Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal
UPC_CoA_917/2025

ORDER

of the Court of Appeal of the Unified Patent Court
issued on 27 April 2026
concerning a request for provisional measures (R. 211 RoP)

HEADNOTE

- Unlike proceedings on the merits, where the Statement of defence shall include a Counterclaim for revocation (R. 25.1 RoP) if there is an assertion that the patent alleged to be infringed is invalid, an invalidity defence raised in proceedings for provisional measures is not a separate action. Similarly, a waiver of an invalidity defence in proceedings for provisional measures is not an application to change the claim or amend the case in the meaning of R. 263 RoP, nor is it a withdrawal in the sense of R. 265 RoP. It follows from Art. 76(2) UPCA that it is for the parties to submit grounds, facts and evidence. If a party declares that it no longer relies on arguments, facts and evidence that it has submitted, the Court can proceed based on the remaining issues in the proceedings. The Court may order the withdrawing party to compensate the costs that the other party has made in connection with the withdrawn arguments, facts and evidence.

KEYWORDS

Provisional measures, waiver of defence, patients' interests

APPELLANTS (AND APPLICANTS BEFORE THE COURT OF FIRST INSTANCE)

1. **Merz Pharmaceuticals LLC**, Unit 35/36, 6601 Six Forks Road, 4th Floor, 27615, Raleigh, North Carolina United States of America
2. **Merz Therapeutics GmbH**, Eckenheimer Landstraße 100, 60318, Frankfurt am Main, Germany
3. **Merz Pharma France**, Tour EQHO, 2 Avenue Gambetta, 92400, Courbevoie, France

(hereinafter jointly 'Merz')

represented by attorney at law Laëtitia Bénard, Allen & Overy Shearman Sterling LLP, Paris, France

RESPONDENT (AND DEFENDANT BEFORE THE COURT OF FIRST INSTANCE)

Viatris Santé, 1 rue de Turin, 69007, Lyon, France (hereinafter 'Viatris Santé')

represented by attorney at law Marc Lauzeral, Schertenleib, Paris, France

PATENT AT ISSUE

EP 2 377 536 (French Supplementary Protection Certificate No. 13C0033)

PANEL AND DECIDING JUDGES

Panel 2
Ingeborg Simonsson, presiding judge and judge-rapporteur
Patricia Rombach, legally qualified judge
Bart van den Broek, legally qualified judge
Anna Hedberg, technically qualified judge
Jeroen Meewisse, technically qualified judge

IMPUGNED ORDER OF THE COURT OF FIRST INSTANCE

Order of 21 November 2025 issued by the Paris Local Division, UPC_CFI_697/2025

LANGUAGE OF THE PROCEEDINGS

English

ORAL HEARINGS

5 February 2026
16 April 2026

SUMMARY OF THE DISPUTE

1. Merz is the registered proprietor of the patent at issue, relating to "Methods of Using Sustained Release Aminopyridine Compositions" for treating multiple sclerosis (MS). The patent application was filed on 11 April 2005 and the divisional application that led to the patent was published on 19 October 2011. Date of publication and mention of the grant of the patent was 6 March 2013. The amendment of the patent in the opposition procedure was published on 17 August 2022. It claims priority from 9 April 2004 (US 560894).

2. Claim 1 of the patent at issue (as amended in the opposition procedure) relates to "[a] sustained release 4-aminopyridine composition for use in a method of increasing walking speed in a patient with multiple sclerosis, wherein said composition is administered twice daily in a dose of 10 milligrams of 4-aminopyridine".

3. Based on the patent at issue, French Supplementary Protection Certificate No. 13C0033 (SPC 033) was issued on 2 November 2015 (whereas the publication of granting was made on 20 November 2015). It will expire on 25 July 2026. SPC 033 concerns the marketing authorisation for the product FAMPYRA® which covers "Fampridine or a derivative thereof" (as active ingredient), indicated for the improvement of walking speed in adult patients with MS.

4. Merz sells its medical product under the tradename FAMPYRA® in France. As set out in the impugned order, Merz Pharmaceuticals LLC is the owner of the patent at issue and of SPC 033, Merz Therapeutics

GmbH is the exclusive licensee, and Merz Pharma France has been granted an exclusive sub-license to these rights in France.

5. The patent at issue and SPC 033 were previously held by Acorda Therapeutics, Inc., but following this company's bankruptcy, Merz acquired the rights. As explained in the impugned order, Merz's entitlement to the patent at issue and SPC 033 is undisputed by Viatris Santé in the proceedings.

6. Merz brought an Application for provisional measures against Viatris Santé before the Paris Local Division, alleging infringement of SPC 033. The alleged infringement relates to FAMPRIDINE VIATRIS®, marketed and sold by Viatris Santé on the French market since 10 June 2025, indicated to improve walking in adult MS patients. As explained in the impugned order, it is common ground that FAMPRIDINE VIATRIS® is a generic of the reference medicinal product FAMPYRA® covered by SPC 033. It will be referred to as "the generic" hereinafter.

7. Viatris Santé objected to the Application and presented the following lines of defence:
- The patent at issue is invalid for lack of inventive step;
- SPC 033 is void due to prior marketing of PYMADIN in Bulgaria and Poland;
- Lack of urgency (unreasonable delay);
- Lack of proportionality of the sought measures;
- In the alternative, Viatris Santé should be allowed to continue marketing subject to a guarantee;
- In the further alternative, the order should be subject to security.

8. The Local Division considered that Merz had failed to demonstrate that it was seeking provisional measures without any unreasonable delay (R. 211.4 RoP), rejected the application and ordered Merz to pay Viatris Santé's interim costs of the proceedings for 56,000 EUR.

9. The Local Division arrived at this conclusion based on the following findings:
- Viatris Santé obtained a marketing authorisation in France for the generic on 19 November 2021.
- On 19 September 2024, the generic was published as a generic specialty in the generic group directory.
- On 22 November 2024, further to its inclusion in the official lists of reimbursable and approved pharmaceutical products, the generic was assigned a price and a reimbursement rate. This finalized the administrative procedure required for the generic to be authorised for marketing in France.
- The Health Products Economic Committee (CEPS) that sets the prices of medicines and medical devices for individual use covered by compulsory health insurance in France informed Viatris Santé that the generic was protected by a patent. Viatris Santé responded on 3 October 2024 that the generic would be marketed on the French market within six months. According to the Local Division this meant by April 2025 at the latest, that is to say, before the expiry of SPC 033 on 25 July 2026.
- CEPS is required to inform the rights holder of the generic manufacturer's response indicating its intention to market its product.
- At that time, the company Biogen was responsible for marketing FAMPYRA® on the French market. The Local Division considered that Merz did not dispute that Biogen was necessarily informed by CEPS of Viatris Santé's response and concluded "*It seems clear to the Court that Biogen informed the patent holder for which it held the rights that an infringement was imminent on the French market*".
- Merz should have carried out a due diligence. Since at least the recovery of direct exploitation rights on 2 January 2025, Merz was or should have been aware of the imminent infringement of SPC 033.

However, Merz did not send a warning letter to Viatris Santé until 18 June 2025, and did not lodge the Application for provisional measures until 31 July 2025.

- Merz should have been particularly vigilant in view of the imminent risk of infringement on French territory, since the validity of its title was weakened by the revocation in Germany of the national part of the patent in question for lack of inventive step by the Bundespatentgericht in March 2024.
- The first act of infringement on the French market on 10 June 2025 cannot be considered as a new starting date for assessing urgency.

10. Merz has appealed the order.

INDICATION OF THE PARTIES REQUESTS

11. Merz requests that the impugned order be set aside and repeats its requests for provisional measures from the first instance proceedings (see paragraph 15 of the impugned order). Merz requests that Viatris Santé be ordered to pay the costs of the proceedings.

12. Viatris Santé essentially requests the Court of Appeal to reject the appeal and uphold the impugned order and order Merz to pay Viatris Santé's costs in the amount of 56,000 EUR. In the alternative,
    - allow the continuation of the making, offering, placing on the market or using, or importing or storing for those purposes, the generic products "FAMPRIDINE VIATRIS LP 10 mg, comprimé à liberation prolongée" and any pharmaceutical composition falling within the scope of French Supplementary Protection Certificate No. 13C0033, including any sustained release 4-aminopyridine composition for use in a method of increasing walking speed in a patient with multiple sclerosis, wherein said composition is administered twice daily in a dose of 10 milligrams of 4-aminopyridine, in particular, if said composition is for administration every 12 hours, in the territory of France, up until 25 July 2026 included;
    - order Viatris Santé to lodge a guarantee to Merz of such amount as the Court shall deem appropriate, but which shall not be higher than 260,000 EUR;

    In the further alternative,
    - reduce the sums of the penalty payments requested to such reasonable amount as the Court shall deem appropriate;
    - set the starting points of penalty payments at a reasonable time as the Court shall deem appropriate, but should be no less than three weeks following the service of the order;
    - order Merz jointly and severally to provide Viatris Santé with a sum of the Court's discretion but which shall not be less than 260,000 EUR for security for enforcement to Viatris Santé by deposit or bank guarantee.

MATTERS OF PROCEDURE

13. As instructed by the judge-rapporteur, Viatris Santé lodged a Statement of response in relation to urgency on 24 December 2025. An oral hearing related to urgency was held on 5 February 2026. On 25 February 2026, Viatris Santé was ordered to lodge a Statement of response to the grounds of appeal in relation to matters other than urgency, and the parties were summoned to an oral hearing on 16 April 2026. Viatris Santé lodged a Statement of response in relation to matters other than urgency on 11 March 2026.

14. On 25 March 2026, the Court of Appeal decided to disregard exhibits 175, 182, 184, 187 and 185 (reduced), brought in the appeal proceedings by Viatris Santé. Viatris Santé was ordered to lodge another Statement of response, leaving out all references to the aforesaid exhibits, but identical in all other respects. Viatris Santé lodged this Statement of response on 31 March 2026.

WAIVER OF THE DEFENCE RELATING TO THE LIKELIHOOD OF INVALIDITY OF THE PATENT AT ISSUE AND SPC 033

15. On 13 April 2026, Viatris Santé submitted an application for unconditional withdrawal of arguments, requesting the Court of Appeal to disregard its arguments, facts and evidence relating to the likelihood of invalidity of the patent at issue and SPC 033. At the same time, Viatris Santé submitted an amended Statement of response. Viatris Santé referred to Art. 76 UPCA and R. 263, R. 9 and R. 222 RoP.

16. When invited to comment on the panel's intention to limit the oral hearing to the remaining issues, Merz stated that it does not object to this limitation.

17. Unlike proceedings on the merits, where the Statement of defence shall include a Counterclaim for revocation (R. 25.1 RoP) if there is an assertion that the patent alleged to be infringed is invalid, an invalidity defence raised in proceedings for provisional measures is not a separate action. Similarly, a waiver of an invalidity defence in proceedings for provisional measures is not an application to change the claim or amend the case in the meaning of R. 263 RoP, nor is it a withdrawal in the sense of R. 265 RoP. It follows from Art. 76(2) UPCA that it is for the parties to submit grounds, facts and evidence. If a party declares that it no longer relies on arguments, facts and evidence that it has submitted, the Court can proceed based on the remaining issues in the proceedings. The Court may order the withdrawing party to compensate the costs that the other party has made in connection with the withdrawn arguments, facts and evidence.

18. For these reasons, the invalidity defence previously raised by Viatris Santé will not be assessed in this order. As infringement of the patent at issue is neither disputed by Viatris Santé, effectively, the only issues at stake in these proceedings are therefore urgency and proportionality.

GROUNDS FOR THE ORDER

Admission of new evidence

19. Pursuant to R. 222.2 RoP, requests, facts and evidence which have not been submitted by a party during proceedings before the Court of First Instance may be disregarded by the Court of Appeal. When exercising discretion, the Court of Appeal shall in particular take into account (a) whether a party seeking to lodge new submissions is able to justify that the new submissions could not reasonably have been made during proceedings before the Court of First Instance; (b) the relevance of the new submissions for the decision on the appeal; and (c) the position of the other party regarding the lodging of the new submissions.

- Exhibits 801, 823, 222 and 225

20. A point of dispute in the proceedings for provisional measures is whether Biogen, a company which at the time was the "exploitant" of the reference medicinal product FAMPYRA® in France, was informed

by CEPS on 9 October 2024 that Viatris Santé had replied to CEPS that it would market the generic within six months and that it considered this to be a non-infringing act.

21. On appeal, Merz provided the Court of Appeal with exhibit 801, which is a letter from Biogen, confirming that it was not informed by CEPS.

22. In the Statement of response related to urgency, Viatris Santé asserted that Biogen's legal counsel, [redacted] was notified by CEPS by letter dated 9 October 2024 of Viatris Santé's price application for the generic and of its undertaking to launch this product on the French market within six months of the publication of a price decision. Viatris Santé relies on newly introduced evidence (exhibit 222) in support of this statement.

23. In response, Merz applied for the admission of a new piece of evidence, exhibit 823, a witness statement from Acorda's Liquidation Trustee. According to Merz, Viatris Santé presented a new factual situation for the first time on appeal, asserting that CEPS had informed "Biogen's legal counsel" on 9 October 2024, and Merz needed to respond to this.

24. Viatris Santé objected to the admissibility of exhibit 823. When invited to comment in substance, Viatris Santé argued *inter alia* that Acorda owned the enforced supplementary protection certificate until 20 February 2025 when the transfer of rights to Merz was registered (exhibit 225).

25. The Court of Appeal has consulted the casefile from the first instance proceedings. Before the Local Division, in the Objection to the Application for provisional measures, Viatris Santé submitted as evidence exhibit PC135. This is a correspondence between CEPS and Viatris Santé where CEPS informs about the patent rights and SPC 033 on 2 September 2024, and Viatris Santé answered on 3 October 2024 stating its intention to make the generics available for sale. Viatris Santé relied on this to support the argument that although it was impossible for it to know when CEPS informed Merz, such information would have been provided promptly under the French regulatory system. In reply, Merz contested that it had been aware of Viatris Santé's price and reimbursement application, adding that it became the operator in France for FAMPYRA® on 1 January 2025, well after the publication of the pricing decision for the generics.

26. There was no documentary evidence available at first instance in support of CEPS having informed Merz, and Merz's awareness was disputed. The Local Division's reasoning instead starts from the assumption as to how information from a generics company is normally sent from CEPS *to the exploitant* (here: Biogen) in accordance with French administrative procedure. This aspect was introduced by the Local Division at the oral hearing. According to the Local Division, Merz did not dispute that Biogen was necessarily informed by CEPS of Viatris Santé's response dated 3 October 2024, and the Local Division concluded: "*It seems clear to the Court that Biogen informed the patent holder for which it held the rights that an infringement was imminent on the French market*".

27. The Local Division's reasoning is consequently based on double assumptions: Biogen was informed by CEPS and Biogen informed the right holder. This is different from what was argued by the parties in the written submissions at first instance and, as explained, it was pointed out by the Local Division at the oral hearing how Biogen was the correct recipient of information from CEPS. Although the parties are

expected to be well-informed about the applicable regulation and able to react to questions raised by the Court at the oral hearing, they could not supply evidence at that point in time. This at least partly justifies that the new evidence could not reasonably have been submitted during the proceedings before the Court of First Instance.

28. The evidence is relevant on appeal since it calls the Local Division's conclusions into question. By its submissions, Merz is trying to refute that the information reached either Acorda (its predecessor in title) or the exploitant Biogen. In response, Viatris Santé has abandoned the assertion that Merz was informed by CEPS and is now trying to demonstrate that CEPS informed Biogen and Acorda on 9 October 2024, and that those companies would have had to inform Merz.

29. Both parties have been provided with the opportunity to reply to what has been brought forward by the other side, thus securing their procedural positions.

30. The Court of Appeal will consequently not disregard exhibits 801, 222, 823 and 225 and the facts relating thereto. The parties are allowed to bring them in the appeal proceedings.

- Exhibits 226 to 231

31. At the oral hearing of 5 February 2026, Viatris Santé argued in the rebuttals that, based on Article 3 of the LEEM–CEPS framework agreement, a generics company may lose its price and reimbursement listing if it did not launch its product within six months. Viatris Santé was informed that this would be considered a new fact if it could not be found in the submissions.

32. On 17 February 2026 Viatris Santé lodged an application for admission of exhibits 226 to 231, concerning the French regulatory framework. Exhibits 226 to 228 are ministerial orders which all pre-date the first instance proceedings, and exhibits 229 to 231 are correspondence between Viatris Santé and CEPS. According to Viatris Santé, these exhibits are necessary for the Court of Appeal to fully understand the legal and regulatory framework in France regarding the requirement for an applicant for price, to market a generic specialty within six months following the publication of the price in the French Official Journal. Essentially, Viatris Santé is asserting that non-compliance with this requirement results in removal from the list of pharmaceutical specialties approved for reimbursement to social security beneficiaries and/or approved for use by local authorities and public services.

33. When invited by the Court of Appeal to comment, Merz objected against the admissibility of exhibits 226 to 231, stating that this post-hearing filing was plainly motivated by Viatris Santé's inability to provide a satisfactory response to the Court's questioning during the oral hearing of 5 February 2026, and stating that filing could also have been done earlier. Merz's position is that admission of these exhibits at this late stage would cause undue prejudice.

34. The Court of Appeal does not agree with Viatris Santé's argument that the existence of an obligation to market generics within six months of publication was never discussed or contested by the parties before the oral hearing of 5 February 2026 and that there was no doubt by both sides and the Paris Local Division regarding Article 3 of the LEEM–CEPS framework agreement and the potential consequences for the defaulting applicant. To the contrary, Merz argued that generics frequently secure pricing and reimbursement well in advance and then either defer launch for an extended period

of time (sometimes years after price grant) or positively commit not to launch before patent expiry (SoG para. 21) and also submitted the supporting evidence referred to above. Viatris Santé should have responded to this in its Statement of response, and should have submitted supporting documents at the same time.

35. Although national law is a source of law pursuant to Art. 24 UPCA, in the context of provisional measures it is for the parties to bring forward facts and evidence about the content of national law and its application (Order of 13 August 2025, UPC_CoA_446/2025 and 520/2025, *Boehringer Ingelheim vs Zentiva*, paragraph 72).

36. Notwithstanding the above and regardless of the belatedness of these documents, the Court of Appeal exercises its discretion here and admits exhibits 226-228 in the proceedings. These exhibits are copies of published Ministry orders on the application of Article 3 of the LEEM–CEPS framework agreement. The exhibits are relevant and the Court of Appeal would have been unhindered to inform itself of these orders. They have been discussed at the oral hearing of 16 April 2026.

37. As will be set out later in this order, Merz's position in the proceedings is not negatively affected by this.

38. Exhibits 229, 230 and 231 (e-mail correspondence between Viatris Santé and CEPS) are disregarded due to belatedness and lack of relevance.

- Exhibits 239–245 and 826–831

39. On 31 March 2026 Viatris Santé submitted a request for admission of exhibits 239 to 245. Building on its previous submission about a product shortage in May 2025, Viatris Santé alleged that these exhibits demonstrate a new and critical development regarding shortage of Merz's product in France. The evidence consists of a report from an MS patient, field reporting, web reports and a report by a bailiff. Viatris Santé submits that this shortage situation emerged in mid-March and that the exhibits could not have been filed sooner. Viatris Santé argues that in view of this shortage, the requested preliminary injunction should be denied.

40. Merz, as invited by the Court of Appeal, has replied on 9 April 2026 that the submission of these exhibits less than two weeks before the oral hearing of 16 April 2026 is not timely. Merz has additionally provided exhibits 826 (monthly GERS data up to and including February 2026), 827 (photographs of pharmacy stock showing shortage of the generics), 828 (Doctoome screenshots of the generic), 830 (Vigirupture screenshots of April 2026) and 831 (Merz France Manager affidavit 2026).

41. The newly filed exhibits 239-245 all relate to alleged stock shortages of Merz´s product on the French market in March 2026. Therefore, these exhibits could not reasonably have been lodged during the proceedings before the Court of First Instance and not within the time period for lodging the Statement of response. If the evidence would substantiate the existence of recent stock shortages, it could potentially have an impact on the proportionality assessment. For this reason, the Court of Appeal exercises its discretion by allowing the exhibits.

42. To ensure equality of arms, Merz's newly filed exhibits 826-831 are allowed too.

43. Exhibits 239–245 and 826–831 have been discussed at the oral hearing of 16 April 2026.

Urgency

- Merz's submissions

45. According to Merz, the urgency requirement is satisfied. Merz essentially acknowledges that Viatris Santé declared to CEPS on 3 October 2024 that the generic does not infringe the rights in question and would be launched within six months. Merz disputes the finding that Biogen was necessarily informed by CEPS of Viatris Santé's response. Moreover, there was no imminent infringement in January 2025 and Merz could not have known through "an audit" (due diligence) by then that Viatris Santé was about to launch its product. Merz had every reason to believe that Viatris Santé willfully refrained from launching on the French market. This was confirmed by Viatris Santé's overall conduct across Europe. A publication of a price for a generic is non-predictive of actual launch on the French market. Launch timing is discretionary and can vary between 0 days and 2,5 years, to no launch at all. The situation in Germany with respect to Merz's patent rights cannot serve to increase the duty of vigilance incumbent upon the patent holder. Furthermore, the outcome before the Bundespatentgericht has been reversed on appeal, where the Bundesgerichtshof has upheld the German part of the patent. Merz had no knowledge of any imminent infringement as of January 2025, having received no notification from CEPS or information from its predecessor in title of any price application by Viatris Santé. Viatris Santé launched the generic in France in June 2025 (some time after the above-mentioned six-month period).

- Viatris Santé's submissions

44. Biogen and Acorda received information from CEPS on 9 October 2024 about Viatris Santé's view that the generic did not infringe and that marketing would begin within six months (intention to launch).

45. In any case, Merz, Acorda and Biogen had the knowledge, or should have had the knowledge, since the price listing on 22 November 2024, that Viatris Santé was planning to launch its generic product, and should have informed the patent holder of this imminent infringement of its rights. The regulatory framework in France requires an applicant for price to market a generic specialty within six months following the publication of the price in the French Official Journal. Non-compliance can result in removal from the list of pharmaceutical specialties approved for reimbursement to social security beneficiaries and/or approved for use by local authorities and public services. Merz should have understood that a launch would be made within this time period.

46. In any event, Merz should have been aware of the imminent infringement since 2 January 2025 the date on which it "*succeeded Biogen to become operator in France of the MA for FAMPYRA and assumed responsibility for marketing FAMPYRA*". As stated by the Local Division, Merz should have acted diligently and carried out an audit of the rights it intended to acquire. It should have acted more diligently as soon as it obtained the exploitation rights of FAMPYRA®.

47. Once the generic has been put on the market there is no urgency since the alleged harm already occurred.

48. In any case, Merz was aware that the product was marketed in France on 10 June 2025 since the declaration of commercialization was published online on 10 June 2025. Also after this date, Merz did not act with sufficient diligence.

- The Court of Appeal's view

Principles for assessment of unreasonable delay

49. Delay within the meaning of R. 211.4 RoP shall be calculated from the day on which the applicant became aware, or should have become aware, of the infringement that would enable him, in accordance with R. 206.2 RoP, to file an application for provisional measures with a reasonable prospect of success. Thus, the decisive point in time is when the applicant has, or should have had, after exercising due diligence, the necessary facts and evidence within the meaning of R. 206.2(d) RoP. Whether there has been an unreasonable delay within the meaning of R. 211.4 RoP depends on the circumstances of the individual case (Order of 25 September 2024, UPC_CoA_182/2024, *Mammut vs Ortovox*).

50. Where a party wishes to act upon an imminent infringement, then delay shall be calculated from the day on which the applicant became aware, or should have become aware, of the imminent infringement (see Order of 13 August 2025, UPC_CoA_446/2025 and 520/2025, *Boehringer Ingelheim vs Zentiva*, paragraphs 86–89).

51. It follows from R. 211.2 RoP that, in taking its decision on provisional measures, the Court may require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that his right is being infringed, or that such infringement is imminent. The standard of proof is whether there is a sufficient degree of certainty, so that the Court is satisfied that on the balance of probabilities it is more likely than not that there is a patent infringement or that an infringement is imminent.

52. A situation of imminent infringement may be characterised by certain circumstances which suggest that the infringement has not yet occurred, but that the potential infringer has already set the stage for it to occur. The infringement is only a matter of starting the action. The preparations for it have been fully completed. These circumstances must be assessed on a case-by-case basis (*Boehringer Ingelheim vs Zentiva*, paragraph 46).

53. In the context of marketing of generic medicines, the mere application for a marketing authorisation by a generics company does not amount to an imminent infringement, nor does the grant of such an authorisation create one. Completion of the national procedures for health technology assessment, pricing and reimbursement for a generic medicine may amount to an imminent infringement. The assessment must be made with due regard to the national regulatory and legislative context and considering the circumstances of the case (*Boehringer Ingelheim vs Zentiva*, paragraphs 47-48).

54. There is no need to determine in this case whether awareness of an imminent infringement also sets the clock in motion for the calculation of delay within the meaning of R. 211.4 RoP caused by an actual infringement. This is because there is insufficient support for the view that Merz was aware or should have been aware of any imminent infringement.

French regulatory framework

55. Based on the facts and evidence brought forward by the parties, the French regulatory framework and administrative procedure entails the following steps (in brief and insofar as relevant):
    - Article 3 of the LEEM–CEPS framework agreement provides that no generic shall be included in the lists of reimbursable products earlier than six months before the expiry of the intellectual property rights notified to CEPS, unless the generic company expressly declares to CEPS that it will launch its product without infringing the notified intellectual property rights.
    - Only the French "exploitant" of the marketing authorisation for the reference medicinal product (i) may notify CEPS of the intellectual property rights and (ii) is the addressee of CEPS' communications regarding declarations submitted by generic companies.
    - Notifications made by the exploitant must be communicated by CEPS to any generic company that applies for a price and the listing of reimbursable products.
    - Any declaration by a generic company to CEPS that it will launch its product without infringing the notified intellectual property rights received by CEPS is then communicated by CEPS to the exploitant.
    - The decisions on price, reimbursable rate and listing on the list of reimbursable products are published in the French Official Journal.
    - Actual commercialisation (marketing launch) of a product must be declared to the National Agency for Medicines and Health Products Safety, ANSM. This declaration is recorded in the ANSM database to be made publicly available. Publication by the ANSM may be subject to a delay as the database is updated approximately monthly.

Sufficient knowledge caused by the e-mail of 9 October 2024?

56. Biogen remained the exploitant for the French market for the reference product FAMPYRA® until 31 December 2024 and this was communicated jointly by Biogen and Merz to the French regulatory authorities in the autumn of 2024.

57. Exhibit 135, presented by Viatris Santé, demonstrates that CEPS informed Viatris Santé on 2 September 2024 about the patent at issue and SPC 033, adding "*Please let me know how the marketing of your generic product is progressing*". In response, Viatris Santé informed CEPS on 3 October 2024 that the generic product "*does not infringe the patents claimed and that it will be available for sale within six months of publication in the JORF*" (which is the French Official Journal).

58. Viatris Santé has submitted as exhibit 222, an e-mail exchange between CEPS and Viatris Santé in which CEPS confirms that "*Le conseil de Biogen,* [redacted] *a été averti par courrier du 9 octobre 2024*". Although the actual communication between CEPS and Biogen has not been submitted, the Court of Appeal finds the evidence in exhibit 222 sufficient for the conclusion that CEPS sent Viatris Santé's response of 3 October 2024 to [redacted] from the law firm [redacted] on 9 October 2024. This evidence is further supported by exhibit 823 (see below).

59. However, in the letter submitted by Merz as exhibit 801, Biogen states that after a reasonable search, they are not aware of Biogen having received any such notice from CEPS in 2024. This statement is supported by the statement in Exhibit 823 (below), according to which [redacted] was Acorda's representative, not Biogen's.

60. Merz's exhibit 823 is a witness statement by Acorda's Liquidation Trustee, who testifies that [redacted] had been mandated by Acorda in 2023. [redacted] received a letter from CEPS on 9 October 2024 advising that Viatris Santé had filed a price and reimbursement application for a generic product of FAMPYRA® and stated its intention to commercialize said generic product within six months without infringing the declared patent rights. [redacted] attempted to relay the CEPS communication to Acorda but was unable to reach his former corporate contacts. The Liquidation Trustee testifies that in light of the plan of liquidation for Acorda having become effective on 23 August 2024 and the post-effective administration through the Liquidation Trust, any communications to Acorda's former corporate contacts would not have reached a functioning corporate recipient since, as from 23 August 2024, the proper addressee was himself serving as Liquidation Trustee, or his counsel. He confirms that he did not receive any communication regarding Viatris Santé's French price and reimbursement application or undertaking to launch its generic product on the French market, whether from [redacted] or from CEPS directly, nor did his counsel.

61. Viatris Santé has brought forward that by notifying the mandated lawyer of – at least – Acorda, CEPS notified Acorda. Acorda had ceased to exist as an operational entity but still existed as a legal entity and as a patent holder, and was duly represented before CEPS by its French counsel. Viatris Santé argues that the Liquidation Trustee clearly admits that said lawyer did attempt to contact Acorda to relay the information on the notification, and that it is more than likely that the French lawyer contacted someone at Acorda (different from the Liquidation Trustee), or at Biogen, or Merz, or any of their outside counsels.

62. However, absent any evidence to the contrary, the Court of Appeal considers that the statements from Biogen and Acorda together create a strong likelihood that the information sent on 9 October 2024 from CEPS never went further than to [redacted]. There is presently no support for the view that Acorda or Biogen were informed.

63. As a result, Merz could not have obtained information about Viatris Santé's response of 9 October 2024 from Acorda or Biogen. It also renders irrelevant the date of ownership transfer of the patent and SPC 033, and whether Merz would have been entitled to receive information from Biogen, the previous exploitant of the reference product on the French market, since Biogen was not in possession of the information in question.

Sufficient knowledge caused by the publication of the price and reimbursement listing on 22 November 2024?

64. Next, the Court of Appeal will address Viatris Santé's assertion that Merz had the knowledge, or should have had the knowledge, that Viatris Santé was planning to launch its generic product within six months from the publication of the price and reimbursement rate in the French Official Journal on 22 November 2024.

65. If Merz had consulted previous issues of the French Official Journal it would have found the information that Viatris Santé had obtained a price and reimbursement rate on 22 November 2024. Based on the circumstances of the case it shall be considered whether Merz, if it had read the French Official Journal publication of 22 November 2024, would have obtained the necessary facts and evidence within the meaning of R. 206.2(d) RoP so as to enable it to file an application for provisional measures with a

reasonable prospect of success.

66. Viatris Santé's position is that there is an obligation under French law for the generics company to launch the generic within six months once it has a price and reimbursement rate, which should cause the right holder to assume that there is a very high likelihood of a launch. Viatris Santé relies in this respect on Article 3 of the LEEM–CEPS framework agreement from which it would follow that a generic company in order to obtain a price and reimbursement rate, has to expressly declare to CEPS, not only that it would be able to launch its product without infringing the notified intellectual property rights (cf Article 3, 2nd paragraph of that agreement), but also that it shall do so within six months after publication of its listing in the French Official Journal.

67. Article 3 of the LEEM–CEPS framework agreement reads as follows:

> Aucune inscription de spécialité générique ou biosimilaire sur la liste des spécialités remboursables aux assurés sociaux et le cas échéant sur les listes prévues aux articles L.162-22-7 du code de la sécurité sociale et L.5126-6 du Code de la santé publique, n'est publiée plus de 6 mois avant la date déclarée de cessation des droits de propriété intellectuelle si elle a été notifiée au Comité.
>
> Toutefois, un laboratoire pharmaceutique qui estime pouvoir commercialiser les spécialités génériques ou biosimilaires concernées sans enfreindre les droits déclarés peut demander leur inscription. Il doit dans ce cas le faire savoir par écrit au Comité qui sans délai en informe l'exploitant de la ou des spécialités visées au premier alinéa ci-dessus et met en œuvre la procédure d'inscription.

In English translation:

> No generic or biosimilar speciality shall be included on the list of reimbursable specialities for persons covered by social security and, where applicable, on the lists provided for in Articles L.162-22-7 of the Social Security Code and L.5126-6 of the Public Health Code shall be published more than six months before the declared date of expiry of intellectual property rights if this has been notified to the Committee.
>
> However, a pharmaceutical company that believes it can market the generic or biosimilar products in question without infringing the declared rights may apply for their registration. In this case, it must notify the Committee in writing, which shall immediately inform the operator of the product or products referred to in the first paragraph above and initiate the registration procedure.

68. The Court of Appeal considers that this provision does not on a literal reading require marketing of the generic within six months from publication. Rather it indicates a limitation as to the timeframe within which a product can be included on the respective lists (not earlier than 6 months before the expiry of the intellectual property right in question), which limitation does not apply if a notification as meant in the second paragraph is made (i.e. the generic company believes it can market the generic without infringing the declared rights).

69. This is supported by documentary evidence relating to actual launches of generics a considerable time – as much as two and a half years – after publication of price and reimbursement rates, which Merz has presented to substantiate its argument that the alleged obligation to market a product within six months after listing does not exist in a situation such as the present one. This evidence has not been contested as such by Viatris Santé.

70. It is also common ground that Viatris Santé launched the generic on the French market on 10 June 2025, some time after the six-month period. Viatris Santé has not explained why this launch would be vitiated by any illegality resulting from the expiry of the six months. When questioned at the oral hearing of 5 February 2025, it stated that it was a minor issue of just two weeks beyond six months.

71. Contrary to what Viatris Santé alleges, also the ministerial orders (exhibits 226-228) do not convey any clear practice pursued by the government authorities of requiring a commitment to launch within six months, coupled with de-listing as a legal consequence in case of non-compliance.

- Exhibit 226 is an order of 23 November 2023 and is based on the fact that the holder of the reference product had declared to CEPS the existence of intellectual property rights in force protecting this product in France until 20 May 2026. Generics were nevertheless listed on 5 June 2023. Letters of intent to delist the generics (dated 11 October 2023) were sent by the administration, and the generics were removed from the list by the order of 23 November 2023. The reasons stated include that the generic companies did not *renew* their *commitment* to market these generic versions within six months of the publication of the registration order of 5 June 2023.
- Exhibit 227 is an order of 22 July 2024 by which a generic that had been listed on 23 October 2023, was delisted because the manufacturer did not *indicate* that it would be able to market the generics within six months without infringing the declared intellectual property rights.
- Similarly, exhibit 228 records a delisting of a generic which was listed on 24 October 2023, but was delisted on 2 September 2024 because the manufacturer of the generic had failed to *indicate* by e-mail dated 12 April 2024 that it would be able to market this drug within six months without infringing the intellectual property rights.

72. The orders do not unambiguously show that the French government requires a marketing of the generic within 6 months after obtaining the price and reimbursement rate. In any event, the evidence does not allow any conclusion going beyond that such practice is flexible. Exhibit 226 allows the generic to renew its listing, going well beyond the 6 month term suggested by Viatris Santé. Exhibits 227 and 228 demonstrate time frames of 9 to 10 months in this regard. Merz is also right in pointing out that the reason given for the de-listing has been that the generics companies did not make statements about launch within six months, rather than any observations about absence of actual market launches.

73. As the publication of the price and reimbursement rate on 22 November 2024 did not provide sufficient certainty that the generics would be launched within six months, Merz had no reason to assume, in the absence of further evidence, that marketing would take place within six months.

Possible awareness on or before 30 June 2025?

74. Viatris Santé's actual launch of the generics was published by the ANSM on 30 June 2025. Prior to this, however, Merz sent a notice letter on 18 June 2025 to Viatris Limited and Generics (UK) Limited t/a Mylan, seeking confirmation that Viatris would not launch its generic in European countries where it had been granted a marketing authorization.

75. It can be left open whether the ANSM publication of 30 June 2025 created an awareness, since Merz

definitely became aware of an ongoing infringement a few days later on 2 July 2025, when Viatris replied by stating that it had already launched the generic in France. Following a brief exchange of warning letter correspondence, Merz lodged the Application for provisional measures on 31 July 2025. This satisfies the requirements of R. 211.4 RoP, even if Merz should have been aware of the imminent infringement on 30 June 2025 by the ANSM publication.

Necessity of provisional measures and balance of interests

- Viatris Santé's submissions (in summary and insofar as relevant)

76. In relation to the needs of the public, it is critical to have the two players (Merz and Viatris Santé) remaining on the market. Merz's inability to supply FAMPYRA® on a continuous basis necessitates the existence of alternative solutions.

77. Viatris Santé refers in this context to a first product shortage that occurred in May 2025 when Merz introduced a new packaging for its products. In addition, recent stock shortages of Merz's product have emerged in mid-March 2026 and continue to develop. Since mid-March 2026, FAMPYRA® is being reported as out of stock by pharmacists in all of France at a significantly and increasingly higher rate than at the beginning of 2026, while the generic has been reliably available for all of 2026, including in the last two weeks of March.

77. Moreover, FAMPYRA®'s new packaging is not suitable for patients. Indeed, it is significantly harder to open. Second, the new packaging has an impact on the expiration date of the medication. Under the former packaging, the expiration period was 36 months as long as the capsules remained in the blister. The new packaging introduces a new expiration date of 7 days following the opening of the bottle.

78. Taking into account the irreparable harm that would be borne not only by Viatris Santé but also by public health systems and patients (the harm borne by social security if Viatris Santé were prevented from marketing its generic, which could not be compensated), the requested measures are disproportionate and should therefore be rejected. Patients are also affected as 85% of the costs are borne by them.

79. Merz's alleged losses are vague and unsupported. Price erosion is not automatic. Article 24 of the framework agreement concluded between the LEEM and CEPS on 5 March 2021 allows Merz to request the suspension of the 20 % discount "*in the event of a dispute that would prevent marketing under conditions of fair competition*". The launch of a generic held infringing can be entirely repaired by damages, since the only loss suffered by the patentee is a loss of money. The alleged price cascade in other countries is speculative and irrelevant.

80. The requested measures are excessive. Although delivery-up to a bailiff is not the same as recall and destruction, regulatory issues can be foreseen.

81. For any alleged automatic and/or irreparable harm to Merz, the order would in any case come too late. There would not be any reason at this point not to wait for proceedings on the merits to determine the best compensation to Merz.

- The Court of Appeal's view

82. It is not in dispute that SPC 033 is valid and infringed. A provisional injunction is necessary to prevent infringement by a directly competing product, and the weighing up of the interests of the parties does not lead to any other conclusion.

83. Art. 25 (a) UPCA confers on the patent proprietor the right to prevent any third party not having the proprietor's consent from making, offering, placing on the market or using a product which is the subject-matter of the patent, or importing or storing the product for those purposes.

84. Pursuant to Art. 30 UPCA, a supplementary protection certificate shall confer the same rights as conferred by the patent and shall be subject to the same limitations and the same obligations.

85. On provisional and protective measures, Art. 62(2) UPCA and R. 211.3 RoP provide that the Court shall have the discretion to weigh up the interests of the parties and, in particular, take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction. The Court must in addition consider the time factor. More specifically, the Court must assess whether it is possible to await proceedings on the merits, or whether provisional measures are necessary (Order of 24 February 2025, UPC_CoA_540/2024, *Biolitec v Light Guide et al*, paragraph 19).

86. Provisional measures will be necessary, for instance, where any delay would cause irreparable harm to the patent holder. Irreparable harm is, however, not a necessary condition for the ordering of provisional measures (Order of 25 September 2024, UPC_CoA_182/2024, *Mammut v Ortovox*, paragraph 237; *Biolitec v Light Guide et al*, paragraph 21).

87. The necessity of provisional measures may also follow from the fact that there is direct competition between the attacked embodiment and the product of the patent holder (see *Biolitec v Light Guide et al*, paragraph 26). In those cases, granting provisional measures may be justified if they are necessary in order to maintain the status quo that existed immediately prior to the alleged infringement until the decision of the Court on the merits (*Mammut v Ortovox*, paragraph 238 et seq; *Biolitec v LightGuide et al*, paragraph 28). The necessity for provisional measures may arise in a move from a market situation where only one product is available to one where there are two such competing products. Such a move can be expected to lead not just to price pressure but to a permanent price erosion (see Order of 3 March 2025, UPC_CoA_523/2024, *Sumi v Syngenta*, paragraph 93).

88. The interests of patients can be a factor to consider in this context (Order of 30 April 2025, UPC_CoA_768/2024, *Insulet vs EOFlow*, paragraph 120).

Provisional injunction

89. Viatris Santé's arguments related to proportionality of the provisional injunction are in summary alleged product shortages, packaging issues, costs borne by the French public health system and patients if only Merz products would be available, absence of price erosion and the fact that there are only a few months left before SPC 033 expires. These will be addressed in the following.

- Product shortages

90. As regards the alleged shortages of Merz's product FAMPYRA® on the French market, Viatris Santé clarified at the oral hearing that those occurred in May 2025 and mid-March 2026. Merz has not disputed as such that there have been product shortages but has provided the following explanations.
    - In May 2025 there was a change in the packaging of the originator product. Merz had to wait for the price and reimbursement rate that had to accompany the change. There was a delay in the publication, but this was resolved in June 2025.
    - The March 2026 shortages of the originator product were due to Viatris Santé's inability to supply the market with the generic. In January 2026, the generic held 39% of the market. By February 2026, that figure had collapsed to just 19%. As the generic became increasingly unavailable in February 2026, this triggered a substitution effect towards Merz's product when pharmacists turned to the only alternative that remained continuously and reliably available. This sudden and unexpected surge in demand for FAMPYRA® is what caused the localised stock tensions. Since the entry of the generic onto the French market, Merz had adjusted the volumes of its product supplied to the French territory in order to reflect the reduced demand, and now it had to re-direct supplies to France. On 8 April 2026, both products were reported labelled with a supply status of "medium" on the Vigirupture platform.

91. The May 2025 shortages indeed seem to have been of limited duration, and were immediately compensated by sales in June 2025, as can be seen from the GERS data (exhibit 826).

92. Concerning the mid-March 2026 shortages, Viatris Santé's evidence indicates transient shortages at different places in France from day to day. Exhibits 827 and 828 brought by Merz provide some indicia about stock shortages of the generic too, but are as inconclusive as the corresponding evidence brought by Viatris Santé. Merz´s narrative (that there was a rush for the originator product in response to shortage of generics) is however supported by the GERS data which shows a sudden drop in the sale of the generic in February 2026. Viatris Santé admitted at the oral hearing that it had experienced issues with delays in international shipments of the generic from the manufacturing side. The affidavit of Merz's French General Manager supports that 4 951 packs of Merz´s products were available in the first week of April 2026, a volume which is not contested as such, nor in relation to the needs of the market.

93. Even though what has happened in the past can be indicative of what will happen after an injunction is issued, it is essentially a forward-looking assessment whether a provisional injunction shall be granted.

94. Merz has argued that the GERS data for pharmaceutical sales and supply data in France conclusively demonstrate the continuous availability of FAMPYRA® throughout 2025 and into 2026. Apart from the arguments about shortages in May 2025 and mid-March 2026, for which credible explanations have been provided, no substantiated concerns have been raised against Merz´s supply capacity.

95. In addition, the General Manager of Merz France confirms in exhibit 831 that Merz is able to supply the entire French market, including to support any additional demand resulting from a potential injunction against Viatris Santé resulting in the withdrawal from the market of FAMPRIDINE VIATRIS®, without any interruptions in supply, and that Merz has received confirmation from its supply chain team that it is

able to support such additional demand and can confirm continued market supply until at least the expiry of the SPC on 25 July 2026.

96. To conclude, the patients' interests of continuous supply cannot be expected to be jeopardized by a provisional injunction.

- Packaging problems

97. As regards the alleged packaging problems, Merz has stated without being contradicted that the French health authorities have approved the packaging and that any alleged shelf-life concern is moot given that each packaging contains multiples of 14 tablet bottles (pursuant to the approved administration twice daily, each bottle lasts seven days; the in-use period). The Court of Appeal is convinced that the national authorities are best placed to act if there are any packaging irregularities that need attention.

- Costs for the French health system and patients

98. When asking the Court of Appeal to refrain from a provisional injunction because it would lead to higher costs for the French health system and patients, Viatris Santé is pursuing a self-interest. It is explicitly asking the Court of Appeal to keep in place a market situation with two products (one originator and one generic). This is not only incompatible with upholding the rights pertaining to SPC 033, but also very different from what will happen soon when SPC 033 expires. By then any company which has fulfilled the regulatory requirements will be able to market generics, and multi-supplier price competition can be expected. Also this argument cannot result in a rejection of the provisional injunction while SPC 033 is still in force.

- Price erosion

99. Merz has argued that CEPS applies a 20 % price reduction to the reference product after the entry of generics onto the market. It has been clarified at the oral hearing that the standard 20 % price reduction to the reference product after the entry of generics onto the market has not been applied yet by CEPS. Merz has argued with reference to Article 24 of the framework agreement between LEEM and CEPS (exhibit 501) that a negative decision from the UPC will surely trigger such a price reduction, whereupon Merz will have to compensate the French health system retroactively. The existence of such a system is supported by the evidence.

100. Given the short time left before the SPC expires, the main issue is not so much price erosion as lost market shares and resulting lost turnover for Merz as SPC holder.

- The fact that there are only a few months left before SPC 033 expires

101. The short time left before SPC 033 expires does not speak against provisional measures, especially since this is due to a reversal of the order of the Local Division on appeal.

Delivery up of stocks

102. According to Art. 62(3) UPCA, the Court may (insofar as relevant here) order delivery up of the products suspected of infringing a patent so as to prevent their entry into, or movement, within the channels of commerce. This is reflected in R. 211.1 (b) RoP.

103. Viatris Santé relied on Article 6.3 of the French Good Distribution Practices of the ANSM and argued that the requested measure would prevent the generics from being reincorporated into the distribution stock (recall/withdrawal from the market). This matter was resolved at the oral hearing where Viatris Santé accepted that delivery up in the sense of applicable UPCA rules is not equal to recall or withdrawal in the sense of Article 6.3 of the French Good Distribution Practices.

104. A delivery up shall be ordered in accordance with the request to prevent further infringing products from entering the market. The order covers products in stock and/or otherwise held, owned, or in the direct or indirect possession of Viatris Santé in France.

Guarantee and security

105. With reference to what has been argued, and given the overall circumstances of the case, Viatris Santé has requested that the Court rejects the measures requested by Merz and allows in place the continuation of the marketing of the generic on French territory subject to the lodging of a guarantee of an amount at the Court's discretion, but which shall not be higher than 260,000 EUR, i.e., the amount of the litigation valuation determined by Merz.

106. Merz has objected and argued that this would amount to a license to infringe. In any event, any calculation should be based on the preliminary estimate of losses Merz would suffer until SPC expiry and could not be lower than 8 million EUR.

107. The Court of Appeal finds that it would be inappropriate to order continuous supply of the generic based on a guarantee, regardless of the value of such a guarantee (see paragraph 98 above).

108. Viatris Santé has additionally requested that the Court of Appeal orders Merz to provide a security to Viatris Santé in the event that the requested provisional measures were granted, not lower than 260,000 EUR, i.e., the amount of the litigation valuation determined by Merz. However, Viatris Santé has not demonstrated why serious difficulties would be expected in connection with the recovery of any possible damages from Merz, given Merz's financial stability and the fact that Merz is located in the EU.

Grace period and penalties

109. Merz suggests a 48-hour grace period for Viatris Santé from service of the order of the Court of Appeal in relation to the provisional injunction, and a one-week grace period in relation to the delivery up to a bailiff of products. Viatris Santé has requested a three-week grace period for both. However no substantiated reasons have been provided for why a three-week period would be called for.

110. Concerning the amount of penalties, Merz has argued that a maximum amount of up to 100,000 EUR per day is reasonable for the provisional injunction, and up to 50,000 EUR per day for the delivery-up. The Court of Appeal considers these amounts to be proportionate to the importance of ensuring compliance with the order to be enforced.

Costs

111. As a result of the setting aside of the impugned order and the granting of Merz' requests, the cost order shall be reversed and Viatris Santé shall be ordered to bear the costs at both instances.

112. An interim award of costs shall be granted. However, as a general rule, Art. 69(1) UPCA and R. 150(2) RoP do not entitle the successful party to an interim reimbursement of representation costs of more than 50% of the ceiling of recoverable costs as adopted by the Administrative Committee under R. 152.2 RoP (see Decision of 25 November 2025, UPC_CoA_464/2024, *Meril vs Edwards*).

113. This results in an interim award of costs of 28,000 EUR per instance, or 56,000 EUR in total.

Conclusion

114. It follows from the above that the appeal is successful and the impugned order must be set aside. The Application shall be granted as set out in the order below.

ORDER

The Court of Appeal:

I. sets aside the order of 21 November 2025 issued by the Paris Local Division, UPC_CFI_697/2025;

II. orders Viatris Santé to refrain, in the territory of France, until 25 July 2026 included, from: making, offering, placing on the market or using, or importing or storing for those purposes, the generic products "FAMPRIDINE VIATRIS LP 10 mg, comprimé à libération prolongée" and any pharmaceutical composition falling within the scope of French Supplementary Protection Certificate No. 13C0033, including any sustained release 4-aminopyridine composition for use in a method of increasing walking speed in a patient with multiple sclerosis, wherein said composition is administered twice daily in a dose of 10 milligrams of 4-aminopyridine, in particular, if said composition is for administration every 12 hours;

III. orders Viatris Santé to comply with the order II above subject to a recurring penalty payment of up to 100,000 EUR for each day in case of non-compliance within 48 hours from service of the order of the Court of Appeal;

IV. orders Viatris Santé to deliver up to a bailiff appointed by Merz, at its own expense, any pharmaceutical composition reproducing French Supplementary Protection Certificate No. 13C0033, in stock and/or otherwise held, owned, or in the direct or indirect possession of Viatris Santé in France, within one week after notification by Merz to Viatris Santé that a bailiff has been duly appointed in France (including relevant details of the bailiff, such as name and address if applicable);

V. orders Viatris Santé to comply with the order IV above subject to a recurring penalty payment of up to 50,000 EUR for each day in case of non-compliance within 1 week from notification by Merz pursuant to paragraph IV above;

VI. orders Viatris Santé to pay Merz an amount of 56,000 EUR as an interim award of costs, within two weeks after this order has been served on Viatris Santé;

VII. orders Viatris Santé to bear the legal costs and other expenses incurred by Merz for the proceedings at first instance and on appeal;

VIII. specifies the date referred to in R. 213.1 RoP at 20 working days after service of this order;

IX. declares the order to be immediately enforceable.

Issued on 27 April 2026

Digitally signed by Åsa Ingeborg Simonsson
Date: 2026.04.27 13:37:47 +02'00'

Ingeborg Simonsson, presiding judge and judge-rapporteur

Patricia Ursula Rombach

Digitally signed by Patricia Ursula Rombach
Date: 2026.04.27 10:24:24 +02'00'

Patricia Rombach, legally qualified judge

Bartholomeus Johannes van den Broek

Digitally signed by Bartholomeus Johannes van den Broek
Date: 2026.04.27 10:36:40 +02'00'

Bart van den Broek, legally qualified judge

Anna Hedberg

Digitally signed by Anna Hedberg
Date: 2026.04.27 10:32:19 +02'00'

Anna Hedberg, technically qualified judge

Jeroen Willem Meewisse

Digitaal ondertekend door Jeroen Willem Meewisse
Datum: 2026.04.27 10:19:52 +02'00'

Jeroen Meewisse, technically qualified judge

For the Registry:

Mihaela CASTRUBIN

Digitally signed by Mihaela CASTRUBIN
Date: 2026.04.27 14:55:41 +02'00'