FRENCH REPUBLIC

IN THE NAME OF THE FRENCH PEOPLE

PARIS COURT OF APPEAL

Division 5 – Chamber 4

JUDGMENT OF 24 SEPTEMBER 2025

(No. 110, 56 pages)

General Register No.: RG 19/19969 – Portalis No. 35L7-V-B7D-CA4LM

Decision under appeal: Judgment of 1 October 2019 – Paris Commercial Court (*Tribunal de commerce de Paris*) – RG No. 2017053369

APPELLANT

CAISSE NATIONALE DE L'ASSURANCE MALADIE ("CNAM"), formerly **CAISSE NATIONALE DE L'ASSURANCE MALADIE DES TRAVAILLEURS SALARIÉS** (CNAMTS), a national public administrative body, registered in the Sirene directory under No. 180 035 024, acting through its duly authorised representatives, having its registered office at:

[Address 1]

Represented by: Me Vincent RIBAUT, of SCP GRV ASSOCIÉS, lawyer (*avocat*) at the Paris Bar, registration No. L0010

Assisted by: Me Olivier CAVÉZIAN, Me Téhani GOY and Me Fanny CALLEDE, of SELARL JOFFE & ASSOCIÉS, all three lawyers at the Paris Bar, registration No. L 108

RESPONDENTS

SANOFI SA, acting through its duly authorised representatives, having its registered office at the address indicated below, registered with the Paris Trade and Companies Register under No. 395 030 844

[Address 2]

[Town 8]

Represented by: Me Matthieu BOCCON GIBOD, of SELARL LX PARIS-VERSAILLES-REIMS, lawyer at the Paris Bar, registration No. C2477

Assisted by: Me Thomas ELKINS and Me Mathieu BLAYNEY, of LINKLATERS LLP, lawyers at the Paris Bar, registration No. J 030

SANOFI WINTHROP INDUSTRIE SA, a public limited company (*société anonyme*) with a board of directors, registered with the Trade and Companies Register under No. 775 662 257, having succeeded to the rights of SANOFI-AVENTIS FRANCE, a public limited company with a board of directors registered with the Créteil Trade and Companies Register under No. 403 335 904, struck off on 9 July 2024 following a merger by absorption, acting through its duly authorised representatives, having its registered office at the address indicated below

[Address 4]

[Town 5]

Represented by: Me Matthieu BOCCON GIBOD, of SELARL LX PARIS-VERSAILLES-REIMS, lawyer at the Paris Bar, registration No. C2477

Assisted by: Me Thomas ELKINS and Me Mathieu BLAYNEY, of LINKLATERS LLP, lawyers at the Paris Bar, registration No. J 030

COMPOSITION OF THE COURT

The case was heard on 18 June 2025, in open court, before the Court composed of:

Ms Brigitte BRUN-LALLEMAND, Presiding Judge

Ms Sophie DEPELLEY, Judge

Mr Julien RICHAUD, Judge

who deliberated on the matter; a report was presented at the hearing by Ms Depelley pursuant to Article 804 of the Code of Civil Procedure.

Registrar at the hearing: Ms Elisabeth VERBEKE

JUDGMENT

— delivered after hearing both parties (*contradictoire*);

— by being made available at the Registry of the Court, the parties having been given prior notice in accordance with the second paragraph of Article 450 of the Code of Civil Procedure;

— signed by Ms Brigitte BRUN-LALLEMAND, Presiding Judge, and by Ms Elisabeth VERBEKE, Registrar, present when the judgment was made available.

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FACTS AND PROCEDURE

1. Sanofi-Aventis France, to whose rights Sanofi Winthrop Industrie has succeeded, is a pharmaceutical company active across the development, manufacture and distribution of medicinal products in France. It is a wholly-owned subsidiary of the Sanofi group, the parent company of which is Sanofi SA (hereinafter "the Sanofi companies").

2. The medicinal product Plavix, whose active ingredient is clopidogrel, was designed and developed by Sanofi and granted a marketing authorisation (MA) on 15 July 1998. It was marketed in France under the operational management of Sanofi-Aventis France. In 2008, it represented the largest single item of reimbursement for the French statutory health insurance scheme.

3. Since the regulatory protection covering the active ingredient of Plavix expired on 15 July 2008, the first generic versions of Plavix began to be marketed from October 2009 onwards, including the one developed by Sanofi-Aventis under the brand name Clopidogrel Winthrop and marketed in France since 5 October 2009.

4. The pharmaceutical company Teva Santé, which specialises in the production of generics and in particular Teva Pharma clopidogrel — marketed on the French retail pharmacy market since 5 October 2009 — lodged a complaint on 2 November 2009 with the French Competition Authority alleging disparaging practices on the part of Sanofi-Aventis targeting generic versions of Plavix in France.

5. Following this referral, by decision of 14 May 2013 (hereinafter "the Decision") the Competition Authority ("the Authority") imposed a fine of EUR 40.6 million on Sanofi-Aventis France, as the perpetrator of the practice, and on Sanofi, in its capacity as parent company, for having infringed, between September 2009 and January 2010, the provisions of Article L. 420-2 of the Commercial Code and those of Article 102 of the Treaty on the Functioning of the European Union (TFEU), by engaging in a practice of disparaging the generic competitors of the medicinal product Plavix on the French market for clopidogrel sold in retail pharmacies, constituting an abuse of a dominant position (Decision No. 13-D-11 of 14 May 2013 concerning practices in the pharmaceutical sector).

6. This decision was upheld by the Paris Court of Appeal in a judgment of 18 December 2014. On 18 October 2016, the Court of Cassation dismissed the appeal on points of law lodged by Sanofi.

7. The sanctioned practice consisted in the implementation by the Sanofi companies, between September 2009 and January 2010, of a communication strategy designed, on the one hand, at the prescription stage, to encourage doctors to mark prescriptions with the words "non-substitutable", and, on the other hand, at the substitution stage, to encourage pharmacists to substitute Plavix with its own generic version to the detriment of competing generics.

8. As the body responsible for managing the reimbursement of healthcare expenditure, the Caisse nationale de l'assurance maladie (hereinafter "CNAM") considers that it has been the victim of the sanctioned conduct, on the grounds that it directly and automatically led to higher reimbursement costs and to the payment of higher remuneration to dispensing pharmacists, the price of originator medicinal products being higher than that of generics.

9. By bailiff's writs of 12 and 13 September 2017, the Caisse nationale de l'assurance maladie des travailleurs salariés (CNAMTS) brought proceedings before the Paris Commercial Court against Sanofi and Sanofi-Aventis France seeking compensation for its loss on the basis of Articles 1240 and 2224 of the Civil Code, Article 102 TFEU, and Articles L. 420-2 and L. 462-7 of the Commercial Code.

10. By judgment of 1 October 2019, the Paris Commercial Court declared the action brought by the CNAMTS time-barred and ordered the latter to pay Sanofi and Sanofi-Aventis France the sum of EUR 15,000 pursuant to Article 700 of the Code of Civil Procedure.

11. The CNAMTS lodged an appeal against this judgment by notice filed with the Registry on 25 October 2019, against companies Sanofi and Sanofi-Aventis France.

12. The CNAMTS subsequently became the Caisse nationale de l'assurance maladie (CNAM) following the integration, by Article 15 of Law No. 2017-1836 of 30 December 2017 on social security financing for 2018, of the social scheme for the self-employed (*régime social des indépendants* — RSI) and the transfer of social protection for the self-employed to the general scheme.

13. By judgment of 19 February 2022, this Court:

— set aside the judgment in its entirety;

— dismissed the plea of inadmissibility based on the limitation period for the CNAM's claim;

— exercising its power to determine the case on the merits (*évocation*),

— held that Sanofi-Aventis and Sanofi had engaged in abusive practices constituting torts within the meaning of Article 1382 of the Civil Code, now Article 1240 of the Civil Code;

— held that these practices had a harmful effect on the CNAM;

— before ruling on the quantum of compensation (*avant dire droit*),

— ordered an expert assessment;

— appointed Mr [P] [K], expert at the Paris Court of Appeal, [K] Advisory [Address 3], with the task of assessing the loss suffered by the CNAM as a result of Sanofi's disparaging practices, and more specifically to:

• give an opinion on the robustness of the counterfactual scenario set out in the RBB Economics report of 30 June 2021 produced by the CNAM, in the event of a change in the group of molecules comparable to clopidogrel, and, where appropriate, to propose adjustments to this scenario based on the principle of comparison with a group of molecules;

• determine the date on which the effects of the disparaging practices implemented by Sanofi ceased, in order to assess the deferred effect of the loss suffered by the CNAM; in the event that the practices continued to have an impact on the market penetration rate of clopidogrel generics, propose an estimate of the loss that may have occurred until the cessation of those effects;

• provide the Court with all the information necessary to determine the losses suffered by the CNAM in relation to the compensation of insured persons and the remuneration of pharmacists;

— stayed the proceedings as regards compensation for the loss and the other claims submitted; reserved the costs.

14. The Sanofi companies lodged an appeal on points of law, which was dismissed by judgment of the Commercial, Economic and Financial Chamber of the Court of Cassation of 30 August 2023, appeal No. 22-14.094.

15. The expert filed his report on 5 March 2024.

16. In its latest pleadings, filed and served on 9 May 2025, the CNAM requests the Court to:

Having regard to Article 102 of the Treaty on the Functioning of the European Union;

Having regard to Article 1240 of the Civil Code;

Having regard to the documents produced in the proceedings;

Declare that the tortious acts of Sanofi SA and Sanofi-Aventis France, to whose rights Sanofi Winthrop Industrie has succeeded, have caused loss to the CNAM amounting to a total of EUR 126,222,994, plus the applicable statutory interest, as quantified by RBB Economics in its note of 14 January 2025, amounting to EUR 23,551,029 as at 30 June 2025 and to be supplemented until full payment of the sums owed by Sanofi SA and Sanofi-Aventis France;

Consequently,

Dismiss the claims of Sanofi SA and Sanofi Winthrop Industrie;

Order Sanofi SA and Sanofi Winthrop Industrie *in solidum* to pay the CNAM, by way of damages, the total sum of EUR 126,222,994, plus applicable statutory interest, as quantified by RBB Economics in its note of 14 January 2025, estimated at EUR 23,551,029 as at 30 June 2025 and to be supplemented until full payment of the sums owed by Sanofi SA and Sanofi-Aventis France;

Order Sanofi SA and Sanofi Winthrop Industrie *in solidum* to pay the CNAM the sum of EUR 1,500,000 pursuant to Article 700 of the Code of Civil Procedure;

Order Sanofi SA and Sanofi Winthrop Industrie *in solidum* to pay the costs at first instance and on appeal, and in particular order them *in solidum* to reimburse the CNAM the sum of EUR 217,641.94 corresponding to the fees of the court-appointed expert.

17. In their latest pleadings, filed and served on 16 May 2025, Sanofi and Sanofi Winthrop Industrie, having succeeded to the rights of Sanofi-Aventis France, request the Court to:

Having regard to Article 1240 of the Civil Code;

Having regard to Articles 175, 237 and 238 of the Code of Civil Procedure;

Having regard to the documents produced in the proceedings;

Primarily,

Set aside the expert's report dated 5 March 2024;

Consequently, appoint a new expert with the following remit:

— to establish a robust control group for the purpose of estimating the counterfactual substitution rate for clopidogrel;

— to take into account the factors specific to Plavix when estimating the substitution rate for clopidogrel;

— to establish the effect over time of Sanofi's practice;

Stay the proceedings pending submission of the new expert report.

In the alternative,

Rule that the effects of Sanofi's conduct ceased no later than two years after the end of its campaign, i.e. in January 2012;

Consequently, declare that any sum awarded to the CNAM may cover only its potential loss for the period from 2010 to 2011;

Dismiss all of the CNAM's contrary claims.

In the further alternative,

Rule that the price reductions imposed by the CEPS in April 2012, November 2013/April 2014 and June 2014 constituted a benefit for the CNAM which must be deducted from its alleged loss;

Dismiss the CNAM's contrary claims.

In any event,

Order the CNAM to pay EUR 150,000 to Sanofi and Sanofi-Aventis France pursuant to Article 700 of the Code of Civil Procedure for costs incurred before the Court of Appeal;

Order the CNAM to pay all costs of the proceedings.

18. The order closing the proceedings was made on 28 May 2025.

19. The Court refers to the decision under appeal and to the aforementioned pleadings for a detailed account of the dispute and of the parties' claims, in accordance with Article 455 of the Code of Civil Procedure.

REASONING

20. The CNAM considers that the loss it has suffered as a result of the anticompetitive practices committed by the Sanofi companies has caused it harm under three heads.

21. First, the CNAM submits that it has suffered a loss relating to the reimbursement of insured persons, namely the difference between (i) the amount it pays in reimbursement for clopidogrel and (ii) the amount it would have paid had Plavix experienced an ordinary rate of generic substitution in the absence of the wrongful practices, given that generic medicinal products are structurally cheaper than their reference originator products. On the basis of the expert report (page 213), the CNAM assesses this loss at EUR 111,666,964.

22. Second, the CNAM considers that it has also suffered a loss relating to pharmacists' remuneration, namely the difference between the amounts it paid to pharmacists from the 2012 National Pharmacists' Convention (*Convention nationale des pharmaciens* — CNP) onwards and the amounts it would have had to pay had clopidogrel followed an ordinary genericisation process. On the basis of the expert report (page 213), the CNAM assesses this loss at EUR 14,556,030.

23. Third, the CNAM seeks the application of compensatory interest on its total loss of EUR 126,222,994 by applying the statutory rate, and assesses its additional loss at EUR 23,551,029 as at 30 June 2025, "to be supplemented until full payment of the sums owed by Sanofi".

24. The Sanofi companies challenge the court-appointed expert's report on numerous points and primarily request the Court to "set aside the report submitted on 5 March 2024" and appoint a new expert.

25. Following a presentation of the characteristics of Plavix (I) and a recap of the anticompetitive practices for which the Sanofi companies were sanctioned (II), the Court will analyse each of the heads of loss put forward by the CNAM on the basis of the court-appointed expert's report and of the Sanofi companies' criticisms thereof (III to V).

I. THE CHARACTERISTICS OF PLAVIX AND OF THE MOLECULE CLOPIDOGREL

26. Plavix is an antiplatelet agent whose active ingredient is clopidogrel. It is used to prevent the recurrence of serious cardiovascular diseases. It was discovered and designed by Sanofi, then developed and marketed under a worldwide alliance with the Bristol Myers Squibb group from the late 1990s. It has been a major success of the global pharmaceutical industry, namely:

— it has been the fourth best-selling medicinal product in the world since its launch;

— in 2008, it generated worldwide sales of EUR 2.6 billion for Sanofi and EUR 550 million in France;

— in 2008, Plavix represented the largest single item of reimbursement for the French statutory health insurance scheme, amounting to EUR 635 million.

27. Plavix is a first-line medicinal product, prescribed for preventive purposes and therefore primarily in the retail pharmacy setting by cardiologists and general practitioners. Available only on prescription, Plavix has four therapeutic indications, including the treatment of acute coronary syndrome (hereinafter "ACS") as part of dual therapy (Decision, paragraphs 27 *et seq.*).

28. The patent protecting Plavix in Europe expired in July 2008 and the first generic versions of Plavix were launched at the beginning of October 2009. Additional patent applications filed by Sanofi led to an extension of the initial protection concerning:

— the type of salt used in Plavix, which remained protected until February 2013, with the consequence that generic versions of Plavix — other than Sanofi's authorised generic — had to use a different salt;

— the indication for the treatment of ACS as part of dual therapy, through the combination of clopidogrel and acetylsalicylic acid (aspirin), which remained protected until February 2017 (hereinafter the "ACS patent"). Consequently, none of the clopidogrel generics had the indication for the treatment of ACS in combination with aspirin.

II. THE SANCTIONED ANTICOMPETITIVE PRACTICES

29. The expiry, on 15 July 2008, of the regulatory protection covering the active ingredient of Plavix led, from October 2009 onwards, to the launch on the market of the first generic versions of Plavix, including the one developed by Sanofi-Aventis under the brand name Clopidogrel Winthrop and marketed in France since 5 October 2009.

30. The sanctioned practices consisted in implementing, between September 2009 and January 2010, a communication strategy designed:

— on the one hand, at the prescription stage, to encourage doctors to mark prescriptions with the words "non-substitutable" (hereinafter the "NS" mention);

— on the other hand, at the substitution stage, to encourage pharmacists to substitute Plavix with its own generic version to the detriment of competing generics.

31. In ruling these practices to be anticompetitive and unlawful, the Authority, upheld by the appellate courts, conducted the following analysis:

32. Sanofi-Aventis, which held a dominant position on the market for clopidogrel sold in retail pharmacies on French territory, implemented a communication strategy directed at healthcare professionals concerning the objective differences between Plavix and its generics, namely:

— on the one hand, the salt contained in those medicinal products;

— on the other hand, the therapeutic indication relating to acute coronary syndrome, which was not covered by the marketing authorisations (hereinafter "MAs") of the generics.

This strategy was deployed by means of sales materials distributed to Sanofi-Aventis's medical representatives and pharmaceutical sales representatives between September 2009 and January 2010, which directly called into question the bioequivalence of the generics and the choices made by the health authorities.

33. The two differences referred to were linked in an inappropriate and ambiguous manner, in order to suggest that the difference in therapeutic indication was due to a medical obstacle resulting from the difference in salts, whereas it was due solely to the legal protection afforded by a patent, the existence and scope of which were concealed in those various communications. Those sales materials moreover recommended or invited doctors to mark prescriptions with the words "non-substitutable", and pharmacists to perform substitution with the authorised generic marketed by Sanofi-Aventis, by stressing the high mortality risks for patients suffering from acute coronary syndrome.

34. However, under European and French legislation, only the existence of "significantly different properties" in terms of safety or efficacy can justify a discourse drawing the attention of healthcare professionals; and, by letter of 24 September 2009, the French Health Products Safety Agency (*Afssaps*), to which Sanofi-Aventis had referred the matter, considered, with regard to the generics of Plavix, that the lack of homogeneity in the indications did not constitute a risk for patients and did not require the inclusion of a specific mention in the directory of generic groups. The Agency reiterated that the generic medicinal products had demonstrated bioequivalence and an efficacy/safety profile at least similar to that of the reference medicinal product.

35. Sanofi-Aventis, which had exploited the Plavix manufacturing patent under monopoly conditions for ten years and belonged to a major group, had thereby acquired a reputation as a benchmark, reinforced by feedback that it brought to the attention of healthcare professionals as part of its communication strategy.

36. Against a background where healthcare professionals not only had little knowledge at the time of pharmacology and of the regulation of generic medicinal products, but were also reluctant to take any risk, the dissemination of negative information — or even the mere instillation of doubt as to the intrinsic qualities of a medicinal product — could immediately discredit it in the eyes of those professionals. The misleading and dissuasive effect of Sanofi-Aventis's communication is established by a body of precise and corroborating evidence proving the fears it aroused, which translated into a large number of "non-substitutable" mentions added to prescriptions in several regions, into substitution carried out predominantly with the authorised generic by pharmacists, and into the dissemination of specific information circulars within pharmacists' groups in order to address the concerns and serious worries of a large number of them.

37. Thus, it was found that:

— a higher rate of "non-substitutable" mentions for Plavix than for other medicinal products;

— an unusual trend in the substitution rate which, after initially rising rapidly and then stagnating early on, fell steadily just a few months after the launch of the first generics, while the authorised

generic consistently accounted for over 30% of sales by volume, leaving only a small share for competitors.

38. It was therefore concluded that the disparagement practice carried out for five months against Plavix's competing generics and the authorised generic, by an undertaking in a dominant position, had had the effect of limiting the entry of its competitors onto the French market for clopidogrel sold in retail pharmacies.

39. The Competition Authority, whose ruling was upheld on appeal, found in its Decision (paragraphs 584 and 669 *et seq.*) that Sanofi-Aventis's disparagement practice had had "the effect of permanently restricting the entry of those generics onto the French market for clopidogrel sold in retail pharmacies". It clearly held that the rate of generic substitution for clopidogrel appeared abnormally low, whether in relation to other comparable molecules, to social security targets, or to the average market penetration rate of generics marketed since 2009, and the Competition Authority concluded that "these factors demonstrate that, in the absence of the practice in question — the effects of which gradually became apparent over time, as previously noted — the genericisation rate for clopidogrel would have been significantly higher".

40. In determining the base amount of the penalty, the Competition Authority held (paragraphs 634 to 637) that, although the practice in question originated in communication activities that took place between early September 2009 and the end of January 2010, it nevertheless "produced effects well beyond that period: the sale of competing generic medicinal products was indeed curbed and constrained for as long as the messaging directed at doctors and pharmacists influenced their behaviour" and held that "the effects of the strategy attributed to Sanofi-Aventis are established at least until the statement of objections was served on that company on 7 December 2011".

41. In its judgment of 9 February 2022, this Court held that Sanofi-Aventis and Sanofi had engaged in abusive practices constituting torts within the meaning of Article 1382 of the Civil Code, now Article 1240 of the Civil Code, and that those practices had a harmful effect on the CNAM.

42. To assess its loss, the CNAM produced a report prepared by the economic consultancy RBB, which quantified the harm by comparing the trend in the genericisation rate of clopidogrel (its "actual genericisation curve") with that which would have been observed in the absence of the practices (the "counterfactual genericisation curve"). The quantification method was challenged by the Sanofi companies, which produced a report by the economic consultancy CRA. Before ruling on compensation for the CNAM's loss, the Court ordered an expert assessment, instructing the expert to:

— give an opinion on the robustness of the counterfactual scenario set out in the RBB Economics report of 30 June 2021 produced by the CNAM, in the event of a change in the group of molecules comparable to clopidogrel, and, where appropriate, to propose adjustments to this scenario based on the principle of comparison with a group of molecules;

— determine the date on which the effects of the disparaging practices implemented by Sanofi ceased, in order to assess the deferred effect of the loss suffered by the CNAM; in the event that the practices continued to have an impact on the market penetration rate of clopidogrel generics, propose an estimate of the loss that may have occurred until the cessation of those effects;

— provide the Court with all the information necessary to determine the CNAM's losses relating to the compensation of insured persons and the remuneration of pharmacists.

III. THE LOSS RELATING TO THE REIMBURSEMENT OF INSURED PERSONS

43. On the basis of the conclusions of the court-appointed expert's report, which it endorses, the CNAM assesses the loss relating to the reimbursement of insured persons at EUR 111,666,964, calculated as follows (CNAM Exhibit No. 8):

— first, for each month, the counterfactual genericisation rate multiplied by the volume of boxes sold yields the counterfactual volume of generic box sales. Consequently, the total monthly volume of boxes sold minus the monthly counterfactual volume of generic boxes sold gives the counterfactual volume of Plavix sales;

— second, for each month, the counterfactual sales value is the price of Plavix multiplied by the counterfactual volume of Plavix sales for that month, plus the price of the generic medicinal product multiplied by the counterfactual volume of generic sales for that month;

— third, the observed reimbursement rate for each month is estimated by dividing the observed total monthly reimbursement by the observed monthly sales values. Since the reimbursement rate does not differ between generics and Plavix, the reimbursement rate is thus calculated for both product categories;

— fourth, the observed monthly reimbursement rate is multiplied by the counterfactual monthly sales value to obtain the counterfactual reimbursement cost;

— fifth and finally, the loss is the difference between the counterfactual reimbursement cost and the observed reimbursement cost.

44. While invoking the "manifestly biased" conduct of the court-appointed expert, the Sanofi companies essentially criticise the selection of molecules in the control group for the construction of the counterfactual scenario, the failure to adjust this scenario to take account of Plavix's ACS indication, and the duration of the effects of the anticompetitive practices adopted by the expert. They further argue that it is necessary to take into account the price reduction imposed by the Economic Committee for Health Products (*Comité économique des produits de santé* — CEPS) in accordance with the principle of full compensation.

45. Accordingly, the Court will first examine the verifications carried out by the court-appointed expert on the construction of the counterfactual scenario for the rate of substitution of Plavix by its generics (A), then analyse the duration of the effects of the sanctioned practices (B), and the impact of the price reduction imposed by the CEPS (C), before finally assessing the scope (D) and the amount of the CNAM's loss relating to the reimbursement of insured persons (E).

A. The counterfactual scenario for the rate of substitution of Plavix by its generics

46. The Court recalls that a counterfactual scenario is a model which, in accordance with the principle of full compensation, makes it possible to assess the situation the victim would have been in had the harm not occurred. Compared with the victim's actual situation, it must allow the amount of the loss suffered to be established.

47. In its judgment of 9 February 2022, this Court:

— rejected the counterfactual scenario constructed by CRA for the Sanofi companies, based on a selection of molecules whose penetration rate was close to that of clopidogrel "in the long term" once generic penetration had stabilised, namely all molecules whose generic penetration rate was

within plus or minus 10 percentage points of that of clopidogrel over the period from April to September 2015, on the assumption that the effects of the practices ceased in March 2015;

— adopted the counterfactual scenario developed by RBB Economics for the CNAM, which it considered more credible and which is based on a comparison group of molecules determined using two criteria, namely sales volume and the date of first genericisation;

— instructed the expert to give an opinion on the robustness of the counterfactual scenario in the RBB Economics report of 30 June 2021 produced by the CNAM, in the event of a change in the group of molecules comparable to clopidogrel, and, where appropriate, to propose adjustments to this scenario based on the principle of comparison with a group of molecules.

48. The CNAM endorses the validation, with a few adjustments, by the court-appointed expert of the comparison group constituted by RBB.

49. The Sanofi companies challenge the court-appointed expert's analysis and, principally, seek a new expert assessment with the specific remit of establishing a robust control group for the purpose of estimating the counterfactual substitution rate for clopidogrel and of taking into account factors specific to Plavix when estimating that rate.

50. Following a presentation of the court-appointed expert's procedures for verifying the robustness of the counterfactual scenario for the rate of substitution of Plavix by its generics (a), the Court will analyse the criticisms made by the Sanofi companies in their latest pleadings concerning the appointment and role of the technical adviser (b), the selection of the control group (c), the impact of Plavix's indication for acute coronary syndrome (ACS) (d) and the reasoning followed by the expert (e).

a. The court-appointed expert's verification procedures regarding the counterfactual scenario for the rate of substitution of Plavix by its generics

51. In accordance with the terms of reference set out above, the expert did not seek to construct a counterfactual scenario but rather to verify the robustness of the counterfactual scenario established by RBB in its report of 3 February 2023 at the CNAM's request for the quantification of its loss. It is recalled that a robustness test is intended to verify that the result does not deviate too greatly from a stated outcome when small variations are applied to the assumptions on which that result is based.

52. To this end, the court-appointed expert first verified the database produced by the CNAM, known as the CNAM 2 database; then verified the selection of molecules in the comparison group; thereafter analysed exogenous factors for their possible inclusion in scenario adjustments; and finally verified the results obtained in three ways.

** Verification of the CNAM 2 database*

53. For the purposes of the expert assessment, on 19 September 2022 the CNAM provided a new database known as CNAM 2, covering the period up to 31 December 2021, supplied in two versions: a raw database collected by the CNAM and a database "cleaned" by RBB. At CRA's request, this database was reworked by RBB to incorporate various adjustments. Initial processing was then carried out on this cleaned database to obtain data exported to Excel and to enable final processing in Excel for the construction of the counterfactual scenario (expert report, pages 25 and 26).

54. The creation of the CNAM 2 database and the initial processing were carried out by RBB using Stata, a statistical and econometric software package. Since the court-appointed expert did not use this software, he sought the assistance of a technical adviser (*sapiteur*) to verify the computer processing of the CNAM 2 database. On 15 September 2023, the technical adviser ultimately appointed submitted his report and concluded that the work carried out on the writing of the Stata code, on its execution and on

the comparison of the data produced with those recorded in the files, did not reveal any anomaly that would affect the results (Annex 6 to the expert report).

**** Verification of the selection of molecules in the comparison group***

55. To this end, the court-appointed expert first verified the categories of molecules to be excluded; then analysed the factors influencing the market penetration of a generic medicinal product in order to compose a sub-sample of medicinal products similar to clopidogrel, as well as exogenous factors for possible consideration.

56. The court-appointed expert first examined each of the six categories of molecules excluded from the analyses by RBB in its report of 3 February 2023, and confirmed the relevance of their exclusion from the comparison group, namely:

— molecules genericised after 2012 (effect of the 2012 Convention);

— molecules with a narrow therapeutic margin;

— antipsychotic and anticancer drugs;

— molecules with a dosage subject to the flat-rate reimbursement tariff (*tarif forfaitaire de responsabilité* — TFR);

— molecules with a small market size.

57. Then, having identified the key characteristics of clopidogrel (a very large market size, a very high initial speed of genericisation, genericisation in 2009 and a large number of generic manufacturers), the court-appointed expert determined the factors influencing the market penetration of a generic medicinal product, in order to compose a sub-sample of medicinal products similar to clopidogrel, namely:

— market size;

— the year of genericisation: the expert considers that molecules genericised in 2010 should be regarded as not comparable to those genericised in 2009, owing to a significantly slower speed of genericisation for the 2010 molecules compared with the 2009 ones; the molecules ultimately selected are those genericised between 2006 and 2009;

— inclusion in the list annexed to the 2012 Convention.

58. This analysis of the selection criteria led the court-appointed expert to confirm the selection of the eight molecules in RBB's comparison group, one of which (gliclazide) was withdrawn following verification for the period from November 2011 onwards.

59. The court-appointed expert then noted that the genericisation rate curves for the molecules in the comparison group follow a common pattern: first a phase of strong growth, then a sort of plateau, followed by a jump in 2012 (caused by a regulatory change) and then a new plateau.

**** Determination of the counterfactual curve***

60. The court-appointed expert then opted to construct the counterfactual curve using the average of the genericisation rates of the molecules in the comparison group.

61. In terms of volume, according to the court-appointed expert's explanations, the effect of the practices corresponds to the gap between the counterfactual market penetration rate and the observed market penetration rate (calculated month by month):

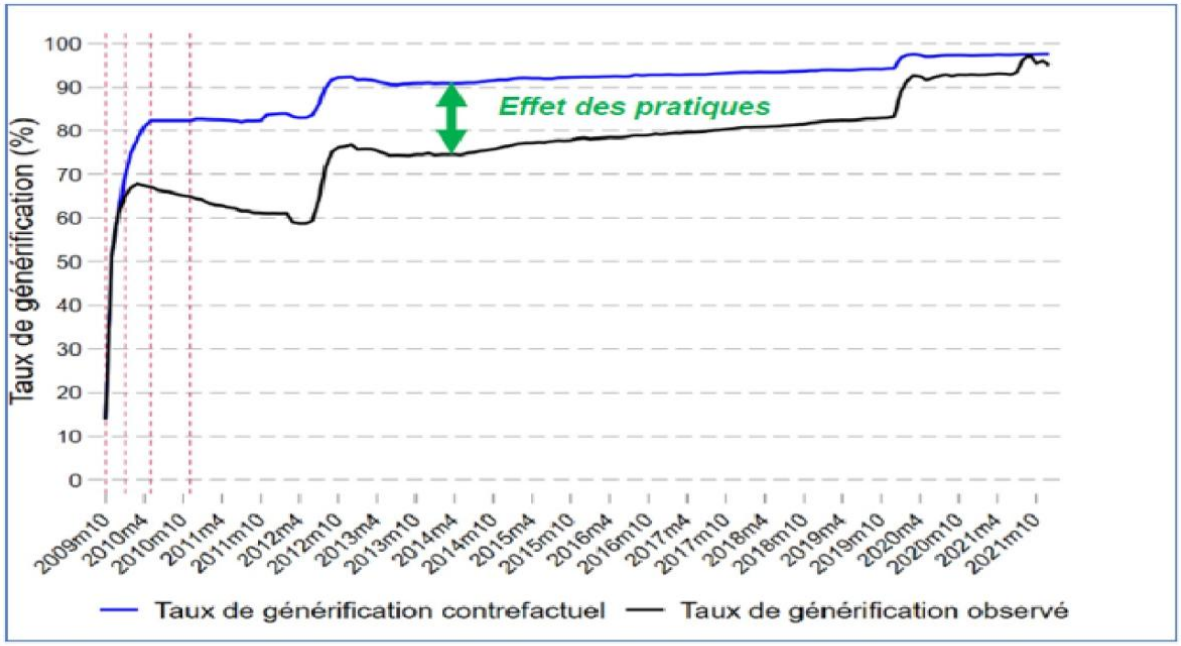


Figure 1: rapport d'expertise page 83

**** Analysis of exogenous factors***

62. The court-appointed expert considers that only a significant exogenous factor specific to clopidogrel could necessitate a specific adjustment. The issue arose in relation to the ACS (acute coronary syndrome) indication for which Plavix is approved, whereas, with the exception of two of them, its generics did not have this indication. According to the court-appointed expert, there is no demonstrated need to adjust the counterfactual scenario as regards the ACS indication, since "NS" (non-substitutable) mentions associated with the ACS indication are infrequent in the counterfactual scenario.

63. Other factors were ruled out by the court-appointed expert: batch withdrawals and the pharmacists' strike against substitution.

**** Verification of the counterfactual genericisation rates***

64. The court-appointed expert then verified, using three methods, the results obtained through RBB's counterfactual scenario:

— by comparison with the Plavix genericisation targets set by the CNAM at the end of December 2010;

— by comparing the result produced by the RBB scenario with that obtained using another method based on "NS" mention rates;

— by comparison with a panel of eight molecules initially presented as comparable by the Sanofi companies before the Competition Authority.

65. Finally, the court-appointed expert did not accept the alternative scenarios presented by CRA.

**** Summary***

66. In conclusion, the court-appointed expert is of the opinion that three adjustments should be made to the counterfactual scenario initially submitted to the Court by the RBB report:

— add a criterion requiring molecules in the comparison group to be on the list of molecules specifically targeted by the 2012 Convention;

— adopt a slightly different mechanism for constructing the counterfactual curve (consisting essentially in establishing the counterfactual genericisation rate for clopidogrel as the arithmetic mean of the genericisation rates of the molecules in the comparison group);

— extend the determination of counterfactual genericisation rates beyond March 2015.

67. The Sanofi companies criticise this verification of the construction of the counterfactual scenario carried out by the court-appointed expert, arguing:

— the attempt to appoint an "anti-vax" technical adviser and the refusal to allow his replacement to work (b);

— the arbitrary and biased rejection of important molecules genericised only four months after Plavix (c);

— the refusal to take into account the importance of Plavix's ACS indication, which the competing generics did not have (d);

— the circular reasoning of the court-appointed expert, which made it impossible to criticise the molecules selected by RBB and prevented any objective assessment of the robustness of the RBB model (e).

b. Criticism of the appointment and role of the technical adviser during the expert assessment

68. In their latest pleadings the Sanofi companies criticise the process by which the court-appointed expert chose the technical adviser, viewing this as proof of the latter's bias — a claim contested by the CNAM.

69. First, the Sanofi companies point out that the court-appointed expert initially proposed a technical adviser who, after a quick internet search, turned out to be a notorious "anti-vaxxer" necessarily opposed to Sanofi's case.

70. However, the Court observes that the court-appointed expert himself explained in his report (page 173) that the initially proposed adviser had skills that were difficult to find, and that his positions taken during the Covid health crisis did not concern any vaccine or product marketed by Sanofi that would justify rejecting the choice without first submitting it to the parties. It is apparent from the minutes of expert meeting No. 5a in version 2, after review by the Sanofi companies (CNAM Exhibit No. 26), that once the latter raised this objection regarding the appointment of the initially proposed adviser, and the CNAM considered it appropriate to consider another profile, the expert took due note of "the parties' reactions" and, by email of 8 May 2023 (Sanofi Exhibit No. 8), called upon another technical adviser whose appointment raised no objection from the parties. Therefore, the Sanofi companies cannot seriously argue that there was any evidence of bias on the part of the expert in this process of choosing the technical adviser.

71. The Sanofi companies further argue, in essence, that the expert refused to involve the appointed technical adviser in the work, meetings and discussions with the parties, the latter being confined to a verification "with due care and diligence" (*en bon père de famille*) of RBB's work alone, without the expert ever sharing with him CRA's comments or analyses.

72. However, the Court notes that it is clear from the minutes of expert meeting No. 5a in version 2 cited above that the court-appointed expert informed the parties of his intention to call upon a technical adviser whose role was to provide "the support of a specialist, should highly technical econometric or statistical issues arise", since the expert himself was not an econometrician or statistician — a point reiterated in the email of 8 May 2023. The court-appointed expert thus instructed the technical adviser

to carry out the customary verifications, "with due care and diligence", on the initial stages of the construction of the counterfactual scenario produced by RBB using the Stata statistical and econometric software, which the expert did not use.

73. Furthermore, as the CNAM points out, the minutes of expert meeting No. 6 of 9 June 2023 (Sanofi Exhibit No. 5) state that the appointed technical adviser was present at this meeting, during which CRA was able to present its analyses and objections concerning, in particular, the selection of molecules in the comparison group, the determination of the duration of the effects of the practices, and the method used to construct the counterfactual curve.

74. The Court further notes that the Sanofi companies did not request any analysis from the technical adviser following his appointment and his presentation at the meeting of 9 June 2023, nor during the expert proceedings leading to the submission of the preliminary expert report in October 2023. It was only after the submission of this preliminary report and in their summary submission (*dire récapitulatif*) of 17 November 2023 that the Sanofi companies sought the technical adviser's opinion on an econometric analysis carried out by CRA. They state that this analysis sought to demonstrate that taking into account the number of generic manufacturers limits the statistical significance of the sales value and significantly reduces the value of its regression coefficient — that is to say, its ability to explain variations in molecules' genericisation rates. On this point, while the court-appointed expert did not accede to the Sanofi companies' request for the technical adviser's opinion, he did, however, respond to CRA's position by considering that the criterion of the number of generic manufacturers was a more robust explanatory factor than the criterion of sales value, as stated in his report (page 48) and in his response to the parties' written submissions (pages 176 and 177), referring to a note of 2 May 2023 (Annex 8) which is not otherwise criticised by the Sanofi companies. The court-appointed expert further clarified that the factor of the number of generic manufacturers was already indirectly taken into account in the selected market size criterion, since all molecules with a large market size have a large number of generic manufacturers (report, page 177).

75. It follows that the Sanofi companies' criticisms of the court-appointed expert's choices regarding the assistance requested from the technical adviser are wholly unfounded.

c. Criticism of the selection of molecules in the comparison group as regards the year of genericisation

Positions of the parties

76. The Sanofi companies challenge the selection of molecules from among those genericised between January 2006 and December 2009 and the exclusion of those genericised in 2010. They argue that it is wholly illogical to go back four years (to January 2006) while excluding molecules genericised only a few months after clopidogrel, notably in February and March 2010. They submit that such an exclusion is not based on any serious justification, but rather on an opportunistic decision to exclude major molecules genericised in 2010 whose substitution rate was lower than the average for the RBB molecules, thereby automatically inflating the assessment of the CNAM's loss.

77. They criticise the court-appointed expert's decision — which they describe as "tragic" — to exclude the molecules genericised in 2010 from the comparison group on the erroneous ground that their substitution rate was "not comparable" to that of the 2009 molecules, whereas, in their view, it is "irrefutable" that the 2010 molecules had a substitution rate closer to that of the 2009 molecules than the 2006, 2007 or 2008 molecules included in the control group. In their view, the objective reality is that the substitution rates achieved by generic medicinal products between 2006 and 2011 declined over time. In this regard, they argue that four of the eight molecules in the comparison group validated by

the expert were genericised in 2006 and 2007, whereas clopidogrel was genericised at the end of 2009, without this being offset by molecules genericised in 2010 having similar objective characteristics, with the effect of inflating the assessment of the CNAM's loss.

78. The CNAM responds that, in accordance with his remit, the court-appointed expert did not himself make any choices, but rather examined and verified the validity of the choices made by RBB in constructing its counterfactual scenario. It notes that the court-appointed expert justified the exclusion of molecules genericised in 2010 as follows:

— the expert notes, supported by a graph, that "compared with molecules genericised in 2009, those genericised in 2010 experienced significantly slower speeds of genericisation" and that "the genericisation rate of a molecule genericised in 2010 is, on average, nearly 20% lower than the same rate for a molecule genericised in 2009";

— he notes, citing supporting evidence, that "the divergent nature of 2010 is also referred to in a 2012 report by the *Mutualité Française*", the source of which he provides;

— finally, he notes that the "first months of genericisation" of Plavix, from October 2009 onwards, "moreover demonstrated a very high speed of genericisation", whereas molecules genericised in 2010 recorded slower genericisation speeds, confirming that the molecules genericised in 2010 are not comparable to Plavix.

The CNAM further submits that, in light of the court-appointed expert's analyses, the Sanofi companies' criticisms are merely "the result of manipulation by CRA in an attempt to mislead the Court".

The Court's response

79. The counterfactual scenario, by definition hypothetical, corresponds to what would have happened in the absence of the harmful events.

80. In the present case, for the construction of the counterfactual scenario for the rate of substitution of Plavix, the comparison group of molecules must consist of molecules unaffected by the practices and whose genericisation rate would have evolved similarly to that of clopidogrel in the absence of the practices.

81. The Sanofi companies do not dispute that the year of a molecule's first genericisation is a determining factor in the evolution of the substitution rate, and therefore a relevant criterion for selecting molecules; but they contest the choice of years of first genericisation for selecting the molecules in the control group.

82. RBB's choice (CNAM Exhibit No. 35 and Exhibit No. 7 annexed to the RBB note of 19 September 2022) is based on an analysis of reimbursement data showing that, on average, the genericisation curves of molecules genericised between 2004 and 2005 and those genericised between 2010 and 2011 differ significantly from those of molecules genericised between 2006 and 2009. The trend in substitution rates for molecules genericised between 2004 and 2005 was on average slower, which can be explained by the fact that the introduction of generic medicinal products in France was still recent at that time. As for molecules genericised between 2010 and 2011, their evolution at the start of the genericisation period was disrupted by the entry into force of the Convention of May 2012, which affected pharmacists' incentives to dispense generics. In order to select the most relevant comparators for Plavix, which was genericised in 2009, RBB chose a year of first genericisation between 2006 and 2009 as one of the criteria for selecting comparator molecules. RBB further notes that the molecules genericised between 2006 and 2009 follow the rapid growth in the genericisation rate of clopidogrel.

83. The Court first observes that the court-appointed expert validly endorsed RBB's methodology (report, page 178) of comparing the genericisation rates of only those molecules with a large market size and that, since these are few in number, it was appropriate to calculate their average genericisation rate by grouping the years in pairs, as otherwise the annual averages might have appeared volatile and difficult to read. Furthermore, it notes that the years 2010 and 2011 were not aggregated.

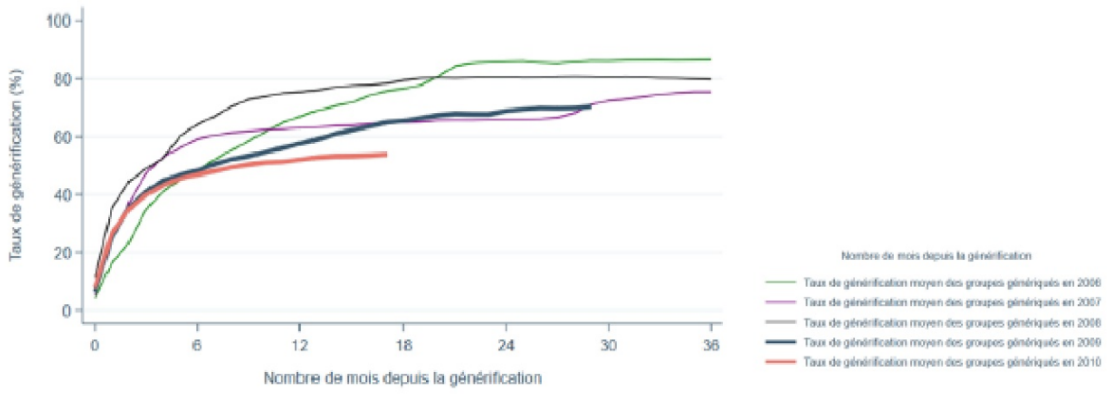
84. The Court further notes that the Sanofi companies and CRA made various proposals concerning the choice of comparable genericisation years, the latest of which, as set out by the court-appointed expert in his report (page 45), consist in extending RBB's 2006–2009 selection period to a 2006–mid-2011 period in order to take account of the fact that several genericised groups during the latter period are more comparable to clopidogrel than some of the comparators selected by RBB (CRA reports of 24 February 2023, Exhibit No. 27 of the report, and of 5 June 2023, Sanofi Exhibit No. 53).

85. The court-appointed expert validly did not endorse this adjustment, which involved including molecules genericised in 2010. He observes that, compared with the molecules genericised in 2009, those genericised in 2010 experienced significantly slower speeds of genericisation. He notes, for example, that twelve months after the start of genericisation, the genericisation rate for a molecule genericised in 2010 is on average nearly 20% lower than the same rate for a molecule genericised in 2009 (report, page 46). Moreover, it is established that one of the key characteristics of clopidogrel is its very high initial speed of genericisation. Within three months of its genericisation — and therefore before the effects of the practices took hold — clopidogrel reached a genericisation rate of 61%. However, the court-appointed expert notes (Annex 2 to the report) that seven of the eight molecules constituting the RBB comparison panel have a genericisation rate of between 44.8% and 60.1% at three months, whereas the molecules in the group genericised in 2010 do not exceed a rate of 42.7% at three months (rates ranging from 24% to 42.7%). The court-appointed expert further notes that, according to RBB, it cannot be ruled out that Sanofi's practices of disparaging clopidogrel generics may have affected all generics. According to the court-appointed expert, even if uncertain, this possibility also militates in favour of limiting, by way of caution, the comparison group to molecules genericised before 2010 (report, page 47).

86. The Court notes that these elements of the court-appointed expert's response, based on objective findings, are not specifically criticised by the Sanofi companies, which essentially confine themselves to considering it "illogical" to select comparison molecules genericised four years before clopidogrel (October 2009) while excluding molecules genericised only a few months after clopidogrel. The Court further observes that such a position contradicts that taken by the Sanofi companies before the Authority. Indeed, they then considered that "only molecules that were genericised in 2009 should be used for the purpose of comparing substitution rates" (Decision, paragraph 552).

87. The Sanofi companies further note in their latest pleadings that the CNAM's analysis reproduced by the expert compares only the progression of molecules genericised in 2009 and 2010, without also showing the differences between the trend in substitution for groups genericised in 2009 and that for groups genericised in 2006, 2007 or 2008. They present Figure 1 (Sanofi pleadings, page 16) which, in their view, shows the average evolution of the genericisation of the groups genericised from 2006 to 2010 and from which it is clear, in their view, that the rates for the 2009 and 2010 molecules are very close:

Figure 1 : Comparaison des groupes génériqués entre 2006 et 2010 (selon la méthode proposée p CNAM et retenue par l'expert dans son pré-Rapport)



Source : Analyse CRA du data pack RBB daté du 21 mars 2023.

They add that the substitution rates achieved by medicinal products genericised between 2006 and 2011 declined over time. They note that Figure 1 also shows that medicinal products genericised in 2006, 2007 or 2008 reached higher substitution rates than those reached by products genericised in 2009 and 2010. They therefore conclude that the fact that four of the eight molecules in the comparison group validated by the court-appointed expert were genericised in 2006 and 2007, whereas clopidogrel was genericised at the end of 2009, without this being "offset" by molecules genericised in 2010 having similar objective characteristics, inflates the assessment of the CNAM's loss.

88. However, the court-appointed expert responded to these analyses (response to Sanofi's summary submission of 17 November 2023 — report, page 179) by rightly pointing out that these trends identified by Sanofi are uncertain and questionable, in that:

— in view of the curves drawn by CRA, the very existence of such a trend is questionable (for example, as regards the 2008 curve);

— the annual averages shown in those graphs are calculated on the basis of small numbers of molecules (significant fluctuations may therefore result from all sorts of causes other than the alleged trend);

— these annual averages include molecules whose market sizes bear no relation to that of clopidogrel (market size of EUR 481 million over the 12 months prior to genericisation). For example, the average genericisation rate for molecules genericised in 2007 takes into account the genericisation rates of ornithine (market size of EUR 30 million); the average genericisation rate for molecules genericised in 2009 takes into account those of levocetirizine (market size of EUR 32 million).

Yet the larger the market size, the greater the number of generic manufacturers.

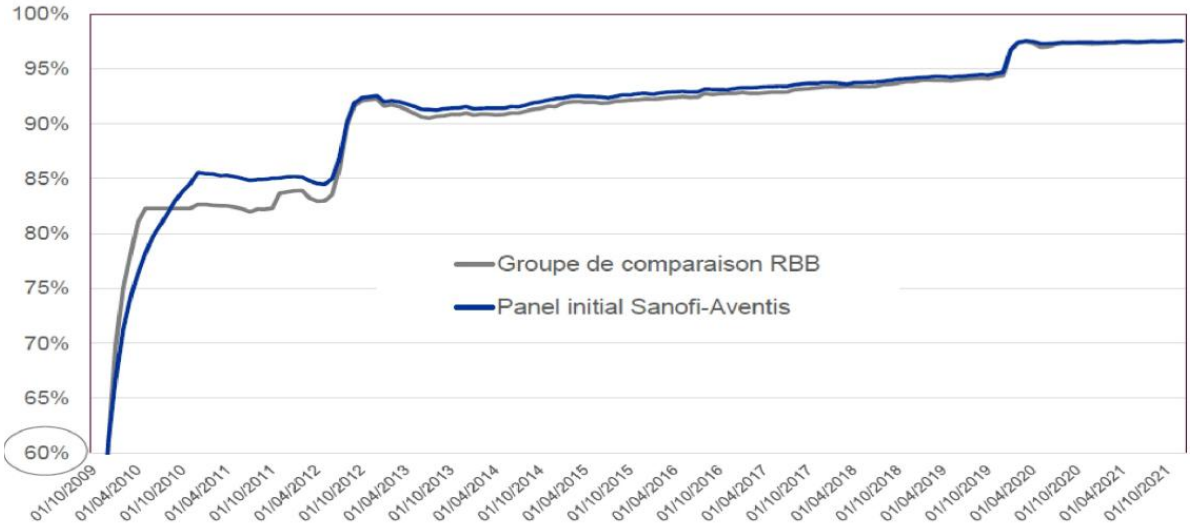
89. These elements of response provided by the court-appointed expert and noted by the CNAM in its pleadings are not specifically criticised by the Sanofi companies in their written submissions (in particular pages 16 and 17, paragraph 1.3).

90. The Court further notes that, in order to assess the harm to the economy, the Authority, in its Decision (paragraphs 672 *et seq.*), analysed the genericisation rates of nine molecules, including clopidogrel, initially selected by Sanofi-Aventis:

Molécule	Date de générification	Mois 1	Mois 2	Mois 3	Mois 4	Mois 12	Mois 24*
Omeprazole	Avril 2004	11 %	39 %	52 %	56 %	65 %	76 %
Simvastatine	Mai 2005	21 %	42 %	49 %	53 %	74 %	86 %
Pravastatine	Juillet 2006	16 %	37 %	50 %	57 %	79 %	90 %
Amlodipine	Août 2007	7 %	44 %	60 %	71 %	85 %	87 %
Lanzoprazole	Déc. 2007	13 %	47 %	58 %	64 %	77 %	83 %
Rispéridone	Déc. 2007	14 %	42 %	51 %	45 %	59 %	64 %
Venlafaxine	Déc. 2008	22 %	54 %	63 %	68 %	79 %	82 %
Pantoprazole	Mai 2009	21 %	49 %	59 %	64 %	76 %	79 %
Clopidogrel	Octobre 2009	23 %	56 %	64 %	67 %	65 %	62 %

The Authority then found that, while clopidogrel's genericisation rate is the highest during the first three months of marketing of the generics of those nine molecules, it is the lowest in the years that follow. After 24 months, it is thus barely above 60%, whereas the genericisation rate for the other molecules — with the exception of risperidone — reaches over 75%.

91. The Court notes that, in this comparison panel initially proposed by Sanofi-Aventis to the Authority, four of the molecules selected were genericised in 2006 and 2007, and none in 2010. Furthermore, the court-appointed expert, in the course of his investigations, found that the counterfactual genericisation rates estimated using Sanofi-Aventis's initial panel differ little from those estimated using the RBB comparison group (report, page 89):



Expert's note: *The vertical axis starts at 60% in order to visually magnify the gaps between the two curves.*

92. The Sanofi companies make no observation in the present proceedings on this analysis by the court-appointed expert based on his initial comparison panel before the Authority. The Court further notes that the Authority emphasised, regarding this initial panel, that (Decision, paragraphs 566 and 567):

> *"As regards the comparison of the genericisation rate of Plavix® with that of the eight molecules used by the Authority's investigating services, it must be noted that Sanofi-Aventis has in no way demonstrated that those molecules could not be used to carry out such a comparison, particularly since it was Sanofi-Aventis itself that proposed them in the context of the interim measures proceedings. The comparison proposed by Sanofi-Aventis in its observations, based solely on the criterion of the year of genericisation, cannot be accepted, as it fails to take into account certain*

factors that are decisive for the success of generic substitution, such as volumes and turnover, price and margin, the number of generic manufacturers present on the market, or any objective difficulties that may hinder the entry of generics."

93. It follows from all these findings that the Sanofi companies cannot seriously maintain that the decision to exclude molecules genericised in 2010, taken by RBB and validated by the court-appointed expert, was — as they vainly allege — "arbitrary and opportunistic" in order to "inflate the assessment of the CNAM's loss".

d. Criticism of the impact of Plavix's ACS indication

Positions of the parties

94. The Sanofi companies state that Plavix had an indication for patients suffering from acute coronary syndrome ("ACS") which the competing generics did not have. They note that the eight molecules selected in the control group share exactly the same indications between the originator and its generics, without taking into account this difference of indication specific to Plavix — a competitive advantage. They criticise the position of the court-appointed expert, who refused to take into account their approach of considering that, of the patients suffering from ACS, who account for 30% of the population treated with clopidogrel, 75% would have been prescribed Plavix with the "NS" mention even in the absence of any anticompetitive practice (i.e. 75% × 30% = 22.5% of Plavix volumes). Claiming this approach to be conservative, they criticise the expert for turning it against them by treating this 75% estimate as uncertain, which would justify the total rejection of any effect of the ACS indication. They further criticise the expert for not validating his cautious estimate of 75% on grounds of uncertainty regarding this figure, even though the expert himself bases his analyses on approximations. They consider that "such blatant bias is disarming" on the part of the expert.

95. The CNAM points out, first, that the expert took into account the ACS indication and its consequence on the genericisation rate through the average "NS" mention rate of the molecules in the RBB comparison group. Furthermore, in its view, the method adopted — based on the construction of a counterfactual scenario using the average genericisation rate of the molecules in the comparison group — necessarily takes account of this difference of indication and of its impact on the genericisation of Plavix. It maintains that, despite the expert's repeated requests, the Sanofi companies have not produced any conclusive evidence capable of supporting their hypothesis that the potential impact of the ACS indication — in proportions potentially higher than the average — was insufficiently taken into account. Second, according to the CNAM, it is clear from the findings of the Authority's decision and of the Paris Court of Appeal's judgment of 18 December 2014 that, in reality, if the difference of indication may have had an impact, it was solely due to the sanctioned practices, which consisted, in particular, in drawing doctors' attention to the difference of indication specifically as regards ACS — a sensitive condition — to encourage them to add the "NS" mention. It adds that the expert made five additional observations justifying RBB's decision not to take greater account of the potential impact of the ACS indication.

The Court's response

96. It is undisputed that, owing to supplementary patent protection, Plavix had an indication for the treatment of acute coronary syndrome (ACS) as part of dual therapy, through the combination of clopidogrel and acetylsalicylic acid (aspirin), which remained protected until February 2017. Consequently, none of the clopidogrel generics had the indication for the treatment of ACS in combination with aspirin (except for the Sanofi and Ratiopharm generics).

97. The Sanofi companies criticise the court-appointed expert for failing to "take into account" this specific feature of Plavix in comparison with its generics in his method for assessing the CNAM's loss.

98. The Court observes, as a preliminary matter, that in their latest pleadings concerning this criticism (pleadings, pages 17 to 19, paragraphs 58 to 69), the Sanofi companies do not clearly explain at what stage of the assessment this specific feature should be "taken into account" and in what manner. According to the summary submission of 17 November 2023 in response to the court-appointed expert's preliminary report, the Sanofi companies argue that it follows from "an objective examination of the evidence in the file" that "the absence of an ACS indication for Plavix generics necessarily had a negative impact on their market penetration, and therefore on Plavix's genericisation rate" and that "this impact must be assessed". The court-appointed expert's reproduction of an extract from Sanofi's submission No. 3 (report, page 62) also refers to a request by the Sanofi companies for the "neutralisation of ACS", which would be relevant "not only as regards the analysis of the NS rate, but also for analysing the counterfactual substitution rate of clopidogrel".

99. In essence, the Sanofi companies are thus requesting that Plavix's ACS indication be "taken into account" in adjusting the counterfactual scenario for its substitution rate, in the sense that even in the absence of Sanofi's anticompetitive practices, there would have been more prescriptions marked "NS" for clopidogrel than for other molecules whose generics had the same indications as the originator product.

100. It must, however, be observed that the court-appointed expert, without being seriously contradicted on this point, consistently considers that what matters as regards Plavix's ACS indication is the order of magnitude of non-substitution prescriptions associated with that reason. Thus, in the counterfactual scenario, the question is whether, in the absence of any anticompetitive conduct by Sanofi, those prescriptions would have been numerous enough to raise the "NS" rate for Plavix significantly above that of the molecules in the comparison group, which would justify adjusting the counterfactual scenario to take account of this particular feature of Plavix.

101. Admittedly, as the Sanofi companies rightly point out, the eight molecules selected in the comparison group share the same indications between originator and generics, and therefore do not have the same objective specificity as Plavix with the ACS indication, which its generics do not have (except for the Sanofi and Ratiopharm generics). Nevertheless, as the court-appointed expert rightly notes, almost every molecule — for reasons specific to it — is subject to non-substitution prescriptions ("NS"). The molecules in the comparison group are no exception; for example, in January 2016 their average "NS" prescription rate was 5.8%. It is therefore important, in order to justify an adjustment, to quantify this lower substitution caused by the ACS indication so as to assess its significance.

102. To this end, in their latest written pleadings, the Sanofi companies claim to demonstrate in a "certain and objective" manner that 30% of patients treated with clopidogrel suffer from ACS and that, for 75% of them, the prescription for Plavix would have been marked "NS" regardless of any anticompetitive practices by Sanofi, which would represent 22.5% (75% × 30%) of Plavix volumes.

103. Assuming that 30% of patients treated with clopidogrel suffer from ACS (only 25% had been mentioned before the Authority), the Sanofi companies, in their latest pleadings (in particular pages 17 to 19), then assert that there is "no reason to believe that, for a condition for which only Plavix had marketing authorisation for that indication, all patients treated for ACS would not have received NS prescriptions". To present a so-called "conservative" approach, the Sanofi companies, in those circumstances, reduced the rate from 100% to 75%.

104. The Court observes, however, that the court-appointed expert did not validate this estimate.

105. Indeed, for various reasons, this quantification by the Sanofi companies does not appear sufficiently reliable to discern and quantify a significant effect of any reduced substitution of Plavix due to the ACS indication and to adjust the counterfactual scenario for the substitution of clopidogrel accordingly.

106. First, the Court notes in this regard that the Sanofi companies refer in their written submissions on the analysis of the high rate of "NS" mentions for Plavix (pleadings, pages 41 and 43, paragraphs 196 *et seq.*) to various assumptions that may support their basic hypothesis that 100% of Plavix prescribed for the ACS indication would not be substitutable, namely the automatic alert messages from prescription-support software for doctors and dispensing-support software for pharmacists, as well as the risk of liability for a doctor prescribing a medicinal product without the ACS indication, particularly in the wake of the Mediator scandal.

107. Apart from the fact that these explanatory factors are exclusively qualitative and not quantitative, as the court-appointed expert points out, it must be noted that these explanations were not accepted by the Authority in its decision, which was upheld by the Court of Appeal in its judgment of 18 December 2014.

108. Thus, it is clearly stated in the Decision (paragraph 450) that:

> *"as previously noted, the differences in salts and indications of Plavix®'s generic competitors, relating solely to intellectual property issues and not to specific chemical or medical properties, have no bearing on the bioequivalence and substitutability of those medicinal products, and this applies to all conditions treated with Plavix®, including ACS. Indeed, once a generic medicinal product is listed in the directory of generics, no legal or regulatory provision prevents its dispensing as a substitute for the reference medicinal product, even if the generic medicinal product does not have all the indications of the latter."*

109. And the Court of Appeal's judgment of 18 December 2014 noted (pages 9, 16 and 17):

> *"(…) However, while it is undisputed that the data published concerned objective differences between Plavix and its generics — namely, on the one hand, that the salt contained in those medicinal products was not the same and, on the other hand, that the marketing authorisation for the originator product covered a therapeutic indication in combination with aspirin for ACS which was not included in the marketing authorisations for the generics — it is not the mere fact of having communicated this data that is held against Sanofi-Aventis, but the manner in which it did so.*
>
> *It should be noted in this regard, first, that those differences result from compliance with existing patents and supplementary protection certificates protecting, on the one hand, clopidogrel hydrogen sulphate and, on the other, the therapeutic indication for ACS in dual therapy; that they are therefore legally imposed differences and do not stem from a choice made by competing pharmaceutical companies; that, furthermore, given the conditions governing the granting of a marketing authorisation, neither of those differences has any bearing on the substitutability of the generics for the originator product.*
>
> *Indeed, regarding the difference in salt, the Afssaps, in a response addressed to the Authority's investigating services, stated that, in view of the data provided for the marketing authorisation applications which 'contained, in addition to a bioequivalence study with the original product Plavix, data demonstrating the safety and efficacy of the different salt (…) [this] does not preclude the classification of a medicinal product as a generic and does not constitute an obstacle to substitution'; that, regarding the difference in therapeutic indications, this body, in response*

to a request from Sanofi-Aventis, stated in a letter of 24 September 2009 that '(...) the lack of homogeneity in the therapeutic indications of the medicinal products in question cannot be regarded as contributing to a situation in which substitution would be likely to entail a particular risk to the health of patients under certain conditions of use, especially since these are generic medicinal products that have demonstrated bioequivalence, have established a satisfactory efficacy/safety profile at least similar to that of your reference medicinal product PLAVIX, and have a package leaflet validated by the French Health Products Safety Agency or, where applicable, the European Medicines Agency (...)'; that it follows from this response that the substitution of a generic medicinal product for Plavix, in the case of a patient being treated for ACS with dual therapy including aspirin, poses no particular risk to that patient's health; that, in those circumstances, the Authority was right to consider that the practices referred to above, which do not merely consist of describing objective differences or informing professionals of the simple characteristics of the medicinal products concerned, constituted an abusive practice; (...)

(...)

Sanofi-Aventis criticises the decision for finding that the practice resulted in a higher rate of 'NS' (for 'non-substitutable') mentions on doctors' prescriptions than is observed for other generics; it argues on this point that 'NS' prescriptions exist for all generics and not solely for clopidogrel, and that the high number of such prescriptions is explained by the fact that Plavix generics do not have the indication for ACS, which remains protected by a patent, whereas this condition accounts for approximately 25% of prescriptions; it maintains that the CNAMTS figures on prescriptions bearing the 'NS' mention should be corrected by excluding prescriptions relating to ACS;

However, considering that, in order to establish the link between the alleged practice and its effects, the decision did not refer solely to the fact that 'NS' was marked on prescriptions, but to the finding that there was a higher rate of this marking for Plavix (12.6%) than for other medicinal products, since across all medicinal products this rate is on average 5%; that in those circumstances, it is immaterial that this possibility exists for all molecules and not just for Plavix; that the Authority noted in this regard that this medicinal product was the one for which this rate was the highest, which is not disputed; that, furthermore, the absence of an ACS indication for dual therapy with the generics does not stem from a biological impossibility, but solely from the fact that this indication is still protected by a supplementary protection certificate, which in no way prevents the doctor or pharmacist from substituting Plavix with a generic in dual therapy with aspirin in cases of ACS, without breaching Article L. 5121-12-1 of the Public Health Code prohibiting off-label prescriptions [emphasis added by the Court]; that consequently, while this data may explain a higher rate of 'NS' mentions by certain doctors who are less well-informed than others, it cannot explain the significant difference in the rates of non-substitution mentions between Plavix and other originator medicinal products; that, finally, Sanofi-Aventis has produced no evidence enabling the Court to find that there is, as it claims, an established trend towards lower substitution in the case of medicinal products intended for conditions with serious consequences, such as atherothrombosis; furthermore, the calculation proposed by the applicant in its pleadings is inappropriate, since it is based on the assumption that all prescriptions for ACS should be excluded from those bearing the 'NS' mention, whereas substitution by the doctor is also possible in such cases, despite the fact that this indication does not appear in the marketing authorisation" [emphasis added by the Court].

110. Furthermore, the screenshots produced (Sanofi Exhibits Nos. 15 and 16) concerning alert messages from prescription-support and dispensing-support software are not dated and therefore do not allow it to be verified that such alerts were present in the software versions during the period in question. Similarly, no information is provided on the rate of deployment and actual use of this software by practitioners during the period in question. Furthermore, the content of the messages appearing on those screenshots in no way demonstrates that they were "such as to influence the overall rate of Plavix genericisation", as the Sanofi companies claim.

111. The Court further notes that, despite this lack of homogeneity in the indication, Plavix very quickly achieved a very high substitution rate in the first months of its genericisation, that is, before the practices took effect (64% at three months, 67% at four months). The very purpose of the sanctioned practices, however, was to draw doctors' attention to the difference in indication regarding ACS — a sensitive condition — in order to encourage them to mark prescriptions "NS".

112. Thus, the Authority noted in its decision that the communications of the two pharmaceutical companies (Sanofi-Aventis and Bristol Myers Squibb) were based on the following arguments (paragraph 123):

— the mention of the differences between Plavix® and its generics, with the exception of Clopidogrel Winthrop® (different salt and absence of the ACS indication in dual therapy);

— emphasis on the significant mortality risks faced by patients suffering from ACS;

— the indication that the risks set out above are known and managed with Plavix®;

— finally, the suggestion to mark prescriptions "non-substitutable" in all cases of dual-therapy prescriptions.

113. And it noted in particular that:

> *"(…) the bulk of the communication strategy aimed at doctors focused on the indication relating to ACS. Thus, Dr [B], a general practitioner in [Locality 6], stated on 25 January 2010 that 'the message conveyed by the sales representatives boiled down to announcing the arrival on the market of CLOPIDOGREL (the generic version of PLAVIX), but with a salt different from that of the originator. Owing to this slight difference in manufacture, the sales representatives told me that substitution for the treatment of arteritis poses no problem, but that substitution for the treatment of coronary syndrome is not recommended, pending any further studies regarding this new salt' (paragraph 151).*
>
> *Dr [Z] Y..., senior registrar in cardiology at [7] Hospital in [Locality 8], also stated on 14 April 2011: 'Yes, I was told to write "non-substitutable". She is a regular SANOFI representative. The excipients are reportedly not the same and there have been cases of thrombosis.' (paragraph 152).*
>
> *These testimonies show that Sanofi-Aventis's medical representatives delivered a message designed to suggest, in particular, that the absence of an ACS indication for Plavix® generics was due to a lack of additional studies, or that the active ingredient in the clopidogrel salts of the generics was not identical to that of Plavix®, or, finally, that there had been serious health problems (cases of thrombosis) due to treatment with the generic. (paragraph 153)*
>
> *(…)*
>
> *In the same region, a pharmacy reported: 'Received a visit from Sanofi to encourage it to stock Clopidogrel Winthrop, which it did not do. The company's arguments: the other generics have not undergone tests with the new salt to prove their efficacy when co-prescribed with aspirin.*

Dispensing a generic may cause bleeding in the patient.' Another pharmacy stated, regarding Plavix®, that it 'was itself reluctant to substitute it because the company had communicated that generics (other than Winthrop) might cause bleeding'. (paragraph 190)

During her hearing, this same representative [from the Health Insurance Fund] stated as follows: 'During our visits regarding the dispensing of generics in general, several pharmacies told us they were having difficulty substituting Plavix®. This was notably due to visits from sales representatives who claimed that the generic of Plavix® contained different salts, that they did not have the same indications, and that only the Winthrop generic could be substituted. They told the pharmacies that by dispensing other generics, they were assuming liability.' (paragraph 191)

(...)

A large number of the pharmacists interviewed also mentioned an unusually high number of 'non-substitutable' or 'NS' mentions on Plavix® prescriptions, which demonstrates the existence of significant concern among these professionals regarding Plavix® generics. (paragraph 221)

Finally, a number of letters provided by Ratiopharm show that the generic manufacturers had to respond to queries from pharmacists concerned about their potential liability in the event of dispensing Plavix® generics (paragraph 222).

(...)

The act of highlighting differences which, in the context of the discourse held and of the conditions in which it is heard, can only be understood as substantial differences — such as to raise unjustified doubt, or even fear, regarding the qualities of competing generic medicinal products — is all the more reprehensible in the present case as it was accompanied by a clear incitement not to substitute, which could only be understood as the conclusion to be drawn from such doubts. (paragraph 471)

Yet the very objective of European and French regulations on generics is to overcome the reluctance and risks of confusion on the part of healthcare professionals, by establishing a substitution mechanism enabling them not to concern themselves with intellectual property issues or differences in marketing authorisations, provided that the generics are authorised and listed in the directory of generics. (paragraph 472)."

114. The Court of Appeal thus held in its judgment of 18 December 2014 that the practice characterised by the Competition Authority as an abuse of a dominant position consisted, on the part of Sanofi-Aventis, in disseminating to healthcare professionals a discourse concerning the differences between Plavix and its generics, through which it provided them with information that was incomplete and presented — having regard to its construction and to the particularly sensitive context in which it was given — in such a way that this information essentially served to discredit the products competing with its own, by unduly casting doubt on their efficacy and safety to the benefit of its own products.

115. It follows that there is no reliable evidence — either qualitative or quantitative — to show that the difference in indication between the originator product and the generics was, in itself, capable of significantly affecting the substitution rate of Plavix in the absence of the Sanofi companies' unlawful practices.

116. Consequently, the court-appointed expert was right to refuse to adjust the counterfactual scenario for the substitution of Plavix as regards the ACS indication.

e. Criticism of the court-appointed expert's reasoning

Positions of the parties

117. The Sanofi companies submit that, relying in particular on an incorrect reading of Sheet 3c of the Paris Court of Appeal, the court-appointed expert considers that having comparators with a homogeneous substitution rate would be a guarantee of the quality of their selection. In their view, this approach by the expert is "fundamentally flawed", in that it serves to justify *a priori* exclusions of molecules on the ground that their substitution rate does not correspond to that of the molecules identified *a posteriori*. In doing so, according to the Sanofi companies, the expert has in fact implicitly introduced an additional selection criterion: any comparator selected must have a genericisation rate "in line with" that of the comparators selected by RBB. They explain that this criterion is fundamentally biased because it renders RBB's model "unchallengeable": regardless of the validity of the argument raised, it will always be dismissed on the ground of its lack of "homogeneity" with the group presented by RBB. They submit that, in reality, the correct interpretation of the aforementioned sheet is that the homogeneity of the medicinal products must be assessed not on the basis of the variable being explained (the genericisation rate), but on the basis of the explanatory factors established as relevant.

118. The CNAM emphasises that the court-appointed expert refers to the concept of homogeneity of the comparison group in a section of his report devoted to the assessment of the alternative scenarios proposed by CRA, but that this concept was never used — either explicitly or implicitly — as a factor in selecting the molecules for the comparison group. It specifies that the criterion of homogeneity does not come into play at the stage of selecting the molecules, but rather in assessing the relevance of the selection factors chosen to compose the control group. It adds that the ultimate homogeneity of the selected molecules has never been used otherwise than as one indicator (among others) of the relevance of the selected factor. In its view, the expert explains this clearly on pages 174 and 175 of his report.

The Court's response

119. The Court notes that the court-appointed expert verified the relevance of the selection criteria for the molecules in RBB's comparison group in terms of their ability to predict the genericisation rate, and not on the basis of a genericisation rate "in line with" that of the comparators selected by RBB.

120. The court-appointed expert first identified the key characteristics of clopidogrel, which were not seriously contested by the Sanofi companies, namely a very large market size, a very high initial speed of genericisation, its date of genericisation in October 2009, and a large number of generic manufacturers.

121. On the basis of these characteristics, the court-appointed expert examined the relevant factors explaining the genericisation rate.

122. As regards market size, the court-appointed expert noted (pages 42 and 43) that RBB's analyses, not seriously contradicted by those of CRA, confirm the relevance of this factor, in that the larger the market size of a molecule, the higher its genericisation rate. He specifies that the concepts of "sales value" and "turnover" are similar or close to that of "market size". He further noted that the other factors — price and volume — when considered jointly, constitute components of market size, whereas when considered in isolation they do not provide additional explanatory power. He concludes that those factors are already implicitly taken into account by the market size factor. The application of this factor led to the selection of molecules with a large market size as belonging to the first quartile, that is, the top 25% of molecules with the largest market size (report, page 42).

123. As regards the year of genericisation, the court-appointed expert noted (report, pages 44 to 48) that RBB's analyses confirm the relevance of this second factor, since the curve of a molecule's genericisation rates changes depending on the year in which it first faced generic competition. The Sanofi companies do not dispute the relevance of this explanatory factor, but have criticised the years selected for the control group, and in particular the exclusion of the year 2010, which is addressed in paragraphs 79 *et seq.* above. The application of this criterion led to the selection of molecules genericised between 2006 and 2009 (inclusive).

124. As regards the number of generic manufacturers — a relevant explanatory factor according to the Sanofi companies — the court-appointed expert concluded (report, page 48), without being seriously contradicted, that while this factor is relevant, it is in fact already taken into account by the market size factor, noting that all molecules with a large market size (those in the first quartile, that is, the 25% of molecules with the largest market size) have a large number of generic manufacturers. He therefore concludes that adding this factor is irrelevant.

125. The court-appointed expert also ruled out the factors of average patient age and therapeutic class on the ground that those criteria do not appear predictive of the genericisation rate (report, page 48).

126. Finally, the court-appointed expert added a third relevant explanatory factor (report, page 49): inclusion in the list annexed to the Convention approved on 4 May 2012, which is specifically intended to encourage substitution. He specifies that this Convention is accompanied by a list naming 26 molecules, including clopidogrel, used to measure changes in substitution rates at a pharmacy and to determine the amount of its bonus. The expert considers that the very fact of specifically naming 26 molecules as priority substitution targets confers on them characteristics (e.g. visibility, perceived importance) that those in the "rest of the directory" do not have. Admittedly, the addition of this factor has no impact on the composition of the RBB group of molecules (7 out of 8 molecules meet the criterion); but as the expert notes (report, page 176), this criterion makes it possible to carry out an additional verification on this comparison group, namely that all the molecules in the group do indeed have an important characteristic that clopidogrel had (except in the specific case of gliclazide, whose atypical nature would render its inclusion on the list irrelevant).

127. The court-appointed expert thus identified three factors influencing the rate of genericisation of molecules (report, page 50): market size, the year of genericisation, and inclusion or non-inclusion on the list annexed to the Convention. He noted that those factors, together with those implicitly taken into account (volume and price, number of generic manufacturers), represent six of the seven possible factors identified by the Authority's Decision (paragraph 567).

128. The application of the factors thus selected resulted in the formation of a comparison group comprising the following eight molecules (with the date of first genericisation): pantoprazole (May 2009), amlodipine (August 2007), cefpodoxime (June 2007), gliclazide (September 2008, withdrawn from November 2011), lansoprazole (December 2007), pravastatin (July 2006), valaciclovir (December 2009) and venlafaxine (December 2008). The expert considered this figure of eight molecules to be satisfactory on the ground that this comparison group is large enough to avoid exposing the counterfactual scenario significantly to any atypicality in a single molecule, and small enough to focus the composition of the group on the most comparable molecules (report, page 53).

129. In view of all the foregoing, the Court finds that, in determining this group of comparator molecules, the expert's approach was to select sets of molecules sharing common characteristics with clopidogrel (i) and (ii) predictive of the genericisation rate. Furthermore, contrary to what is argued by the Sanofi companies, the court-appointed expert did not rely on an additional selection criterion of

homogeneity — even implicitly — such that any comparator selected had to have a genericisation rate in line with that of the comparators selected by RBB. It was in fact only after these selection criteria had been determined and the control group composed that the expert set about verifying the homogeneity of the group thus obtained and assessing the alternative scenarios proposed by CRA.

130. CRA had in fact proposed two revised groups of comparators for clopidogrel (report, page 92).

131. For the first alternative scenario proposed, CRA selected all generic groups from the CNAM 2 database, in accordance with the CRA filter, satisfying the following three conditions:

— their sales value exceeds the first quartile measured on this basis (i.e. EUR 27.88 million, adjusted to EUR 27.7 million to include finasteride, whose sales value is below but extremely close to the first quartile threshold);

— the number of generic manufacturers at six months is greater than or equal to 13;

— the date of entry of the generics is between 2006 and the end of the first half of 2011.

132. For the second alternative scenario proposed, CRA selected:

— all comparators with a sales value exceeding EUR 66 million (the RBB criterion) and genericised between 2006 and the first half of 2011;

— comparators with 13 or more generic manufacturers and a sales value of more than EUR 27.7 million.

133. As regards alternative scenario No. 1, the expert noted, on the one hand, that the comparison group resulting from this scenario produces counterfactual genericisation rates generally lower than those of RBB, but nevertheless higher than the rates observed for clopidogrel (report, page 93). On the other hand, the expert observed that the molecules in the CRA comparison group show significantly less homogeneity than those in the RBB comparison group (report, page 94). Essentially the same observations were made for alternative scenario No. 2.

134. These findings led the court-appointed expert to conclude, rightly, that the revised comparison groups proposed by CRA were not a preferable alternative to the RBB scenario.

135. Furthermore, the homogeneity of the genericisation rates of the molecules in the comparison group is indeed used as an indicator that the factors selected upstream to compose it are of suitable quality to predict the genericisation rate. Conversely, it is clear from the expert's explanations (report, pages 174 to 176) that, in his approach, the heterogeneity or atypical nature of molecules identified according to criteria defined upstream does not *ipso facto* lead him to exclude those molecules from the comparison group, but rather to question the reasons for that divergence and the quality of the selection criteria defined upstream.

136. Consequently, as the CNAM points out, the ultimate homogeneity of the selected molecules was never used by the court-appointed expert otherwise than as one indicator, among others, of the relevance of the selection factors chosen upstream. The method used by the court-appointed expert is therefore not biased, as the Sanofi companies maintain.

***

137. Based on all of these findings and assessments by the Court, the counterfactual scenario for the rate of substitution of Plavix, developed by RBB and adjusted by the court-appointed expert, is adopted by the Court for the assessment of the CNAM's loss.

B. The duration of the effects of the anticompetitive practices

Positions of the parties

138. The Sanofi companies recall that the practices in question lasted only five months and ceased entirely in January 2010. In their view, Sanofi's discourse could not have continued to produce any effects, even residual ones, beyond a maximum of two years after the end of the practice, that is, beyond January 2012. They state that their position is corroborated by the implementation of a Convention in April 2012 which entirely transformed the financial incentives for pharmacists to substitute, at a time when the practice had ceased to produce any effect. They consider "absurd" the position of the court-appointed expert that Sanofi's five-month discourse continued to produce effects until 2021, that is, for nearly 12 years. They criticise the expert who, instead of carrying out a concrete analysis as required by his remit, merely (i) provided a partial and biased reading of the Paris Court of Appeal's judgments of 2014 and 2022 to avoid any analysis on his part of the "2009–2013 period" and then (ii) confined himself to a purely theoretical — and incorrect — reading of the RBB model for the period after 2015.

139. Thus, according to the Sanofi companies, given the practical manner in which sales visits are conducted and how doctors and pharmacists obtain information, this discourse could not have had a lasting effect over nearly 12 years on their substitution practices. They criticise the CNAM for seeking to reverse the burden of proof, which lies with the CNAM to demonstrate the continuation of the effects of the practices over time, and for imposing an impossible burden of proof on Sanofi. In any event, they set out eight factors justifying that a maximum of two visits over five months could not have produced effects after 2012, namely:

— the sales visit is very short (a few minutes) and of moderate frequency (about once every two months);

— the marketing of Plavix generics was not accompanied by any abnormal increase in pharmacovigilance reports;

— healthcare professionals continuously obtain information from numerous sources;

— clopidogrel prescriptions are renewed on average once every seven weeks, so there is no residual effect beyond this short period;

— the effect of medical promotional discourse is non-existent beyond two years;

— the fact that the Plavix substitution target set for 2012 was exceeded confirms that Sanofi's practice was already producing no effect by that date;

— the publication of the Competition Authority's Decision in May 2013 was widely publicised, and no doctor or pharmacist could have failed to notice this information.

140. According to the Sanofi companies, the court-appointed expert failed to provide any concrete analysis to assist the Court in determining the actual date on which the effects ceased. They submit that, for the period 2009–2013, the expert and the CNAM refer this Court to its own judgment on the basis of a truncated reading of it, in that the Court is said to have already ruled that the effects of the practices continued until 2013. They further note that the Authority's Decision — in the method used to determine the financial penalties, confirmed by the Court of Appeal's judgment of 18 December 2014 and by the Court of Cassation — indicates a duration of effects of one year.

141. For the 2015 period, the Sanofi companies criticise the court-appointed expert for having based his assessment on a mere observation divorced from any practical consideration, namely that during the period in question, the "NS" prescription rate for Plavix remained higher than that of the "30 best-selling molecules", while at the same time the counterfactual curve of the RBB model only converges

with the actual curve in September 2021. They note, first, that the expert provided no indication of the criteria used to select the 30 comparison molecules. They then point out that the expert's reasoning is based entirely on an unsupported assumption, namely that Plavix should have had an "NS" mention rate in 2015 identical to that of the other molecules. Finally, they argue that a rigorous analysis of the data shows that the conclusion reached by the expert is "grossly erroneous", in that one must obviously compare the relative trends in the "NS" mention rates of the various molecules. Once this relative comparison is made (using a common base of 100 in January 2019), it is observed, with supporting graphs (page 40), that the "NS" mention rate for Plavix evolved in exactly the same way as (i) the average of the 30 molecules and (ii) the RBB comparators. They add that the inherently higher rate for Plavix can be explained by various factors unrelated to Sanofi's discourse, in particular the difference of indication between Plavix and its generics, the latter not having the indication for the treatment of patients with ACS — i.e. 30% of patients — which necessarily weighed on the overall "NS" mention rate for the clopidogrel molecule and was facilitated by prescription-support software for doctors and dispensing-support software for pharmacists.

142. The Sanofi companies therefore challenge the court-appointed expert's analysis and consider that Sanofi's conduct could not have continued to produce any effect, even residual, beyond two years after the end of the practice at the latest, that is, beyond January 2012.

— Principally, they seek a new expert assessment with the specific remit of establishing the duration of Sanofi's practice;

— In the alternative, they ask the Court to rule that the effects of Sanofi's conduct ceased no later than two years after the end of its discourse, that is, in January 2012, and consequently to declare that any sum awarded to the CNAM may cover only its potential loss for the period from 2010 to 2011, and to dismiss the CNAM's contrary claims.

143. The CNAM points out that, in his analysis of the duration of the effects, the court-appointed expert relied on the parties' submissions, on extracts from the Decision and from the judgments of the Court of Appeal, and on his own analysis of the data communicated to him. On this last point, the CNAM notes that the expert carried out a concrete analysis of the objective data provided to him concerning specifically the trend in the rate of "NS" mentions on Plavix prescriptions compared with that of the 30 best-selling molecules, and that he found that, until December 2019, the rate of "NS" mentions remained significantly higher for Plavix (13.8%) than the average for the 30 best-selling molecules (4.6%), revealing a gap of 9.2% in December 2019, and concluded that the practices had produced effects at least until December 2019. It maintains that this analysis is central to the expert's report and that, as such, it is based on concrete observations drawn from the CNAM DCIR data. It further notes that the expert addressed all the Sanofi companies' observations on this analysis in his report and in his responses to the parties' written submissions. It emphasises that the expert thus observed, supported by a graph, a convergence of the two curves in September 2021: the end of the effects of the practices according to RBB (the counterfactual genericisation rate matches the actual genericisation rate) coincides with the disappearance of the gap in the rate of "NS" mentions observed by the expert between Plavix prescriptions and those of the 30 best-selling molecules.

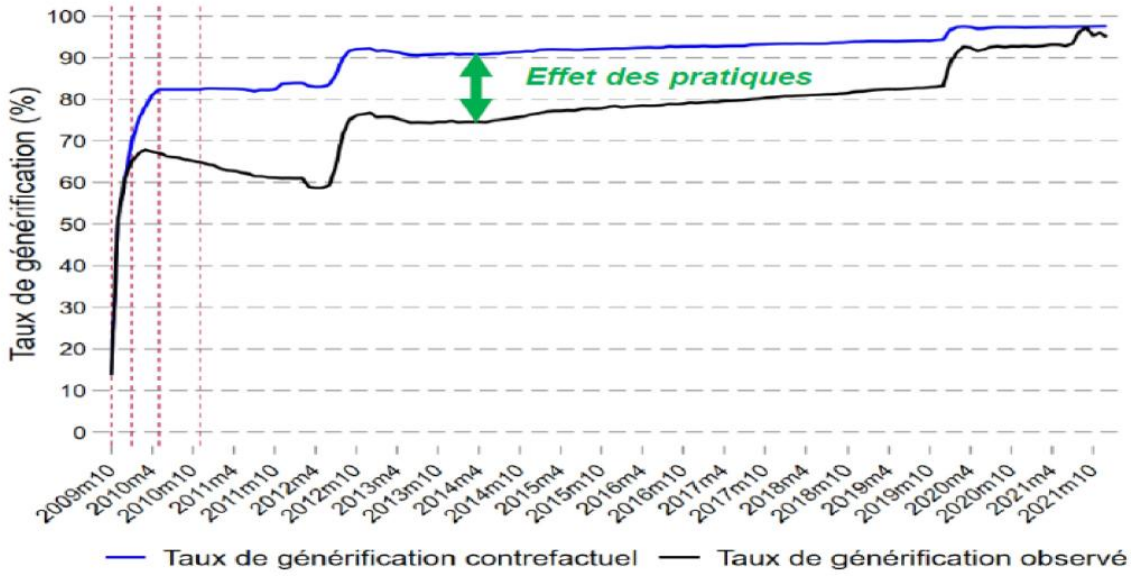
144. The CNAM highlights the inconsistency of the Sanofi companies' position with the counterfactual scenario put forward by their own experts during the expert assessment, which results in a convergence of the actual and counterfactual scenarios suggesting that the effects of the practices end in 2021 rather than in 2012. It then refutes all the factors put forward by the Sanofi companies.

The Court's response

145. In its judgment of 9 February 2022, this Court held that, while it is indisputable that Sanofi-Aventis's disparagement strategy produced harmful effects beyond the time and scope of the communication actions, it is also not excluded that the harmful effect was long-lasting over several years, even beyond 2015, and in particular instructed the appointed expert to:

> *"determine the date on which the effects of the disparagement practices implemented by the Sanofi companies ceased, in order to assess the deferred effect of the loss suffered by the CNAM; in the event that the practices continued to have an impact on the market penetration rate of clopidogrel generics, propose an estimate of the loss that may have occurred until the cessation of those effects."*

146. At the conclusion of his expert assessment, the court-appointed expert estimated the duration of the effects of the anticompetitive practices to extend until September 2021. This date — marking the end of the effects of the sanctioned practices — corresponds to the point of convergence of the curves of the validated counterfactual genericisation rate for Plavix and of the actually observed genericisation rate for Plavix



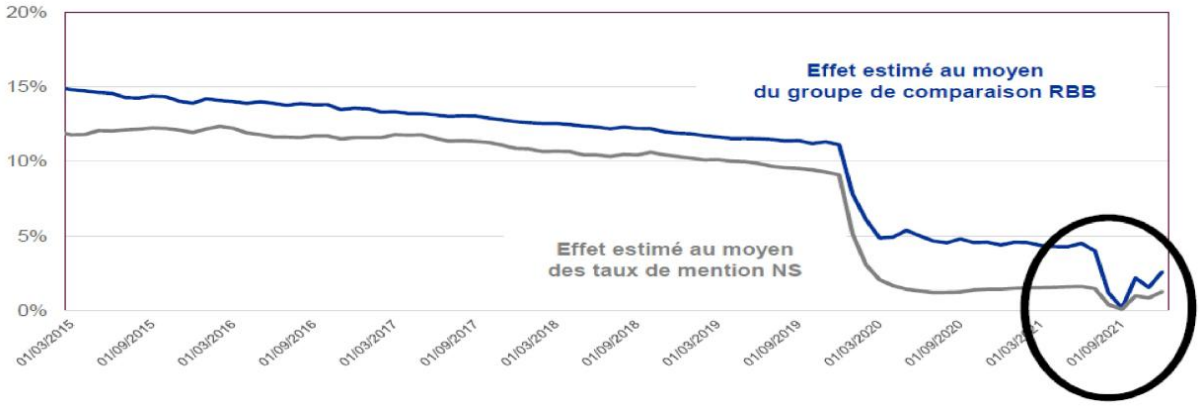
The expert compared this result with another analysis of data collected by the CNAM and produced during the expert assessment concerning the "non-substitutable" rate for the 30 best-selling molecules.

147. Already, in its Decision of 14 May 2013 (paragraphs 522 and 523), the Authority referred to a June 2012 study by the French statutory health insurance scheme on the use of the "NS" mention by doctors, highlighting an unusual proportion of this "non-substitutable" mention for the clopidogrel molecule. This study, which was the subject of a press briefing on 6 June 2012, had been conducted in 100 local health insurance funds (*CPAMs*) and was based on the analysis of a sample of 12,000 prescriptions. According to the Authority, the study shows that, generally speaking, doctors make limited use of the "non-substitutable" mention, with the proportion of such mentions being below 5% across all molecules, and that the molecule with the highest rate of "non-substitutable" mentions was clopidogrel at 12.6%.

148. From this June 2012 study, the expert notes that the average rate of "NS" mentions for clopidogrel was 12.6%, whereas that for the 30 most commonly dispensed molecules was 3.5% (report, page 78).

149. During the expert assessment, the CNAM provided data (referred to as "CNAM DCIR") enabling the rate of "NS" mentions to be determined, month by month, for clopidogrel and other molecules over the period 2015–2019. After verifying the quality and reliability of these data (report, page 79) — a verification that is not seriously contested — the court-appointed expert found that analysis of these data showed that the average rate of "NS" mentions for clopidogrel over this period was around 16%, whereas that for the same 30 best-selling molecules was 5% (report, page 82). It follows that over these two periods (2012 and 2015–2019) the rate of "NS" mentions for clopidogrel was, on average, three times higher. This rate then normalised in early 2020 following a regulatory change restricting the use of the "NS" mention (Order of 10 November 2019). The expert states that analysis of the CNAM DCIR data on the rate of "NS" mentions indicates the existence of an effect of one of the practices until at least December 2019 (report, pages 105 and 189) and that, after that date, the regulatory change attenuates that effect without, however, eliminating it entirely.

150. The court-appointed expert then produced two curves for the period 2015 to 2021: one estimating the gap between the counterfactual genericisation rate for Plavix and the actually observed genericisation rate; the other estimating the gap between the actually observed rate of "NS" mentions for Plavix and the average rate of "NS" mentions for the 30 best-selling molecules (report, pages 82 to 87). The expert observed that these two curves — produced using different comparison groups and different data — are close and evolve in parallel, and that by September 2021 both curves indicate only a negligible effect. He concludes that these findings strongly support, on the one hand, the relevance of the RBB counterfactual scenario (report, page 87) and, on the other hand, the end date of the effects in September 2021 (report, page 106):



151. Already at this stage, the Court observes that, contrary to the arguments put forward by the Sanofi companies, the court-appointed expert did not merely rely on "a mechanical conclusion derived from a theoretical model" but, on the contrary, was able to carry out an analysis other than the counterfactual scenario, based on direct evidence collected by the CNAM concerning the upstream effect sought by the practices, namely the marking of "NS" on clopidogrel by prescribing doctors.

152. Furthermore, contrary to what the Sanofi companies claim, it does not appear from the report that the court-appointed expert considered the question of the duration of the effects over the 2009–2013 period to be settled and limited himself solely to analysing the 2015–2021 period.

153. Indeed, the Court notes that the court-appointed expert's central analysis of the duration of the effects rests on a comparison of the levels of "NS" mentions on clopidogrel and on the 30 best-selling molecules over two periods: 2012 and 2015–2019. For this analysis, it is not seriously disputed that the expert had access to CNAM DCIR data of unusually high quality, on the one hand owing to their relevance — in that they precisely measure the effect sought by one of the practices (the number of

"NS" mentions added by doctors to Plavix prescriptions) — and on the other hand owing to their robustness, since they measure the number of "NS" mentions across all dispensing of clopidogrel and not merely on a sample. These are therefore not analyses divorced from any concrete observation, as the Sanofi companies claim. Here, it is not only the counterfactual scenario that demonstrates the significance of a deferred effect of the practices, but also the analysis of the CNAM DCIR data, independent of the counterfactual scenario and of the RBB comparison group. Admittedly, there are no data on "NS" mentions for the years 2013 and 2014, but the court-appointed expert rightly points out (report, page 187) that it makes no sense to think that the effects of the practices seeking to persuade doctors to mark prescriptions for Plavix "NS" could have ceased in the period prior to December 2019 and then resumed, given that those effects vary little from one month to the next, with the exception of a trend towards a slow decline.

154. Furthermore, contrary to the Sanofi companies' assertions, the court-appointed expert did not select the 30 molecules subject to the comparative analysis, but based his work on the 2012 statutory health insurance study cited in the Decision, which refers to a list of 35 molecules whose "NS" mention rate had been collected. From this list, the court-appointed expert removed five molecules for the analysis, namely clopidogrel; levothyroxine — which has the particular feature of being a molecule with a narrow therapeutic margin — and three other molecules (chlorhexidine/chlorobutanol, domperidone and oxomemazine) for which the CNAM DCIR data were missing or incomplete. Furthermore, the composition of this group of 30 molecules bears no relation to the selection criteria for the molecules constituting the comparison panel for Plavix's substitution rate.

155. Furthermore, it is very clear that the court-appointed expert's reasoning is not based on the underlying assumption that Plavix should have had an "NS" mention rate in 2015 identical to that of the other molecules, as the Sanofi companies claim. The Court notes that the expert's reasoning is rather aimed at examining the significance of the gap between the average "NS" mention rate for clopidogrel and that of the 30 other best-selling molecules over the same period. In the preceding grounds (paragraphs 96 to 116), it has been held that the difference of ACS indication between the originator product and the generics of Plavix was not, in itself, capable of explaining the size of the gap in the rate of "NS" mentions between Plavix and other originator medicinal products, independently of the unlawful practices of the Sanofi companies. On the contrary, while one of the effects of the practices was to persuade doctors to mark Plavix prescriptions "NS", the significantly higher rate of "NS" mentions for clopidogrel can only be explained by the practices, the unlawfulness of which has been definitively established.

156. The Sanofi companies further argue that a rigorous analysis of the CNAM DCIR data shows that the conclusion reached by the court-appointed expert is incorrect, since it is necessary to compare the "relative" trends in the rates of "NS" mentions for the various molecules. They maintain, with supporting graphs (pleadings, page 40, Figures 3 and 4), that when this relative comparison is made (using a common base of 100 in January 2015), it is apparent that the rate of "NS" mentions for Plavix evolved in exactly the same way as (i) the average of the 30 molecules and (ii) the RBB comparators. They note that this analysis of "relative trends" shows, in particular, that the rate of "NS" mentions for Plavix and the other molecules (the 30 molecules and the RBB comparators) all fell by around 80% following the entry into force of the Order of 19 November 2019, which placed very strict restrictions on the use of "NS" mentions. They consider that, if a significant effect of Sanofi's practice had persisted in 2020, the rate of "NS" mentions for Plavix should have fallen more sharply than that of the other molecules.

157. However, the Court first notes that the expert observed that, from January 2020 onwards, the figures become small — the average rate for clopidogrel in the second half of 2020 being only around 2% — calling for caution. Interpreting gaps between small figures, or trends towards small figures, carries a greater risk of error than interpreting gaps between large figures (those prior to December 2019). This point, highlighted by the CNAM in its written submissions, is not the subject of any specific observation by the Sanofi companies.

158. Furthermore, the Court observes that comparing the "relative" trends in the curves of average "NS" rates for clopidogrel, for the RBB comparators and for the 30 best-selling molecules is irrelevant, since the effect of the practices is demonstrated by the persistent gap between the various curves and not by their comparable evolution over time. The Sanofi companies' argument that, since the rate of "NS" mentions for Plavix experienced in 2020 a relative fall identical to that of the comparators (−80%), it can only be inferred that the effects of the practices no longer existed after 2020 — and did not exist in November 2019 either — cannot therefore be accepted.

159. Moreover, the court-appointed expert's reasoning is not contradicted by the method used by the Authority to calculate the penalty for the Sanofi companies' anticompetitive practices, since the latter is independent of the assessment of the specific harm caused by these practices to the CNAM and, at the time of its sanctioning decision, the Authority did not have access to the additional CNAM DCIR data produced during the expert assessment.

160. Finally, the Sanofi companies emphasise that their practices lasted only five months and ceased entirely in January 2010, so that their effects cannot seriously have persisted for 12 years. They argue that a concrete analysis of the case — in particular of how a sales visit actually takes place and how healthcare professionals obtain information — leads to the conclusion that there were no residual effects from 2012 onwards.

161. Admittedly, as the Sanofi companies point out, healthcare professionals only received Sanofi's commercial discourse during very short sales visits (averaging 8 minutes according to a 2007 IGAS report) and, during those visits, the company representatives generally presented 3 or 4 products, amounting to a discourse of no more than 3 to 4 minutes on Plavix. It is undisputed that the marketing of Plavix generics was not accompanied by any abnormal increase in pharmacovigilance reports and that pharmacists and doctors have access to multiple, different and independent sources of information, such as the press, conferences, exchanges with peers, distance information and training (Sanofi Exhibits Nos. 30 to 34). An internal Sanofi study of September 2020 has also been produced, showing that the effect of medical promotion does not extend beyond two years, with generally 70% of the effect in year N when the promotion takes place and 30% of the effect in the following year N+1 (Sanofi Exhibit No. 27).

162. Nevertheless, the Sanofi companies' arguments rely primarily on general studies which cannot fully reflect the actual effects of the discourse delivered by Sanofi's representatives to healthcare professionals during the wholly singular promotional campaign for Plavix and its authorised generic.

163. Indeed, it is clear from the Authority's Decision and from the judgment of 18 December 2014 that the disparaging discourse of the Sanofi companies was disseminated in a highly structured manner through multiple communication channels other than medical representatives (press releases, print media, radio, a telephone campaign targeting 4,790 retail pharmacies, conferences), and this against a background of widespread reluctance towards generic medicinal products and strong resistance to change among prescribing doctors and pharmacists.

164. It is thus noted that as early as May 2009, immediately after the "generic" marketing authorisations were granted by the Committee for Medicinal Products for Human Use of the European Medicines Agency, Sanofi-Aventis issued, by way of a press release, a discourse highlighting the difference in salts between Plavix and the generics, with the latter presented as an untested novelty, while Plavix had a decade of experience and an established efficacy and safety profile; this discourse was supplemented by an interview with the chairman of Sanofi published in the journal *Le Quotidien du médecin* on 15 October 2009, which linked the difference in salts between Plavix and the generics to the difference in therapeutic indication for ACS, before going on to state that "nevertheless" the Medicines Agency had considered that it could not uphold any differentiation between Plavix and its generics, and to point out that the authorised generic Clopidogrel Winthrop was itself entirely identical to the originator product. These remarks suggested that the granting of marketing authorisations to the generics could be questionable in terms of patient safety, but that, in any event, there existed a perfectly safe and effective generic, the authorised generic Clopidogrel Winthrop. Furthermore, this discourse was relayed by medical representatives to doctors and by pharmaceutical sales representatives to pharmacists. The sales materials distributed by Sanofi-Aventis to those professionals conveyed the same message, but also emphasised the high mortality risks for ACS patients and encouraged the representatives to recommend or invite doctors to mark prescriptions "NS" and pharmacists to substitute with the authorised generic Clopidogrel Winthrop.

165. Thus, Plavix was the subject of very significant promotional efforts by the Sanofi companies, amounting to EUR 18 million in 2009 (Decision, paragraph 546). This originator medicinal product was presented in 79% of cases as either the first or second choice during sales visits — supposed to last less than ten minutes — and during the six months following the launch of the generics, Plavix continued to be presented in first or second place in 73% of cases, it being noted that in 2009 Plavix was the fourth best-selling medicinal product in the world and had been on the market for over 10 years (judgment of 18 December 2014, page 14). It is recalled that Sanofi-Aventis enjoyed the position of a benchmark pharmaceutical company on the French market, particularly for cardiovascular diseases, and had around ten years' experience of marketing Plavix since 1999, enabling it to argue that its product was well-established and to benefit from an unrivalled level of trust and brand recognition.

166. Although they have multiple sources of information, the fact remains that the sales visit constitutes, for doctors, a major source of information on medicinal products, owing to its accessibility, the fact that it is free of charge and its interactive nature (Decision, paragraph 352).

167. The major potential effects of the practice thus implemented by Sanofi-Aventis during its representatives' visits were noted by the Authority (Decision, paragraphs 488 to 491 and 547) in the following terms:

> *"As noted in the preceding developments, the discourse intended for healthcare professionals was disseminated to all of Sanofi-Aventis's medical representatives and pharmaceutical sales representatives responsible for promoting Plavix® and Clopidogrel Winthrop® during back-to-work seminars held at the end of summer 2009. Sanofi-Aventis's discourse therefore enjoyed significant coverage throughout French territory.*
>
> *Furthermore, it should be noted that Plavix® and its generics are used to treat very serious cardiovascular conditions, with a high risk of recurrence. Taking this medicinal product also requires special monitoring, since it can increase the risk of bleeding. Such a situation reinforces healthcare professionals' mistrust of medicinal products presented as new and lacking sufficient track record (generics with different salts), particularly as they show a particular receptiveness to the disparagement of generic medicinal products, given their lack of understanding of*

marketing authorisation procedures, a poor grasp of the regulatory framework relating to substitution, and a desire to protect themselves against any risk of having their civil or criminal liability engaged.

In this context, any negative assessment of Plavix® generics was inevitably likely to cause concern among healthcare professionals, who are primarily concerned with ensuring the safety of their patients. This effect was further reinforced by the fact that, on the one hand, Sanofi-Aventis enjoys a wholly particular position, owing to its more than ten-year monopoly on the clopidogrel molecule and, more generally, its status as a benchmark pharmaceutical company on the French market; and, on the other hand, generic manufacturers do not usually have sales forces capable of countering the discourse delivered to doctors by Sanofi-Aventis.

However, any questioning, whether direct or indirect, of the efficacy and safety of Plavix®'s generic competitors could only have a significant effect on healthcare professionals [emphasis added by the Court] anxious to protect their patients' interests, and encourage them to favour Sanofi-Aventis's products over the competing generics."

(...)

"It follows from all the foregoing that Plavix®'s generic competitors were the subject, on the part of healthcare professionals — and in particular doctors — of a wholly singular mistrust, perceptible throughout French territory. This singular mistrust cannot be explained objectively, since the generic competitors of Plavix® were granted marketing authorisations by the health authorities, those marketing authorisations were not legally challenged by the originator company, and within the framework of pharmacovigilance, no particular problems have been reported in connection with treatment using Plavix®'s generic competitors. This mistrust is, however, to be linked to Sanofi-Aventis's discourse, which sought to sow doubt and concern among healthcare professionals and largely succeeded in doing so."

168. Thus, it was found that Plavix's generic competitors were met with a wholly singular mistrust, perceptible throughout the territory, even though they had been granted marketing authorisations by the health authorities, which had not been legally challenged, and no pharmacovigilance issues relating to treatment with Plavix's generic competitors had been reported. The frequency of clopidogrel prescription renewals — on average every seven weeks — was not an obstacle to the impact of the discourse, but its effect became apparent gradually over time. According to the Authority, this mistrust could only be explained by the effects of the disparagement practices of the Sanofi companies, which permanently restricted the entry of these generics onto the French market for clopidogrel sold in retail pharmacies.

169. Furthermore, as the CNAM points out, even though the sanctioning Decision was widely published in the press in May 2013 and the Sanofi companies were ordered to publish an extract of it in the specialist press most widely read by doctors and pharmacists, those companies at the same time widely communicated the fact that they were challenging that decision, asserting that they had done nothing other than legitimately inform doctors of objective facts (Exhibit No. 48).

170. Finally, while the National Pharmacists' Convention of April 2012 may have affected pharmacists' incentives to substitute, notably through the introduction of remuneration based on public health objectives, it does not explain the potential impact on prescribing doctors and on their use of the "NS" mention. In fact, the 2012 Convention event explains the shift from one plateau to another in the counterfactual and actual genericisation curves for Plavix, but does not lead to their convergence, which only occurs in 2021. Furthermore, it has been found that the average rate of "NS" mentions for

clopidogrel remained very significantly higher than that of the 30 best-selling molecules over the periods 2012 and 2015–2019. Moreover, the fact that clopidogrel achieved the substitution target set in 2012 is not a relevant indicator, given that substitution targets are defined on the basis of observed genericisation curves, and the end-2012 target was therefore defined by reference to a period affected by the practices.

171. Consequently, the particularly lasting effect of the disparagement practices of the Sanofi companies is demonstrated not only by the convergence of the counterfactual and actual Plavix substitution rate curves but also by a concrete analysis of the impact of these practices on healthcare professionals' habits regarding the substitution of Plavix. Furthermore, all these findings, which are not effectively challenged by the Sanofi companies, demonstrate that, even though these practices took place over a period limited to five months, they produced an effect well beyond two years, that is, until 2021, as analysed by the court-appointed expert — a date which the Court will accordingly adopt.

C. The price-reduction mechanism and its effects on the alleged loss

Positions of the parties and of the expert

172. The Sanofi companies first recall that the principle of full compensation requires that the damages awarded to a victim must compensate for the loss suffered without resulting in either loss or gain for the victim. In their view, a claimant is entitled to compensation for the entirety of its loss but not to derive any benefit from it, as this would constitute unjust enrichment. They submit that it follows that the court must deduct from the amount of damages any benefits the victim may have derived from the harmful situation.

173. The Sanofi companies then point out that the loss claimed by the CNAM is directly the result (i) of the difference between the number of units of the originator Plavix and the number of units of its generics dispensed, multiplied by (ii) the difference in price (and therefore in reimbursement by the CNAM) between the originator Plavix and its generics. They infer from this that fluctuations in the prices of Plavix and of its generics directly affect the amounts reimbursed and thus the CNAM's loss. They therefore submit that, of the numerous price reductions applied to Plavix, three of them are identified as being directly and solely motivated by the substitution rate of Plavix being deemed insufficient, namely the reductions (i) of April 2012, (ii) of November 2013/April 2014 (a reduction implemented in two stages), and (iii) of October 2014. They cite as evidence the contemporary documents of the Economic Committee for Health Products (CEPS) and its clear responses to the court-appointed expert. In their view, without the three identified price reductions, Plavix would have undergone price reductions wholly "in line" with the control group molecules selected by the CNAM (Figure 5, page 59 of Sanofi's pleadings: evolution of the actual and counterfactual price of Plavix compared with that of the RBB comparators adopted by the expert). They conclude that, should the Court consider that Sanofi's practice continued, in 2012 and beyond, to produce effects on Plavix's substitution rate, then — since it is this rate that prompted several price reductions — the principle of full compensation requires that those price reductions, regarded as a benefit, be taken into account in the assessment of the CNAM's loss.

174. To quantify the impact of those price reductions in the assessment of the loss, the Sanofi companies maintain that the calculation is straightforward, since, in their view, in order to neutralise these reductions, one need only proceed as follows:

— for the period from 2012 to 2014, it suffices to extend the pre-tax manufacturer prices observed for Plavix and its generics prior to each of the three reductions in question, and to extend them

until the next reduction, which yields a constant price for Plavix between March 2012 and October 2014;

— for the period after October 2014, it suffices to apply each of the successive price reductions (which would have occurred in any event) to the counterfactual prices of Plavix and its generics; for example, if the actual price of Plavix fell by 15% after 2014, then it suffices to apply a 15% reduction to the counterfactual price of Plavix on that same date.

175. They explain that CRA calculated the CNAM's loss by basing the counterfactual scenario on:

— the counterfactual substitution rate of Plavix put forward by the CNAM (and adopted by the expert);

— the counterfactual price of Plavix after neutralising the three contested reductions.

176. They specify that the counterfactual Plavix price scenario thus constructed was subjected to two robustness tests by CRA in order to address the CNAM's criticisms.

177. Using a table (Table 2, page 66), the Sanofi companies thus present the CNAM's total loss (relating to reimbursements and to pharmacists' remuneration), taking into account the effect of the three price reductions in question, which reduced the amounts of reimbursements made by the CNAM. They infer that, if the Court were to find that the practices had effects:

— until December 2011 (as mentioned in the Decision), the loss is estimated at EUR 53,532,356;

— until April 2012 (entry into force of the 2012 CNP), the loss is estimated at EUR 59,984,034;

— until 2015, the loss is estimated at EUR 6,755,356.

178. The Sanofi companies consider that these three additional price reductions, decided by the CEPS "with a view to obtaining the same savings as a satisfactory substitution", fulfilled their objective, since they "more than offset" the lower substitution of Plavix. In their view, this conclusion was to be expected, on the one hand because, mechanically, the effect of a price cut constitutes a benefit for the CNAM across the entire volume of clopidogrel, whereas its loss relates only to a small share of clopidogrel volumes, namely the volumes of Plavix that would have been substituted in the counterfactual scenario. This is so because, where the expected savings target is not achieved through stronger substitution, the CEPS imposes a TFR or price reductions "so as to obtain the savings that successful substitution would have yielded", and that, according to the Sanofi companies, is what happened with clopidogrel.

179. They conclude that, since it has been demonstrated that the insufficient substitution rate of Plavix was the cause of the three exceptional price reductions of April 2012, November 2013/April 2014 and October 2014, the principle of full compensation requires that the benefits which the CNAM may have derived from those price reductions be taken into account by way of compensation for its loss.

180. The CNAM contests the Sanofi companies' position. It submits that benefits should be taken into account only if they are the direct and necessary consequence of the harmful situation. It explains that a variety of criteria other than the genericisation rate of an originator product are taken into account to justify and bring about a price reduction by the CEPS, such as the scale of potential savings on a given molecule — in other words, the amount of expenditure (at the initial price and high volumes) — or the trend in European prices for the generics of the molecule concerned. According to the CNAM, an analysis of the responses and of the facts of the case shows, first, that it is impossible to conclude, solely on the basis of the CEPS's statements, that an insufficient substitution rate was the sole and exclusive cause of the price reductions for Plavix observed between April 2012 and October 2014, and second, that no other ground for a price reduction would have been applicable in the absence of the practices.

181. Furthermore, it submits that, even assuming that one or more of the disputed price reductions were decided in light of the insufficient genericisation rate of Plavix due to the practices, the Sanofi companies do not demonstrate that, without the practices and therefore in the presence of a "normal" substitution rate, the price reductions of April 2012, November 2013/April 2014 and October 2014 would not nevertheless have been decided on the basis of factors other than the substitution rate. It states that the main factors explaining the price trends of Plavix and of its generics are the following:

— the potential for price reductions for Plavix and its generics was particularly significant due to the high initial price of Plavix;

— the French price of the generic followed the trend in the average European price of the generic, in accordance with the principle of comparison of European generic prices;

— the prices of the originator and of the generic must evolve together in a consistent manner, so that during the various price reductions undergone by the generic and the originator, the price gap between the generic and the originator never exceeds the initial price gap, and they must converge after five years of marketing of the first generics (Figure 1, page 95; Figure 2, page 96).

182. It adds that, generally speaking, price reductions for medicinal products are aimed at generating savings for the statutory health insurance scheme, and that, with this in mind, even in the absence of the practices, the CEPS would have sought to achieve savings on Plavix (or clopidogrel) through price reductions, given that Plavix represented the main item of reimbursement for the CNAM at the time the generics arrived on the market and that its price was exceptionally high in France and therefore represented a major lever for the CEPS in pursuing its objective of savings through price reductions. It states that an insufficient substitution rate is not a ground for reducing the price of a generic, which applies only to the originator product.

183. It also criticises, on several points, the method applied by CRA on Sanofi's behalf to establish the counterfactual price curve (Figure 5 cited above).

184. Finally, the CNAM points out that the Sanofi companies' quantification of the savings allegedly generated by the practices implies that the CNAM would have suffered no loss — or even that it would have benefited from the practices — which is not credible, given that the existence of the harm to the economy (in this case to the CNAM's expenditure) has been irrevocably established and that the calculation is in reality far more complex, as explained by the expert (page 192 of the report).

185. The court-appointed expert's position is as follows.

186. The court-appointed expert organised a consultation of the CEPS by means of a questionnaire drawn up jointly with the parties, which gave rise to two responses from the CEPS dated 8 September 2023 and 3 October 2023. On the basis of these responses and of the parties' positions, the expert considered that there were several uncertainties as regards the impact of the price reductions:

— the very existence of a sum received or saved by the CNAM;

— assuming the existence of a sum saved by the CNAM is accepted, it is unclear whether this sum would meet the necessary legal conditions (the benefit must, for example, be a direct and necessary consequence of the harmful situation).

187. The court-appointed expert thus concludes that it is premature at this stage to quantify any such benefit.

The Court's response

188. The principle of full compensation requires that the damages awarded to a victim should compensate for the loss suffered without resulting in either loss or gain for the victim (in this regard, *Cass.* 2nd Civ., 5 July 2001, appeal No. 99-18.712, *Bulletin civil* 2001, II, No. 135).

189. In light of this principle, the Sanofi companies essentially argue that the CNAM derived a benefit from the practices, in that three price reductions identified in (i) April 2012, (ii) November 2013/April 2014 and (iii) October 2014 (among the numerous price reductions for Plavix) were decided on the basis of a Plavix genericisation rate deemed insufficient. Taking the view that those price reductions would not have occurred had Plavix had a "normal" substitution rate in the absence of the practices, the Sanofi companies conclude that the CNAM in fact benefited from a positive consequence of those practices, namely "exceptional" price reductions on all reimbursed boxes of Plavix, which more than offset the loss incurred on the volume of Plavix boxes that would have been substituted in the counterfactual scenario.

190. If the Sanofi companies' reasoning is followed to its conclusion, from 2016 onwards the CNAM would even have benefited from the practices owing to those price reductions (Table 2: summary of the price effect on total loss; Sanofi's pleadings, page 66).

191. However, as the court-appointed expert rightly pointed out, the Court must first consider the very existence of the alleged benefit to the CNAM arising from the harmful conduct, before assessing the conditions for its "inclusion" in the calculation of the CNAM's damages.

192. Assessing the existence of the alleged benefit requires examining the three price reductions identified by the Sanofi companies in order to verify whether each of these reductions occurred on the ground of an insufficient substitution rate of Plavix and, if so, whether those price reductions would not have occurred in any event, in the absence of the effects of the practices, on other grounds.

193. As a preliminary step, it is necessary to analyse the mechanisms for reducing the prices of originator and generic medicinal products implemented by the public authorities.

194. The Economic Committee for Health Products (CEPS) is tasked by Article L. 162-17-3 of the Social Security Code with setting the prices of medicinal products covered by compulsory health insurance. Decisions of the CEPS are taken collectively.

195. It is clear from the CEPS's responses to the court-appointed expert (Annex 4 to the report) that, in order to meet savings targets under the National Healthcare Expenditure Target (*Objectif national des dépenses d'assurance maladie* — ONDAM), this Committee must draw up a price-reduction plan by selecting products. These are essentially products that have been listed for a long time, whose sales volumes are increasing, whose assessment or place in the therapeutic strategy is being reviewed by the High Authority for Health, or which face competition from a less expensive product for the same indication. During the period in question, decisions of the CEPS were subject to deliberation on a case-by-case basis under the framework agreement in force and the guidelines received from ministers.

196. Before 2015, the CEPS's remit was governed by two successive framework agreements, from 2008 to 2012 and then from 2012 to 2015, and by the ministerial instruction of 2 April 2013, which set out the following guidelines (Sanofi Exhibit No. 18):

> *"We wish the CEPS to continue to contribute effectively to controlling expenditure on medicinal products and medical devices. Several strategic priorities must guide your action.*

Tariff negotiations, as the law provides, will take into account the results of health-economic evaluations (…).

The Committee will endeavour to ensure the efficiency of the reimbursement of healthcare products on the basis of data collected on those products in real-world conditions (…).

The pricing of innovative products (see below) is part of a policy to support research, the corollary of which is the absence of economic rents once patent protection expires. The major savings linked to the generics market depend on increased prescription within the directory, the maintenance of high substitution rates, and prices set as fairly as possible. Your action will ensure that price reductions are proportionate and phased in — beyond the 60% discount applied to the price of the originator — based on sales volumes and using methodologically sound European price comparisons.

This effort must also extend to medicinal products whose patents are due to expire but for which generic versions are not yet available, so that the expiry of those patents can result in significant savings for the statutory health insurance scheme.

The Committee will also continue to implement the additional price reductions applicable to pharmaceutical specialities belonging to generic groups not subject to a flat-rate reimbursement tariff (TFR), at 12.5% for originator products and 7% for generics, 18 months after the first generic of the relevant originator product is marketed. These price reductions will take the form of a gradual decrease in the prices of originator products from the date the first generic is launched. Save in exceptional cases, the price of the originator product will converge with that of its generics at the end of a five-year period from the date the first generic is launched. In order to accelerate the penetration of generics prior to this convergence, the policy of placing products under TFR on a rolling basis will be continued from the current substitution thresholds, adjusting them where necessary. As regards genericised originator products which are little substituted but for which the conditions for switching to TFR cannot be met (limited supply, narrow substitution window, etc.), you will ensure that additional price reductions are applied to them so as to obtain the savings that successful substitution would have yielded. Furthermore, particularly in classes with a high proportion of generics, you will bring about price convergence within therapeutic classes whose products provide a homogeneous level of medical service, by aligning them on the lowest price (…).”

197. In this context, the timing and extent of price reductions for originator and generic medicinal products by the CEPS were discussed within the Generics Monitoring Committee (*Comité de suivi des génériques* — CSG) and negotiated with the companies, with the aim of reducing public expenditure as reflected in a savings target through price reductions set out in the annexes to the Social Security Financing Act (LFSS) each year. Certain timetables and ranges were moreover standardised:

For originator products:

— an “automatic” 15% reduction (in 2009) on the launch of the generic;

— an “automatic” 12.5% reduction 18 months after the launch of the generics;

— an objective of convergence of the price of the originator with that of its generics at the end of a five-year period from the date the first generic is launched; before this convergence, the possibility of accelerating generic penetration through a policy of “rolling” placement under a flat-rate reimbursement tariff (TFR) on the basis of substitution thresholds;

— the framework agreements also encouraged the CEPS to ensure price consistency and not to allow a significant gap to persist between the prices of the most expensive medicinal products — in particular those protected by a patent — and those of the least expensive molecules (Article 13 *bis*).

For generics:

— the initial price of the generic is set with a substantial discount on the originator (55% in 2009);

— an "automatic" 7% reduction is scheduled 18 months after the launch of the generics;

— price reductions are scheduled based on sales volumes and in comparison with European prices for generics.

198. It was only with the 2015–2018 framework agreement — extended until March 2021 — that the approach became "standardised", with more systematic mechanisms of price reductions at fixed intervals, based on the substitution rate (notably at the end of the 18-month period following marketing), price convergence, European price benchmarking and the reduction of the price gap between originator and generic medicinal products (notably at the end of a five-year period following marketing).

199. The Court notes at this stage that, as the Sanofi companies point out, Plavix/clopidogrel was not the subject of a class-based price-convergence exercise aimed at converging the pre-tax manufacturer prices (*prix fabricant hors taxes* — PFHT) of originator products with one another, and of generic products with one another, within a therapeutic class whose products provide a homogeneous level of medical service. However, this convergence mechanism must be distinguished from the convergence aimed at reducing the price gap between an originator and its generics, implemented at the end of a five-year period of effective marketing of the generics — a process to which Plavix/clopidogrel may indeed have been subject.

200. It is clear from the CEPS's responses (Annex 4 to the report — Question 2 and responses § 1 to 7) that before 2015, since the CEPS did not follow a standardised process regarding price reductions, it was difficult to identify and isolate a specific factor that might have prompted the price reductions for Plavix during that period, apart from the automatic reductions of the originator at the start of the marketing of the generic.

201. Having examined each of the price reductions identified by the Sanofi companies, the Court makes the following findings.

**** Plavix price reduction of 1 April 2012 (15%)***

202. The Court observes that the extracts from the CEPS's minutes from late 2011 and 2012 (annexed to the CEPS's response of 3 October 2023) in no way show that this price reduction was principally and exclusively motivated by a Plavix substitution rate deemed insufficient, as the Sanofi companies argue. In fact, those extracts indicate that the reduction was initiated as part of a price-reduction plan for generics and originators in targeted classes, in the context of which letters requesting a 15% reduction were sent to Sanofi (minutes of 22 December 2011). Subsequently, Sanofi requested that the reduction sought be lowered to 10%, which was discussed by the CEPS on 26 January 2012, during which meeting the Sanofi companies received the support of representatives of the Ministry of Industry, given their position in the sector and their contribution to the total savings sought, exceeding their market share (minutes of 26 January 2012). Discussions took place during the meetings of 16 and 23 February 2012 regarding Sanofi's counter-proposal of a price guarantee and the non-application of a TFR until the end of 2013 in return for the 15% reduction sought, owing to the two successive and closely spaced "extraordinary" reductions on Plavix. Those guarantees were not granted, and a 15% price reduction on

Plavix was sought from Sanofi as of 1 April 2012, "without any commitment regarding the future evolution of prices".

203. Furthermore, those extracts contain no information concerning a Plavix substitution rate deemed insufficient, capable of establishing a definite and exclusive link with this 15% reduction. Admittedly, the Sanofi companies point to the fact that this additional reduction took place very quickly, that is, six months after the previous automatic reduction of 12.5% in November 2011 following 18 months of generic competition, that it was described as "extraordinary" and decided without discussion within the CSG.

204. Nevertheless, the Court notes that those factors may equally support the position of the Sanofi companies, as to a Plavix substitution rate deemed insufficient, as that of the CNAM, which points to a probable failure by the CEPS to anticipate the overall savings to be achieved through price reductions for the year 2012 (EUR 780 million), the savings target for which was significantly higher than that sought in 2011 (EUR 500 million). The extract from the minutes of January 2012 indeed states: "The price reductions on patented medicinal products implemented by the CEPS this summer represent savings of EUR 623 million for 2012. The postponement of the effective dates of certain reductions granted to companies by the Committee, given the significant impact on those companies' turnover, has unquestionably reduced the additional savings the CEPS had anticipated: there remains a shortfall of EUR 20 to 30 million for 2012."

205. Consequently, it cannot be asserted, as the Sanofi companies maintain, that in a counterfactual scenario in which Plavix had had a "satisfactory substitution", this price reduction applied to Plavix and to its generics would not have taken place.

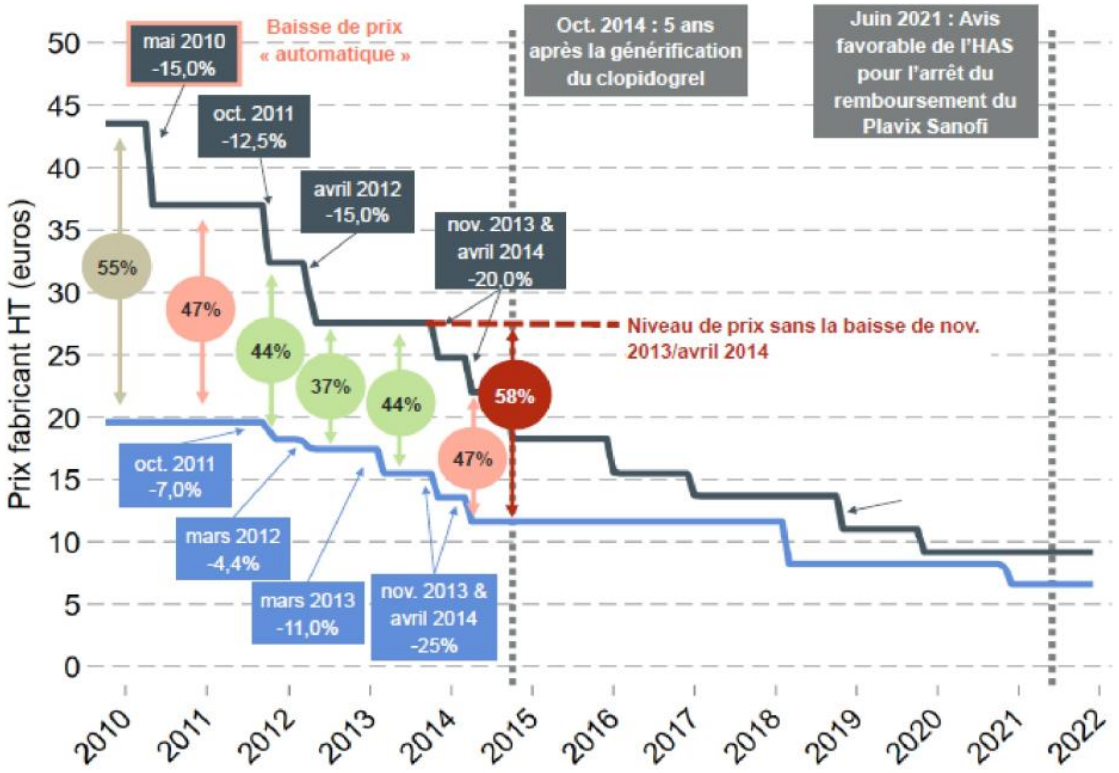
**** Plavix price reduction in November 2013 – April 2014 (20%)***

206. It is apparent from the extracts of the minutes of the CEPS meetings of 23 May and 25 July 2013 that the chairman had been in contact with Sanofi regarding the introduction of responsibility-based pricing on the clopidogrel group, to which Sanofi preferred a price reduction of around 15% as of 1 October 2013, and that on 25 July, the Committee decided to implement a two-stage price reduction on the originator Plavix and on the generics in November 2013 and January 2014 (less than 10% at each stage for Plavix and 12.5% for the generics). Since this price reduction was an alternative to placement under the TFR scheme, the CEPS, in its response of 3 October 2023, confirmed that the phasing (and not the bringing forward) of this reduction had been implemented owing to insufficient substitution, as recommended by the ministerial guidelines of 2013. It is therefore established that this two-stage 20% reduction, decided in July 2013, notified to Sanofi-Aventis on 30 July 2013 (Sanofi Exhibit No. 20) and published in the Official Journal on 10 September 2013, was indeed motivated by insufficient substitution.

207. However, as the CNAM rightly points out, without being effectively contradicted by the Sanofi companies, a price reduction could have occurred at the same time and to the same extent had the substitution rate been deemed satisfactory. Indeed, the alignment of the prices of clopidogrel generics with European prices as of 1 January 2014 was discussed at a meeting of the Generics Monitoring Committee (CSG), concurrently with the decision to reduce the price of Plavix by 20% in two stages, as evidenced by an Excel document entitled "CEPS Decision following CSG Molecules 06-2013" produced by the CNAM (Exhibit No. 58), which was communicated during the expert assessment (Exhibit No. 67, email of 10 October 2023, and Exhibit No. 50, page 21). This decision to align generic prices with European prices follows the guidelines set out in the aforementioned ministerial instruction of April 2013. Yet, had there been no price reduction for the originator Plavix during the same period,

the price gap between it and its generics — which had undergone a 25% reduction by alignment in November 2013 and April 2014 — would have been around 58% from April 2014 onwards, that is, a gap greater not only than the previous gaps (between 47% and 37%), but also than the initial price discount applied to the price of the originator (55%) to set the starting price of the generic (CNAM pleadings, Figure 2, page 96):

Figure 2: Evolution du prix fabricant du Plavix et de ses génériques, et de l'écart de prix entre les deux



208. It is clear from the minutes of the CSG and CEPS meetings that the consistency of the manufacturer's price gap between Plavix and its generics is one of the parameters taken into account in proposals for, and decisions on, the magnitude of price reductions. Similarly, it is clear from the CNAM's analysis of the actually observed trend in the pre-tax manufacturer's price (PFHT) of Plavix and of its generics that the PFHT of Plavix (black curve) evolves consistently with that of its generics (blue curve) and tends to converge with it in the long term, given that an insufficient substitution rate is not a ground for reducing the price of the generic. Furthermore, the alignment of the prices of generics with European prices, as recommended by the 2013 ministerial instruction, constitutes an indirect factor influencing the price of the originator, through the effect of the price-consistency and price-convergence mechanisms.

209. The CNAM thus demonstrates that it was entirely plausible that, at that time, a price reduction for Plavix would have occurred on the ground of price consistency, or even of price convergence between the originator and the generic, even if the substitution rate of Plavix had been higher, given that the price of Plavix (and of its generics) was particularly high in France (Decision, paragraphs 296–297; 655).

**** Plavix price reduction of October 2014 (17%)***

210. It is clear from the minutes of the meeting of 19 June 2014 of the Generics Monitoring Committee (CSG) that, for the clopidogrel/Plavix group, a reduction of the originator's price was proposed to the

CEPS in order to obtain the savings that an 85% substitution would have yielded, whereas the actual substitution rate was 72.80% in March 2014. A 17% reduction of Plavix's price was consequently applied in October 2014.

211. The Sanofi companies note that, in the CNAM's counterfactual scenario adopted by the court-appointed expert, Plavix's substitution rate would have been 90% in June 2014, and infer that the reduction in expenditure sought by the CEPS at that time would already have been largely achieved, and therefore the "extraordinary" price reduction of October 2014 would not have taken place.

212. However, the Court observes that, while the insufficient substitution rate and the placement under responsibility-based pricing may, on account of the practices, have been used as levers by the CEPS to bring about a further price reduction in October 2014, this does not necessarily imply that price reductions would not have taken place over the same period in the absence of the practices, for other reasons in light of the guidelines given to the CEPS to seek savings.

213. Indeed, it is clear from the analysis of the ministerial guidelines that savings were sought through various levers made available to the CEPS, namely the placement of the originator under responsibility-based pricing (TFR) or the negotiation of a price reduction where the substitution rate fell below a certain threshold, but also — in addition to automatic reductions — the convergence of prices between the originator and its generics by alignment on the lowest price, implemented at the end of a five-year period of effective marketing of the generics. This principle of price convergence was provided for in the ministerial instruction of 2 April 2013 and was subsequently formalised by the 2015 framework agreement; however, it is established that price convergence for originator products that had been genericised for five years had already been initiated in 2013 by the CEPS (CNAM Exhibit No. 61 — 'CEPS Activity Report 2014/2015').

214. Moreover, regarding the price reduction of October 2014, the following question was put to the CEPS: "Can we infer that, had the substitution rate for clopidogrel been higher, the CEPS would not have imposed such a significant price reduction on clopidogrel?" To which the CEPS replied in its letter of 8 September 2023: "At that time, there was no standardised approach in the framework agreement for price adjustments based on substitution or other factors. It is therefore not possible to make a definitive statement regarding an alternative scenario. In addition to insufficient substitution, there were other grounds for price reductions that might have been invoked at that time."

215. It follows that, even if Plavix's substitution rate had been above the 85% substitution threshold in the absence of the practices, price reductions could nevertheless have been decided by the CEPS from October 2014 onwards using other levers, such as the convergence of the originator's price with that of its generics, given that the first generic version of Plavix entered the market in October 2009.

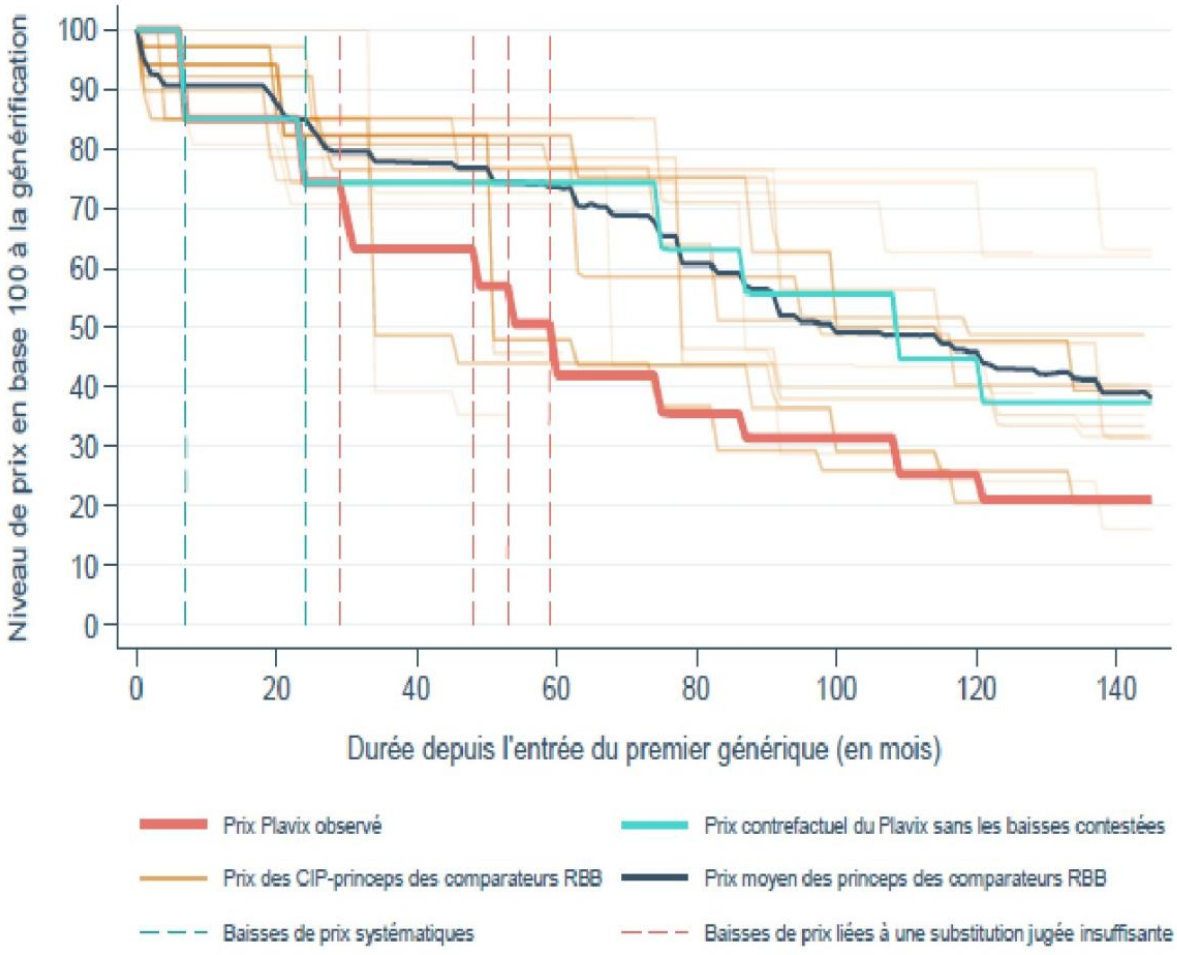
216. The Court notes that the ministerial guidance letter of 16 August 2016 reiterates this aim of price convergence between originator and generic medicinal products: "the Committee will also, from 2016 onwards, supplement its doctrine on the setting of prices for generic medicinal products. It will propose, within the framework of the objectives set for it, higher discount levels (than those currently applied) and applied more rapidly for generic groups in therapeutic classes where generic supply is already well established, or for medicinal products whose cost to the statutory health insurance scheme is high. In all cases, the price of the originator product must converge with that of the generic product."

217. Likewise, in its supplementary response of 3 October 2023, to the question: "Does the CEPS identify certain reductions in the pre-tax manufacturer price (PFHT) of Plavix or of clopidogrel generics as being motivated by the insufficient substitution rate of clopidogrel? If so, is this the sole reason for these reductions, or are there other concurrent reasons?", the CEPS replied in particular: "Not all price

reductions in the clopidogrel group were motivated on this basis [insufficient substitution], and evidence of this can be found in the minutes through international price comparisons, as well as price-convergence operations within the group."

218. More generally, the Court notes that Plavix, owing to its price and very high sales volumes, undoubtedly represented a substantial savings potential in view of the amount of expenditure for the statutory health insurance scheme. This confirms that, even without the effects of the practices on the market penetration rate of its generics, Plavix and its generics would still have undergone price reductions at a frequency and to an extent similar to what is actually observed, in line with the general national objective of seeking savings for the statutory health insurance scheme.

219. Finally, the Court notes that the Sanofi companies' position is not further supported by their comparison of the actual and counterfactual prices of Plavix with those of the RBB comparators adopted by the expert. The comparison consists, for the Sanofi companies, in establishing a counterfactual price curve for Plavix by neutralising the three reductions identified in April 2012, November 2013–April 2014, and October 2014. This counterfactual price curve is compared with a curve of the actually observed price of Plavix, with a curve of the average prices of the originator products among the RBB comparators, and with the price curves of each of the originator products among the RBB comparators, on a price level with a base of 100 at the time of generic entry, and over a period of nearly 140 months from the entry of the first generic (Sanofi pleadings, page 59, Figure 5):



220. From this comparison, the Sanofi companies make two observations (pleadings, page 59):

(1) Plavix (thick red curve) underwent more frequent and greater price reductions than the molecules in the control group highlighted by the CNAM ("RBB comparators") and adopted by the expert (thin orange curves). Thus, during the first five years following Plavix's genericisation, after the third extraordinary reduction in October 2014:

— the price of Plavix had fallen by more than 50% compared with its pre-genericisation price;

— conversely, at the end of the same genericisation period, the average price of the molecules in the CNAM's control group (dark blue curve) had fallen by only 25% compared with their pre-genericisation price.

(2) Had the genericisation rate of Plavix been deemed sufficient and the three extraordinary price cuts not taken place, the price of Plavix (thick turquoise curve) would have evolved in a manner perfectly consistent with that of the control group molecules selected by the expert (thick navy curve) over the entire period.

221. The relevance of this comparative exercise must, however, be seriously called into question for various reasons.

222. First, the Court notes that the construction of the counterfactual price curve for Plavix is limited to neutralising the disputed price reductions, without any serious analysis of all the factors that may influence the evolution of the originator's price over time from the date of its effective genericisation, in particular in light of the guidelines given to the CEPS, on the one hand, and of the impact of the originator's initial price on the savings potential, on the other — it being further noted that each price reduction is not independent of those preceding it.

223. Next, this counterfactual price curve for Plavix is compared with the price trends of the molecules in the RBB comparison group, as adopted by the expert in the preceding developments. However, this panel of comparator molecules was selected on the basis of factors explaining the market penetration rate of a generic medicinal product, and not on the basis of factors explaining the trend in the price of an originator medicinal product since the entry of the first generic. Nothing in the preceding developments suggests that the circumstances capable of influencing the price trend of an originator product are limited to the criteria used to constitute the comparator group on the question of generic substitution, and in particular that of market size. Furthermore, it has not been seriously demonstrated that a comparison of the actual and counterfactual price trends of Plavix (and of its generics) with those of the molecules in the substitution-rate control group is relevant, nor that there is an evolution "in line with" or "consistent with" Plavix's price reductions and those of the molecules in the genericisation-rate control group.

224. Finally, the Court observes that the purpose of a counterfactual scenario is to represent what would have happened, all other things being equal, in the absence of the practices in question. It follows that, from the date on which the effects of the practices cease, the price in the counterfactual scenario should no longer differ from the actually observed price. Yet more than 140 months after the entry of the first generic (nearly 12 years), the prices of Plavix in the Sanofi companies' counterfactual scenario (Figure 5, page 59 of the pleadings) remain significantly higher than the actual price of Plavix, given that the date on which the effects of the practices cease has been set at September 2021. The same observations apply to the "robustness tests" presented by the Sanofi companies (pleadings, pages 68 and 69, Figures 8 and 9).

225. From all of these findings and assessments, the Court concludes that the very existence of any "benefit" or "positive consequences" that the CNAM could have derived from the anticompetitive

practices is not demonstrated, since, without the effects of the practices on the market penetration rate of its generics, Plavix would still have undergone price reductions at a frequency and to an extent similar to what is actually observed, in line with the general national objective of seeking savings for the statutory health insurance scheme.

D. The scope of reimbursement of insured persons

Positions of the parties

226. With effect from 1 January 2020 and 1 September 2019 respectively, the RSI and the student scheme were integrated into the general scheme. The CNAM seeks compensation for expenditure incurred in respect of these insured persons from those dates onwards.

227. The Sanofi companies maintain that, in initiating its action in September 2017, the CNAM had always limited its claim for compensation to the general scheme, and that it was only at the expert's initiative — and following his insistence and repeated requests in the CNAM's favour, "marking a parti pris" — that the CNAM formulated a claim for compensation extended to the special schemes. They add that, despite their objections during the expert proceedings on the manifest inadmissibility of such a claim as being new and time-barred, the court-appointed expert disregarded those objections and included this issue within the scope of his remit. They further note that the expert "went back on his word" by presenting, in his preliminary report and again in his final report, an aggregated calculation across all schemes, without distinguishing the figures relating to the two additional schemes included on his own initiative. Moreover, in their view, the expert also, on his own initiative, repeatedly urged the CNAM to provide him with data to enable him to quantify any potential loss relating to the local mutual sections, even though the CNAM had never made any claim for compensation in this regard.

The Court's response

228. The Court first observes that the CNAM brought its action in 2017 and that, in the latest version of its pleadings in the proceedings leading to the judgment of 9 February 2022, it argued that the assessment of its loss — as ascertained at the end of March 2015 — was a minimum assessment, based on the analysis carried out by RBB Economics, which had not been able to provide its figures for the period after March 2015, given that its actually suffered loss did not cease in March 2015 and that the period of compensable loss could not be limited to the period of the abusive practices.

229. Since the court-appointed expert's remit was to determine the duration of the effects of the unlawful practices, which could extend beyond 2015, and to provide the Court with the information necessary to assess the CNAM's losses relating to the compensation of insured persons, the expert — noting that the CNAM had since integrated into the general scheme at least two previously separate schemes, namely the RSI and the Students' scheme — relevantly, and within the scope of his remit, asked questions in order to circumscribe the CNAM's claims under the general scheme (minutes of expert meeting No. 2, page 5, Sanofi Exhibit No. 2, and expert report, page 21), without these constituting "insistent" requests for the benefit of the CNAM. On the contrary, as the latter points out, without the expert's intervention, reimbursements to insured persons of the former RSI and Students' schemes would have been included by default in the calculation of the loss, given that they had been affiliated to the general scheme during the period of the effects of the practices, namely from 1 September 2019 and 1 January 2020. Furthermore, no claim was made in respect of the local mutual sections.

230. In the course of the subsequent proceedings, the Sanofi companies reserved the right to contest the compensable nature of the loss relating to those special schemes (Sanofi Exhibit No. 4) and did not

object "to the expert providing an estimate of this potential loss, provided that the amount is communicated separately or disaggregated" (Sanofi Exhibit No. 4, expert meeting minutes No. 4, and expert report, page 21).

231. In his report (page 22), the court-appointed expert sets out "his disaggregation method". He first notes that the CNAM 2 file does indeed include reimbursements to former insured persons of the Students' scheme (since September 2019) and of the RSI (since January 2020). He then notes that in 2018 (i.e. a full year before integration), insured persons of the Students' scheme accounted for 0.04% of clopidogrel purchases, and in 2019 (a full year before integration), insured persons of the RSI accounted for 7.26% of clopidogrel purchases. He infers that, were the Court to uphold Sanofi's argument on the limitation period, the amounts of any damages would have to be reduced as follows:

— loss suffered by the CNAM for the year 2019: reduce by 0.01%;

— loss suffered by the CNAM for the years 2020 and following: reduce by 7.30%.

232. Far from disregarding the Sanofi companies' objections or showing a parti pris in favour of the CNAM, the expert did indeed quantify the amount of the loss linked to Plavix reimbursements for former insured persons of the RSI and Students' schemes on a disaggregated basis, the method not being explicitly criticised by the Sanofi companies in their latest pleadings (in particular pages 13 and 14), thereby enabling them to raise their "legal objections" before the Court.

233. The Court observes that, while in their latest written submissions the Sanofi companies refer to the inadmissibility of the CNAM's compensation claim as new and time-barred in respect of the RSI and Students' schemes, they do not explicitly raise this point in the operative part of their pleadings. For the sake of completeness, the Court notes that the CNAM's claim relating to reimbursements for Plavix and clopidogrel for former insured persons of the Students' and RSI schemes is limited to expenditure incurred only from the date of their integration into the general scheme, namely from 1 September 2019 and 1 January 2020 respectively, that is to say during the period of the effects of the practices, as identified in the foregoing grounds. Consequently, the CNAM's compensation claim incorporating these reimbursements can be neither time-barred, by reference to the date on which the loss arose, nor regarded as new, by reference to the initial compensation claim relating to reimbursements to insured persons of the general scheme arising from the effects of the sanctioned practices.

234. It follows that there is no reason to exclude from the amount of the claim relating to reimbursements to insured persons those reimbursements arising from the integration of the Students' and RSI schemes into the general scheme as of 1 September 2019 and 1 January 2020.

E. Assessment of the loss relating to the reimbursement of insured persons

235. On the basis of the court-appointed expert's analyses, the CNAM requests the Court to set the loss relating to the reimbursement of its insured persons at EUR 111,666,964 and to order the Sanofi companies *in solidum* to pay this sum.

236. As is apparent from the foregoing grounds, the Court has not upheld any of the Sanofi companies' criticisms regarding the conclusions reached by the court-appointed expert in his report, given that he remained within the scope of the remit assigned to him by the Court and complied with the obligations imposed on him by Articles 237 and 238 of the Code of Civil Procedure.

237. Therefore, there is no basis to grant the Sanofi companies' requests to have the court-appointed expert's report "set aside" and to order a new expert assessment.

238. On the basis of this expert report, the Court assesses the CNAM's loss relating to the reimbursement of insured persons at EUR 111,666,964, ascertained at the end of August 2021 (without deduction in respect of the RSI and Students' schemes integrated on 1 September 2019 and 1 January 2020), broken down as follows (expert report, page 213 — the expert's amendment highlighted in yellow):

Préjudice lié au remboursement des assurés

	Remboursement observé	Remboursement contrefactuel	Préjudice remboursement
2010	311 355 686	286 742 612	24 613 073
2011	286 468 415	257 549 133	28 919 283
2012	221 074 617	202 369 091	18 705 526
2013	181 472 836	169 485 046	11 987 790
2014	139 968 083	128 980 038	10 988 045
2015	109 387 654	103 298 473	6 089 181
2016	95 803 727	92 239 027	3 564 700
2017	86 121 361	84 397 430	1 723 931
2018	70 926 339	67 965 593	2 960 746
2019	56 027 916	54 272 846	1 755 070
2020	51 902 180	51 737 325	164 855
2021	27 758 742	27 563 977	194 765
Dommage total			**111 666 964**

239. Consequently, Sanofi and Sanofi Winthrop Industrie, having succeeded to the rights of Sanofi-Aventis France, shall be ordered *in solidum* to pay the CNAM the sum of EUR 111,666,964 in damages by way of compensation for the loss arising from reimbursements to insured persons.

IV. THE LOSS RELATING TO PHARMACISTS' REMUNERATION

Positions of the parties

240. The CNAM states that, as part of the health policy, the National Convention governing the relations between dispensing pharmacists and the statutory health insurance scheme introduced in 2012 a new remuneration scheme for the 22,000 retail pharmacies across French territory. It notes that this convention established, in particular, a remuneration system taking into account, for each molecule and each pharmacy, the change in the substitution rate over a period compared with a previous period, it being noted that this remuneration was based on the increase in the substitution rate and proportional to the difference between the two periods. Thus, it states that the payment made to each pharmacist depended, for a given molecule, on the expected potential savings on that molecule and on the year-on-year increase in substitution. Furthermore, according to the CNAM, in so far as payments to pharmacists depended on the gap between the substitution rate achieved in 2012 and that of the second half of 2011, the delay in the genericisation of clopidogrel had an impact on the amounts paid to pharmacists in respect of the delayed adoption of generics for this molecule. It states that, in the absence of these practices, the substitution rate in 2011 would have been significantly higher and, given that molecules with a low substitution rate experienced a greater increase in 2012, the amount of remuneration paid to pharmacists for clopidogrel was extraordinarily high. It infers that it has suffered a loss equal to the difference between the amounts it paid to pharmacists from 2012 to 2019 and the amounts it would have had to pay had clopidogrel followed an ordinary genericisation process. To estimate this loss, it explains that, through RBB, it submitted three valuation methods to the court-appointed expert, who selected the second as the most comprehensive, and to which it refers in assessing its loss at EUR 14,556,030.

241. The Sanofi companies make no specific observation on the principle or the amount of the CNAM's loss relating to pharmacists' remuneration.

The Court's response

242. The National Convention of 4 May 2012 governing the relations between dispensing pharmacists and the statutory health insurance scheme (CNAM Exhibit No. 12) states that the signatory parties wished to recognise the commitment of dispensing pharmacists to the dispensing of generic medicinal products and decided to establish a scheme (Article 29 *et seq.*) aimed, on the one hand, at encouraging the pharmacist to progress in the dispensing of generic medicinal products and, on the other hand, for those who had already reached a high level, at recognising their commitment to substitution.

243. The operation of the target-based remuneration scheme rests on various indicators, including progress towards and the achievement of a substitution rate for the molecules in Annex II.1, which includes clopidogrel. This efficiency of pharmacy practice as regards generic medicinal products is measured as follows (Article 31.3):

> *Individual indicators are assessed for each year N. The molecules covered by these indicators are determined by the signatory parties on the basis of the potential savings yet to be realised in terms of substitution levels.*
>
> *For each pharmacy, the 'starting' reference period is the second half of 2011. This reference is valid until the end of 2014.*
>
> *For each pharmacy, the 'ending' reference period is year N.*
>
> *The list of target molecules referred to in Article 29 is revised annually by way of an amendment and is set out in Annex II.1 to the present convention. The parameters are updated annually by way of an amendment to take account, in particular, of price changes and, where applicable, of the scope of the agreed list as set out in the national agreement referred to in Article L. 162-16-7 of the Social Security Code.*
>
> *The calculation is based on the following principles:*
>
> *• if the substitution rate achieved by the pharmacist is below the lower threshold set by indicator as defined in Annex II.1, the pharmacist receives no remuneration;*
>
> *• if the substitution rate achieved by the pharmacist is above the lower threshold set by indicator but below the intermediate threshold, the pharmacist receives remuneration based on his progress between the two reference periods;*
>
> *• if the substitution rate achieved by the pharmacist is above the intermediate threshold, the pharmacist receives remuneration based on the level reached during the 'ending' reference period.*
>
> *The calculation methods are set out in Annex II.1.*

244. It is undisputed that, in so far as this remuneration to pharmacists depended on the gap between the substitution rate achieved in 2012 and that of the second half of 2011, the delay in the genericisation of clopidogrel had an impact on the amounts paid to pharmacists in respect of the delayed adoption of

generics for this molecule, namely higher remuneration calculated from a lower starting point as a result of the practices.

245. For the assessment of the loss linked to the remuneration of pharmacists by the CNAM, the court-appointed expert made adjustments to the initial and subsequent valuation proposed by RBB (report, pages 139 to 162). The court-appointed expert proposed (report, page 161) two valuations of EUR 14,354,904 (Valuation 1) and EUR 14,556,030 (Valuation 2), each taking into account the corrective method proposed by CRA on one of the parameters used to determine the amount of pharmacists' remuneration, namely the actual potential savings. The second valuation takes into account an additional adjustment to the amount of counterfactual remuneration paid, taking into account the effects of two further factors determining pharmacists' remuneration, and described as "more comprehensive" by the expert.

246. The CNAM bases its claim of EUR 14,556,030 on the court-appointed expert's second valuation, which is not the subject of any specific criticism by the Sanofi companies, and which the Court endorses. This sum breaks down for each year as follows:

Préjudice lié à la rémunération des pharmaciens

Année	Préjudice
2012	2 684 648
2013	2 814 214
2014	2 620 700
2015	1 730 203
2016	2 081 703
2017	1 532 323
2018	510 854
2019	581 385
Total	**14 556 030**

247. Consequently, Sanofi and Sanofi Winthrop Industrie, having succeeded to the rights of Sanofi-Aventis France, shall be ordered *in solidum* to pay the CNAM the sum of EUR 14,556,030 by way of damages in compensation for the loss relating to pharmacists' remuneration.

V. THE CLAIM FOR COMPENSATORY INTEREST

Positions of the parties

248. The CNAM seeks compensatory interest on its loss by taking into account statutory interest, which increases the nominal amounts of the loss — EUR 111,666,964 relating to the reimbursement of insured persons and EUR 14,556,030 relating to pharmacists' remuneration. In the latest version of its assessment (Exhibit No. 22 — note of 14 January 2025), taking into account the assumption of the Sanofi companies and of CRA that the loss would have been incurred mid-period, the CNAM assesses this compensatory interest at a total of EUR 23,551,029 as at 30 June 2025. It seeks an order *in solidum* against the Sanofi companies for payment of this sum, "to be supplemented until full payment of the sums owed" by the Sanofi companies.

249. The Sanofi companies essentially contest the method used to calculate this compensatory interest.

250. The court-appointed expert considered that the assessment of compensatory interest did not fall within the scope of his remit.

The Court's response

251. The CNAM seeks compensatory interest on its nominal loss by applying the statutory interest rate, to be supplemented "until full payment of the sums owed". While the CNAM does not further explain the nature of its claim, the Court notes, on examination of the calculation method used to assess this claim, that it aims not only to apply the statutory interest rate to the nominal loss to compensate for an additional loss arising from the temporary deprivation of the sums awarded under the principal heads of loss, but also to apply this statutory interest rate to compensate for any delay in the payment of the damages awarded by the court decision (in this sense, a claim to be supplemented "until full payment of the sums owed"). The regimes governing compensatory and default interest are not, however, the same.

252. While default interest sanctions, without proof of loss by the creditor, a delay in the payment of a monetary obligation or of an order to pay an indemnity within the meaning of Articles 1231-6 and 1231-7 of the Civil Code, compensatory interest is intended to compensate for the additional loss arising from the prolongation in time of an economic loss. This loss is thus directly linked to the event giving rise to it, and not to the delay attributable to the debtor.

253. The possibility of compensating for such an additional loss linked to the passage of time — which may at the very least cover monetary erosion and which flows from the principle of full compensation — is recognised in domestic law (in this regard, *Cass.* Com., 1 March 2023, appeal No. 20-20.416, 20-18.356) and in EU law (in this regard, in the general framework of non-contractual liability, ECJ, *Mulder and Others*, 27 January 2000, C-104/89 and C-37/90, paragraph 51: 'The reparation of damage in the context of non-contractual liability is intended to restore, as far as possible, the assets of the victim. Consequently, where the conditions for non-contractual liability are met, the unfavourable consequences resulting from the lapse of time between the occurrence of the harmful event and the date of payment of the compensation cannot be ignored, despite an express declaration to that effect by the applicant, in so far as account must be taken of monetary erosion'; ECJ, *Manfredi*, 13 July 2006, C-294/04, paragraph 100: 'It follows from the principle of effectiveness and from the right of any individual to seek compensation for damage caused by a contract or by conduct liable to restrict or distort competition that injured persons must be able to seek compensation not only for actual loss (*damnum emergens*) but also for loss of profit (*lucrum cessans*) and the payment of interest.' Directive 2014/104 of 26 November 2014 on actions for damages by victims of anticompetitive practices also refers to the need to take account of the passage of time (recital 12 and Article 3(2)).

254. Since they fall under the general law of civil liability, compensatory interest is awarded if it appears that financial loss has been suffered. The rate of compensatory interest is determined according to the nature of the loss suffered, which it is for the victim to establish. Furthermore, since the loss arising from the deprivation of the sums — the accrual of which ceases on the date of the judgment, the compensation claim then automatically bearing statutory interest until full payment in accordance with Article 1231-7 of the Civil Code — must be awarded by taking into account the gradual constitution of this loss (*Cass.* Com., 7 June 2023, appeal Nos. 22-10.545, 22-11.099, 22-11.100).

255. This additional financial loss is not contested in principle by the Sanofi companies, and therefore its existence is not in dispute. Indeed, the Sanofi companies do not contest the compensatory interest on the CNAM's nominal loss running from the event giving rise to the loss and the application of the

statutory interest rate to a loss progressively constituted, but they criticise the CNAM's calculation method on various points set out below.

256. It is undisputed that the loss suffered by the CNAM began in 2010 in respect of the loss relating to reimbursements to insured persons and in 2012 in respect of the loss relating to pharmacists' remuneration. Consequently, each of these two years must be taken as the starting point for the calculation of compensatory interest. Furthermore, the statutory interest rate is determined annually until 2015, and half-yearly since then, by order of the Minister for the Economy.

257. The CNAM's loss was not entirely constituted immediately, but rather over several years; it is therefore necessary to take this gradual nature into account when calculating the compensatory loss linked to the passage of time. The nominal loss suffered by the CNAM each year is set out in the table established by the expert for the two heads of loss (expert report, page 213, and paragraphs 238 and 246 of the present judgment).

258. Initially, the CNAM had calculated this compensatory interest year by year, considering it as fully constituted on 1 January for the period from 2010 to 2014, and for the subsequent period, on the first day of each half-year. The Sanofi companies objected to this method during the proceedings, arguing that it was more appropriate to consider that the annual losses were incurred mid-period. The CNAM accepted this criticism. The parties then agreed to consider that the loss is incurred at the mid-point of the period of application of the statutory interest rate (annually before 2015, half-yearly thereafter). The Court notes that this method allows greater precision in the calculation, since it takes into account the fact that the loss — incurred over a period (annually before 2015, half-yearly thereafter) — accumulates progressively over time, until the end of the period.

259. However, in a second step, the CNAM (RBB note, Exhibit No. 22) "refined" this correction so as to apply it only to part of the total loss and not to the entirety. More specifically, for each period considered in the calculation of compensatory interest (i.e. the year or half-year), according to the CNAM, the total loss must be divided into two components:

— the "new loss" generated during the current period;

— the "existing loss" carried over from previous periods.

For the new loss generated during the current period, the CNAM accepts the Sanofi companies' criticism that the loss accumulates progressively over time until the end of the current period. For this part of the loss, the CNAM considers it acceptable to use the assumption proposed by the respondents that the loss is incurred mid-period (year or half-year). On the other hand, the existing loss (carried over from previous periods) is, according to the CNAM, entirely generated at the end of the previous periods and therefore exists in full from the first day of the current period.

260. The Sanofi companies contest this method of calculating financial loss, in which two components of the nominal loss are subject to compensatory interest separately. In their view, this change of calculation convention is arbitrary and does not improve the soundness of the calculation, but is simply intended to offset the reduction that the CNAM was forced to concede in respect of its previous corrected calculation errors, and leads to an artificial increase in the amount of the compensatory interest. In essence, they criticise the CNAM for having calculated interest over a "half-period", whereas it should have been calculated over a full period. More specifically, they advocate the application of the rate for year N from 1 July of year N to 30 June of year N+1 for the period 2010 to 2014, and from the middle of half-year S to the middle of half-year S+1 for subsequent half-years.

261. The Court endorses the CNAM's reasoning, which distinguishes between new loss incurred over a period and existing loss carried over from previous periods. While it is true that the former is

constituted throughout the year, the latter is, by its very nature, already entirely constituted from the first day of the current period. It follows that, while it is appropriate, for the loss constituted in the course of the year (or half-year after 2015), to take a calculation date in the middle of the year (or half-year after 2015) in order to take account of the gradual nature of the constitution of the loss, this method cannot be applied to the existing loss carried over from previous periods. Furthermore, the method advocated by the Sanofi companies leads to applying the interest rate of one year to part of the following year, which is inconsistent with the statutory interest rate, which is fixed by decree for each current calendar year and, from 1 January 2015, for each current half-year.

262. It follows from all of the foregoing that the additional financial loss must be assessed in accordance with the method and the calculations carried out by the CNAM in Exhibit No. 22.

263. For the period from 1 January 2010 to 31 December 2021, the nominal loss relating to the reimbursement of insured persons amounts to EUR 111,666,964, and that relating to pharmacists' remuneration amounts to EUR 14,556,030 (see CNAM Exhibit No. 22, Table 2, and the expert's final report, page 213). These losses are entirely constituted as at 31 December 2019 for the loss relating to pharmacists' remuneration, and as at 31 December 2021 for the loss relating to reimbursements to insured persons.

264. On the basis of these elements, for the period from 1 January 2010 to 30 June 2025, the amount of compensatory interest relating to the nominal loss of reimbursement of insured persons is assessed at EUR 21,000,049 and the amount of compensatory interest relating to the nominal loss of pharmacists' remuneration is assessed at EUR 2,550,980 (see CNAM Exhibit No. 22).

265. The Court recalls that the period of accrual of compensatory interest ends on the date of the court decision establishing the existence of the economic loss serving as the basis for the financial loss: from that date, the financial loss is definitively constituted and the failure to pay it is a delay remedied, in accordance with Article 1231-7 of the Civil Code, by the award of default interest produced by the compensation claim to which it relates (in this regard, *Cass.* Com., 1 March 2023, No. 22-16.329, paragraphs 32 and 33, and *Cass.* Com., 7 June 2023, appeal Nos. 22-10.545, 22-11.099, 22-11.100, paragraph 63).

266. In the present case, the financial loss is incurred up to 24 September 2025, the date of the present judgment. It is therefore necessary to assess this loss up to that date. The remaining period is 86 days (31 days in July, 31 days in August and 24 days in September). The statutory interest rate applicable from 1 July 2025 is 2.76%. Consequently, the amounts of compensatory interest for the period from 1 July to 24 September 2025 amount to:

— EUR 862,735 (0.0276 × 86/365 × 132,667,013) for the loss relating to the reimbursement of insured persons;

— EUR 111,247 (0.0276 × 86/365 × 17,107,010) for the loss relating to pharmacists' remuneration.

267. Consequently, the Sanofi companies shall be ordered *in solidum* to pay the CNAM the sum of EUR 21,862,784 in damages by way of compensation for the financial loss relating to the reimbursement of insured persons, and the sum of EUR 2,662,227 in damages by way of compensation for the financial loss relating to pharmacists' remuneration.

268. From the date of the present decision, the sums awarded as damages shall bear interest at the statutory rate under the conditions laid down in Article 1231-7 of the Civil Code.

VI. COSTS AND APPLICATION OF ARTICLE 700 OF THE CODE OF CIVIL PROCEDURE

269. Sanofi and Sanofi Winthrop Industrie, as the unsuccessful parties, shall be ordered *in solidum* to pay the costs at first instance and on appeal, including the fees of the court-appointed expert amounting to EUR 217,641.94 inclusive of tax.

270. Pursuant to Article 700 of the Code of Civil Procedure, the claims of the Sanofi companies shall be dismissed and they shall be ordered *in solidum* to pay the CNAM the sum of EUR 500,000.

ON THESE GROUNDS

The Court,

Having regard to the judgment of 9 February 2022, which set aside the judgment under appeal in its entirety and dismissed the plea of inadmissibility based on the limitation period for the action brought by the *Caisse nationale de l'assurance maladie* (CNAM);

Having regard to the judgment of the Commercial, Economic and Financial Chamber of the Court of Cassation of 30 August 2023, appeal No. 22-14.094;

Ruling afresh,

Dismisses the application of Sanofi SA and Sanofi Winthrop Industrie SA to have the expert report filed on 5 March 2024 "set aside" and to order a new expert assessment;

Orders Sanofi SA and Sanofi Winthrop Industrie SA, *in solidum*, to pay the *Caisse nationale de l'assurance maladie* (CNAM), in compensation for its loss suffered as a result of the anticompetitive practices sanctioned by Decision No. 13-D-11 of 14 May 2013 of the Competition Authority, the total sum of EUR 150,748,005 in damages, broken down as follows:

— EUR 111,666,964 in compensation for the loss relating to the reimbursement of insured persons, plus EUR 21,862,784 in resulting financial loss;

— EUR 14,556,030 in compensation for the loss relating to pharmacists' remuneration, plus EUR 2,662,227 in resulting financial loss;

Holds that the sum awarded as damages shall bear interest at the statutory rate from the date of the present decision pursuant to Article 1231-7 of the Civil Code;

Orders Sanofi SA and Sanofi Winthrop Industrie SA, *in solidum*, to pay the costs at first instance and on appeal, including the fees of the court-appointed expert amounting to EUR 217,641.94 inclusive of tax;

Pursuant to Article 700 of the Code of Civil Procedure, **dismisses** the claims of Sanofi SA and Sanofi Winthrop Industrie SA and **orders** them *in solidum* to pay the *Caisse nationale de l'assurance maladie* (CNAM) the sum of EUR 500,000.

THE REGISTRAR **THE PRESIDING JUDGE**