



Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

11 January 2024*

(Reference for a preliminary ruling – Intellectual and industrial property – Medicinal product for human use – Supplementary protection certificate (SPC) – Directive 2004/48/EC – Article 9(7) – Placing on the market of products infringing SPC rights – Provisional measures ordered on the basis of an SPC – Subsequent invalidity of the SPC and revocation of the measures – Consequences – Right to appropriate compensation for losses caused by the provisional measures – Liability of the applicant for those measures for losses caused by them – National legislation providing for strict liability)

In Case C-473/22,

REQUEST for a preliminary ruling under Article 267 TFEU from the markkinaoikeus (Market Court, Finland), made by decision of 14 July 2022, received at the Court on 14 July 2022, in the proceedings

Mylan AB

v

Gilead Sciences Finland Oy,

Gilead Biopharmaceutics Ireland UC,

Gilead Sciences Inc.,

THE COURT (Third Chamber),

composed of K. Jürimäe (Rapporteur), President of the Chamber, N. Piçarra, M. Safjan, N. Jääskinen and M. Gavalec, Judges,

Advocate General: M. Szpunar,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Mylan AB, by A. Jäälinoja and B. Rapinoja, asianajajat,

* Language of the case: Finnish.

- Gilead Sciences Finland Oy, Gilead Biopharmaceutics Ireland UC and Gilead Sciences Inc., by R. Hilli and M. Segercrantz, asianajajat,
- the Finnish Government, by M. Pere, acting as Agent,
- the Netherlands Government, by M.K. Bulterman and J.M. Hoogveld, acting as Agents,
- the European Commission, by S.L. Kalèda, P.-J. Loewenthal, J. Ringborg, J. Samnadda and I. Söderlund, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 21 September 2023,

gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of Article 9(7) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ 2004 L 157, p. 45, and corrigendum OJ 2004 L 195, p. 16).
- 2 The request has been made in proceedings between Mylan AB, on the one hand, and Gilead Sciences Finland Oy, Gilead Biopharmaceutics Ireland UC and Gilead Sciences Inc. (together, ‘Gilead and Others’), on the other hand, concerning compensation for losses suffered by Mylan as a result of a provisional measure adopted with regard to it upon the application of Gilead and Others, which was subsequently revoked.

Legal context

International law

- 3 The first paragraph of the preamble to the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘the TRIPS Agreement’), which constitutes Annex 1C to the Agreement establishing the World Trade Organization (WTO), signed in Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), is worded as follows:

‘Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade’.

- 4 Article 1(1) of the TRIPS Agreement, entitled ‘Nature and Scope of Obligations’, provides:

‘Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to

determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’

5 Article 50 of that agreement, entitled ‘Provisional measures’, provides in paragraph 7:

‘Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.’

European Union law

6 Recitals 4, 5, 7, 8, 10 and 22 of Directive 2004/48 state:

‘(4) At international level, all Member States, as well as the [European] Community itself as regards matters within its competence, are bound by [the TRIPS Agreement].

(5) The TRIPS Agreement contains, in particular, provisions on the means of enforcing intellectual property rights, which are common standards applicable at international level and implemented in all Member States. This Directive should not affect Member States’ international obligations, including those under the TRIPS Agreement.

...

(7) It emerges from the consultations held by the [European] Commission on this question that, in the Member States, and despite the TRIPS Agreement, there are still major disparities as regards the means of enforcing intellectual property rights. For instance, the arrangements for applying provisional measures, which are used in particular to preserve evidence, the calculation of damages, or the arrangements for applying injunctions, vary widely from one Member State to another. ...

(8) The disparities between the systems of the Member States as regards the means of enforcing intellectual property rights are prejudicial to the proper functioning of the Internal Market and make it impossible to ensure that intellectual property rights enjoy an equivalent level of protection throughout the Community. ...

...

(10) The objective of this Directive is to approximate legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market.

...

(22) It is also essential to provide for provisional measures for the immediate termination of infringements, without awaiting a decision on the substance of the case, while observing the rights of the defence, ensuring the proportionality of the provisional measures as appropriate to the characteristics of the case in question and providing the guarantees

needed to cover the costs and the injury caused to the defendant by an unjustified request. Such measures are particularly justified where any delay would cause irreparable harm to the holder of an intellectual property right.’

7 Article 1 of that directive provides:

‘This Directive concerns the measures, procedures and remedies necessary to ensure the enforcement of intellectual property rights. For the purposes of this Directive, the term ‘intellectual property rights’ includes industrial property rights.’

8 Article 2 of that directive, entitled ‘Scope’, provides, in paragraph 3 thereof:

‘This Directive shall not affect:

...

(b) Member States’ international obligations and notably the TRIPS Agreement, including those relating to criminal procedures and penalties;

...’

9 Chapter II of Directive 2004/48, entitled ‘Measures, procedures and remedies’, contains Articles 3 to 15 of that directive. Article 3 of that directive, entitled ‘General obligation’, provides:

‘1. Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays.

2. Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.’

10 Article 7 of that directive, entitled ‘Measures for preserving evidence’, is worded as follows:

‘1. Member States shall ensure that, even before the commencement of proceedings on the merits of the case, the competent judicial authorities may, on application by a party who has presented reasonably available evidence to support his/her claims that his/her intellectual property right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information. Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto. Those measures shall be taken, if necessary without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the rightholder or where there is a demonstrable risk of evidence being destroyed.

...

4. Where the measures to preserve evidence are revoked, or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures.

...'

11 Article 9 of that directive, entitled 'Provisional and precautionary measures', provides:

'1. Member States shall ensure that the judicial authorities may, at the request of the applicant:

(a) issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right, or to forbid, on a provisional basis and subject, where appropriate, to a recurring penalty payment where provided for by national law, the continuation of the alleged infringements of that right, or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the rightholder; an interlocutory injunction may also be issued, under the same conditions, against an intermediary whose services are being used by a third party to infringe an intellectual property right; injunctions against intermediaries whose services are used by a third party to infringe a copyright or a related right are covered by Directive 2001/29/EC [of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (O) 2001 L 167, p. 10)];

(b) order the seizure or delivery up of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce.

2. In the case of an infringement committed on a commercial scale, the Member States shall ensure that, if the injured party demonstrates circumstances likely to endanger the recovery of damages, the judicial authorities may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of his/her bank accounts and other assets. To that end, the competent authorities may order the communication of bank, financial or commercial documents, or appropriate access to the relevant information.

3. The judicial authorities shall, in respect of the measures referred to in paragraphs 1 and 2, have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the rightholder and that the applicant's right is being infringed, or that such infringement is imminent.

4. Member States shall ensure that the provisional measures referred to in paragraphs 1 and 2 may, in appropriate cases, be taken without the defendant having been heard, in particular where any delay would cause irreparable harm to the rightholder. In that event, the parties shall be so informed without delay after the execution of the measures at the latest.

A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable time after notification of the measures, whether those measures shall be modified, revoked or confirmed.

5. Member States shall ensure that the provisional measures referred to in paragraphs 1 and 2 are revoked or otherwise cease to have effect, upon request of the defendant, if the applicant does not

institute, within a reasonable period, proceedings leading to a decision on the merits of the case before the competent judicial authority, the period to be determined by the judicial authority ordering the measures where the law of a Member State so permits or, in the absence of such determination, within a period not exceeding 20 working days or 31 calendar days, whichever is the longer.

6. The competent judicial authorities may make the provisional measures referred to in paragraphs 1 and 2 subject to the lodging by the applicant of adequate security or an equivalent assurance intended to ensure compensation for any prejudice suffered by the defendant as provided for in paragraph 7.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures.'

Finnish law

- 12 Chapter 7 of the oikeudenkäymiskaari (Code of Judicial Procedure) contains Paragraph 11 according to which, where a provisional measure has been obtained unnecessarily at the request of a party, that party must compensate the other party for the injury caused by that measure and its implementation, including the costs incurred.

The dispute in the main proceedings and the questions referred for a preliminary ruling

- 13 On 3 December 2009, the Patentti – ja rekisterihallitus (Patent and Registration Office, Finland) granted Gilead and Others, on the basis of European Patent No EP 0 915 894, designating the Republic of Finland, supplementary protection certificate No 266 'Tenofovir disoproxil (TD) and the salts, hydrates, tautomers and solvates thereof, in combination with emtricitabine' ('the SPC at issue') for an antiretroviral medicine indicated for the treatment of people with HIV.
- 14 In spring 2017, Mylan tendered for public contracts organised by two Finnish health districts in order to supply its generic medicine 'EMTRICITABINE/TENOFOVIR DISOPROXIL MYLAN 200 mg/245 mg, film-coated tablet' ('the generic medicine at issue'). The company won both tenders.
- 15 European patent No EP 0 915 894 expired on 25 July 2017.
- 16 On 15 September 2017, Gilead and Others brought an action before the markkinaoikeus (Market Court, Finland) for infringement of the SPC at issue. Gilead also filed an application for provisional measures against Mylan. Mylan opposed the infringement action and the application for provisional measures. On 30 November 2017, it also brought an action before that court seeking a declaration of invalidity of the SPC at issue.
- 17 By decision of 21 December 2017, the markkinaoikeus (Market Court) upheld Gilead and Others' application for provisional measures on the basis of the SPC at issue and prohibited Mylan, on pain of a fine of EUR 500 000, from offering, placing on the market and using the generic medicine at issue during the period of validity of the SPC at issue, and from importing, manufacturing and

possessing the generic medicine at issue for those purposes. Further, it ordered that those measures were to remain in force until a decision was delivered in the main proceedings or until further notice.

- 18 The abovementioned provisional measures were later revoked by order of the Korkein oikeus (Supreme Court, Finland) on 11 April 2019, at the request of Mylan.
- 19 By judgment of 25 September 2019, the markkinaoikeus (Market Court) found the SPC at issue to be invalid. An appeal against that judgment was lodged before the Korkein oikeus (Supreme Court), which, by order of 13 November 2020, refused Gilead and Others' request for leave to appeal, with the result that that judgment became final.
- 20 Under Paragraph 11 of Chapter 7 of the Code of Judicial Procedure, transposing Article 9(7) of Directive 2004/48 into Finnish law, Mylan then applied to the markkinaoikeus (Market Court), the referring court in the present case, for an order that Gilead and Others pay it compensation in the amount of EUR 2 367 854.99, plus default interest, as compensation for the injury caused by the provisional measures unnecessarily obtained on the basis of the SPC at issue, which was subsequently found to be invalid.
- 21 According to Mylan, the Court's interpretation of Article 9(7) in the judgment of 12 September 2019, *Bayer Pharma* (C-688/17, EU:C:2019:722; 'the judgment in *Bayer Pharma*'), does not support a finding that that directive precludes the application of the principle of strict liability, provided for by Finnish law. On the contrary, Gilead and Others maintain that the judgment in *Bayer Pharma* gave an interpretation of that provision which precludes an obligation to pay compensation being imposed solely because the SPC at issue, the infringement of which justified the adoption of the order for provisional measures, was subsequently found to be invalid.
- 22 The referring court recalls that, according to Finnish case-law and academic writing, Paragraph 11 of Chapter 7 of the Code of Judicial Procedure provides for liability without fault, that is to say strict liability. It follows that a person who obtains a provisional measure is liable to pay compensation if the intellectual property right on the basis of which the provisional measure was granted is subsequently found to be invalid.
- 23 That being so, the referring court notes that, according to settled Finnish case-law, including in the cases referred to in that provision, the amount of compensation may be reduced on the ground that the defendant himself or herself enabled the injury to occur or failed to take reasonable measures to avoid or mitigate the injury and thereby contributed to its occurrence.
- 24 In addition, the referring court points out that the principle of strict liability, as it appears in the Finnish legal system, is also taken into account when granting a provisional measure. According to that court, in order for such a measure to be granted, it is necessary to assess the likelihood of the intellectual property right on which that measure is based being declared invalid following a possible action seeking a declaration of invalidity. As regards the respective losses incurred, the loss caused to the subject of the order for the provisional measure, on the one hand, should be weighed against the loss that would be caused to the applicant if it were not granted.
- 25 However, in the light of the interpretation adopted by the Court in the judgment in *Bayer Pharma*, the referring court asks whether a system of compensation based on strict liability may be regarded as compatible with Article 9(7) of Directive 2004/48.

- 26 In that context the markkinaoikeus (Market Court) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:
- ‘(1) Is a compensation regime based on strict liability, such as that ... in force in Finland, to be regarded as compatible with Article 9(7) of [Directive 2004/48]?’
 - (2) If the first question is answered in the negative, what then is the nature of the liability for compensation on which the liability under Article 9(7) of [Directive 2004/48] is based? Is that liability to be regarded as a form of liability based on fault, an abuse of rights, or some other ground?
 - (3) In relation to the second question, what circumstances must be taken into account in assessing the existence of liability?
 - (4) In particular, as regards the third question, must the assessment be made solely on the basis of the circumstances known at the time when the provisional measure was obtained, or is it permissible to take into account, for example, the fact that the intellectual property right on whose alleged infringement the provisional measure was based was subsequently, after that measure was obtained, found to be invalid *ab initio* and, if so, what significance is to be attached to that circumstance?’

Consideration of the questions referred

The first question

- 27 By its first question, the referring court asks, in essence, whether Article 9(7) of Directive 2004/48 must be interpreted as precluding national legislation which provides for a mechanism for compensation for any injury caused by a provisional measure, within the meaning of that provision, based on a system of strict liability of the applicant for those measures, in the context of which the court is, however, entitled to adjust the amount of damages by taking into account the circumstances of the case, including whether the defendant played a part in the occurrence of the injury.
- 28 Article 9(1) and (2) of Directive 2004/48 provides that a holder of an intellectual property right may apply to the competent judicial authorities for the adoption of various provisional measures which are set out in that provision and which allow, inter alia, immediate termination of the infringement of that right, without awaiting a decision on the substance of the case. Those provisional measures must, however, as stated in recital 22 of that directive, be adopted while observing the rights of the defence, be proportionate in the light of the characteristics of the case in question and provide the guarantees needed to cover the costs and the injury caused to the defendant by an unjustified request.
- 29 In this regard, Article 9(7) of that directive provides that, where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities are to have the authority to order that applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures.

- 30 It is thus clear from the wording of that provision that it is for the judicial authority to which such an application has been made to examine whether the three conditions laid down in that provision are satisfied. First, it must ascertain whether the provisional measures have been revoked or have lapsed due to any act or omission by the applicant, or whether there has been no infringement or threat of infringement of that applicant's intellectual property right. Second, it must assess the existence of injury. Third, it must determine whether there is a causal link between that injury and those measures.
- 31 However, it should be noted that that provision does not mention among those conditions the existence of fault on the part of the applicant for provisional measures.
- 32 In order to determine whether Article 9(7) of Directive 2004/48 imposes on Member States a specific liability regime for an applicant for provisional measures, it is necessary to take into consideration the context of that provision, the objectives pursued by the legislation of which it forms part and the origin of that legislation.
- 33 In that regard, it must be recalled that, according to settled case-law, the provisions of that directive are not intended to govern all aspects of intellectual property rights, but only those aspects inherent, first, in the enforcement of those rights and, second, in infringement of them, by requiring that there must be effective legal remedies designed to prevent, terminate or rectify any infringement of an existing intellectual property right. In so doing, the EU legislature chose to provide for minimum harmonisation concerning the enforcement of intellectual property rights in general (see, to that effect, judgment of 28 April 2022, *Koch Media*, C-559/20, EU:C:2022:317, paragraphs 31 and 32 and the case-law cited).
- 34 As regards, more specifically, the right to compensation for the injury suffered by the defendant as a result of provisional measures, the wording of Article 9(7) of that directive corresponds, in essence, to that of Article 50(7) of the TRIPS Agreement. That agreement expressly provides, in Article 1(1), that the members of the World Trade Organisation are free to determine the appropriate method of implementing the provisions of that agreement within their own legal system and practice.
- 35 Thus, by reproducing, in Article 9(7) of Directive 2004/48, the very broad wording of Article 50(7) of the TRIPS Agreement, the EU legislature expressed its intention, first, not to harmonise the rules on compensation for defendants beyond what is required by that agreement and, second, to allow the Member States discretion as to the specific implementation of the rules governing the applicant's liability.
- 36 It follows that Article 9(7) of Directive 2004/48, read in the light of Article 50(7) of the TRIPS Agreement, must be interpreted as laying down a minimum standard concerning the enforcement of intellectual property rights while, in principle, leaving the Member States leeway to opt, as the case may be, for a strict liability regime or a fault-based liability regime.
- 37 It is true that, in the judgment in *Bayer Pharma*, the Court held that Article 9(7) of that directive did not preclude, in principle, national legislation refusing compensation to a defendant subject to provisional measures where that defendant had not acted as would generally be expected of any person seeking to avoid or mitigate his or her loss, even though the patent on the basis of which those measures had been granted was subsequently found to be invalid. The Court, however,

expressly stated that such legislation was compatible with that provision only if the court could take into account, in deciding whether to make such a refusal, all the circumstances of the case (see, to that effect, the judgment in *Bayer Pharma*, paragraph 71).

- 38 By contrast, it cannot be inferred from that judgment, in the light of the specific scenario to which the Court confined its reply in that judgment, that Article 9(7) of Directive 2004/48 provides for compensation to be paid to the defendant only in the event of fault on the part of the applicant for the provisional measures. As is apparent from paragraph 51 of the judgment in *Bayer Pharma*, the Court merely intended to remind the judicial authority that it is for it to assess the particular circumstances of the case before it in order to decide whether the applicant should be ordered to pay the defendant ‘appropriate’ compensation, that is to say, compensation justified in the light of those circumstances.
- 39 Although the power of the competent national courts to grant such compensation is strictly subject to the conditions set out in Article 9(7) of Directive 2004/48, the fact that those conditions are satisfied in a specific case does not mean that those courts are automatically and in any event obliged to order the applicant to provide compensation for any injury suffered by the defendant as a result of those measures (see, to that effect, the judgment in *Bayer Pharma*, paragraph 52).
- 40 It follows that, when the Member States transpose Article 9(7) of Directive 2004/48, they must take account of the requirement that the court must be able to take into account all the circumstances of the case before it, including the conduct of the parties (see, to that effect, the judgment in *Bayer Pharma*, paragraph 71), irrespective of the liability regime adopted.
- 41 The Member States’ leeway as regards that transposal is also subject to the requirements laid down in Article 3 of Directive 2004/48. The means provided for by those States to ensure that intellectual property rights are enforced under that directive must in particular, by virtue of Article 3, be equitable, proportionate and dissuasive and applied in such a manner as to avoid the creation of barriers to legitimate trade, the protection of which is, in accordance with the first paragraph of the preamble to the TRIPS Agreement, one of the objectives of that agreement, and to provide for safeguards against their abuse.
- 42 In order to determine whether a system of strict liability complies with the requirements of Article 3 of Directive 2004/48, it is necessary to place it in the context of the provisional measures provided for in Article 9 of that directive and to examine whether the system resulting from the combination thereof is equitable and proportionate and whether it does not create a barrier to legitimate trade while remaining dissuasive.
- 43 In the present case, it is apparent from the explanations provided by the referring court that, under the national legislation at issue in the main proceedings, an applicant that has obtained an unnecessary or unfounded provisional measure must compensate the defendant for the loss caused by the provisional measure and by its enforcement, as well as for the costs incurred in that regard. It is therefore not necessary, in the context of such legislation, for the applicant to be at fault in order to be held liable. It follows that any person who requests a provisional measure is required to pay damages to cover the injury caused by that measure if the intellectual property right on the basis of which that measure was granted is subsequently found to be invalid. That being so, according to national case-law, the amount of compensation may be reduced where the defendant himself or herself enabled the injury to occur or failed to take reasonable measures to avoid or mitigate the injury and thereby contributed to its occurrence.

- 44 As regards, first, the proportionality and equitable nature of a system of provisional measures incorporating a strict liability regime to ensure compensation for a defendant who has suffered loss caused by unjustified provisional measures, it should be noted that, by Directive 2004/48, the EU legislature provided for legal instruments which make it possible to mitigate comprehensively the risk that the defendant will suffer loss as a result of provisional measures, thereby ensuring protection of that defendant (see, to that effect, judgment of 28 April 2022, *Phoenix Contact*, C-44/21, EU:C:2022:309, paragraph 44). In so doing, the EU legislature sought to strike a balance between a high level of protection of intellectual property rights and the rights and freedoms of the defendant.
- 45 It is apparent from the measures, procedures and remedies provided for in Directive 2004/48 that the legal remedies designed to ensure the protection of intellectual property rights are supplemented by actions for damages which are closely linked to them. Thus, first, Article 7(1) and Article 9(1) of that directive provide for precautionary and provisional measures intended, in particular, to prevent any imminent infringement of an intellectual property right, which include, inter alia, the seizure of goods suspected of infringing such a right. Second, in order to ensure the balance referred to in paragraph 44 of the present judgment, Article 7(4) and Article 9(7) of that directive provide for measures enabling the defendant to claim compensation where it subsequently becomes apparent that there has been no infringement or threat of infringement of an intellectual property right. As is apparent from recital 22 of that directive, those compensation measures constitute guarantees which the legislature deemed necessary as a counterweight to the prompt and effective provisional for which it made provision (judgment of 16 July 2015, *Diageo Brands*, C-681/13, EU:C:2015:471, paragraph 74).
- 46 It cannot be argued that a strict liability mechanism such as that at issue in the main proceedings would upset the balance described in the preceding paragraph by deterring the holder of an intellectual property right from bringing legal proceedings and relying on that right. The provisional measures are intended to prevent an imminent infringement of such a right or to prevent the continuation of an alleged act of infringement. However, if it ultimately transpires that there has been no infringement of that right, the basis for the provisional measures disappears, which, in principle, obliges the applicant to provide compensation for any injury caused by those unjustified measures. In that last regard, it should, however, be noted that a strict liability mechanism such as that at issue in the main proceedings, in the context of which the court seised may take into account all the circumstances of the case, including any participation by the defendant in the occurrence of the injury, makes it possible, inter alia, to adjust the amount of damages and thereby mitigate any deterrent effect for the holder of the intellectual property right.
- 47 The fact that the applicant for such measures is required to assess the risk of their being enforced corresponds to the risk taken by the defendant in deciding to market products that may constitute an infringement. Thus, a mechanism of strict liability, based on the risk incurred by the applicant, appears to be proportionate to the EU legislature's objective of ensuring the enforcement of intellectual property rights while comprehensively mitigating the risk that the defendant will suffer loss as a result of provisional measures.
- 48 Moreover, a balance between the rights of the applicant and of the defendant appears to be fully ensured by a strict liability mechanism such as that at issue in the main proceedings. The fact that the defendant does not have to demonstrate fault committed by the applicant is a

counterweight to the fact that that applicant was able to obtain such measures without having to adduce definitive evidence of any infringement, in accordance with Article 9(3) of Directive 2004/48.

49 As regards, second, the absence of any barrier to legitimate trade, it should be noted that the presumption of validity of an intellectual property right allows its holder to act and apply for provisional measures before any substantive action is brought. However, the defendant must bring infringement proceedings within the period prescribed by Article 9(5) of Directive 2004/48, that action generally being accompanied by an action or counterclaim for a declaration of invalidity of that right brought by the defendant. If, at the end of those proceedings, the intellectual property right which served as the basis for the provisional measures is declared invalid retroactively, as is the case in the main proceedings, it must then be held that the acts of the defendant prevented by those measures were fully part of legitimate trade and should not have been hindered. Similarly, in that situation, the high level of protection of intellectual property intended by the EU legislature cannot be invoked since the intellectual property right, which has been declared invalid retroactively, is deemed never to have existed. It follows that a system of provisional measures incorporating a strict liability regime such as that at issue in the main proceedings does not create a barrier to legitimate trade.

50 As regards, third, the dissuasive nature of a system of provisional measures, such as that provided for in Article 9 of Directive 2004/48, incorporating a strict liability regime such as that described in paragraph 43 of this judgment, it should be noted that, since the court hearing an application for compensation may take account of all the circumstances of the case, including the defendant's conduct, in order to determine the amount of damages, such a strict liability regime is not capable of calling into question the dissuasive nature of the system of provisional measures. The right to compensation is strictly limited to the injury suffered by the defendant and caused by the unjustified provisional measures sought by the holder of the intellectual property right at issue. From that point of view, the right to compensation provided for in Article 9(7) of that directive cannot be relied on to cover the part of the injury resulting from the conduct of that defendant which may have caused the injury initially caused by the provisional measures to be aggravated.

51 In the light of the foregoing considerations, the answer to the first question is that Article 9(7) of Directive 2004/48 must be interpreted as not precluding national legislation which provides for a mechanism for compensation for any injury caused by a provisional measure, within the meaning of that provision, based on a system of strict liability of the applicant for those measures, in the context of which the court is entitled to adjust the amount of damages by taking into account the circumstances of the case, including whether the defendant played a part in the occurrence of the injury.

The second to fourth questions

52 In view of the answer given to the first question, and in so far as the second to fourth questions are asked only in the event of a negative response to that question, there is no need to answer those questions.

Costs

- 53 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

Article 9(7) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights

must be interpreted as not precluding national legislation which provides for a mechanism for compensation for any injury caused by a provisional measure, within the meaning of that provision, based on a system of strict liability of the applicant for those measures, in the context of which the court is entitled to adjust the amount of damages by taking into account the circumstances of the case, including whether the defendant played a part in the occurrence of the injury.

[Signatures]