on the market of 23 September 1997. Since the appellant maintained that in those circumstances whether or not Broncho-Air's activity was resumed depended on the Commission decision,[20] it was for the General Court to verify the existence of a causal link between the Commission's unlawful conduct after 7 January 1998 and the harm allegedly sustained with respect to the Inhaler device, from 15 September 2006, for the reasons set out above.

71. Second, as regards the reasoning in the judgment under appeal concerning the certainty of a favourable reply from the Commission, it should be observed that that reasoning is intended to respond to the appellant's arguments set out especially in paragraphs 103 and 104 of its written observations under the heading 'causal link', since he claimed to have sustained economic damage, which must be distinguished from the damage linked with the loss of opportunity which was not invoked, caused by the failure to market the medical device at issue. Nonetheless, it must also be stated that, in paragraph 1 of those observations, generally, and then in paragraphs 7 and 94, concerning the period during which the Inhaler device was placed on the market, as also stated in paragraph 82 of the judgment under appeal, concerning the alleged costs, the appellant considered that some harm originated in the Commission's failure to give a positive or negative response. Thus, the parties' written observations had related to the need to have recourse to alternative solutions, such as setting up another company (atmed) and distributing the device under another name (effecto). Those arguments of the appellant, linked directly with the Commission's failure to act, concerning the Inhaler device, or, in other words, with the expectation that a decision would be taken, irrespective of whether it was positive or negative, should have been examined by the General Court without being limited to the legal fees and the costs linked with the loans entered into in order to fund the proceedings that had been initiated.

18 Words taken from the judgment of 16 July 2009, *Commission* v *Schneider Electric* (C-440/07 P, EU:C:2009:459, paragraphs 192 and 193).

19 See paragraphs 52 to 55 of the judgment under appeal.

20 As was observed at the hearing, the competent authority responsible for examining the opposition procedure stayed proceedings pending that decision (see paragraphs 57 and 58 of the appeal and Annex A.40).

72. In my view, the question of the certainty of the Commission decision on which the appellant relied as the basis for his claim for compensation for loss of profits ought, in accordance with the case-law of the Court of Justice, to have been examined under the head of the reality or the scope of the harm [21] in connection with the Inhaler device, and not at the stage of the examination of the causal link. Furthermore, as I have already observed, the compensation can apply only to the harm alleged to have been sustained after 15 September 2006, whereas the effecto device was marketed after the Inhaler device in 2002.

73. Third, it may also be observed that the General Court did not respond to the appellant's argument relating to the causal link between the costs of the proceedings, which were indeed initiated before the German authorities, but were extended owing to the Commission's failure to respond after 7 January 1998, it being understood that only the harm sustained after 15 September 2006 is eligible for compensation.

74. Having regard to all of the foregoing considerations, I propose that the Court should rule that the fifth ground of appeal is well founded, set aside the judgment under appeal in part and refer the matter back to the General Court for an assessment, within the limits described above, either of the causal link or of the reality and scope of the alleged harm on the basis of complex factual elements, which leads me to consider that the state of the proceedings does not permit a decision by the Court of Justice.

V. Costs

75. As the case must be referred back to the General Court, the costs relating to the present proceedings on appeal must be reserved.

VI. Conclusion

76. Having regard to the foregoing considerations, I propose that the Court should:

(1) Set aside the judgment of the General Court of the European Union of 28 September 2016, *Klein* v *Commission*, (T-309/10 RENV, not published, EU:T:2016:570) in part in that it dismissed Mr Christoph Klein's action on the ground that he had not established a direct and sufficient causal link, capable of rendering the European Union liable, with the alleged harm;

(2) Dismiss the remainder of the appeal;

(3) Refer the case back to the General Court of the European Union;

(4) Reserve the costs.

21 Cf. the judgments of 19 May 1992, *Mulder and Others* v *Council and Commission* (C-104/89 and C-37/90, EU:C:1992:217, paragraphs 26 and 28), and of 14 October 2014, *Giordano* v *Commission* (C-611/12 P, EU:C:2014:2282, paragraph 40).