UPC_CFI_697/2025
FINAL ORDER
of the Court of First Instance of the Unified Patent Court
delivered on 21/11/2025
concerning provisional measures (R.206 RoP)

APPLICANTS

1) **Merz Therapeutics GmbH**
Eckenheimer Landstraße 100
60318 Frankfurt am Main - DE

2) **Merz Pharmaceuticals LLC**
Unit 35/36,
6601 Six Forks Road, 4th Floor
27615 Raleigh, North Carolina - US

3) **Merz Pharma France**
Tour EQHO, 2 Avenue Gambetta
92400 Courbevoie – FR

Represented by
Laëtitia Bénard
Charles Tuffreau
Edward Oates
Agathe Michel-de Cazotte

DEFENDANT

Viatris Santé
1 rue de Turin
69007 Lyon – FR

Represented by
Marc Lauzeral
Denis Schertenleib

PATENT AT ISSUE

Patent no.	*Proprietor*
EP2377536	Merz Pharmaceuticals, LLC

Patent no.	*SPC details*	
EP2377536	SPC ID	FR13C0033
	National Designations	FR

Patent no.	*SPC ID*	National Designations	Holders
EP2377536	FR13C0033	FR	Merz Pharmaceuticals, LLC

COMPOSITION OF PANEL – FULL PANEL

Presiding judge & Judge-rapporteur	**Camille Lignières**
Legally qualified judge	**Carine Gillet**
Legally qualified judge	**Samuel Granata**
Technically qualified judge	**Rainer Friedrich**

LANGUAGE OF PROCEEDINGS: English

ORDER

THE PARTIES

1. The Applicants (hereinafter "MERZ") are part of the MERZ Group, an international pharmaceutical group of German origin. Applicant 1 is Merz Pharmaceuticals LLC, a US company settled in the State of North Carolina. Applicant 2 is Merz Therapeutics GmbH, a German company, specialised in the research, development and marketing of innovative healthcare products. Merz Therapeutics' portfolio focuses on (i) neurology, (ii) hepatology and (iii) dermatology. Applicant 3 is Merz Pharma France, a French company settled in Courbevoie.

2. The Defendant is VIATRIS Santé (hereinafter “VIATRIS”), a French company settled in Lyon, which is part of the global Viatris Group, specialised in the development, manufacture, and distribution of generic pharmaceutical products. VIATRIS is the marketing authorisation holder for the product “FAMPRIDINE VIATRIS LP 10 mg, comprimé à libération prolongée”, which is a generic of the reference medicinal product FAMPYRA. It is notably responsible for the marketing of this generic product in France.

PROCEEDINGS

3. On 31 July 2025, MERZ lodged an application (hereinafter “the Application”) for provisional measures (pursuant to Art. 62 UPCA and R. 206 RoP) before the Paris Local Division, against VIATRIS, for infringement of French Supplementary Protection Certificate No. 13C0033 (hereinafter “SPC 033” or the “SPC”) based on European Patent No. 2 377 536 (hereafter “EP 536” or the “Patent”) due to the offering, placing on the market, and using, as well as importing and storing for those purposes in France of generic medicinal products “FAMPRIDINE VIATRIS LP 10 mg, comprimé à libération prolongée”, which are alleged as generics of the reference medicinal product FAMPYRA covered by SPC 033.

4. No protective letter has been filed before the introduction of the Application by VIATRIS.

5. Jurisdiction of the UPC and the internal competence of the Paris Local Division were not contested by the Defendant. This is a dispute concerning the marketing of a French SPC based on a European patent, and the Defendant is a French company. The Court confirmed its jurisdiction to hear the dispute under Articles 32.1(a) and 33.1(a) and (b) of the UPCA.

6. According to a timetable set by the Judge-Rapporteur by procedural order of 17 September 2025, VIATRIS filed its objection on 15 September 2025. MERZ filed its reply to the objection on 29 September 2025, and VIATRIS submitted its Rejoinder on 3 October 2025.

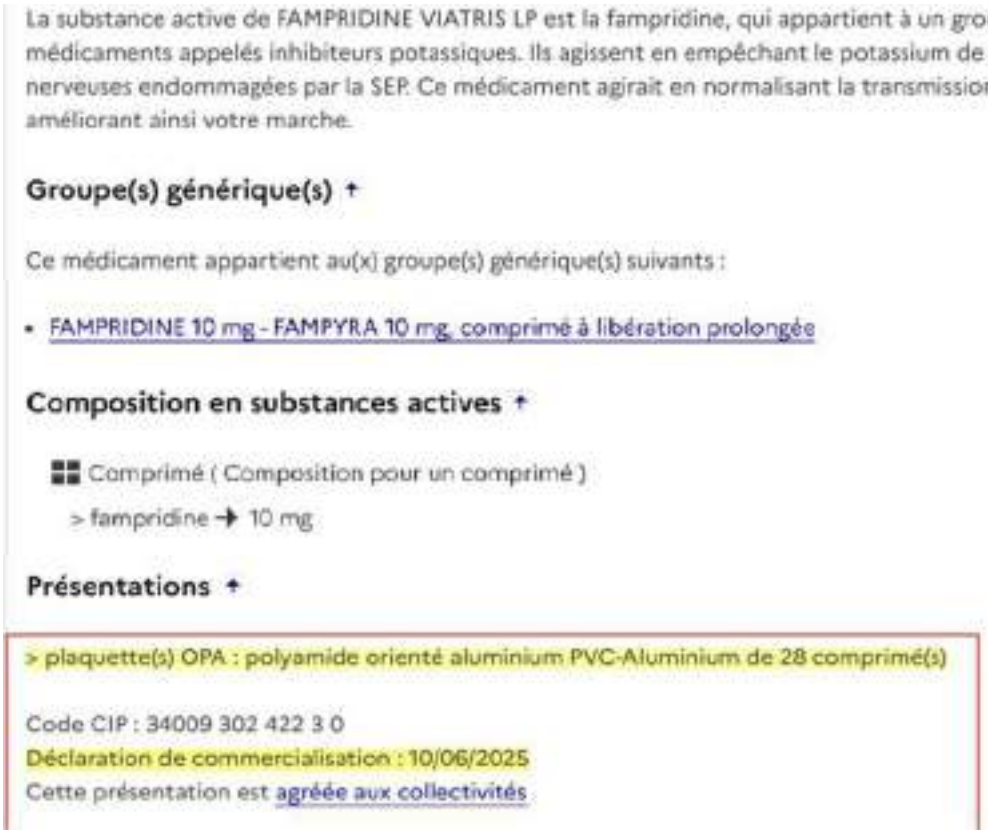
7. A technically qualified judge has been allocated to the panel upon the judge rapporteur's request at the earliest stage of the proceedings.

SUMMARY OF FACTS

8. MERZ asserts that VIATRIS infringes its French SPC 033 based on EP 536.

9. Merz Pharmaceuticals LLC (Applicant 1) is the owner of the Patent and the SPC in suit, Merz Therapeutics GmbH (Applicant 2) is the exclusive licensee, and Merz Pharma France (Applicant 3) has been granted an exclusive sub-licence to these rights in France. (Exhibits MERZ n°203 and 204)

10. The accused product, FAMPRIDINE VIATRIS, was introduced on the French market on 10 June 2025, as follows (Exhibit MERZ n°6) after the grant of a marketing authorisation in France on 19 November 2011 (Exhibit MERZ n° 116):



La substance active de FAMPRIDINE VIATRIS LP est la fampridine, qui appartient à un groupe de médicaments appelés inhibiteurs potassiques. Ils agissent en empêchant le potassium de sortir des cellules nerveuses endommagées par la SEP. Ce médicament agirait en normalisant la transmission des influx nerveux, améliorant ainsi votre marche.

Groupe(s) générique(s)

Ce médicament appartient au(x) groupe(s) générique(s) suivants :

- FAMPRIDINE 10 mg - FAMPYRA 10 mg, comprimé à libération prolongée

Composition en substances actives

Comprimé (Composition pour un comprimé)

> fampridine → 10 mg

Présentations

> plaquette(s) OPA : polyamide orienté aluminium PVC-Aluminium de 28 comprimé(s)

Code CIP : 34009 302 422 3 0
Déclaration de commercialisation : 10/06/2025
Cette présentation est agréée aux collectivités

11. EP 536, on which SPC 033 is based, is entitled “Methods of using sustained release amino-pyride compositions”. The Patent consists of two independent claims: claim 1 and its dependent claims 2 to 4 and claim 5 and its dependent claims 6 and 7. MERZ has based its present application for provisional measures on claims 1 and 5 of the Patent and claims 3 and 7 of the Patent.

12. Claim 1 reads as follows: “1. 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.” (Exhibit MERZ n° 205)

13. MERZ argues that since SPC 033 covers the active fampridine, FAMPRIDINE VIATRIS falls within the scope of the SPC in suit for any of its authorised uses as a medicinal product.

14. The Applicants argue that the requirements for ordering provisional measures are met, whereas the Respondent objects that the Applicants’ requests must be rejected because no pro-visional measures are necessary in the present case.

PARTIES’ REQUESTS

15. In its last submission (Reply dated 29 September 2025), MERZ requests that the Court grant the following provisional measures:

- The Respondent shall be enjoined 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, (Direct infringement of French Supplementary Protection Certificate No. 13C0033 based on claims 1 and 5 of the Patent)
in particular, if said composition is for administration every 12 hours. (Direct infringement of French Supplementary Protection Certificate No. 13C0033 based on claim 3 and 7 of the Patent)

B) In the event of failure to comply with the order under item A within 48 hours from service of the order, the Respondent shall make a (if applicable periodic) penalty payment to the Court of up to 100,000 euros for each day of failure to comply.

C) The Respondent shall be ordered to deliver up to a bailiff appointed by the Applicant, 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 the Respondent in France, in order to prevent their entry into or movement within the channels of commerce.

D) In the event of failure to comply with the order under item B within 1 week from the date of service of the order, the Respondent shall make a (if applicable periodic) penalty payment to the Court of up to 50,000 euros for each day of failure to comply.
E) The Respondent is ordered to provisionally reimburse the Applicants for costs in the amount of 56,000 euros.

F) The Respondent is ordered to pay the costs of the proceedings.

G) The orders are effective and enforceable immediately.

In addition, the Applicants request that:

H) Any claims, requests and arguments from VIATRIS be rejected.

16. In its last submission (Rejoinder dated 3 November 2025), VIATRIS requests the Court to:

Primarily,

- Hold that the French Supplementary Protection Certificate No. 13C0033 is more likely than not invalid,

- Hold that the provisional measures requested are disproportionate,

- Consequently, dismiss the application and all of the claims, requests and conclusions of MERZ.

In the alternative,

- Dismiss the request of MERZ for VIATRIS to be enjoined 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 libeération 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,

- Dismiss the request MERZ for VIATRIS to be ordered to make a penalty payment (if applicable periodic) to the Court of up to 100,000 euros for each day of failure to comply in the event of failure to comply with the previous request within 48 hours from the date of service of the order.

- Dismiss the requests of MERZ for VIATRIS to be ordered to deliver up to a bailiff appointed by the Applicants, 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 the Respondent in France, in order to prevent their entry into or movement within the channels of commerce at its own expense.

- Dismiss the request MERZ for VIATRIS to be ordered to make a (if applicable periodic) penalty payment to the Court of up to 50,000 euros for each day of failure to comply with the previous request 1 week from the date of service of the order.

- 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 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, in the territory of France, up until 25 July 2026 included.

- Order VIATRIS to lodge a guarantee to MERZ of such amount as the Court shall deem appropriate, but which shall not be higher than 260.000 euros,

In the further alternative,

- Reduce the sums of the penalty payments requested to such reasonable amount as the Court shall deem appropriate, but which shall not be higher than 260.000 euros,

- 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 to provide VIATRIS with a sum of the Court’s discretion, but which shall not be less than 260.000 euros for security for enforcement to VIATRIS SANTE by deposit or bank guarantee,

In any event,

- Dismiss the request of MERZ to order VIATRIS to pay the sum of 56,000 euros as interim award of costs;

- Order MERZ entities jointly and severally to pay EUR 56,000 as reimbursement of costs of the proceedings.

PRESENTATION OF THE TITLES: the basic Patent and the SPC in suit

17. The Patent titled "Methods of using sustained release aminopyride compositions", was filed as a divisional application with the European Patent Office on 29 March 2011, claiming the filing date of its parent application WO2005US12427 dated 11 April 2005, as well as US priorities dated 9 April 2004 and 8 April 2005. Mention of the grant of the patent at issue was published on 6 March 2013. (Exhibit MERZ n°205). The Patent expired on 11 April 2025.

18. EP 536 was subject to proceedings before the EPO: the Board of Appeal set aside the Opposition Division decision, which had revoked the patent for lack of novelty, and ordered the Opposition Division to maintain the patent in amended form in a decision of 4 September 2019. (Exhibit MERZ n° 300, EPO T 0799/16 decision).

19. The German Federal Patent Court invalidated on 4 March 2024 the German part of EP'536 for lack of inventive step. (Exhibit MERZ n° 301, and translation in EN. Exhibit n° 302)

20. EP 536 relates generally to a dosage regimen for a sustained release 4-aminopyridine composition for use in a method of increasing walking speed in a patient with multiple sclerosis.

21. EP 536 comprises 7 claims, notably Claim 1, an independent purpose-related product (Article 54(5) EPC) claim, and Claim 5, an independent purpose-related process (Swiss-type) claim.

22. Claim 1 of the patent, as maintained by the EPO Board of Appeal, reads as follows (the "feature breakdown" presentation by the Applicants is not contested by the Respondent and adopted by the Court):

Feature 1.1: A sustained release 4-aminopyridine composition

Feature 1.2: for use in a method of increasing walking speed in a patient with multiple sclerosis,

Feature 1.3: wherein said composition is administered twice daily in a dose of 10 milligrams of 4-aminopyridine.

Claim 5 is in Swiss-type claim format, and reads as follows:

Feature 5.1: Use of 4-aminopyridine

Feature 5.2: in the manufacture of a sustained release composition for increasing walking speed in a patient with multiple sclerosis,

Feature 5.3: wherein said composition is administered twice daily in a dose of 10 milligrams of 4-aminopyridine.

23. The validity of the basic patent, EP 536 is contested by VIATRIS, arguing its lack of inventive step.

24. MERZ claims that the EP 536, in its amended version upheld by the EPO BoA, is inventive and valid.

The SPC in suit:

25. The French SPC 033, filed on 24 June 2013, was granted on 20 November 2015, and it will expire on 25 July 2026.

26. SPC 033 concerns the marketing authorisation for the product FAMPYRA (EU/1/11/699/001 granted on 20 July 2011 and notified on 25 July 2011).

27. FAMPYRA covers “Fampridine or a derivative thereof” (as active ingredient).

28. The product FAMPYRA is indicated for the improvement of walking speed in adult patients with multiple sclerosis.

29. It is not contested by the parties that VIATRIS Fampridine is a generic of the reference medicinal product FAMPYRA covered by SPC 033.

30. VIATRIS contests the validity of the SPC at hand, asserting that this SPC is void due to prior marketing of PYMADIN in Bulgaria and Poland.

31. MERZ responds that Bulgarian and Polish sales at the time of the registration of SPC 033 were illegal.

APPLICANT’s ENTITLEMENT

32. MERZ explains that following bankruptcy proceedings initiated on 1 April 2024 by Acorda Therapeutics, Inc. (the initial patent owner), Merz Pharmaceuticals LLC acquired on 10 July 2024 by way of an assignment agreement the rights (Exhibit MERZ n° 212) to the reference medicinal product FAMPYRA (fampridine).

33. Acorda Therapeutics, Inc. ceased to exist as an operational entity as of the effective date of its court-approved liquidation plan, namely as of 23 August 2024.

34. Since 2 January 2025, Merz has assumed all management, distribution and marketing responsibilities for the FAMPYRA product in 45 countries, including France.

35. MERZ mentions also that on 28 March 2025, the assignment of the French designation of EP 536 and of SPC 033 from Acorda Therapeutics, Inc. to Merz Pharmaceuticals LLC was published in the French Official Intellectual Property Bulletin. (Exhibits MERZ n°200 and 201)

36. MERZ’s entitlement regarding EP 536 and SPC 033 at the time of filing the present application is not contested by VIATRIS.

THE REQUIREMENT of “any unreasonable delay in seeking provisional measures” under R.211.4 RoP

Legal framework:

37. Rule 211 – Order on the Application for provisional measures foresees in its point 4: “The Court shall have regard to any unreasonable delay in seeking provisional measures. “

38. UPC CoA ORD_44387/2024, Mammut Sports v Ortovox, Order of 25 September 2024, Headnotes 5, states that: “The 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.” (English translation of the Order in the German language)

39. UPC CoA, 446/2025, Order of 13 August 2025, Boehringer v Zentiva indicates:

- in its HEADNOTES 1 to 3 regarding the assessment of an imminent infringement in the context of marketing a generic medicine, that:
  “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 can 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. “

- And regarding the requirement of R. 211.4 RoP, the UPC Court of Appeal states in § 87 that: “The 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. (CoA, order of 25 September 2024, UPC_CoA_182/2024, APL_21143/2024, Mammut vs Ortovox). “

Parties’ arguments:

40. According to MERZ, the starting date to be considered is the letter dated 2 July 2025 received from VIATRIS informing that they have just started marketing FAMPRIDINE VIATRIS in France (Exhibits MERZ 125 and 126). MERZ argues that the launch in France without clearing the way by a revocation action of the patent on which the SPC is based was a surprise for them. (§43-77 of the Application). MERZ notes in its application (§18) that VIATRIS obtained a marketing authorisation for FAMPRIDE VIATRIS in France on 10 November 2021 and was granted a price and a reimbursement rate in November 2024 (Exhibits MERZ n° 118 and 120).

41. MERZ adds that undue delay must be assessed by reference to the knowledge of the actual infringement, not its imminence. A restrictive interpretation, encouraging the patent holder to file an application when infringement is imminent, would be contrary to Article 47 of the Charter of Fundamental Rights of the EU and Article 6 of the European Convention on Human Rights, as it would deprive the applicant of effective access to a court. Factual circumstances did not allow the applicant to consider that its application for interim measures, based on imminent infringement, had any chance of success in the absence of a real and concrete risk of infringement.

42. According to VIATRIS, the starting point to be considered is 22 November 2024, the date on which FAMPRIDINE VIATRIS' price was published (§61-75 of the Objection):

At this date, MERZ should have been aware of the imminent infringement and thus able to apply for provisional remedies. VIATRIS argues that they were contacted by the CEPS (French Economic Committee of Health Products) in the course of their application for pricing and reimbursement of FAMPRIDINE VIATRIS and were informed of MERZ's intellectual property rights (Communication between the CEPS and VIATRIS and that VIATRIS replied that they will not infringe MERZ's intellectual property rights (Communication between the CEPS and VIATRIS - Exhibit n°135, page 1).

43. In its letter dated 2 July 2025 to MERZ, VIATRIS stated that it had already begun selling its product in France (Letter from Viatris to Merz dated 2 July 2025 - Exhibit n°146, page 1). They argue that MERZ was aware that the contested product was marketed in France on 10 June 2025 (Extrait de la Base de Données Publiques des Médicaments Fampridine Viatris 10 mg 3- Exhibit n°82, pages 1 and 2).

44. VIATRIS adds that imminent infringement and ongoing infringement are distinct situations and cannot constitute two separate starting points for assessing the patentee's time limit for bringing a PI application. This is a matter of legal certainty for the defendant and for third parties, who may be required to recall all products and find themselves in difficulty if the infringed products have been distributed on the market for a long time.

Grounds for the order:

45. The rules of procedure of the UPC require that applicants seeking provisional measures justify that they have been sufficiently diligent to have access to an expedited procedure before this Court. Such expedited procedure implies on the one hand that the defendants defend themselves within a stringent timeframe according to the schedule drawn up by the judge-rapporteur, setting strict deadlines for the exchange of submissions (R. 209.1 RoP) and, on the other hand, that the Court deal with the case as a matter of urgency, in priority over the substantive cases brought before it. As the Hague UPC LD has already explained in a recent decision: "R. 211.4 RoP thus ensures that an applicant whose conduct already indicates that it is not in a hurry, cannot expect assistance in the form of an order for provisional measures. In other words, given that the main proceedings at the UPC are (to be) concluded within a little over one year, a patent holder who acts with unreasonable delay, shall not be allowed to jump the queue." (UPC_CFI_374/2024, 29 August 2025, Cilag v Rivolution, §38). Once the applicant is in possession of all the knowledge

and documents that are reasonably likely to lead to a successful prosecution of the case, it must normally file an application for provisional measures without delay (LD Munich 21 May 2024, UPC_CFI_443/2023 and 27 August 2024, UPC_CFI_201/2024).

46. The UPC has previously had to interpret what may be considered to be a lack of diligence by an applicant seeking a PI. Thus, on two occasions the UPC Court of Appeal stated that to determine the starting point of the reasonable time limit for taking action, the Court should consider the following question: 'When did the applicant become 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?'

This question requires that the case *in concreto* be examined.

47. The case in dispute has two distinctive features:

- the product alleged to be infringing is a generic version of a product protected by an SPC,

- the rights to the title on which the application is based were repurchased by the Defendant during the same period when the administrative procedure for authorising the generic product to be placed on the French market was ongoing.

48. This prompts the following question: In the context of a generic product, at what point was or should the person who purchased the rights have been informed of an event that could justify an application for interim measures?

49. The Applicants argue that the UPC texts provide for two possible starting points regarding the reasonable time limit for taking PI action, which are successive points in time: a first starting point would be that of becoming aware of imminent infringement, and a second starting point would be the act of infringement itself.

50. The court does not follow this line of reasoning, given that Article 62.1 UPCA and Rule 211.2 RoP mention the following condition: 'the right is infringed or such infringement is imminent', and do not make a distinction between two separate and consecutive situations that would create two phases likely to trigger the urgency criterion. Rather, the aforementioned Article and Rule provide for two alternative situations that allow for a preliminary injunction (PI) claim to be brought before the UPC. Accordingly, establishing the existence of either situation allows for a PI action to be taken with a reasonable chance of success.

51. The criterion of imminent risk of infringement is particularly relevant in the context of a generic product being placed on the market. Indeed, the applicant need not wait for the product to be placed on the market in order to analyse it and gather sufficient evidence to demonstrate that such product infringes, at least prima facie, the claims of their title (patent or SPC). Such a product automatically falls within the scope of protection once it is classified as a generic version of the product protected by said title and declared as such.

52. In the present case, it is necessary to determine the event in the French administrative procedure allowing the generic manufacturer to place its product on the market. The parties agree that this event is the obtaining of the price and reimbursement rate.

53. A review of the chronology of events demonstrates that:

- On 19 November 2021, VIATRIS obtained an authorisation to market the generic version of Fampridine Viatris in France (Exhibit VIATRIS n° 82) for its product Fampridine Viatris, which is undisputedly the generic version of the product FAMPYRA protected by the French SPC in question, which is in force until 25 July 2026.

- On 19 September 2024, Fampridine Viatris was published as a generic speciality in the Group's generic directory (Exhibit MERZ n° 117).

- On 22 November 2024, further to its inclusion on the official lists of reimbursable and approved pharmaceutical products (Exhibit MERZ n°118), the product was assigned a price and a reimbursement rate (Exhibit MERZ n° 120).

54. The administrative procedure required for Fampridine Viatris to be authorised for marketing in France was therefore finalised on 22 November 2024.

55. The documents in the file also show that, in accordance with the French administrative procedure for the marketing of a medicinal product protected by an SPC, the Health Products Economic Committee (CEPS or the Committee), i.e. the interministerial body that sets the prices of medicines and medical devices for individual use covered by compulsory health insurance (see Viatris Exhibit 148), had informed VIATRIS that the generic product for which a marketing authorisation had been requested was protected by a patent. VIATRIS responded (by email) on 3 October 2024 that Fampridine Viatris would be marketed on the French market within six months, as follows: (Exhibit VIATRIS n°135)

Thursday, August 21, 2025 at 10:22:41 AM Central European Summer Time

Objet: RE: Fampridine
Date: jeudi 3 octobre 2024 à 14:30:18 heure d'été d'Europe centrale
De: [redacted]
À: [redacted]
Pièces jointes: image002.png, image003.png, image004.png, image005.png

Monsieur [redacted]

Nous vous confirmons que notre spécialité Fampridine Viatris n'enfreint pas les brevets revendiqués et que la commercialisation sera effective dans les 6 mois suivant la publication au JORF.

Cordialement

[redacted]
Directeur des Affaires Économiques

A compter du 1er avril 2023, la dénomination sociale de Viatris Médical devient Viatris Santé

Viatris Santé
1, bis place de la Défense, Tour Trinity,
92400 Courbevoie

[redacted]@viatris.com

VIATRIS

SCHERTENLEIB

Pièce n°135

56. It has therefore been demonstrated that VIATRIS had informed the Committee of its intention to market the generic drug within six months, i.e. by April 2025 at the latest, that is to say, before the expiry of the SPC on 25 July 2026.

57. The Committee is required to inform the rights holder of the generic manufacturer's response indicating its intention to market its product (Art. 3 of the LEEMS CEPS agreement - §23 Objection. PJ 5 and PJ 5bis VIATRIS), as can be seen from the extract from the agreement:

Article 3. Intellectual property

Companies exploiting chemical or biological specialities for which they hold one or more patents or CCPs shall declare, for information purposes, to the Committee in Annex 7 of the multi-annual agreement the titles concerned and their expiry dates for the three years following the initial signature and that of each update.

The Committee shall make these statements available to any pharmaceutical company that requests them.

No generic or biosimilar speciality shall be included on the list of specialities eligible for reimbursement to 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 it 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.

58. It was clarified at the oral hearing, in response to a question from the panel, that BIOGEN was responsible for marketing FAMPYRA on the French market at that time. Moreover, MERZ does not dispute that BIOGEN was necessarily informed of this response by the Committee.

59. 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, further to the letter sent on 3 October 2024 by VIATRIS to the Committee.

60. In any event, upon acquiring the basic patent and the SPC in question, it should have carried out an audit (due diligence) of the rights it intended to acquire. Furthermore, MERZ was aware that BIOGEN was responsible for marketing FAMPYRA in France. This acquisition was important for MERZ, as evidenced by the announcement made by the MERZ group on its website on 10 July 2024 - Exhibit MERZ n° 6, as follows:


A&O Shearman

Ex. No. 6

NEWS RELEASE

Merz Therapeutics Closes $185M Asset Purchase Agreement with Acorda Therapeutics

Frankfurt, Germany · July 10, 2024

61. This date of acquisition by the MERZ group in 2024 is also set out in the warning letter sent to VIATRIS on 18 June 2025: (Exhibit MERZ n° 125)

[redacted]@viatris.com; reception@viatris.com

Copy by courier

Your ref
Our ref G072608PT
Date 18 June 2025

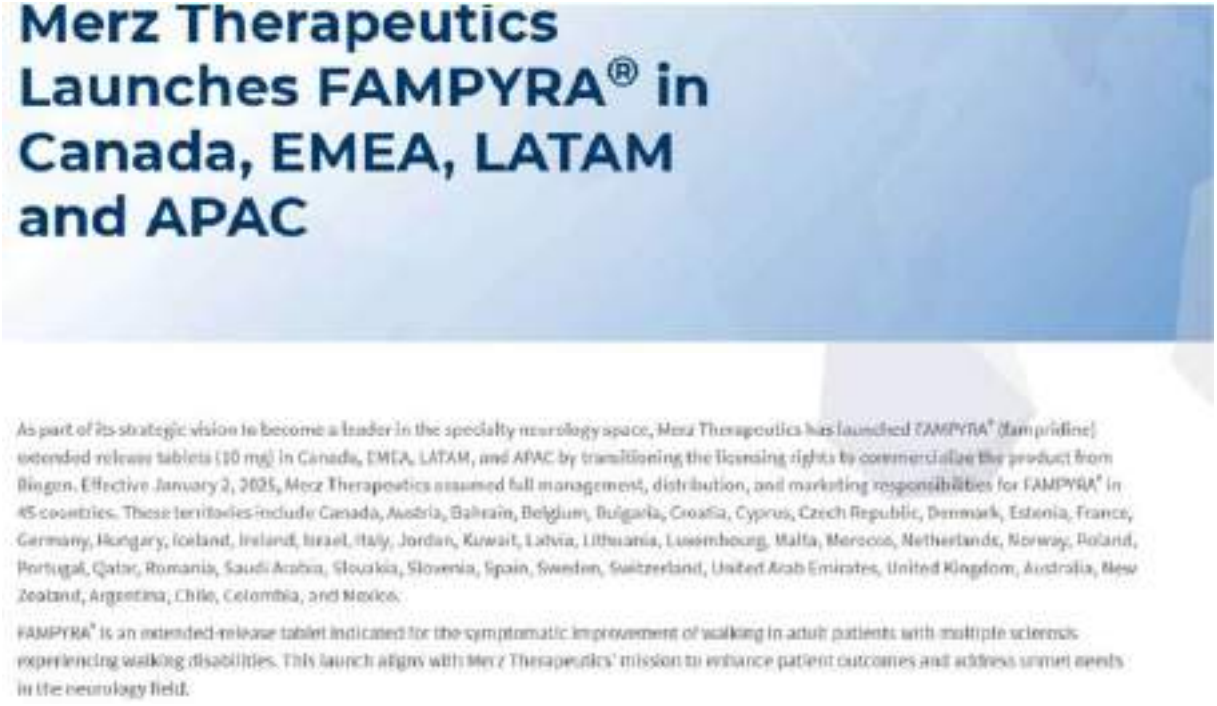
Dear Sirs,

GENERIC FAMPRIDINE – VIATRIS

We act for Merz Pharmaceuticals, LLC ("Merz Pharmaceuticals"), Merz Therapeutics GmbH and associated affiliates which together form part of the Merz group of companies (together, "Merz"). In 2024, Merz acquired, inter alia, the product Fampyra (fampridine) and associated assets from

62. MERZ claims that it did not recover the direct exploitation of FAMPYRA from the licensee BIOGEN until 2 January 2025.

63. This information was announced on its website as follows: (Exhibit MERZ n° 100)



Merz Therapeutics Launches FAMPYRA® in Canada, EMEA, LATAM and APAC

As part of its strategic vision to become a leader in the specialty neurology space, Merz Therapeutics has launched FAMPYRA® (fampridine) extended release tablets (10 mg) in Canada, EMEA, LATAM, and APAC by transitioning the licensing rights to commercialize the product from Biogen. Effective January 2, 2025, Merz Therapeutics assumed full management, distribution, and marketing responsibilities for FAMPYRA® in 45 countries. These territories include Canada, Austria, Bahrain, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Latvia, Lithuania, Luxembourg, Malta, Morocco, Netherlands, Norway, Poland, Portugal, Qatar, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom, Australia, New Zealand, Argentina, Chile, Colombia, and Mexico.

FAMPYRA® is an extended-release tablet indicated for the symptomatic improvement of walking in adult patients with multiple sclerosis experiencing walking disabilities. This launch aligns with Merz Therapeutics' mission to enhance patient outcomes and address unmet needs in the neurology field.

64. At the latest on the date of recovery of the direct exploitation rights, MERZ necessarily reviewed with its licensee BIOGEN the status of the exploitation of the product FAMPYRA, for which the generic manufacturer VIATRIS had already obtained authorisation to enter the French market with a fixed price and reimbursement rate and had indicated its intention to enter the French market by spring 2025 at the latest.

65. 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 the SPC it holds.

66. However, MERZ did not send a warning letter to VIATRIS until 18 June 2025, five months after it regained direct exploitation rights from its licensee BIOGEN. This warning letter was drafted in these terms: (Exhibit MERZ n°125)

It has come to Merz's attention that Viatris, either directly or via one of its group companies or affiliates has obtained the following marketing authorisations in the jurisdictions identified below for fampridine 10 mg prolonged-release tablets:

Table 2

Country	MA applicant/holder	Product Description	Registration Number
Denmark	Viatris Limited	Fampridine "Viatris"	72870
France	Viatris Limited	Fampridine "Viatris"	No. CIP: 34009 302 422 3 0 34009 302 422 4 7 (and others - according to the number of tablets per pack)
Iceland	Viatris Limited	Fampridine Viatris	IS/1/25/077/01
Netherlands	Viatris Limited	Fampridine Viatris	RVG 134388
Portugal	Viatris Limited	Fampridine Mylan	5904668 - 28 tablets 5904851 - 56 tablets
UK	Generics (UK) Limited t/a Mylan	Fampridine Mylan	PL 04569/1868

Merz is furthermore aware that Viatris has listed a price for its generic version of FAMPYRA in the French Journal Officiel in relation to the products for which the CIP numbers are provided above.

Based on this publicly available information, Merz understands that Viatris' marketing authorisations are for a generic version of FAMPYRA. Merz's position is that Viatris's generic fampridine product falls within the scope of protection conferred by the SPCs detailed above. It is therefore Merz's position that any making, disposing of, offering to dispose of, use, importation and/or any other related activity in respect of generic fampridine in the jurisdictions set out above will infringe the relevant SPCs while they remain in force. Any such infringement would be unacceptable to Merz.

In order to avoid unnecessary litigation and legal expenses, and for Merz to be able to protect its SPC rights, please confirm as soon as possible, and in any event by **2 July 2025**, that Viatris and/or any affiliates thereof and/or any third parties with whom Viatris is collaborating or may in future collaborate in relation to generic fampridine will:

(a) respect Merz's SPC rights; and thus
(b) not seek to market and/or launch a generic fampridine in the any of the countries listed above in Table 1 while the relevant SPC is in force, whether approved under the marketing authorisation / CIP numbers listed above, or otherwise.

67. The Court notes that the Applicants did not take provisional measures before the present UPC division until 31 July 2025, i.e. six months after it became or should have become aware of the imminent launch of the generic product on the French market, as announced by VIATRIS for spring 2025.

68. And yet 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 German Federal Court in March 2024, as is clear from VIATRIS' official response to MERZ (Exhibit VIATRIS n°146):

Carpmaels & Ransford LLP
One Southampton Row
London
WC1B 5HA

Your ref: G0729000PT

By e-mail only [redacted]@carpmaels.com)

2 July 2025

Dear Sirs

Re: fampridine

We refer to your letter dated 18 June 2025.

We note that your letter does not refer to the decisions of the German Federal Patent Court which held that EP 548 and EP 536 were invalid. We understand that a number of generic products are currently on the market in Germany.

In view of the German invalidity decisions and the absence of any warning letters from Aegerion Biopharma or your client, Viatris Santé **has already launched its fampridine product in France**

Yours faithfully

[redacted]

Senior Patent Litigation Counsel
Viatris

69. In this context, the fact that the first act of infringement on the French market did in fact occur on 10 June 2025 (date of publication of the French market launch - Exhibit MERZ n° 6) cannot be considered as a new starting point that creates urgency and justifies a diligent filing of the application for provisional measures by MERZ. Thus, to quote the terms of The Hague LD, this fact "was already (to be) expected and does not revive urgency". (UPC_CFI_374/2024, 29 August 2025, Cilag v Rivolution)

70. The Court further notes that MERZ, in defending itself against a lack of diligence, cannot legitimately argue that being denied access to an application for provisional measures due to insufficient diligence constitutes a breach of the principle of access to justice under the Charter of Human Rights. Indeed, it has been demonstrated above that MERZ had the opportunity to act more promptly in interim measures. Furthermore, MERZ is not deprived of all rights since it has access to an infringement action on the merits before the UPC (with a targeted period of 12 months for processing the case).

71. Moreover, MERZ cannot rightly argue that the CoA's decision of 13 August 2025 created a new legal situation that cannot be invoked in the present dispute in the name of legal certainty, as this change in the UPC case law would set new conditions for the characterisation of imminent infringement in the context of a generic product. Indeed, this decision of the Court of Appeal was merely an interpretation of existing rules. (Art. 62.1 UPCA and R. 211.2 RoP). In addition, when questioned by the panel at the oral hearing, MERZ's representatives admitted that the Boehringer v Zentiva decision merely assessed the facts of the case in accordance with Portuguese administrative procedure and did not create a new legal situation for applicants for provisional measures before the UPC.

72. In view of these elements, MERZ fails to demonstrate that it was seeking provisional measures against VIATRIS within the reasonable delay provided for by Rule 211.4 RoP. Consequently, MERZ's request for provisional measures against VIATRIS shall be rejected, as well as all of its other subsequent requests.

73. As MERZ's claims have been rejected, it is not necessary to examine VIATRIS's subsidiary claims, in particular the claim for a guarantee.

COSTS

74. The application for provisional measures is rejected. The consequence of this for the costs is that MERZ shall be ordered to pay the legal costs of the proceedings incurred by VIATRIS. R.211.1(d) RoP provides the opportunity to give an interim award of costs in these proceedings. In this case, both parties asked for reimbursement of the costs for the amount of 56.000 euros to be awarded to the winning party. The Court considers this amount as reasonable and proportionate in the present case. MERZ will be ordered to pay to VIATRIS this amount as an 'interim' award of costs.

ORDER

1. The Application for provisional measures is rejected.

2. The Court orders the Applicants to pay to the Defendant interim costs of the proceedings for 56.000 euros.

An appeal to this order may be brought in accordance with Art. 73 (2) (a) UPCA and R. 220.1 (c) and 224.1(b) RoP within 15 calendar days of the notification of the order to the Applicants.

Issued in Paris, on 21 November 2025.

Camille Lignières, Presiding judge & Judge-rapporteur

Camille Lignières Date : 2025.11.21 09:56:44 +01'00'

Carine Gillet, Legally qualified judge

Carine Gillet 2025.11.20 16:20:47 +01'00'

Samuel Granata, Legally qualified judge

Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 2025.11.20 15:57:55 +01'00'

Rainer Friedrich, Technically qualified judge

Rainer Martin Hermann Friedrich Digital unterschrieben von Rainer Martin Hermann Friedrich Datum: 2025.11.20 21:14:58 +01'00'

Charlotte Ferhat, clerk

CHARLOTTE CAMILLE CLAIRE FERHAT

Signature numérique de CHARLOTTE CAMILLE CLAIRE FERHAT
Date : 2025.11.21 10:03:48 +01'00'

ORDER DETAILS

UPC number: UPC_CFI_697/2025
Application Type: Application for provisional measures (RoP206)
Date of issue: 21/11/2025