

Court of Justice EU, 11 January 2024, Mylan v Gilead



## ENFORCEMENT

**Article 9(7) of the Enforcement Directive does not preclude strict liability-based national legislation which provides for a mechanism for compensation for any injury caused by a provisional measure**

- [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](#)

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 seized 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.

Source: [ECLI:EU:C:2024:8 / C-473-22](#)

**Court of Justice EU, 11 January 2024**  
(K. Jürimäe (Rapporteur), N. Piçarra, M. Safjan, N. Jääskinen and M. Gavalec)  
JUDGMENT OF THE COURT (Third Chamber)

11 January 2024 <sup>(1)</sup>

(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. Jääliñoja and B. Rapinoja, asianajajat,

- 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 Organisation (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*

<sup>1</sup> Language of the case: Finnish.

*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 (OJ 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.**

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**OPINION OF ADVOCATE GENERAL M. SZPUNAR**

OPINION OF ADVOCATE GENERAL  
 SZPUNAR

delivered on 21 September 2023 (1)

Case C-473/22

Mylan AB

v

Gilead Sciences Finland Oy,

Gilead Biopharmaceutics Ireland UC,

Gilead Sciences Inc.

(Request for a preliminary ruling from the markkinaoikeus (Market Court, Finland))

(Reference for a preliminary ruling – Intellectual property – 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 annulment 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 the provisional measures for losses caused by them – National legislation providing for strict liability)

#### Introduction

1. Where the protection conferred on the holder of an intellectual property right, such as a patent or a right derived therefrom, expires or where that right is considered legally vulnerable and likely to be declared invalid, the holder's competitors may be tempted to place on the market products infringing that right without waiting for it to lapse. By placing their products on the market prematurely, they obtain a competitive advantage which allows them to gain market share before other more scrupulous competitors arrive. This is common practice, particularly in the pharmaceutical market, where manufacturers of generic medicines do not always wait until the protection of the originator product has ceased to be effective before placing their own product on the market, in the hope that that protection will expire quickly.

2. Such a practice is referred to as 'launch at risk'. The perpetrator faces the risk of opposition from the holder in the form of measures seeking to protect the intellectual property right in question. This could consist, inter alia, in a provisional measure ordered by a court to stop the infringement with immediate effect. In this situation, the holder's competitor bears the risk of making a financial loss, since it might not see a return on its investment.

3. However, in the event that, after the provisional measure has been adopted, the intellectual property right to be protected by that measure is declared invalid, or if it is found that there was no infringement of that right, the question arises of the right of the person whose economic activity has thus been unduly hindered to claim compensation for losses from the holder of the intellectual property right who applied for the provisional measure.

4. Although the provision of EU law – itself derived from international law – requiring Member States to provide for such a right of redress in their national legal systems is tersely and generically worded, the Court of Justice, in its judgment in Bayer Pharma, (2) gave it a more precise meaning, further framing the Member States' margin of discretion.



5. In the present case, it is necessary to analyse, in the light of the guidance provided in that judgment, the liability regime adopted in Finnish law. This is similar to the regimes in force in the national law of several other Member States – that is to say, a strict liability regime.

#### Legal framework

##### International law

6. Article 1(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('the TRIPS Agreement'), which forms the subject of Annex 1C to the Agreement establishing the World Trade Organisation (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), (3) provides as follows:

'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.'

7. Pursuant to Article 50(7) of that agreement:

'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

8. Articles 2, 3, 5, 13 and 15 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, (4) in the version in force at the material time, provided that:

'Article 2

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure ... may, under the terms and conditions provided for in this Regulation, be the subject of a [supplementary protection] certificate ['the certificate' or 'the SPC'].

Article 3

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

...

Article 5

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent

and shall be subject to the same limitations and the same obligations.

...

Article 13

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the [Union], reduced by a period of five years.

...

Article 15

1. The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 3; ...'

9. Pursuant to Article 3 of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights: (5)

'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 9 of that directive 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;

...

...

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.

...

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**

11. It is clear from Paragraph 11 of Chapter 7 of the oikeudenkäymiskaari (Code of Judicial Procedure), which transposes Article 9(7) of Directive 2004/48 into Finnish law, that, if a party applies for a provisional measure which is obtained unnecessarily, that party must compensate the other party for the losses caused by that measure and its enforcement and for the costs incurred. According to the referring court, that provision is interpreted, in the case-law of the Finnish courts, as providing for strict liability.

#### **The facts, the procedure and the questions referred for a preliminary ruling**

12. On 3 December 2009, the Patentti- ja rekisterihallitus (Patent and Registration Office, Finland) granted SPC No 266, 'Tenofovir disoproxil (TD) and the salts, hydrates, tautomers and solvates thereof, in combination with emtricitabine' ('the SCP at issue') covering an antiretroviral medicine indicated for the treatment of people with human immunodeficiency virus (HIV), on the basis of European patent No FI/EP 0 915 894, validated in Finland ('the basic patent at issue').

13. In spring 2017, the company Mylan AB put forward its medicinal product 'EMTRICITABINE/TENOFOVIR DISOPROXIL MYLAN 200 mg/245 mg, film-coated tablet' (generic medicine based on tenofovir disoproxil and emtricitabine; 'the generic medicine at issue') in response to public calls for tender from two Finnish nursing care districts. The company won both tenders.

14. The basic patent at issue expired on 25 July 2017. On the same date, the SPC at issue came into effect.

15. On 15 September 2017, the companies Gilead Sciences Finland Oy, Gilead Biopharmaceutics Ireland UC and Gilead Sciences, Inc. (together 'Gilead and Others') brought an action before the markkinaoikeus (Market Court, Finland) against Mylan for infringement of the SPC at issue and filed an application for provisional measures, which Mylan opposed. On 30 November 2017, Mylan brought an action for annulment of the SPC at issue.

16. By decision of 21 December 2017, the markkinaoikeus (Market Court) granted the application for provisional measures and prohibited Mylan from offering, marketing or using the generic medicine at issue and from importing, manufacturing or possessing it for those purposes during the period of validity of the SPC at issue, on pain of a fine.

17. On 25 July 2018, the Court of Justice delivered the judgment in *Teva UK and Others* (6) concerning the interpretation of Article 3 of Regulation No 469/2009. It follows from that judgment that an SPC similar to the SPC at issue, granted in the United Kingdom for the same originator medicine, was found to be invalid on the ground that it had been granted contrary to that provision.

18. The provisional measures obtained by Gilead and Others against Mylan 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 the judgment of the markkinaoikeus (Market Court) became final.

20. Under Paragraph 11 of Chapter 7 of the Code of Judicial Procedure, Mylan applied to the markkinaoikeus (Market Court) – the referring court in the present case – for an order requiring Gilead and Others to pay it compensation of EUR 2 367 854.99, plus default interest, as compensation for the losses caused by the aforementioned provisional measures, unnecessarily obtained on the basis of an SPC that was subsequently found to be invalid.

21. The referring court recalls that, according to Finnish case-law, Paragraph 11 of Chapter 7 of the Code of Judicial Procedure provides for liability without fault, that is to say strict liability. Thus, a person who obtains a provisional measure is liable for compensation if the intellectual property right on the basis of which the provisional measure was granted is subsequently found to be invalid. However, in view of the case-law established by the Court of Justice in the judgment in *Bayer Pharma*, the referring court has doubts as to whether a strict liability regime can be regarded as being compatible with Article 9(7) of Directive 2004/48.

22. In those circumstances 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?’

23. The request for a preliminary ruling was registered at the Court on 15 July 2022. Written observations were submitted by the parties in the main proceedings, the Finnish and Netherlands Governments and the European Commission. The Court decided to proceed to judgment without a hearing.

#### **Analysis**

24. The referring court refers four questions for a preliminary ruling. The first question is the most important, as it concerns the compatibility with Article 9(7) of Directive 2004/48, read in the light of the judgment in Bayer Pharma, of a strict liability regime for losses caused by unnecessarily obtained provisional measures. The other three questions ask whether – if such a regime is incompatible – on what grounds the liability provided for in that provision should be based. I will analyse the questions referred in the order in which they were asked.

#### **The first question referred for a preliminary ruling**

25. By way of reminder, in the dispute in the main proceedings, the provisional measure against Mylan was adopted in Gilead and Others’ favour in order to protect the intellectual property rights that those companies derived from that SPC at issue. Since that SPC was subsequently found to be invalid, the intellectual property right proved to be non-existent, such that there was no infringement of that right. By its first question, the referring court therefore seeks to ascertain, in essence, whether Article 9(7) of Directive 2004/48 must be interpreted as precluding national legislation providing, in the situations covered by that provision, for a strict liability regime for the applicant for provisional measures.

26. The answer to that question requires that provision to be interpreted in the light of the judgment in Bayer Pharma. I will therefore begin my analysis with a summary of the guidance provided in that judgment.

#### **The judgment in Bayer Pharma**

27. The case giving rise to the judgment in Bayer Pharma concerned whether Article 9(7) of Directive 2004/48 precluded a liability regime provided for in the national law of a Member State, under which compensation to the defendant for an unfounded provisional measure was not granted, where the losses were incurred as a result of the defendant’s conduct, provided that the applicant (for the provisional measure) had acted as would be expected of a person in that situation.

28. In his Opinion in that case, Advocate General Pitruzzella noted, first of all, that the purpose of Article 9(7) of Directive 2004/48 is to implement, at the level of EU law, Article 50(7) of the TRIPS Agreement, which leaves the signatory States a broad margin of discretion and does not prejudice the liability regime in the national

law of those States. In his view, the same must apply to the interpretation of Article 9(7) of that directive, provided that that liability regime allows the defendant to obtain compensation for any losses incurred and does not unduly discourage the holders of intellectual property rights from seeking provisional measures under Article 9(1) and (2) of that directive. (7)

29. More specifically, as regards the liability regime at issue in the case giving rise to the judgment in Bayer Pharma, Advocate General Pitruzzella concluded that although Article 9(7) of Directive 2004/48 does not preclude the conduct of the defendant from being taken into account in determining the right to compensation and the amount thereof, it does, conversely, preclude the fact that the defendant has placed on the market a product infringing an intellectual property right, without waiting for that right to be declared invalid, from being sufficient, on its own, to deny the defendant the right to compensation. (8)

30. However, in its judgment, the Court of Justice adopted a solution more protective of the holders of intellectual property rights. (9)

31. First, the Court observed that the TRIPS Agreement expressly allows its signatories to implement more extensive protection of intellectual property rights than is required by that agreement and that this was precisely the choice made by the EU legislature in adopting Directive 2004/48. It therefore found that the concept of ‘appropriate compensation’, referred to in Article 9(7) of Directive 2004/48, the interpretation of which was requested by the referring court in the judgment in Bayer Pharma, was an autonomous concept of EU law which must be given a uniform interpretation in different Member States. (10)

32. The Court further held that it was for the national courts to assess ‘whether it [was] appropriate to order the applicant to pay to the defendant compensation’, (11) since such compensation could only be regarded as ‘appropriate’ if it were justified in the light of the particular circumstances of a given case. Thus, the mere fact that the conditions for such compensation provided for in Article 9(7) of Directive 2004/48 were satisfied – namely, that the provisional measures had been repealed or ceased to be applicable because of any action or omission on the part of the applicant, or that it was subsequently found that there was no infringement or threat of infringement of an intellectual property right – did not mean that the national courts should automatically and in any event be obliged to order the applicant to provide compensation for any losses suffered by the defendant as a result of those provisional measures. (12)

33. Pursuing this line of reasoning, the Court noted, referring to the context of Article 9(7) of Directive 2004/48, and in particular recital 22 thereof, that the aim of that provision was to ensure that the defendant receives compensation for injury caused by an unjustified application for provisional measures. However, a finding that such an application is unjustified presupposes, primarily, that there is no risk that irreparable harm may be caused to the holder of an



intellectual property right in the event of delay in the adoption of those measures. (13)

34. As regards the particular circumstances of the dispute in the main proceedings in the case giving rise to the judgment in Bayer Pharma, which are similar to those of the dispute in the main proceedings in the present case, the Court found that the marketing of a medicine infringing a patent constituted *prima facie* a risk of irreparable harm, such that the application for provisional measures made in response to such conduct cannot be regarded *a priori* as unjustified. (14)

35. As for any subsequent repeal of the provisional measures, (15) the Court found that, although that was one of the conditions necessary for the exercise by the national courts of the authority to order compensation, it cannot, by contrast, be regarded in itself as a decisive factor in proving the unjustified nature of the application for those provisional measures. It added that a different interpretation could have the effect of discouraging holders from availing themselves of the measures referred to in Article 9(1) *et seq.* of Directive 2004/48, and would thus run counter to the objectives of that directive. (16)

36. Lastly, the Court imposed on national courts, in the light of Article 3(2) of Directive 2004/48, the obligation to ensure that provisional measures are not abused by the holders of intellectual property rights. To that end, the national courts must, once again, take due account of all the circumstances of the case in which they are required to give a ruling. (17)

37. It is in the light of the judgment in Bayer Pharma that the first question referred for a preliminary ruling should be answered.

#### **Application in the present case of the approach adopted in the judgment in Bayer Pharma**

38. In the light of the foregoing, it must now be determined whether Article 9(7) of Directive 2004/48, as interpreted by the Court in the judgment in Bayer Pharma, precludes the liability of the applicant for provisional measures provided for therein from being strict liability in the national law of a Member State.

39. I must state from the outset that this would seem to me to be the case.

40. It is clear that, as stated by the interested parties who submitted observations in the present case, Article 9(7) of Directive 2004/48 does not positively determine the liability regime to be adopted in the Member States in the context of the transposition of that provision. The judgment in Bayer Pharma does not alter that fact.

41. However, it is common ground that a regime of strict liability, also known as ‘liability for risk’ or ‘no-fault liability’, is characterised by the fact that the person concerned is liable by the mere fact of his or her status, (18) without the injured party having to prove any failure in the conduct of that person. In other words, strict liability is automatic and independent of the particular circumstances of the case. Specifically, the absence of any fault on the part of the person held liable does not exempt him or her from liability. It is only in certain legal systems that this principle of strict liability is mitigated by exceptional circumstances, such as force

majeure or the decisive contribution of the injured party or a third party to the occurrence of the loss. (19)

42. However, this is precisely what is precluded by Article 9(7) of Directive 2004/48, as interpreted by the Court in the judgment in Bayer Pharma. Indeed, according to the Court, that provision requires that the national court authorised to order the applicant for provisional measures to compensate the defendant for any injury caused by those measures, if they were obtained unnecessarily, be able to examine all the circumstances of the case in order to assess whether it is necessary to order such compensation. That is the case if the application for provisional measures was unjustified, bearing in mind also that simply revoking those measures, or finding the absence of infringement of an intellectual property right, is not sufficient to establish the unjustified nature of that application.

43. Obviously we can attempt – as several interested parties who submitted observations in the present case do – to split hairs and look for a particular characteristic of a given strict liability regime in order to demonstrate that it complies with Article 9(7) of Directive 2004/48 and with the judgment in Bayer Pharma.

44. However, in my view, the interpretation of that provision, as summarised in point 41 of the present Opinion, quite simply precludes the liability under that provision from falling under a strict liability regime. The specific characteristics of a given liability regime cannot alter that finding.

45. This is particularly true given that – as noted by the referring court – in the Finnish system, the defendant’s conduct may be taken into account for the purpose of determining the amount of compensation. Indeed, the Court expressly required, in the judgment in Bayer Pharma, that the national courts take into account the circumstances of each case in order to assess whether it is appropriate to award compensation. Reducing the amount of compensation, when the actual principle of liability is maintained, is not sufficient to meet that requirement.

#### **Further considerations**

46. I would wish to add that the interpretation of Article 9(7) of Directive 2004/48 resulting from the judgment in Bayer Pharma seems to me perfectly in line with the spirit and scheme of that directive. It is important to interpret that provision taking into account its different contextual elements.

47. In the first place, all the provisions contained in Article 9(7) of Directive 2004/48 must be taken into account.

48. In the judgment in Bayer Pharma, the Court observed that to regard the repeal of the provisional measures, in itself, as a decisive factor in proving the unjustified nature of the application which gave rise to those measures could have the effect of discouraging the holder of the patent in question from availing himself or herself of the measures referred to in Article 9 of Directive 2004/48 and would thus run counter to that directive’s objective of ensuring a high level of protection of intellectual property. (20) In my view, this consideration merits further examination.

49. The article at issue enshrines the right of holders, for the purposes of protecting their intellectual property rights, to apply for provisional measures against any infringer, including a potential infringer, in order to prevent an imminent infringement of those rights. That is the principal objective of that article.

50. It is solely to balance the interests of all the parties to the case that Article 9(5) to (7) of Directive 2004/48 provides for measures to protect the defendants' interests, by providing that the provisional measures should be revoked if the applicant fails to act and that the applicant must compensate the defendant for any injury caused as a result of the unnecessarily obtained provisional measures. The purpose of those provisions is to prevent the abuse of the provisional measures.

51. However, those provisions would undermine the effectiveness of Article 9 of Directive 2004/48 as a whole if they were interpreted and transposed into national law in such a way as to place the applicant at a disproportionate risk of having to compensate the other party as a result of the measures granted in order to protect his or her intellectual property rights. According to the logic of that article, the risk is not shared equally between the holder of the intellectual property rights and the infringer – or potential infringer – of those rights. It is the latter who runs a risk by infringing, even if only potentially, an intellectual property right. This may be deliberate if the infringer considers the holder's position to be weak, for example because the intellectual property right is vulnerable. Nevertheless, the decision whether or not to bear that risk is taken in full knowledge of the facts.

52. By contrast, it would be contrary to the spirit and objective of Article 9 of Directive 2004/48 to expose the holder of the intellectual property rights to any risk in defending those rights. Provided that the holder cannot be accused of failing to fulfil his or her obligations, he or she should be free to make full use of the measures provided for in that directive, including those provided for in Article 9 thereof, without being discouraged by the prospect of adverse consequences arising from recourse to those measures. This is particularly the case when the intellectual property right in question results from a decision of the public authority, such as a patent or an SPC, as in the present case, and the lapse of the provisional measures is the result of that right being declared invalid. The holder should be able to have confidence in that decision and not have to contend with the risk that it might be unlawful.

53. Furthermore, by definition, the provisional measures provided for in Article 9 of Directive 2004/48 do not prejudice the substantive outcome of the case. However, holding the party who applied for those provisional measures liable automatically whenever he or she is unsuccessful for any reason would have the effect of distorting the provisional nature of those measures – contrary, once again, to the objective of that article.

54. In the second place, it is necessary to take into account all the provisions of that directive and, in particular, its general rules.

55. The Finnish Government explains in its observations that, in Finnish law, the strict liability of the applicant for provisional measures is the corollary to the significant ease of obtaining those measures, which are granted almost automatically. According to the Finnish Government, if the principle of strict liability were abandoned, the courts would be forced to examine more thoroughly the merits of the applicant's claims, which would be an unwelcome development.

56. I do not share that view. The position of the Finnish Government reflects a somewhat 'Wild West' approach to the relationships established by Article 9 of Directive 2004/48: on one side is the sheriff (the holder of the intellectual property right); on the other, the gunfighter (the infringer or potential infringer); the person who is quickest on the draw (in reality, the one with the best lawyers) wins. However, it does not seem to me that this vision of a legal O.K. Corral (21) is what the EU legislature intended when it adopted Directive 2004/48, and Article 9 thereof in particular, in order to protect intellectual property rights.

57. Indeed, Article 3(2) of Directive 2004/48 requires the measures it provides for to be effective and dissuasive, but also proportionate, and applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. However, the application of those measures is primarily the responsibility of the national courts. It is, therefore, the national courts that must ensure the prima facie justified nature of the measures applied for by the holders of intellectual property rights, and of the provisional measures in particular. Only an assessment by the court of the proportionality of the application can ensure that the provisional measures adopted are proportionate, do not create barriers to legitimate trade and are not abused. (22) This is moreover expressly provided for in Article 9(3) of Directive 2004/48, which authorises the judicial authorities to require the applicant for provisional measures to provide any evidence of the justified nature of the application. That provision would be irrelevant if those measures were to be adopted automatically.

58. Therefore, it seems necessary to consider the merits of the application and to weigh up the interests of the two parties in general when granting provisional measures in the light of the objectives of Directive 2004/48. The vigilance of the courts called upon to order provisional measures must, therefore, be the first line of defence against the abuse of those measures by the holders of intellectual property rights. (23)

59. As regards completing the procedure as quickly as possible, Article 9(4) of Directive 2004/48 allows, in cases of extreme urgency, provisional measures to be adopted without the defendant even having been heard, subject to review at the request of the defendant. This may result in the measures being modified, revoked or confirmed. It goes without saying that, in order to ensure the effectiveness of that provision, any modification or revocation of those measures after review does not mean that the applicant is automatically liable.

60. It is, therefore, with some caution that national courts should, in accordance with Article 3(2) of Directive 2004/48, order the measures provided for in that directive, including the provisional measures referred to in Article 9(1) and (2) thereof. The same caution should also be reflected in the liability regime implemented under Article 9(7) of the directive.

61. As a general rule, strict liability occurs in three types of situation: as a result of a risky activity related, *inter alia*, to the use in the context of an activity of ‘forces of nature’ that the user does not fully control; as a result of the actions of third parties for whom the interested party is responsible, such as employees or minors; and, lastly, as a result of ‘nuisance’, that is to say damage caused by the use of a building. By contrast, it seems to me to be inconsistent with the spirit and logic of Directive 2004/48 that applicants for the provisional measures provided for in Article 9 of that directive should automatically be held liable as a result of decisions concerning such measures ordered, after a thorough examination of the application, by the national courts. The liability of those applicants should instead be limited, as is apparent from the judgment in Bayer Pharma, to failures regarding their own conduct, particularly when submitting the application for provisional measures.

62. In the third and last place, all the provisions of EU law in the field of intellectual property should be taken into account.

63. Although Directive 2004/48 is strongly inspired by Part III of the TRIPS Agreement, (24) which it transposes into EU law, the fact remains that it is part of a much broader process of harmonising the substantive provisions concerning the different categories of intellectual property rights, in particular patents, trade marks, designs, and copyright and related rights. Indeed, its role is to ensure a high, equivalent and homogeneous level of protection of those rights. (25)

64. Article 9(7) of Directive 2004/48 must, therefore, be interpreted homogeneously not only in the context of the pharmaceutical market or patent law, but also in different areas of intellectual property law and in the different legal systems of the Member States. However, the balance of power between the parties to a dispute concerning the various intellectual property rights varies considerably. In my view, the appropriate solution for each situation will only be found if the court called upon to order compensation takes due account of all the circumstances of the case. It is essential, therefore, that the national law of each Member State allows those circumstances to be taken into account.

#### **Proposed answer to the first question referred**

65. It seems to me that both the solutions found by the Court of Justice in the judgment in Bayer Pharma and the scheme and objectives of Directive 2004/48 preclude the liability provided for in Article 9(7) of that directive from falling under a strict liability regime like the one adopted in Finnish law. However, since it is for the Member States to define that liability regime, the answer to this question must be formulated in a more abstract way, so as not to limit their margin of discretion unduly.

66. I therefore propose that the answer to the first question referred for a preliminary ruling be that Article 9(7) of Directive 2004/48 must be interpreted as precluding national legislation providing, in the situations referred to in that provision, for a liability regime for the applicant for provisional measures that does not allow the court hearing an action for compensation of the loss caused by those measures to take into account – in addition to the premisses of that liability set out in that provision – other relevant circumstances of the case in order to assess whether or not to order such compensation.

#### **The second to fourth questions referred for a preliminary ruling**

67. The second to fourth questions referred were based on the assumption that it would follow from the answer to the first question that Article 9(7) of Directive 2004/48 precludes a strict liability regime for the loss caused by unnecessarily obtained provisional measures. In view of the answer that I propose to give to the first question, it is necessary to analyse the second, third and fourth questions.

#### **The second question referred for a preliminary ruling**

68. By its second question, the referring court asks, in essence, what type of liability regime is compatible with Article 9(7) of Directive 2004/48.

69. As I have already stated, that article does not prescribe a specific system of liability, such that it is for the Member States to define and organise that system.

70. However, it follows directly from the answer that I propose to give to the first question referred for a preliminary ruling that the liability regime under Article 9(7) of Directive 2004/48 must allow the court hearing a claim for compensation for losses caused by unnecessarily obtained provisional measures to take into account – in addition to the premisses of the liability set out in that provision – other relevant circumstances of the case in order to assess whether or not to order such compensation. Thus, if the Court of Justice were to follow that proposed answer, it would not, in my view, be necessary to give a separate answer to the second question referred for a preliminary ruling.

#### **The third and fourth questions referred for a preliminary ruling**

71. By its third and fourth questions, which I propose to analyse together, the referring court asks, in essence, what circumstances the court hearing a claim for compensation of injury under Article 9(7) of Directive 2004/48 must take into account to assess whether or not to order such compensation.

72. As the Commission rightly observes, it is difficult to enumerate all the circumstances that the court might have to take into account in such a situation. However, the judgment in Bayer Pharma gives some general guidance on the subject.

73. It follows from that judgment that the liability of the applicant for the provisional measures results from the unjustified nature of the measures sought. Whether they are justified is assessed in the light of the existence of a risk of irreparable harm likely to be caused to the



applicant in the absence of those provisional measures. The fact that the provisional measures have been repealed – or, more generally, that the premisses for the applicant’s liability under Article 9(7) of Directive 2004/48 are satisfied – does not in itself prove that the application was unjustified. (26)

74. It follows, first, that the circumstances to be taken into account by the court hearing an action for compensation under Article 9(7) of Directive 2004/48 are those that enable it to assess whether the application for provisional measures was justified. To be comprehensive, such an assessment must, in my view, relate not only to the original application for provisional measures, but also to the applicant’s subsequent conduct as regards any maintenance, extension or renewal of those measures. Indeed, the justified nature of such an application may change depending on circumstances such as how the dispute unfolds between the applicant and the opposing party.

75. Second, it is evident that the court must take into account the circumstances following the application, granting and enforcement of the provisional measures. These include the circumstances mentioned in Article 9(7) of Directive 2004/48, namely the revocation of the provisional measures (and the grounds for that revocation) and the finding of no infringement of an intellectual property right. However, those circumstances must be taken into account not as a post factum confirmation of the unjustified nature of the application for provisional measures, but for the purpose of assessing the justified nature of the application at the time of its submission (or at the time of subsequent applications).

76. For example, a possible indication that the applicant erred in assessing the merits of his or her claim is that the intellectual property right at issue is found to be invalid after the provisional measures have been adopted. However, if such an error were to be considered excusable in a given case, it could not result in the applicant being held liable, otherwise it would undermine the effectiveness of Article 9 of Directive 2004/48 as a whole. (27)

77. Third, whether an application for provisional measures is justified must be assessed in the light of a risk of irreparable harm to the applicant – that is to say, by definition, the probability of such harm. That probability concerns not only the occurrence of an event detrimental to the applicant’s interests, but also the very legitimacy of those interests, including the validity of the intellectual property right at issue. If that right is subsequently found to be invalid, it does not, therefore, mean that, at the time of the application for the provisional measures, the risk of irreparable harm did not exist.

78. Fourth, and last, the revocation of the provisional measures or the finding of no infringement or threat of infringement of an intellectual property right may be an indication of abuse of those measures by the applicant. Such abuse must, in my view, be considered equivalent to an unjustified application for provisional measures and give rise to an obligation to provide compensation

for the injury caused by that application, as the Court held, in essence, in the judgment in Bayer Pharma. (28) 79. Thus, although Article 9(7) of Directive 2004/48 does not set out the specific causes of the liability it provides for, it is still possible to give the competent courts guidance as to the circumstances to be taken into account in their assessment. I therefore propose that the answer to the third and fourth questions referred for a preliminary ruling be that the court hearing an action for compensation for losses under Article 9(7) of the directive must take into account, in order to assess whether or not to order such compensation – in addition to the premisses of that liability set out in that provision – other relevant circumstances of the case, both before and after the application for the provisional measures at issue, which allow it to assess the justified nature of that application in the light of the risk of irreparable harm caused to the applicant in the absence of such measures.

### Conclusion

80. In the light of all of the foregoing considerations, I propose that the Court of Justice should answer the questions for a preliminary ruling referred by the markkinaoikeus (Market Court, Finland), as follows:

(1) 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 precluding national legislation providing, in the situations referred to in that provision, for a liability regime for the applicant for provisional measures that does not allow the court hearing an action for compensation of the loss caused by those provisional measures to take into account – in addition to the premisses of that liability set out in that provision – other relevant circumstances of the case in order to assess whether or not to order such compensation.

(2) The court hearing an action for compensation for losses under Article 9(7) of Directive 2004/48 must take into account, in order to assess whether or not to order such compensation – in addition to the premisses of that liability set out in that provision – other relevant circumstances of the case, both before and after the application for the provisional measures at issue, which allow it to assess the justified nature of that application in the light of the risk of irreparable harm caused to the applicant in the absence of such measures.

### Sources

- 1 Original language: French.
- 2 Judgment of 12 September 2019 (C-688/17, ‘the judgment in Bayer Pharma’, EU:C:2019:722).
- 3 OJ 1994 L 336, p. 1.
- 4 OJ 2009 L 152, p. 1.
- 5 OJ 2004 L 157, p. 45, corrigendum in OJ 2004 L 195, p. 16.
- 6 C-121/17, EU:C:2018:585.
- 7 Opinion of Advocate General Pitruzzella in Bayer Pharma (C-688/17, EU:C:2019:324, points 26 to 48).
- 8 Opinion of Advocate General Pitruzzella in Bayer Pharma (C-688/17, EU:C:2019:324, points 49 to 60).
- 9 That interpretation of the judgment in Bayer Pharma is also found in the literature. See, in particular, Dijkman, L., ‘CJEU rules that repeal of provisional

measure does not automatically create liability for wrongful enforcement’, *Journal of Intellectual Property Law & Practice*, No 12, 2019, p. 917; de Haan, T., ‘The CJEU sides with IP right holders: the Bayer Pharma judgment (C-688/17) and the consequences of the Europeanisation of provisional and precautionary measures relating to IP rights’, *European Intellectual Property Review*, No 11, 2020, p. 767; Tilmann, W., ‘Consequences of the CJEU’s Bayer v Richter decision’, *Journal of Intellectual Property Law & Practice*, No 6, 2022, p. 526; as well as, critically, Felthun, R., et al., ‘Compensating wrongly restrained defendants in pharmaceutical patent cases: recent developments in the EU, England and Australia’, *Bio-science Law Review*, No 6, 2020, p. 234; and Sztoldman, A., ‘Compensation for a wrongful enforcement of a preliminary injunction under the Enforcement Directive (2004/48/EC)’, *European Intellectual Property Review*, No 11, 2020, p. 721.

10 Judgment in Bayer Pharma, paragraphs 47 to 49.

11 Judgment in Bayer Pharma, paragraph 51 (my emphasis).

12 Judgment in Bayer Pharma, paragraphs 51 and 52.

13 Judgment in Bayer Pharma, paragraphs 60 to 62.

14 Judgment in Bayer Pharma, paragraph 63.

15 In the dispute in the main proceedings in that case, the provisional measures were set aside on the grounds of procedural defect, but were not subsequently renewed due to the advanced stage of the proceedings for a declaration of invalidity of the patent on which they were based, that patent eventually being declared invalid (see judgment in Bayer Pharma, paragraphs 23 to 26).

16 Judgment in Bayer Pharma, paragraphs 64 and 65.

17 Judgment in Bayer Pharma, paragraphs 68 to 70.

18 And, of course, the occurrence of a loss.

19 On strict liability, see, for example, Knetsch, J., ‘The Role of Liability without Fault’, in Borghetti, J.-S., Whittaker, S., (ed.), *French Civil Liability in Comparative Perspective*, Hart Publishing, Oxford, 2019, pp. 123 to 142, and Szpunar, A., ‘La responsabilité sans faute dans le droit civil polonais’, *Revue internationale de droit comparé*, No 1, 1959, pp. 19 to 33.

20 Judgment in Bayer Pharma, paragraphs 64 and 65. A similar observation had already been made in the Opinion of Advocate General Pitruzzella in Bayer Pharma (C-688/17, EU:C:2019:324, point 47).

21 I am referring of course to John Sturges’s famous 1957 western, *Gunfight at the O.K. Corral*.

22 See, to that effect, Sikorski, R., ‘Patent Injunctions in the European Union Law’, in Sikorski, R. (ed.), *Patent Law Injunctions*, Kluwer Law International, 2018, p. 22.

23 As the Court observed, moreover, in the judgment in Bayer Pharma, paragraphs 66 to 70.

24 This part is entitled ‘Enforcement of Intellectual Property Rights’.

25 See, in particular, recitals 3 and 10 of Directive 2004/48.

26 Judgment in Bayer Pharma, paragraphs 60, 62 and 64.

27 See points 48 to 52 of the present Opinion and the judgment in Bayer Pharma, paragraph 65.

28 Paragraphs 66 to 70.