Reports of Cases

JUDGMENT OF THE GENERAL COURT (First Chamber)

21 January 2014*

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

In Case T-309/10,.

Christoph Klein, residing in Groβgmain (Austria), represented by D. Schneider-Addae-Mensah, lawyer,

applicant,

v

European Commission, represented by A. Sipos and G. von Rintelen, acting as Agents, assisted by C. Winkler, lawyer,

defendant,

supported by

Federal Republic of Germany, represented initially by T. Henze and N. Graf Vitzthum, and subsequently by T. Henze and J. Möller, acting as Agents,

intervener,

APPLICATION for compensation based on the combined provisions of Article 268 TFEU and the second paragraph of Article 340 TFEU, seeking damages for loss allegedly suffered by the applicant following a breach by the Commission of obligations under Article 8 of Council Directive 93/42/EEC, of 14 June 1993, concerning medical devices (OJ 1993 L 169, p. 1),

THE GENERAL COURT (First Chamber),

composed of S. Frimodt Nielsen, acting as President, M. Kancheva (Rapporteur) and E. Buttigieg, Judges,

Registrar: K. Andová, Administrator,

having regard to the written procedure and further to the hearing on 18 June 2013,

gives the following

* Language of the case: German.

Judgment

Legal context

1 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1) aims to harmonise procedures for the certification and control of medical devices. It provides for the affixing of the CE marking to medical devices which have undergone a conformity assessment procedure and, as a result, are considered to meet the essential requirements set out in the directive. Conformity with the essential requirements is demonstrated by the manufacturer on his own account or by certifying bodies designated by Member States.

2 Article 1(1) of Directive 93/42, headed 'Definitions, scope', states:

'This Directive shall apply to medical devices and their accessories … Both medical devices and accessories shall hereinafter be termed devices.'

3 Article 2 of Directive 93/42, headed '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.'

4 Article 3 of Directive 93/42, headed 'Essential requirements', sets out:

'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.'

5 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.'

6 Article 8 of Directive 93/42, headed '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 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 Community.

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.'

7 Article 9 of Directive 93/42, headed 'Classification', provides for a classification of medical devices in accordance with the rules set out in Annex IX.

8 Article 11(5) of Directive 93/42 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.'

9 Article 17(1) of Directive 93/42 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.'

10 Article 18 of Directive 93/42, headed '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 Community 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 laid down in Article 8.'

11 Article 19 of Directive 93/42, headed 'Decision in respect of refusal or restriction', provides:

'1. Any decision taken pursuant to this Directive:

(a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

(b) to withdraw devices from the market,

shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time-limits to which such remedies are subject.

2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorised representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.'

12 Annex I to Directive 93/42 contains the essential requirements which must be met by the medical devices covered. In particular, it provides:

'I. GENERAL REQUIREMENTS

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.

…

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

…

13. Information supplied by the manufacturer

…

13.6. Where appropriate, the instructions for use must contain the following particulars:

…

(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

…

(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

…

(p) degree of accuracy claimed for devices with a measuring function;

…’

13 Annex VII to Directive 93/42, headed ‘EC declaration of conformity’, describes the procedure that manufacturers of medical devices belonging to Class I must follow in order to ensure and declare that the products concerned meet the provisions of the directive which apply to them. The Annex also defines the technical documentation that the manufacturer of medical devices belonging to Class I must make available to the national authorities for inspection purposes for a period as provided in the Annex. The technical documentation includes, among other things, a risk analysis and an evaluation of clinical data to be carried out in accordance with Annex X to Directive 93/42, as well as the label and instructions for use.

14 Annex IX to Directive 93/42, headed ‘Classification criteria’, sets out the rules for determining the classification of medical devices covered by Directive 93/42. In particular, it provides:

‘III. CLASSIFICATION

1. Non-invasive devices

1.1. *Rule 1*

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in Class I.

…’

15 Annex X, Section 1, to Directive 93/42, headed ‘Clinical evaluation’, provides, in the version applicable to the facts of the case, as follows:

‘1. General provisions

1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I under the normal conditions of use of the device and the evaluation of the undesirable side-effects must be based on clinical data in

particular in the case of implantable devices and devices in Class III. Taking account of any relevant harmonised standards, where appropriate, the adequacy of the clinical data must be based on:

1.1.1.
either a compilation of the relevant scientific literature currently available on the intended purpose of the device and the techniques employed as well as, if appropriate, a written report containing a critical evaluation of this compilation;

1.1.2.
or the results of all the clinical investigations made, including those carried out in conformity with Section 2.

1.2. All the data must remain confidential, in accordance with the provisions of Article 20.'

Background to the dispute

16 The applicant, Mr Christoph Klein, is the director of atmed AG, a public limited company incorporated under German law which is currently insolvent. He is also the inventor of an inhalation-assisting device for asthmatics which he patented at the beginning of the 1990s.

Decision to ban the Inhaler device

17 From 1996 to 2001, the applicant's inhalation-assisting device was manufactured by Primed Halberstadt GmbH and distributed by the German company Broncho-Air Medizintechnik AG under the name 'Inhaler Broncho Air®' ('the Inhaler'). When it was launched on the German market, the device bore the CE marking, to indicate that it conformed to the essential requirements of Directive 93/42.

18 In 1996, the German authorities sent Broncho-Air Medizintechnik a draft decision intending to prohibit the distribution of the Inhaler device. In the draft, the authorities explained that, due to the absence of an exhaustive clinical evaluation, they had some doubts over the conformity of the device with the essential requirements under Directive 93/42. They also expressed their intention to proceed to a withdrawal of all instances of the device already in circulation.

19 Following a conversation with the German authorities, Broncho-Air Medizintechnik sent them a letter on 22 May 1997, informing them that the Inhaler device had not been placed on the market since 1 January 1997 and that its distribution would be 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.

20 On 23 September 1997, the German authorities nevertheless took the decision to prohibit the placing on the market of the Inhaler device. In that decision, the German authorities remarked, in essence, that, in the opinion of the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal institute for medicines and medical devices, the 'BfArM'), the medical device in question did not satisfy the essential requirements of Annex I to Directive 93/42 in that its safety had not been sufficiently established in a scientific manner in the light of information supplied by the manufacturer.

21 On 7 January 1998, the German authorities sent the Commission of the European Communities a letter headed 'Safeguard clause procedure under Article 8 of Directive 93/42/EEC relating to inhalation device … "Inhaler Broncho Air"', in which it informed the Commission of its prohibition decision and of the grounds for such a decision.

22 Following notification by the German authorities, the Commission did not take any decision.

Decision to ban the effecto device

23 From 2002 onwards, the applicant's inhalation-assistance device was exclusively distributed by atmed under the name 'effecto®' ('the effecto device'). In 2003, atmed also took on its manufacture. When it was placed on the German market, this device bore the CE marking, indicating that it conformed to the essential requirements of Directive 93/42.

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

25 On 16 January and 17 August 2006, atmed contacted the Commission to complain that the German authorities had not informed the Commission of their decision to prohibit the placing on the market of the effecto device. It said that a safeguard clause procedure should be initiated under Article 8 of Directive 93/42.

26 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.

27 On 12 December 2006, the Federal Republic of Germany explained to the Commission that it believed the procedure commenced in 1998 in respect of the Inhaler device constituted a safeguard clause procedure as referred to in the said provision and that a new procedure, for the same device under another name, was not justified. Moreover, the German authorities informed the Commission of their continuing doubts about the conformity of the effecto device with the essential requirements under Directive 93/42 and, therefore, asked the Commission to confirm their prohibition decision.

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

29 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.

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

31 On 18 July 2007, the Commission informed the German authorities it had concluded this was a case of a wrongly affixed CE marking and therefore needed to be dealt with under Article 18 of Directive 93/42. In this regard, the Commission queried the fact that the effecto device could not fulfil the essential requirements provided for in the 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 applicant with a copy of its letter to the German authorities in this regard.

32 In 2008, the applicant presented a petition to the European Parliament concerning the failure of the Commission to take sufficient action in his case and the harmful impact of this on the company concerned.

33 On 12 January 2011, Parliament adopted Resolution B7-0026/2011.

34 On 9 March 2011, the applicant asked the Commission to pay compensation of EUR 170 million to atmed AG and EUR 130 million to himself.

35 On 11 March 2011, the Commission rejected the applicant's claim for compensation.

Procedure and forms of order sought

36 By a document lodged at the Court Registry on 27 July 2010, the applicant applied to the Court for legal aid pursuant to Articles 94 and 95 of the Rules of Procedure of the General Court, prior to bringing a claim for compensation.

37 By order of the President of the Court dated 13 September 2010, the Court allowed the application.

38 By a document lodged at the Court Registry on 2 May 2011, the applicant applied to the Court for further legal aid pursuant to Articles 94 and 95 of the Rules of Procedure.

39 By order of the President of the Court dated 9 June 2011, the Court rejected that application.

40 By an application lodged at the Court Registry on 15 September 2011, the applicant brought this action.

41 By a document lodged at the Court Registry on 12 January 2012, the Federal Republic of Germany sought leave to intervene in support of the Commission. By order of 19 April 2012, the President of the Seventh Chamber of the Court granted leave to intervene. The Federal Republic of Germany submitted its statement in intervention on 4 June 2012.

42 Following changes to the composition of the Chambers of the General Court, the Judge-Rapporteur was assigned to the First Chamber, to which the present case has therefore been allocated.

43 On hearing the report of the Judge-Rapporteur, the General Court (First Chamber) decided to invite the parties, by way of measures of organisation of procedure pursuant to Article 64 of its Rules of Procedure, to reply in writing to some questions. The parties complied with that request within the prescribed period.

44 At the hearing on 18 June 2013 the parties presented oral argument and replied to the questions put by the Court.

45 The applicant claims that the Court should:

— order that the Commission, by failing to act in the safeguard clause procedure commenced in 1998 for the disputed medical devices and by not initiating a safeguard clause under Article 8 of Directive 93/42 after the German authorities had decided to prohibit distribution, breached the obligations incumbent upon it under Directive 93/42 and Union law, and thus directly caused damage to the applicant;

— order the Commission to compensate for the damage, as yet to be determined, that has been caused to the applicant;

— order the Commission to pay the costs.

46 The Commission contends that the Court should:

— reject the application as inadmissible in so far as it relates to damage allegedly suffered prior to 29 July 2006, and in any event as unfounded;

— order the applicant to pay the costs.

47 The Federal Republic of Germany supports the Commission's claim that the compensation claim be rejected as unfounded and its claim that the applicant be ordered to pay the costs.

Law

Admissibility

48 The Commission considers that the rights to damages claimed by the applicant are partially time-barred under Article 46 of the Statute of the Court of Justice of the European Union.

49 The applicant disputes the Commission's claims.

50 It should be noted that, pursuant to Article 46 of the Statute of the Court, which applies to the procedure before the General Court, in accordance with the first paragraph of Article 53 of that Statute, proceedings against the Union in matters arising from non-contractual liability shall be barred after a period of five years from the occurrence of the event giving rise thereto. The period of limitation shall be interrupted if proceedings are instituted before the Court or if prior to such proceedings an application is made by the aggrieved party to the relevant institution of the Union. In the latter event, the proceedings must be instituted within the period of two months provided for in Article 263 TFEU.

51 According to settled case-law, the period of limitation cannot begin until all the requirements governing an obligation to provide compensation for damage are satisfied and, in particular, once the damage to be made good has materialised (Case C-282/05 P *Holcim (Deutschland)* v *Commission* [2007] ECR I-2941, at paragraphs 29 and 30, and order of 1 April 2009 in Case T-280/08 *Perry* v *Commission*, not published in the ECR, at paragraph 36).

52 In addition, in a case of continuing damage, the limitation period referred to in Article 46 of the Statute of the Court applies, by reference to the date of the event which interrupted the limitation period, to the period preceding that date by more than five years and does not affect any rights arising during subsequent periods (Case T-369/03 *Arizona Chemical and Others* v *Commission* [2005] ECR II-5839, at paragraph 116, and order of 10 April 2008 in Case T-336/06 *2K-Teint and Others* v *Commission and EIB*, not published in the ECR, at paragraph 106).

53 In the present case, the file shows that the applicant made a prior request to the Commission for compensation for the damage caused to him. That request, presented on 9 March 2011, cannot be considered to constitute an action interrupting the limitation period for the purposes of Article 46 of the Statute of the Court on the ground that it was not followed by the bringing of an application in the subsequent two months as required by the said provision. In the circumstances, only the application lodged in this matter on 15 September 2011 can be considered as constituting an action interrupting the limitation period.

54 In the light of the above, this claim, on the assumption of continued damage, must in any event be dismissed as inadmissible in so far as it relates to damage allegedly suffered before 15 September 2006.

Substance

Introductory observations

55 Pursuant to the second paragraph of Article 340 TFEU, in the case of non-contractual liability, the Union shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties.

56 It is settled case-law that in order for the Union to incur non-contractual liability under the second paragraph of Article 340 TFEU for unlawful conduct of its institutions, a number of cumulative conditions must be satisfied: the institution's conduct must be unlawful, actual damage must have been suffered and there must be a causal link between the alleged conduct and the damage pleaded (Case 26/81 *Oleifici Mediterranei* v *EEC* [1982] ECR 3057, at paragraph 16, and Case T-383/00 *Beamglow* v *Parliament and Others* [2005] ECR II-5459, at paragraph 95).

57 First of all, as regards the condition relating to the unlawfulness of the alleged conduct of the institution or body concerned, case-law requires there to be established a sufficiently serious breach of a rule of law intended to confer rights on individuals (Case C-352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I-5291, at paragraph 42). In relation to the requirement for the breach to be sufficiently serious, the decisive criterion for establishing this is whether the Union institution or body in question manifestly and gravely disregarded the limits on its discretion. Where that institution or body only possesses a considerably reduced discretion, or even none at all, the mere infringement of Union law may be sufficient to establish the existence of a sufficiently serious breach (Case C-312/00 P *Commission* v *Camar and Tico* [2002] ECR I-11355, at paragraph 54, and Joined Cases T-198/95, T-171/96, T-230/97, T-174/98 and T-225/99 *Comafrica and Dole Fresh Fruit Europe* v *Commission* [2001] ECR II-1975, at paragraph 134).

58 Next, as regards the condition relating to actual damage being suffered, the Union's liability only arises if the applicant has actually suffered real and certain loss (Case T-108/94 *Candiotte* v *Council* [1996] ECR II-87, at paragraph 54). It is for the applicant to produce to the Court the evidence to establish the fact and the extent of such loss (Case 26/74 *Roquette frères* v *Commission* [1976] ECR 677, at paragraphs 22 to 24, and Case T-575/93 *Koelman* v *Commission* [1996] ECR II-1, at paragraph 97).

59 Lastly, as regards the condition that there be a causal link between the alleged conduct and the loss pleaded, the said loss must be a sufficiently direct consequence of the conduct complained of, which must be the determinant cause of the loss, whereas there is no obligation to compensate for every harmful consequence, even a remote one, of an unlawful situation (Joined Cases 64/76, 113/76, 167/78, 239/78, 27/79, 28/79 and 45/79 *Dumortier and Others* v *Council* [1979] ECR 3091, at paragraph 21, and Case T-279/03 *Galileo International Technology and Others* v *Commission* [2006] ECR II-1291, at paragraph 130 and the case-law cited). It is for the applicant to adduce evidence of a causal link between the conduct complained of and the loss pleaded (Case T-149/96 *Coldiretti and Others* v *Council and Commission* [1998] ECR II-3841, at paragraph 101 and the case-law cited).

60 If any one of the three conditions required for the Union to incur non-contractual liability is not satisfied, the damages claims must be dismissed without there being any further need to consider whether the other two conditions are met (see, in this regard, Case C-146/91 *KYDEP* v *Council and Commission* [1994] ECR I-4199, at paragraph 81, and Case T-170/00 *Förde-Reederei* v *Council and*

Commission [2002] ECR II-515, at paragraph 37). Furthermore, the Court is not obliged to examine those conditions in any particular order (Case C-257/98 P *Lucaccioni* v *Commission* [1999] ECR I-5251, at paragraph 13).

61 In the present case, the applicant maintains that the three conditions required for the Union to incur non-contractual responsibility are satisfied. The Court considers it appropriate to examine, firstly, the existence of unlawful conduct alleged on the part of the Commission, secondly, the existence of the alleged loss, and, lastly, the existence of a causal link between the two preceding elements.

Unlawful conduct

62 The applicant pleads, in substance, that the Commission breached the obligations incumbent upon it under Article 8 of Directive 93/42. Firstly, he alleges that the Commission did not take a decision following receipt of the letter of 7 January 1998 relating to the prohibition on placing the Inhaler device on the market. Secondly, he maintains that the Commission should have initiated a safeguard clause procedure as soon as it was made aware of the decision to prohibit placing the effecto device on the market, taken on 18 May 2005. Thirdly, the applicant maintains that the two failings on the part of the Commission breach the Charter of Fundamental Rights of the European Union.

– Ban on the Inhaler device

63 In relation to the prohibition decision on the Inhaler device, the applicant notes that the German authorities, by a letter of 7 January 1998, initiated a safeguard clause procedure, but that the Commission never concluded this by means of a definitive decision. The applicant alleges that this constitutes a failure to act contrary to Directive 93/42 since, according to Article 8(2) of that directive, when the Commission receives a national decision prohibiting the placing on the market of a medical device, it must take a decision determining whether or not such a measure is justified. In addition, under Article 8(4) of Directive 93/42, the Commission should have communicated its decision to the Member State as well as to the parties affected by the said procedure.

64 The Commission rejects those claims.

65 As a preliminary observation, the Court observes that the aim of Directive 93/42, as stated in its third recital, is the harmonisation of provisions for safety and health protection with regard to the use of medical devices, in order to guarantee the free movement of such devices within the internal market (Case C-288/08 *Nordiska Dental* [2009] ECR I-11031, at paragraph 19). Directive 93/42 therefore aims to reconcile the aim of protecting patients' health with the principle of free movement of goods (Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557, at paragraph 52, and judgment of 22 November 2012 in Case C-219/11 *Brain Products*, not published in the ECR, at paragraph 28).

66 Pursuant to Article 2 of Directive 93/42, medical devices within its scope may be placed on the market only if they satisfy the requirements set out in the directive. Under Article 3 of Directive 93/42, this essentially means that the medical devices must meet the essential requirements listed in Annex I.

67 Furthermore, Article 4 of Directive 93/42 provides that Member States shall not create any obstacle, within their territory, to the placing on the market or putting into service of medical devices meeting the essential requirements set out in the directive and bearing the CE marking in accordance with Article 17(1) of the directive. Once those devices comply with the harmonised standards and are certified in accordance with the procedures provided for by that directive, they must be presumed to comply with those essential requirements and therefore be deemed to be appropriate for the use for which they are intended. In addition, these medical devices must benefit from free movement within the Union (*Medipac-Kazantzidis*, at paragraph 42, and *Nordiska Dental*, at paragraph 22).

68 The presumption of compliance of medical devices can, however, be rebutted (*Medipac-Kazantzidis*, at paragraph 44, and *Nordiska Dental*, at paragraph 23).

69 In particular, Article 8(1) of Directive 93/42 requires Member States which have found there to be risks linked to medical devices which have been certified as compliant with that directive to take all appropriate interim measures to withdraw those medical devices from the market or prohibit or restrict their being placed on the market or put into service. In those circumstances, the Member State concerned is required by that same provision to notify the Commission immediately of the measures taken, indicating in particular the reasons for the measures. Under Article 8(2) of Directive 93/42, the Commission, in turn, is required to examine whether these interim measures are justified and, if so, to immediately notify the Member State which initiated the measures, as well as the other Member States (*Medipac-Kazantzidis*, at paragraph 46, and *Nordiska Dental*, at paragraph 24).

70 Article 8(3) of Directive 93/42 provides that, should it transpire that a medical device bearing the CE marking is not in fact compliant with the essential requirements provided in the directive, the Member State in question must take appropriate measures and must inform the Commission and the other Member States thereof. Meanwhile, under Article 18 of Directive 93/42, where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorised representative established within the Union is obliged to end the infringement under conditions imposed by that Member State (*Medipac-Kazantzidis*, at paragraph 47).

71 In the present case, the parties agree that the Commission did not take any decision after receiving the letter of 7 January 1998 relating to the prohibition on placing the Inhaler device on the market. However, the parties disagree over the Commission's duty on receipt of that letter. Whilst the applicant maintains that the letter of 7 January 1998 constituted a safeguard clause notification as referred to in Article 8(2) of Directive 93/42 and that the Commission should therefore have taken a decision under that provision, the Commission considers, to the contrary, that the said letter merely notified it of a case of a wrongly affixed CE marking under Article 18 of Directive 93/42 and that, consequently, in view of Article 8(3) of the same directive, it had no obligation to act.

72 In this regard, the Court notes, firstly, that the applicant does not dispute that the Inhaler device was a medical device within the meaning of Article 1 of Directive 93/42 and therefore subject to the provisions of that directive, nor that, in order to be placed on the market, it needed to satisfy the essential requirements laid down in Annex I. The applicant also admits that the said device had initially been placed on the market bearing the CE marking, to indicate that it conformed to the provisions of Directive 93/42.

73 Secondly, during the hearing, the Commission stated, and the applicant did not dispute, that the Inhaler device was a Class I medical device within the meaning of Article 9 and of Annex IX to Directive 93/42. In this regard, it should be noted that, pursuant to Article 11(5) of Directive 93/42, for Class I devices, it is the responsibility of the manufacturer of the medical device to ensure, on his own account, that the said device conforms with the essential requirements of Directive 93/42 in order that the CE marking can be affixed before it is placed on the market. Meanwhile, in accordance with the procedure set out in Annex VII, in addition to an EC declaration of conformity ensuring and declaring the conformity of the device to the essential requirements, the manufacturer is supposed to make available to the national authorities for inspection purposes the technical documentation enabling this conformity to be proven. In particular, the technical documentation includes a risk analysis and the clinical data to be carried out in accordance with Annex X to Directive 93/42 together with the label and instructions for use.

74 Lastly, by letter of 7 January 1998, the Federal Republic of Germany informed the Commission, as the German authorities had already declared in their draft decision in 1996 and their decision of 23 September 1997 (see paragraphs 18 and 20 above), that the manufacturer of the Inhaler device had not been in a position to provide clinical data to establish the safety and guaranteed efficiency of the

device for the purposes of the essential requirements of Directive 93/42. In particular, the said authorities, basing their opinion on the BfArM's advice, claimed that the information provided by the manufacturer about the said device was not sufficient to eliminate doubt over any danger posed by the inhaler, nor to prove that the essential requirements in paragraphs 1 and 3 of Annex I to Directive 93/42 were met. In addition, the German authorities informed the Commission that the information supposed to accompany the medical device to enable its correct and safe use in accordance with paragraph 13.6 of Annex I to Directive 93/42 was missing.

75 The German authorities were therefore faced with a case of the CE marking being wrongly affixed by the manufacturer to the Inhaler device since, in essence, verification of conformity of the said device with the essential requirements had not been carried out in accordance with Directive 93/42 and, in particular, had not complied with Annex VII or Annex X of that directive. In this respect, it should be noted that the distribution company itself had acknowledged, in the letter it sent to the German authorities on 22 May 1997 (see paragraph 19 above), the need to carry out further trials and studies on the conformity of the medical device with Directive 93/42.

76 In the circumstances, the letter addressed by the German authorities to the Commission on 7 January 1998 can only be considered as being intended to inform the Commission of a decision to prohibit placing on the market taken in accordance with Article 18 of Directive 93/42.

77 Further, in so far as Article 8(3) of Directive 93/42 establishes only an obligation on the Member State to inform the Commission of a prohibition decision, and not an obligation on the Commission to act (see also the case-law cited at paragraph 70 above), it must be held that the Commission did not have to take any decision following receipt of the said letter.

78 The findings above are not affected by the fact that the letter of 7 January 1998 referred, in its heading, to the safeguard clause procedure provided for in Article 8 of Directive 93/42.

79 In this regard it should be borne in mind that, in accordance with settled case-law, the legal effect of any administrative act must always be examined in terms of its substance rather than its formal appearance (in this regard, see Case 60/81 *IBM* v *Commission* [1981] ECR 2639, at paragraph 9, and Case T-160/98 *Van Parys and Pacific Fruit Company* v *Commission* [2002] ECR II-233, at paragraph 60).

80 In the present case, the fact that the heading on the letter of 7 January 1998 referred to the safeguard clause procedure under Article 8 of Directive 93/42 does not invalidate the finding that the said letter, in view of its content and the fact that it was based on the prohibition decision of 23 September 1997, notified the Commission of a case of unduly affixed CE marking, so that no obligation to take a decision could arise on the part of the Commission under Article 8(2) of Directive 93/42. Furthermore, it should be noted that, during the hearing, the German authorities acknowledged, in response to a question posed by the Court, that the heading of the letter of 7 January 1998 was incorrect and that this error was due to the fact that the decision relating to the Inhaler device was one of the first decisions that the said authorities had taken in the context of Directive 93/42.

81 The applicant also maintains that the requirement for the Commission to take a definitive decision under Article 8(2) of Directive 93/42 rests on the fact that any manufacturer affected by a prohibition decision must be able to know whether or not a decision by national authorities to impose a prohibition on placing on the market is justified. In essence, he considers that, in the absence of intervention by the Commission, the right to free movement of medical devices advocated by Directive 93/42 would be rendered worthless.

82 However, the Court finds that Directive 93/42 provides that it is for national courts to verify the legality of prohibition decisions on placing on the market taken by the national authorities in this connection. Article 19 of Directive 93/42 provides that any decision taken by the national authorities

pursuant to that directive, amounting to a refusal or restriction on placing on the market or a withdrawal of devices from the market, must be notified to the interested party, clearly indicating the legal remedies available according to the national law in force in the Member State in question and the time-limits in which these remedies need to be applied for. In the present case, it is apparent from the letter of 23 September 1997 that the German authorities notified the applicant of the remedies available to him in order to challenge the decision of the said authorities. In addition, the applicant states in his documents that he appealed to the competent national German authority to challenge the legality of the prohibition decision on the Inhaler device.

83 Finally, the applicant asserts that, in the present case, the obligation on the Commission to take a decision under Article 8(2) of Directive 93/42 arises from the principle of good government as described firstly in the White Paper on European Governance (OJ 2001 C 287, p. 1, 'the White Paper') and secondly in the Commission's *Guide to the implementation of directives based on the New Approach and the Global Approach* ('the Guide').

84 In this regard, firstly, it is important to remember that the White Paper is only a document containing proposed actions of the Union in a specific field. Generally speaking, a white paper is often the extension to a green paper, the aim of which is to initiate a consultation process at European level. It is therefore a communication intended to launch political debate and not to create obligations on the part of the Commission in a case such as the present one.

85 Secondly, aside from the fact that the Guide cannot constitute the legal basis for an obligation on the part of the Commission as is alleged by the applicant, the Guide states that the actions to be undertaken by the national authorities and by the Commission, in the context of a breach of the provisions of a so-called New Approach directive such as Directive 93/42, must be decided on a case by case basis, depending on the type of non-compliance established. In particular, the Guide states that cases, such as the present one, where the obligation to make available to the competent authorities the information required by the directive, such as technical documentation or clinical data, has been insufficiently complied with, are examples of 'non-substantial non-compliance'. In such cases, the national authorities must oblige the manufacturer to end the infringement, restrict or prohibit the placing on the market of the product in question and, if necessary, ensure that the said product is also withdrawn from the market. Cases of 'non-substantial non-compliance', as opposed to those arising from a 'substantial non-compliance', also covered by the Guide, do not justify invoking the safeguard clause procedure provided for in Article 8(2) of Directive 93/42 (see paragraph 8.2.2 of the Guide, headed 'Corrective actions').

86 In the light of the foregoing, it must be concluded that, contrary to the applicant's assertions, and although it is regrettable that the Commission made no reaction to being informed by the German authorities of their prohibition decision on the Inhaler device, no illegal conduct by the Commission can be deduced from the fact that it did not take a decision under Article 8(2) of Directive 93/42 following the said notification.

– Ban on effecto device

87 In relation to the prohibition decision on the effecto device, the applicant essentially raises two heads of claim. The first is that the Commission should have taken a decision under Article 8(2) of Directive 93/42, despite there being no formal notification on the part of the German authorities. In this regard, the applicant considers that the Commission should have acted at the moment when it became aware of the existence of a prohibition decision on the effecto device. The second head of claim is that the Commission should at the very least have taken infringement proceedings against the Federal Republic of Germany to oblige it to communicate the said prohibition decision.

88 The Commission rejects those claims.

89 In relation to the first head of claim, alleging that the Commission should, of its own initiative, have commenced a safeguard clause procedure in relation to the effecto device, it must firstly be held, as is the Commission's view, that this is a misinterpretation of the division of powers between the Commission and the Member States established by Directive 93/42. Pursuant to Article 8(1) of that directive, it is for Member States to take necessary measures so that medical devices cannot be placed on the market if they compromise the safety and health of patients. In these circumstances, the directive provides for a system in which market surveillance falls to the national authorities and not the Commission. In addition, according to Article 8 of Directive 93/42, initiating a safeguard clause procedure falls entirely within the remit of the Member States, so that they are the only ones who can commence the said procedure. In this regard, it must be held that Article 8 of Directive 93/42 does not provide for the Commission, of its own initiative, to inform Member States of its findings in relation to national measures.

90 Next, the applicant claims that any solution other than an obligation on the Commission to automatically commence a safeguard clause procedure in a case such as this one would not be effective. In this regard, it need only be reiterated that, in accordance with the principle of division of powers enshrined in Article 5(2) of the TEU, the Union shall only act within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. In the present case, the Commission could not act outside the competences thus established by Directive 93/42 and cannot be criticised for that on the grounds of effectiveness.

91 Finally, in relation to the applicant's assertion that the Commission failed in its obligation by not acting when it became aware of the prohibition decision on the effecto device, this has no factual basis.

92 Firstly, the e-mail of 16 January 2006 which, according to the applicant, should have provided a basis for the Commission to take action, contained only abstract questions, with no concrete reference to the prohibition decision of 18 May 2005. The Commission was not in a position to know, in the light of the content of this e-mail, that the German authorities had taken a prohibition decision on the medical device in question. Secondly, as soon as the Commission became aware of the prohibition decision on the effecto device, via further information from the applicant, it initiated a series of steps to establish whether or not the German authorities' prohibition decision was justified. In particular, the Commission firstly approached the said authorities to ask why it was that they had not proceeded to communicate the prohibition decision under Article 8(1) of Directive 93/42. Secondly, the Commission expressed its intention to examine the German decision on the basis of Article 18 of Directive 93/42 in order to avoid a new notification. Furthermore, the Commission regularly kept the applicant informed of the responses received from the German authorities to the questions posed by the Commission as well as of its own actions (see paragraphs 26 to 31 above).

93 The first head of claim must, therefore, be rejected.

94 In relation to the second head of claim, in which the applicant bases his claim for damages on the fact that the Commission did not initiate an infringement procedure against the Federal Republic of Germany in accordance with Article 226 EC, it is sufficient to observe that, according to settled case-law, the Commission has discretion over whether or not to initiate an infringement procedure (Case 247/87 *Star Fruit* v *Commission* [1989] ECR 291, at paragraph 11, and Case T-47/96 *SDDDA* v *Commission* [1996] ECR II-1559, at paragraph 42). Despite the invitation to the Commission to commence an infringement procedure, this Court finds that the Commission was not obliged to start such a procedure, so that failure to do so does not constitute a breach of a rule of EU law.

95 The second head of claim must, therefore, be dismissed.

96 It follows that, contrary to the applicant's assertions, no illegal conduct on the part of the Commission can be deduced from the fact that it did not commence a safeguard clause procedure under Article 8(2) of Directive 93/42 or that it did not initiate a procedure under Article 226 EC at the time of becoming aware of the German authorities' prohibition decision on the effecto device in 2005.

– Breach of Charter of Fundamental Rights

97 In his Reply, the applicant accuses the Commission of having breached his fundamental rights as set out in the Charter of Fundamental Rights. In essence, he considers that the Commission's failure, together with the inability to market his medical devices, amounts to a breach of freedom to choose an occupation, freedom to conduct a business and right to property as set out in Articles 15, 16 and 17 respectively of the said charter.

98 The Court notes that, under the first paragraph of Article 48(2) of the Rules of Procedure, no new plea in law may be introduced in the course of the proceedings unless it is based on matters of law or of fact which come to light in the course of the procedure.

99 In the present case, it should be noted that the applicant's allegations in relation to a breach of fundamental rights were made for the first time at the time of the reply and are not based on matters of law or of fact that came to light during the procedure. Neither do they constitute the amplification of a ground advanced previously by the applicant.

100 Therefore, the applicant's claims must be rejected as being inadmissible.

– Conclusion on unlawful conduct

101 It is apparent from paragraphs 62 to 100 above that the applicant has not shown that the Commission failed in its obligations under Article 8 of Directive 93/42, nor that it breached another rule of law of the Union as referred to in the case-law cited in paragraph 57 above. Consequently, no unlawful conduct can be found in the present case.

Damage and causal link

102 In accordance with the case-law cited at paragraph 60 above, the conditions required for the Union to incur non-contractual liability are cumulative. The absence of one of the said conditions is therefore sufficient to conclude that the said liability does not exist.

103 In the present case, as is apparent from paragraph 101 above, the applicant has not shown that the condition relating to actual unlawful conduct on the part of the Commission was satisfied.

104 Therefore, the applicant's damages claim for the loss allegedly suffered by reason of the prohibition on placing the Inhaler and effecto devices on the market in 1998 and 2005 respectively must, to the extent that it is not time-barred, in any case be rejected as being unfounded without there being any need to examine whether the other two conditions for liability are met in this case.

105 In the light of all the foregoing, the application must therefore be dismissed in its entirety.

Costs

106 Under Article 87(2) of the Rules of Procedure, an unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful in the entirety of his claim and the Commission has applied for costs, the applicant must be ordered to bear his own costs and to pay those of the Commission.

107 Under the first subparagraph of Article 87(4) of the Rules of Procedure, Member States which have intervened in the proceedings are to bear their own costs. The Federal Republic of Germany must therefore be ordered to bear its own costs.

On those grounds,

THE GENERAL COURT (First Chamber)

hereby:

1. Dismisses the action;

2. Orders Mr Christoph Klein to bear his own costs and pay those incurred by the European Commission;

3. Orders the Federal Republic of Germany to bear its own costs.

Frimodt Nielsen Kancheva Buttigieg

Delivered in open court in Luxembourg on 21 January 2014.

[Signatures]