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JUDICIARY COURT OF PARIS

3rd Chamber, 3rd Section

Case No.: 17/10421
Portalis No: 352J-W-B7B-CK7KO

ORIGINAL NO.: 1

Complaint of:
29 March 2017

JUDGMENT
Issued on 11 September 2020

CLAIMANTS

The company ELI LILLY AND COMPANY
Lilly Corporate Center
IN 46285
INDIANAPOLIS (USA)

The company LILLY FRANCE
24 boulevard Vital Bouhot
CS 50004
92521 NEUILLY SUR SEINE CEDEX

represented by Stanislas ROUX-VAILLARD, Attorney at Law, of PARTNERSHIPS HOGAN LOVELLS (PARIS) LLP, Bar of PARIS, Reg. No. #J0033

DEFENDANTS

The company FRESENIUS KABI FRANCE
5 place du Marivel
92316 SEVRES

The company FRESENIUS KABI GROUPE FRANCE
5 place du Marivel
92316 SEVRES

represented by Elisabeth BERTHET-MAILLOLS, Attorney at Law, of SELAFA PROMARK, Bar of PARIS, Reg. No. #R0162

Enforceable certified copies issued on: 15/09/2020

COMPOSITION OF THE COURT

Carine GILLET, Presiding Judge
Laurence BASTERREIX, Presiding Judge
Elise MELLIER, Judge

assisted by Alice ARGENTINI, Clerk of the Court

TRIAL

At the public hearing of 01 July 2020

JUDGMENT

Pronounced publicly through availability at the Clerk's Office
in the presence of all of the Parties
at first instance

The company Eli Lilly and Company, a US pharmaceutical company established in 1876, developed a drug marketed under the brand name Alimta® for the treatment of two types of lung cancer (malignant pleural mesothelioma and non-small-cell bronchial cancer), the active ingredient of which is a compound referred to as pemetrexed, belonging to the antifolates, a category of anticancer therapeutic agents.

The antifolates are used in the context of chemotherapy treatment of cancerous tumours in order to inhibit tumour growth by affecting cell division capacity and by interfering with certain enzymes involved in cellular replication that constitute part of the metabolic pathway of the folates, the latter having the property to accelerate tumour growth. However, the antifolates do not distinguish cancerous cells from healthy ones, affecting both, which results in serious side effects for patients, including lethal side effects, and although they are considered to be promising anticancer agents, having been researched since the 1950s, few of them have been granted marketing authorization because of their strong toxicity and the difficulty of controlling said toxicity.

The active ingredient pemetrexed (which is not *per se* at issue in the present proceedings) was developed by the company Eli Lilly and is the subject matter of Patent Application EP 677 of 10 December 1990 as a component of the drug Alimta®, but it has not been widely used because of its severe adverse effects.

On 15 June 2001, the company Eli Lilly filed Patent Application EP 508, with US priority dates of 30 June 2000, 27 September 2000 and 18 April 2001, granted on 18 April 2007, entitled "*Combination containing an antifolate and methylmalonic acid lowering agent*". Patent EP 508 will expire on 15 June 2021. The patent relates to a combined administration of the drug Alimta®/pemetrexed with vitamin B12 and optionally folic acid for treating two types of lung cancer by making it possible to reduce the toxicity of the active ingredient while preserving its therapeutic efficacy.

It constitutes the first and only authorized therapeutic use. The patent was maintained as granted by a Decision of the EPO of 27 December 2010, upon opposition from the company TEVA.
To be administered, the drug is presented in the form of an acid or of salts (neutral pharmaceutical forms of the active component of a drug), composed of the active component of the compound pemetrexed or pemetrexed anion, associated with two counterparts of sodium (cation) or "pemetrexed disodium".

The company Lilly France, a subsidiary of Eli Lilly, distributes the drug Alimta® in France.

In France, the company Fresenius Kabi France markets the generic version of Alimta® under the name "Pemetrexed Fresenius Kabi", presented in the form of a diacid of pemetrexed (the sodium cations are replaced by hydrogen cations), for which the company Fresenius Kabi Oncology Plc obtained, on 22 July 2016, a marketing authorization issued by the European Medicines Agency (EMA).

Asserting that this generic drug infringed on their rights, the companies Eli Lilly and Lilly France, by petition of 29 March 2017, summoned the companies Fresenius Kabi France and Fresenius Kabi Groupe France to appear before this Court for infringement of the French part of European Patent EP 1 313 508, in addition to other measures.

In foreign proceedings against various manufacturers of generic versions of the drug Alimta®, the LILLY companies indicate that they have obtained injunction measures in the United Kingdom, Switzerland, Italy, Germany, Sweden, Austria, Finland, Denmark, Portugal, Spain, and the Netherlands, but also outside of the territory of Europe (with the exception of an isolated decision at first instance of the District Court of The Hague of 19 June 2019 against the FRESENIUS KABI companies, which has been appealed).

Moreover, the patent has been declared valid by the EPO in opposition proceedings, by the District Court of The Hague, and its Japanese and American equivalents as well, with the exception of a decision at first instance of the German Federal Patent Court (Bundespatentgericht) which declared invalid the German part of the patent; this decision was then overturned by the German Federal Supreme Court on 07 July 2020 (as the Parties informed the Court by mail on 03 August 2020).

The Lilly companies submitted their final pleadings on 04 October 2019, in which they request that the Court:
by application of the aforementioned texts and having seen the exhibits submitted, the list of which is contained in the slip attached to the present Summons,

- declare that the claims of the companies Eli Lilly and Lilly France are admissible and well founded;

- state and declare that:

    - the companies Fresenius Kabi France and Fresenius Kabi Groupe France committed acts directly infringing on the entirety of the claims of the French part of European Patent EP 1 313 508 by manufacturing, offering, marketing, using, importing, exporting, transhipping, or possessing Pemetrexed Fresenius Kabi for the

aforementioned purposes,

- the companies Fresenius Kabi France and Fresenius Kabi Groupe France committed acts of contributory infringement on the claims of the French part of European Patent EP 1 313 508 by delivering or offering to deliver Pemetrexed Fresenius Kabi in France,

therefore:
- prohibit the companies Fresenius Kabi France and Fresenius Kabi Groupe France from directly or indirectly manufacturing, offering, marketing, using, importing, exporting, transhipping or possessing for the aforementioned purposes, supplying, delivering or offering to supply, on French territory, to anyone other than those authorized to exploit the invention, Pemetrexed Fresenius Kabi or any other product making it possible to reproduce the claims of European Patent EP 1 313 508, subject to a penalty of 5,000 euros per vial counting from the date of notification of the judgment to be rendered,

- order the recall of all the stocks in France of Pemetrexed Fresenius Kabi or of any other product making it possible to reproduce the claims of European Patent EP 1 313 508, at the expense of the companies Fresenius Kabi France and Fresenius Kabi Groupe France, subject to a penalty of 5,000 euros per vial counting from the date of notification of the judgment to be rendered,

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to compensate for the damage suffered by the company Eli Lilly due to infringement of its rights on the French part of European Patent EP 1 313 508, and therefore to pay to the company Eli Lilly the sum of 10,000,000 euros in provisional damages and interests, subject to adjustment upward or downward, as detailed below,

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to fully and entirely compensate for the damage suffered by the company Lilly France as the distributor of the proprietary medicinal product Alimta® in France, and therefore to pay to the latter the sum of 30,000,000 euros in provisional damages and interests, subject to adjustment upward or downward, as detailed below;

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to submit all documents and information necessary for evaluating the damage suffered by the companies Eli Lilly and Lilly France, specifically:
  - the names and addresses of the manufacturers, wholesalers, importers, exporters, transhippers and other holders of these products,
  - the quantities stored, produced, imported, exported, transhipped, marketed, delivered, received or ordered, as well as their delivery dates and price,
  - the brand names of the relevant products and all of the elements identifying the products, such as the designation, the article name, and the serial number of the product,
  - the gross margin realized on the sale of Pemetrexed Fresenius Kabi as well as any other preparation making it possible to reproduce the claims of Patent EP 508,
  - the names and addresses of the clients of the companies Fresenius Kabi France and Fresenius Kabi Groupe France, from 1 April 2012 to the date on which the judgment to be rendered is issued, this being subject to a penalty of 5,000 euros counting from the

date of notification of the judgment to be rendered, with the Court reserving the right to directly enforce the penalty,

- state and declare that these information sharing and account rendering proceedings will be conducted under the supervision of the pre-trial judge, with the Court continuing to handle the dispute so that, once the rendering of accounts is completed, it can rule on the amount of the petitions for compensation of damages made by the companies Eli Lilly and Lilly France,

- defer the interlocutory proceedings on determination of damages to the pre-trial proceedings in order to allow follow-up and monitoring of the notification and account rendering proceedings and for the final pleadings of the companies Eli Lilly and Lilly France on the damages they have claimed,

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to send to each of the clients to whom they offered to sell, sold, or delivered the infringing products the following letter, by registered mail with acknowledgment of receipt, subject to a penalty of 5,000 euros per day of delay per client from the date of notification of the judgment to be rendered:
"IMPORTANT
Dear […]
It is our duty to inform you that the Paris Court of First Instance, by decision of […], has ruled that supplying or offering to supply the proprietary medicinal product Pemetrexed Fresenius Kabi constitutes infringement of Patent EP 1 313 508 and that this product therefore cannot be sold, delivered, used, offered for sale, or kept in storage in France. We hereby request that you return to us all of the aforementioned products that are in your possession as soon as possible. We will immediately reimburse you for the purchase price and the expenses connected with returning these products.
The companies Fresenius Kabi France and Fresenius Kabi Groupe France"

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to send to the counsels of the Lilly companies a copy of the letters sent to their clients, with this being subject to a penalty of 5,000 euros per day of delay counting from the date of notification of the judgment to be rendered,

- state and declare that the Court will have jurisdiction over execution of the penalties that it orders, pursuant to Article L. 131-3 of the Code of Civil Execution Procedure,

in any event,

- dismiss the counterclaims of the companies Fresenius Kabi France and Fresenius Kabi Groupe France,

- order the provisional enforcement of the judgment to be rendered, notwithstanding appeal and without surety;

- order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to pay to the companies Eli Lilly and Lilly France, *in solidum*, the sum of 403,459.51 euros pursuant to Article 700 of the Code of Civil Procedure, subject to adjustment upward or downward,

- finally, order the companies Fresenius Kabi France and Fresenius Kabi Groupe France to pay all of the expenses of the instance, with costs to be awarded to Stanislas Roux-Vaillard, Attorney at Law, pursuant to Article 699 of the Code of Civil Procedure.

*

The company FRESENIUS Kabi France SAS and the company FRESENIUS Kabi Groupe France SASU have submitted their pleadings, No. 7, electronically on 02 October 2019, requesting that the Court do the following:
pursuant to Articles L. 613-3, L. 613-4, L. 613-9, L. 614-12 and L. 615-2 of the Intellectual Property Code,
pursuant to Articles 43, 52, 54, 56, 69, 83, 84 and 123 (2) and 138 (1) a), b) and c) of the European Patent Convention,
pursuant to Article 1240 of the Civil Code,
pursuant to Articles 31, 32-1, 122 and 700 of the Code of Civil Procedure,

in limine litis
- declare the petitions of the company LILLY FRANCE inadmissible,
in any and all circumstances:

- declare inadmissible the action of the companies ELI LILLY AND COMPANY and LILLY FRANCE against the company FRESENIUS KABI GROUPE FRANCE,

accordingly,
- free the company FRESENIUS KABI GROUPE FRANCE of all liability,

in any and all circumstances,

primarily,
- find that the scope of the French part of Patent EP 1.313.508 B1 does not extend to the product Pemetrexed FRESENIUS KABI,

accordingly,
- state and declare that the companies FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE have not committed any act of infringement on the French part of European Patent EP 1.313.508 B1,

in any and all circumstances,
- state and declare that the companies FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE have not committed any act of unfair competition,

accordingly,
- dismiss the respective petitions of the companies ELI LILLY AND COMPANY and LILLY FRANCE alleging infringement and unfair competition,

in the alternative,
- declare invalid the entirety of the claims of the French part of Patent EP 1.313.508 B1 for

insufficiency of disclosure,

- declare invalid the entirety of the claims of the French part of Patent EP 1.313.508 B1 for extension of subject matter beyond the content of the application as filed,

- declare invalid the entirety of the claims of the French part of Patent EP 1.313.508 B1 for lack of inventive step,

- order that the judgment to be rendered be transcribed in the National Patent Register of the INPI at the request of the Chief Clerk of the Court,

in any case,
- dismiss all of the petitions, pleas, and claims of the companies ELI LILLY AND COMPANY and LILLY FRANCE,

under any and all circumstances,
- jointly order the companies ELI LILLY AND COMPANY and LILLY FRANCE to pay to the companies FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE the sum of 5 million euros (five million euros) for unfair competition;

- jointly order the companies ELI LILLY AND COMPANY and LILLY FRANCE to pay to the companies FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE the sum of 404,420 euros (four hundred and four thousand four hundred and twenty euros) pursuant to Article 700 of the Code of Civil Procedure,

- jointly order the companies ELI LILLY AND COMPANY and LILLY FRANCE to pay all of the costs of the instance and state that such costs will be recovered in accordance with Article 699 of the Code of Civil Procedure.

*

The proceedings were closed by Order of 17 October 2019, and the case was scheduled to be pleaded on 26 March 2020. As this hearing was cancelled due to the health situation in France since 17 March 2020, hearing of the case was postponed to 1 July 2020.

Pursuant to the provisions of Article 455 of the Code of Civil Procedure, reference is made to the aforementioned pleadings of the Parties for a presentation of their respective claims and the grounds developed therein.

GROUNDS FOR THE DECISION

I – On Patent EP 1313508

- On the presentation of the patent

Patent EP 1313 508, owned by the company Eli Lilly, the application of which was filed on 15 June 2001 with US priority dates of 30 June 2000, 27 September 2000 and 18 April 2001, and which was granted on 18 April 2007 and maintained as granted by the decision of the EPO of 27

December 2010, upon opposition from the company TEVA, is entitled "*Combination containing an antifolate and methylmalonic acid lowering agent".* It relates to a combined administration of the drug Alimta®/pemetrexed disodium with vitamin B12 and optionally folic acid for treating two types of lung cancer.

According to the description given in the patent, the antifolates are antineoplastic agents intended to block the proliferation of cancerous cells that have been studied for approximately 50 years and constitute a standard component of effective chemotherapeutic regimens for malignancies [page 1, lines 11-13, lines 14-15], which inhibit key folate-requiring enzymes which are involved in cellular replication [page 2, lines 1 ff.]. Several antifolate drugs were under development [page 2, lines 11-12; lines 1 ff, lines 20 ff.], specifically including pemetrexed disodium (Alimta® of the company Eli Lilly), which has an inhibitory effect on several enzymes (such as thymidylate synthase (TS), dihydrofolate reductase (DHFR) and glycinamide ribonucleotide formyl transferase (GARFT)). Nevertheless, the toxicity of the antifolates [page 7, lines 11 to 22] and the inability to control said toxicity and therefore their efficacy constitute a major obstacle to the administration of these substances and have led to the abandonment of their clinical development [page 1, lines 4-5, page 2, lines 24-25 and 29-30]. In order to alleviate the toxicity of the antifolates, without however managing to entirely suppress this toxicity, folic acid or nutritional compositions (vitamin B12, folate, and vitamin B6 supplements) may be administered (US Patent No. 521797, Patent EP A 0546870: vitamin A supplements), but toxicity remains a major concern [page 3, lines 8 ff.] and the ability to reduce cytotoxic activity would represent an important advance [page 4, lines 1-2].

In order to alleviate these severe adverse effects, the description of the patent discloses the surprising and unexpected finding that the toxic adverse effects can be significantly reduced by means of an agent such as vitamin B12, which allows the level of methylmalonic acid, which is a predictor of toxic events [page 8, lines 27 ff.], to be reduced, but without affecting the therapeutic efficacy of the antifolate. Similarly, the hitherto unknown combination of vitamin B12 and a binding agent such as folic acid (known for the prevention and treatment of cardiovascular diseases but not for treating antifolate toxicity), combined with antifolate drugs, significantly reduces the toxicity of the latter [page 4, lines 3 ff.].

Administration of the substances may be carried out in any order or simultaneously in the form of a single composition or two different compositions, or also sequentially, preferably in the following order: vitamin B12, followed where appropriate by folic acid, and then antifolate [page 7, lines 28 ff., page 8, lines 1 to 15, page 11, lines 28 ff.] and preferably by parenteral injection [page 9, lines 27 to 30] and orally for folic acid [page 12, lines 1 and 9, page 17]. Studies were conducted on nude female mice bearing breast carcinoma [page 12, lines 25 ff. to page 16, lines 1 to 10] and on cancer patients [page 16, lines 11 ff., pages 17 to 21], demonstrating a reduction in drug toxicity without adversely affecting tumour activity.

The patent comprises 14 claims, use claims (independent Claim 1 and dependent Claims 2 to 11) of the Swiss type (second medical use of a known compound) and product claims (Claims 12 to 14), having the following wording:
"1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals, wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin,

aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin."

"2. Use according to Claim 1, wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid or a physiologically acceptable salt or ester thereof."

"3. Use according to Claim 2, wherein the folic binding protein binding agent is folic acid."

"4. Use according to any one of Claims 1 to 3, wherein the vitamin B12 or pharmaceutical derivative thereof is vitamin B12, cobalamin or chlorocobalamin."

"5. Use according to any one of Claims 1 to 3, wherein the vitamin B12 or pharmaceutical derivative thereof is selected from vitamin B12 or hydroxocobalamin."

"6. Use according to any one of Claims 1 to 5, wherein the medicament, the vitamin B12 or pharmaceutical derivative thereof and optionally the folic binding protein binding agent are to be administered simultaneously, separately or sequentially."

"7. Use according to any one of Claims 1 to 6, wherein the medicament is to be administered after administration of the vitamin B12 or pharmaceutical derivative thereof."

"8. Use according to any one of Claims 1 to 7, wherein the medicament is to be administered after the folic binding protein binding agent."

"9. Use according to any one of Claims 2 to 8, wherein the medicament is to be administered after pre-treatment with the vitamin B12 or pharmaceutical derivative thereof followed by folic acid."

"10. Use according to any one of Claims 1 to 9, wherein vitamin B12 or the pharmaceutical derivative thereof is to be administered as an intramuscular injection."

"11. Use according to any one of Claims 2 to 10, wherein the folic binding protein binding agent is to be administered orally as a tablet."

"12. Product containing pemetrexed disodium, vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and, optionally, a folic binding protein binding agent selected from the group consisting of folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically acceptable salt or ester thereof, as a combined preparation for simultaneous, separate or sequential use in inhibiting tumour growth."

"13. Product according to Claim 12, wherein the vitamin B12 or the pharmaceutical derivative thereof is vitamin B12, cobalamin or chlorocobalamin and, if present, the folic binding protein binding agent is folic acid."

"14. Product according to Claim 12, wherein the vitamin B12 or pharmaceutical derivative thereof is vitamin B12 or hydroxocobalamin and, if present, the folic binding protein binding agent is folic acid."

Therefore, according to the description, the invention relates in general to the use in manufacturing of a drug, for a combined administration, of an antifolate, pemetrexed, and vitamin B12, alone or in combination with folic acid, in order to reduce the toxicity of the antifolate drugs and to inhibit tumour growth [page 5, lines 7 ff. and 10 ff.], and in particular, to the use of the antifolate pemetrexed disodium [page 5, lines 15 and 21, page 6, lines 3, 9 and 19-20] in combination with vitamin B12 or a pharmaceutical derivative thereof, and optionally with folic acid. The invention makes it possible to reduce the toxic effects of the active ingredient of the antifolate pemetrexed, but without affecting its therapeutic efficacy.

The "person skilled in the art" refers to a plural team composed of an oncologist possessing specialized knowledge and a pharmacologist having experience in the use of antifolates for the treatment of tumours.

- On the scope of the patent

The Eli Lilly companies maintain that the problem solved by the patent is that of reducing the toxic effects of the active ingredient of the antifolate pemetrexed, without adversely affecting its therapeutic efficacy, by using the combination of pemetrexed, in any form, with vitamin B12, each of these substances already being known on the priority date. This is a combination of two different means, which constitutes the essential means of the invention, the primary function or technical effect of which is to arrive at the double result sought. The form of pemetrexed used to allow its administration by infusion is completely irrelevant, as only the anion of pemetrexed, which has a therapeutic effect but which is also responsible for the adverse effects, produces a technical effect, the counterions having no technical effect for solving the technical problem, so that selection of the salt has no effect whatsoever, as the person skilled in the art is perfectly aware. The person skilled in the art is thus capable of understanding that the "pemetrexed disodium" referred to in the claims is a synonym for "pemetrexed".

The Lilly companies indicate that the scope of protection conferred by the patent is not limited to the literal wording of the claims and that it must be determined, even in the absence of ambiguity of the claims, in accordance with Article 69 of the European Patent Convention (EPC) and the protocol for its interpretation and must be extended to cover the equivalents of the claimed invention.
During the examination at the time of granting of the patent, the term "antifolate" initially referred to in the main claim of the patent as filed was replaced with "pemetrexed" in order to exclude other antifolates which were not envisaged by the patentee and in order to remedy a defect of clarity, but also in order to overcome a possible objection with respect to novelty and inventive step (because certain documents of the prior art referred to antifolates other than pemetrexed). After this, the examiner made an exclusively formal objection for addition of subject matter, without raising any lack of inventive step, as "pemetrexed" constitutes a

chemical compound different from "pemetrexed disodium", referred to in the patent application, so that in the claims, the term "pemetrexed" mentioned was replaced by "pemetrexed disodium" in order to refer to the preferred embodiment of the invention. However, the examination proceedings before the EPO have no effect on the assessment of the scope of the patent, as said proceedings constitute only one factual element taken into consideration, particularly as the Lilly companies, although they amended the contents at the request of the examiner, did not intend to limit the scope of the patent, neither implicitly nor explicitly. The amendment made is strictly formal in nature and was made in order to avoid an addition of subject matter, which constitutes a condition of form, rather than to counter objections based on the prior art. It has no effect on the substance of the inventive contribution of the patent. This amendment has no bearing on the assessment of infringement by variants or by equivalence; otherwise, this theory would be stripped of any effect. The consultations produced by their opponent (with Profs. Michel VIVANT and Jacques RAYNOUARD) are irrelevant.

For their part, the Defendants are of the view that because the claims are clear and not open to interpretation, referring to a particular rather than a general means, given the limitations that took place during the granting procedure and in view of the requirement of reasonable legal certainty of third parties and fair protection of the patentee, the scope of the patent is strictly limited to "pemetrexed disodium" alone, with any other product, and specifically the other salts of the molecule, being excluded. Indeed, a claim limited to only one form of a salt of a product cannot cover "all the other derivatives thereof", and the patentee can only be granted a monopoly on the enrichment that his invention actually provides. Furthermore, the theory of equivalents is not applicable in the event, as is the case here, of restrictive wording of the specification, because the feature added (the disodium salt and not its equivalents) constitutes an essential element that is necessary for the validity of the patent.

In a superfluous manner, the FRESENIUS companies contend that the attitude and the limitations, which were carried out voluntarily by the applicant during the granting procedure, which are equivalent to a waiver on the latter's part, and without which the patent would be null and void, must be taken into consideration in order to ensure consistency between the examination and the validity of the patent.
The Defendants add, in response to the arguments brought forward by the Eli Lilly companies, that the lack of novelty of the function of the means does not constitute the sole exception to the application of the doctrine of equivalents; that the precedents in case law, which limit the scope of a patent solely to the salts specifically mentioned in the description, are applicable; that the claimed invention is not of a pioneering nature and cannot confer an expanded protection if the claims are worded in restrictive terms; that the claims relate not to a product but to a specific use, and that the invention does not constitute a novel and inventive combination (which would therefore be patentable). It cannot be asserted that only the anion pemetrexed would be responsible for the activity and could function with any salt other than the disodium salt, because the "inventive concept" here is limited solely to the disodium salt, thus excluding the doctrine of equivalents, and this argument has never before been presented before the EPO or in the patent itself, and the "inventive concept" or the "underlying technical problem" are notions foreign to patent law.

On this matter,
According to Article 84 of the EPC, "*The claims shall define the matter for which protection is sought. They shall be clear and concise*", and pursuant to Article 69 of the EPC, "*The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings [which determine the subject matter of the patent] shall be used to interpret the claims".*
This interpretation is made in accordance with Article 1 of the protocol on the interpretation of said Article, by reconciling the imperative of fair protection granted to the patent holder and that of the reasonable degree of legal certainty of third parties, according to a middle way, excluding any extreme interpretation, without stopping at the literal and narrow meaning of the text of the claims, and without considering that the claims serve only as guidelines as to what the patentee intended to protect. According to Article 2 of the same protocol, the determination of the scope of the patent takes "into account any element equivalent to an element indicated in the claims".

This interpretation therefore serves not only to determine the very letter of the wording of the claim, but also the true scope of the claim, in order to give it its full meaning. The scope of the claim is determined in light of the description and the drawings, and also, where appropriate, considering the elements taken from the examination file during the granting procedure, as well as the amendments made and the arguments brought forth by the patentee, which constitute factual elements to be considered among others.

In the present case, even though the claims of the patent refer only to "pemetrexed disodium", for use in combination with vitamin B12 for the treatment of certain lung cancers, the description of the patent refers in general to the administration of an "antifolate" (page 4, line 20) or to "antifolate drugs" (page 4, line 27, page 5, line 2 and line 7), and in particular to "the antifolate pemetrexed disodium" (page 5, lines 15-16), indicating that "the antifolate" or the "antifolate drug" is "Alimta® pemetrexed disodium" as manufactured by Eli Lilly & Co (page 8, lines 21 to 23) and used in the clinical trials discussed in the patent. The person skilled in the art knows that the active part of the active ingredient pemetrexed is the anion (which causes both the therapeutic effects and the adverse side effects), which is combined with vitamin B12 (and optionally folic acid), and will understand without stopping at the literal wording of the claims that the invention lies in the combined administration of the active ingredient, regardless of its form, with the other substances claimed in the patent.
This interpretation is in compliance with the principles restated above, without it being possible to take into consideration, not only elements foreign to the patent (such as the formulation of other patents of the patent holder which, contrary to the present patent, refer to the same active ingredient and "its pharmaceutically acceptable salts"; the experience of the applicant in the field of patents; or even its status as a pharmaceutical company), but also elements related to the administrative granting procedure. Indeed, given that the patent is a self-sufficient document, the examination procedure before the Office, which can only optionally be invoked as a mere tool of interpretation, has no effect on the scope of the patent and binds neither the judge nor the patent holder. The behaviour of the patentee having complied with a request of amendment from the examiner cannot be interpreted as an admission which could be binding upon the Court, and has no impact whatsoever on the scope of the claim. It does not amount to an acknowledgment or a waiver on his part, nor may it be considered as a statement, all the more so in the present case, where the company Lilly intended to refer to a preferred embodiment but without stating any intention to modify the scope of its patent, irrespective of the fact that it may not have raised any argumentation to counter the examiner, while, moreover, an amendment for

addition of subject matter under Article 123 §2 of the EPC is not meant to overcome prior art that could call into question the validity of the patent, and is carried out for considerations of pure form only. The amendment for addition of subject matter is not of such nature that it could prohibit the patentee from claiming infringement by equivalents, since it is a condition of form relating to the literal content of the specification and the subject-matter of the inventive contribution, that prohibits the patentee from adding an element which could not be derived directly and unambiguously from the patent; it by no means modifies the basis on which the interpretation must be made and it has no effect whatsoever on the scope of protection conferred. On the contrary, with respect to the assessment of the scope of the patent, the aforementioned Article 69 of the EPC requires that the equivalents must be considered. It can be inferred from this that an addition of subject matter in the context of the granting procedure does not prohibit the assertion of infringement by equivalence, provided that the particular means or combination of means claimed (here the combined use, with the active ingredient, of vitamin B12 and optionally of folic acid) has a novel function (i.e., reduction of toxic effects without affecting therapeutic efficacy); otherwise, the doctrine of equivalents would be devoid of any effect. The consultations conducted by the Defendant companies with Profs. Vivant and Raynard are of no relevance for resolving the present litigation, aside from the fact that the first one relates to the concept of legal certainty, based on the premise that the company Eli Lilly expressly renounced the "other salts" and therefore could not re-introduce what it had excluded, while this author previously maintained that the conditions of form are only interesting from a "logistical standpoint" and do "not require the same amount of development", and the second one relates to the voluntary choice of the patent applicant with respect to the wording of the claims, which nevertheless has no effect on the scope of the patent.

It follows from this that the technical problem to be solved is that of reducing the toxicity of the antifolate pemetrexed without affecting its therapeutic efficacy, and that the solution proposed in the patent, despite the restrictive wording of the claims, is that of the combined administration of the anion pemetrexed and the other substances specified in the patent, without the form in which this antifolate is administered having any importance. The scope of the patent therefore extends to all pharmaceutically acceptable forms of pemetrexed (salts or others) used in combination with the two other substances.

II – On the inadmissibility of the action

The Defendant companies maintain that the claims of the company LILLY FRANCE are inadmissible because this Plaintiff, which is presented as the simple "distributor" or "marketer", is not the holder of the patent and is not the licensee of Eli LILLY, holder of the patent, while the facts alleged with respect to unfair competition are not distinct from those of the infringement.
The company Kabi Groupe France requests to be exonerated, because it may not be blamed for any of the acts of infringement with respect to its activity as stated in its Kbis.

The company Lilly FRANCE states that it distributes the proprietary medicinal product Alimta in France, as stated in the Vidal, and indicates that it has brought legal action against the Defendants, the actions of which have prevented it from distributing the patented drug, thus causing it personal damage on the basis of unfair competition, which is different from infringement, without there being any grounds for producing a licensing agreement, which in any case would relate to a question of substance rather than a motion of inadmissibility.

On this matter,
- On the admissibility of the claims of the company Lilly FRANCE

As the claims of this Plaintiff are based on unfair competition pursuant to Article 1240 of the Civil Code and are not made in its capacity as the licensee of the patent holder, the provisions of Article L 613-9 of the Intellectual Property Code determining the admissibility of the action of the licensee with respect to infringement do not apply.
The filed motion to dismiss must therefore be rejected.

- On exonerating the company Fresenius Kabi Groupe France

This company operates within the framework of *"holding of shares, in whatever form, in all companies, and management of all its shares and all commercial, industrial, and financial operations or operations relative to movable or real property directly or indirectly relating thereto"*. The broad financial wording of the activities of the defendant, which moreover is indicative, does not exclude the involvement and indirect benefit of the latter in the activities of the Co-defendant, because while the UK company FRESENIUS KABI ONCOLOGY Plc is the holder of the marketing authorization issued by the European Medicines Agency, the generic drug refers to the company Fresenius Kabi France as the holder in France of the marketing authorization, and the company Fresenius Kabi Groupe France is domiciled at the same address as the latter.
There is therefore no serious reason to order that the company Fresenius Kabi Groupe France be exonerated.

III - On infringement

The company Eli LILLY maintains that the generic drug distributed by the Defendants constitutes a direct infringement by reproduction of the product whose use is covered in Patent EP 508, in a literal manner, as all of the essential means of the invention are reproduced therein, irrespective of the amendment of form, matter, or disposition through the use of a different salt, indicating that the addition of a feature during the granting procedure (by referring to pemetrexed disodium), for formal reasons and in order to overcome a ground for invalidity of the patent, does not make said feature essential. In this case, the acidic or disodium variant is secondary, and it is the combination of the substances that constitutes the essential means, because it is novel and inventive.

The generic drug also constitutes a direct infringement by equivalent, as the combination of means disclosed in the patent, which constitutes the essential means, is novel and the product distributed by the Defendants, which consists of a combination of means of differing structure but fulfilling the same overall function with respect to such a result, is equivalent and therefore infringes. The same applies even if the means of the disodium salt were considered to be essential, and the doctrine of equivalents cannot be ruled out when the means is taken up in a different form as long as the patent covers the function and not solely the form of the means and this function is not already known in the prior art.

Contributory infringement, literal and by equivalent, is also established according to the Lilly companies, as the conditions referred to in Article L. 613-4 of the Intellectual Property Code are fulfilled.

The FRESENIUS companies respond that direct literal infringement is by no means established, as all of the foreign courts have held, because the allegedly infringing product is different from the claimed product, in that the essential element consisting in the disodium salt is by no means reproduced and the claimed combination is neither novel nor inventive. The patent by no means proposes that a person skilled in the art should use another salt, much less the diacid tromethamine, which is very rarely used for intravenous administration. Moreover, the company FRESENIUS was granted a patent in Europe and the USA for this molecule, without any objection for lack of inventive step. As for direct infringement by equivalence, this is excluded and cannot be asserted by the patent holder, on the one hand because of the restrictive wording of the patent and on the other hand because the allegedly infringing product does not comprise the specific element related to the form of the active ingredient, which it designates as essential, because it was added during the granting procedure solely in order to obtain granting of the patent. Finally, the combination at issue, and therefore its function, is not patentable.

The conditions of contributory infringement, claimed in a manner totally contradictory to direct infringement, are not fulfilled. It cannot be considered that after dissolution in the body of the patient, only the anion pemetrexed would remain, while this is not an essential element of the invention. The FRESENIUS companies do not provide any means relating to the invention, nor do they incite third parties to commit any infringement, indicating that medical professionals are strictly obligated to respect the MA of the Fresenius drug, recommending dilution in glucose, so the risk of substitution with sodium chloride is unlikely.

On this matter,
- Direct infringement by reproduction or by equivalent

Direct infringement implies the reproduction of the essential means of the invention, i.e. those which are necessary and sufficient to ensure the primary function of the invented means, and it is acknowledged when the essential similarities are reproduced, notwithstanding secondary differences.
In the present case, in view of the scope of the patent, and given that the formal amendment during the granting procedure does not confer any essential character on the amended element, because the granting of the patent was not conditioned to it, as was stated above, the essential means of the invention consists of the combined administration of the active ingredient pemetrexed, regardless of its form, with vitamin B12 or its other derivatives, and optionally, with folic acid or its other derivatives.
The generic drug of Fresenius is composed of the same active ingredient, pemetrexed, and its administration must be combined, as provided by Patent EP 508, with vitamin B12 and folic acid. It matters little that the allegedly infringing compound uses a diacid solution to allow administration of this combination, since this does not produce any particular technical effect, keeping in mind that it is admitted that a specialist in formulation is capable of proposing a certain number of possible counterions other than sodium, in the form of a free acid or in the form of a certain number of well-known pharmaceutically acceptable salts. The selection of the form of the salt is therefore of no importance whatsoever, the only thing that matters being the therapeutic effect of the pemetrexed anion combined with other substances. The lack of

obviousness alleged by the Defendants with respect to the use of this particular salt, classified in 10th place among frequently utilized salts, which is a criterion of validity of an invention and not a criterion of infringement, or else the fact that the company Fresenius obtained patents (EP 768 and US 9,421,207) for this form of salt, are irrelevant.
The variation related to the use of a different salt is of totally secondary importance. Pemetrexed Fresenius Kabi is administered according to the use provided for by the invention, and it is intended to treat the same cancerous diseases with the same technical effect. It was authorized as a generic drug of the reference drug.
Infringement by reproduction is established.

Given that direct infringement by reproduction is established, in consideration of the scope of the patent as determined, there is no reason to make a determination about infringement by equivalence.

- Contributory infringement

These claims are without object since direct infringement is established.

IV – On the invalidity of the patent

In a subsidiary manner, in the event that infringement is declared to be established, the FRESENIUS companies claim invalidity of Claims 1 and 2, and subsequently, that of dependent Claims 3 to 14, of the patent, for extension of subject matter beyond the content of the application, for insufficiency of disclosure, and for lack of inventive step.
They maintain that the prior art documents on the priority date and/or the general knowledge of the person skilled in the art would allow said person to obviously arrive at the invention.
The Defendants state that the combination of pemetrexed and folic acid for alleviating the toxicity of the antifolate is known (US Patent 5,217,974, Worzalla and Jackman – exchanges between Lilly and the European Medicines Agency (EMA) regarding the application for an MA for the drug Alimta®), with there being no bias whatsoever against using folic acid. Moreover, it was documented that the toxicity of pemetrexed is correlated with a high homocysteine level, which could be reduced by vitamin B12 and folic acid, allowing the person skilled in the art to consider the use of vitamin B12 harmless. In this case, these combined teachings would permit the person skilled in the art to obviously arrive at the solution proposed by the patent. Moreover, the German Federal Patent Court declared the patent to be invalid by decision of 17 July 2018.

The company Eli Lilly asks that the petitions for invalidity of the patent due to lack of inventive step be rejected, indicating that combination therapy with pemetrexed and vitamin B12 was by no means obvious on the priority date; that none of the documents cited, the number of which alone is suspect, contains any reference to vitamin B12 and to a combination with pemetrexed. On the contrary, there was a bias against using vitamin B12, which was thought to have an effect of accelerating tumour cell division, a bias that was overcome by the patent. The documents cited would not have been combined with one another, and would not even have been consulted in the case of some of them. The Jackman anthology is a collection of articles, two chapters of which concern an antifolate and only one chapter of which relates to pemetrexed, the other referring to vitamin B12, and subsequent Hammond studies did not advocate the use of a folic acid (which, on the contrary, would reduce the efficacy of pemetrexed). The Niyikiza study, considered by the EPO, demonstrates that the toxicity of

pemetrexed is not correlated with the vitamin B12 deficiency marker. The Scott document (folate cycle) is irrelevant. The alleged correlation between the homocysteine level and the toxicity of pemetrexed does not mean that homocysteine is the cause of the toxicities, and that it is sufficient to administer vitamin B12 in order to reduce this level. The document IBIS relates to a different antifolate used for the treatment of a different disorder (rheumatoid arthritis). On the contrary, the Hammond document suggests that supplementation with folic acid reduces the therapeutic efficacy of pemetrexed.
The Lilly companies add that the claims for insufficient disclosure and undue extension of subject matter beyond the content of the application are not more founded; that the patent does not extend its subject matter and is not speculative, as the scope of the patent does not relate to all of the antifolates, but to other variants of pemetrexed disodium; that the assessment and establishment of infringement have no effect on the validity of the patent. Undue extension can only be constituted by an amendment made to the patent and cannot result from the assessment by the Court of the scope of the patent or else of the MA (which combines both supplementation with vitamin B12 and folic acid). The same applies with respect to insufficient disclosure. Furthermore, the tests mentioned in the patent also concern only the combination of pemetrexed and vitamin B12.

On this matter,
A European Patent is declared invalid by legal decision for the grounds specified in Article 138 § 1 of the EPC, specifically insufficient disclosure (b/), extension of subject matter beyond the content of the application (c/) and non-patentability of the invention, specifically lack of inventive step (a/ and Article 56 of the same text).

- On extension of subject matter beyond the content of the application and insufficient disclosure

In this case, extension of subject matter beyond the content of the application is not characterized, as the patent was amended during the granting procedure, for addition of subject matter, in order to conform to the description of the patent and claim "pemetrexed disodium", expressly referred to in the description as a particular embodiment. The invention is also sufficiently described, as the teachings of the patent, described and documented by tests, including those relative to the combination referred to in Claim 1 (pemetrexed and vitamin B12 alone), allow the invention to be implemented. In any event, these grounds of invalidity cannot be upheld with regard to the mechanisms of interpretation used by the Court to determine the scope of the patent and the caracterization of infringement, by variants or by equivalence.

- On lack of inventive step

According to Article L. 611-14 of the Intellectual Property Code, *"An invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents referred to in the third paragraph of Article L. 611-11, such documents shall not be considered in deciding whether there has been an inventive step"*. In order to assess inventiveness, one must determine whether, with respect to the prior art, the person skilled in the art, in light of the problem that the invention claims to solve, refraining from any *a posteriori* analysis, would have arrived at the technical solution claimed by the patent by using his professional knowledge and carrying out

simple operations. Inventive step is defined with respect to the specific problem with which the person skilled in the art is confronted and is assessed on the priority date (in this case, 2000).

The problem to be solved is that of reducing the cytotoxicity of the antifolate pemetrexed without affecting its therapeutic efficacy. The argument, supposedly to the contrary, made in 2004 by the company Eli Lilly before the European Medicines Agency for the granting of an MA, in addition to the fact that it is not part of the prior art because it was after the claimed priority date and that it has no connection with inventive step, is not relevant for assessing the inventive step of the patent at issue.

The Jackman document (Fresenius exhibit nos. 97, 128, 132) of 1999 is a reference work composed of a series of articles written by researchers in the field of folate biochemistry, of which Chapter 8 (Fresenius exhibit nos. 97 and 132) concerns MTA LY231514 or pemetrexed, wherein it is indicated that the combination of this "classic antifolate" with folic acid supplementation makes it possible to achieve an excellent antitumor dose/response ratio, and that "these data suggest that supplementation with folate not only modulates the toxicity but also slightly improves the antitumor response of MTA". Reference is made in this to the Worzalla study of 1997, conducted on mice supplemented with folic acid. As for Chapter 12, it relates to a different antifolate (lometrexol), wherein it mentions that supplementation with folic acid normalizes the dose/response ratio in order to achieve antitumor activity, and contemplates the use of suitable amounts of vitamins B12 and B6, "which can strongly influence the severity of the toxicity observed". The Adjei and Crips articles concern a colorectal cancer and refer to the studies cited in Worzalla or HAMMOND.
These documents therefore suggest that the combination of pemetrexed or antifolate and folic acid is of interest with regard to the subject matter of the invention.

Nevertheless, apart from the fact that it has by no means been proven that the person skilled in the art interested in pemetrexed would also have consulted the article concerning another antifolate having different mechanisms of action and not having an inhibitory effect on the same enzymes, and that it therefore does not appear that supplementation with vitamin B12 in combination with pemetrexed has been proposed, subsequent studies (HAMMOND I and II) conducted on humans completely alter these considerations, as it was found that supplementation with folic acid reduces toxicity and even improves the tumour response, but nonetheless requires the use of higher doses of pemetrexed, with the potential risks of other adverse effects (a large number of patients develop renal insufficiency).

Therefore, it cannot be considered, as the Defendant companies suggest, that the Jackman document constitutes the most relevant prior art, as it compiles articles written in 1997, while studies that were conducted thereafter but published before the priority date alter these teachings.

Moreover, Prof. Ann Jackman herself (HL exhibit nos. 61 and 61 bis) indicates that the Worzalla study involving mice cannot be applied to humans; that the other contemporary articles as of the priority date raised concerns about the decreasing efficacy of the antifolate in co-administration with folic acid, and that in 2000, the scientific community was "hesitant to use folic acid in co-administration with antifolates in general, and pemetrexed was no exception". On this date, therefore, there was no serious incentive to combine an administration of folic acid with pemetrexed in humans.

With respect to supplementation with vitamin B12, the Niyikiza document shows no link between methylmalonic acid (a specific marker of vitamin B12 deficiency) and the toxicity of pemetrexed, so the person skilled in the art would have concluded that vitamin B12 is not involved in the toxicity observed. The other documents cited (Patent EP 0595.005, Clarke, Brönstrup, Murray, Brattstrom, Ubbink: Fresenius exhibit nos. 53, 76, 79, 104, 129) relative to homocysteine levels in the body, without any relation to anticancer treatment and to the antifolates, are irrelevant.
The Scott document of 1999 (Fresenius exhibit nos. 98 and 116) describes the role played by the folates and vitamin B12 in the biochemical process of the life of a human cell, for the formation of DNA, and in the process of transformation of homocysteine into methionine. It does not specifically concern the treatment of cancers either, belongs to the field of nutritional research, and by no means teaches the use of vitamin B12 for reducing the toxicity of pemetrexed.

Furthermore, in 1999, the Vidal (HL exhibit no. 50), regarding vitamin B12, issued a counterindication to the use of vitamin B12 for the treatment of malignant tumours because of the action of this vitamin on the growth of tissues with a high rate of cellular proliferation. Patent WO 96/8515 of 13 September 1995 for its part suggested that the total absence of vitamin B12 (or a deprivation of vitamin B12) could be useful in the treatment of cancer and other disorders characterized by uncontrolled cellular growth (HL exhibit nos. 56 and 56 bis). Therefore, as the Lilly companies suggest, there were objectively justified reasons for not using vitamin B12 in chemotherapy treatments.

Moreover, this analysis is confirmed both by Prof. Bruce A. CHABNER and Prof. Jackman, who concludes that "co-administration of vitamin B12 was not on the radar of the antifolate community in 2000" (HL exhibit nos. 74 and 74 bis).

The document IBIS (Fresenius exhibit nos. 77 and 101) is not relevant, as it concerns a different antifolate (methotrexate) used in the treatment of a different disorder (rheumatoid arthritis).

Thus, nothing makes it possible to conclude that the person skilled in the art, seeking to solve the specific problem of the patent, in its two branches, would have used one of any of the numerous documents cited, alone or in the combinations suggested, and would have obviously arrived at the solution provided by the patent, it being emphasised that the invention came after several decades of unsatisfactory scientific research in order to meet a need felt for a long time and that it constitutes an undeniable technical advance.

The claim for lack of inventive step of Claims 1 and 2 and the dependent claims must therefore be rejected.

V – Orders for compensation

The Plaintiffs, as compensation for the damage caused by the acts of infringement and unfair competition, impairing distribution in France due to marketing of the product Pemetrexed Fresenius Kabi, apply for injunction against the manufacture, offering, marketing, and use of the infringing drug, ordering recall of the products, confiscation and destruction thereof, notification by the Fresenius Kabi companies with respect to their clients, disclosure of elements within the framework of the right of information (manufacturers, quantities stored, produced, and

imported, gross margin, names and addresses of the clients, etc.), as well as provisional orders of indemnification of 10,000,000 euros and 30,000,000 euros respectively.

The FRESENIUS companies contest the license fee rate requested of 40%, which seems obviously disproportionate. They contest the soundness of the claims of the company Lilly France, which are based on facts identical to those of the infringement, and in any event the damage resulting therefrom are not justified regarding the loss connected with sales and the supposed erosion of the price of Alimta®. They ask that the claims for supplementary remedies (recall of the products and advertising measures) be rejected, as well as the right of disclosure, as the data in question are public.

On this matter,
The infringement on the intellectual property rights of the company Eli Lilly Company causes, by the mere fact of infringement, damage for which the Fresenius companies must compensate.
Notwithstanding the absence of a licensing contract, the company Lilly France, in its capacity as the distributor of the products on French territory, suffered economic and commercial damage, independent of and different from that caused by the acts of infringement, which it does not claim, due to the introduction on the market of the generic drug at issue that has impaired its activity and its organization, and the faults of the Defendants, although they result from the same acts, constitute different offences with respect to each of the Plaintiffs and cause different damages on different grounds, for which compensation must be paid.

The economic damage to the company Eli Lilly, the patent holder, is evaluated based on the license fee, increased, that it could have expected if it had granted an authorization to its opponents. With respect to the number of 100 mg (20,742) and 500 mg (46,862) vials sold, as shown by the public data available from the Groupement pour l'Elaboration et la Réalisation des Statistiques [Group for the Compilation and Preparation of Statistics] (GERS) and the sales revenues thus generated, and applying an increased license fee of 25%, it appears justified to provisionally order an indemnification of 8 million euros as compensation for said damage.

Regarding indemnification for the economic damage to the company Lilly France resulting from the acts of unfair competition, limited to lost profits, taking into account the differences between the face value published in the Official Gazette and that effectively granted after conventional and commercial discounts, and the erosion of the price of Alimta®, which is inevitable independently of any marketing of the generic and for which the Defendants are only partially responsible, this indemnification shall be provisionally set at the sum of 20 million euros.

The petition regarding disclosure of information, as provided for by Article L. 615-5-2 of the Intellectual Property Code, which is broader than only the data available via the GERS mentioned above, is valid and shall be granted within the limits specified in the operative provisions of the present decision, and specifically, counting from the date of granting the MA for the generic in July 2016 (and not on 1 April 2012 as claimed), with the Parties being required to use this information among themselves, where appropriate within the framework of a circle of confidentiality, and to determine among themselves the damage, and in the absence of an agreement, to apply to the Court again so that it will settle this difference.

Once the Court has settled the question of infringement, the complementary petition for an injunction order for the future is to be granted according to the terms specified in the present

decision, but without ordering the recall of the products already in circulation at the wholesalers, as this measure appears to be disproportionate, it being observed that the Lilly companies did not make the procedural choice of applying for an order of preliminary injunction and thus allowed this situation to continue throughout the entire duration of the proceedings.

The order to notify their clients also does not appear to be justifiable and proportionate, as the Defendants will in any event have to explain to their clients the imminent discontinuation of all supply due to the order of prohibition.

VI - Counterclaim of the Fresenius companies

The Fresenius companies claim that the patent holder engaged in unfair behaviour resulting from the communication to third parties, not justified by the need to inform said parties, by mail of 31 January 2017, of fragmentary and non-objective accusations of infringement concerning said companies, without mentioning not yet contested decisions that were favourable to them, and request that the Plaintiffs be jointly ordered to pay the sum of 5 million euros.

The Lilly companies request that this claim be rejected.

On this matter,
The disclosure by one company of information that can discredit another company, and specifically the disclosure of the existence of a legal action, constitutes an act of denigration, unless the information in question relates to a subject of general interest and is sufficiently based in fact, with the proviso that it must be expressed with a certain degree of restraint.

In the present case, the company Lilly France did indeed send on 31 January 2017 (Fresenius exhibit no. 40) a letter to two companies, which group together numerous health care establishments, to inform them of the property rights they held until 2021, indicating that it considered its patent to be valid and that it would act accordingly in order to defend its rights if a laboratory intended to market a generic of Alimta in France, and that various proceedings were already in progress in Europe.

Apart from the fact that the information was general, measured, and objective, it did not name any company, particularly not the company Fresenius. Unfair communication of information to the detriment of the Defendants is therefore not established, and the claims to this effect will be dismissed.

VII - On the other petitions

The Fresenius companies, who are the unsuccessful parties, shall suffer their own costs, as well as the expenses into the hands of Stanislas Roux-Vaillard, Attorney at Law.
Pursuant to the provisions of Article 700 of the Code of Civil Procedure, the party ordered to pay the expenses of the proceedings, or in the absence thereof, the losing party, is ordered to pay a sum by way of costs incurred and not included in the expenses of the proceedings, taking into account fairness or the financial situation of the losing party.
The Fresenius companies shall be ordered to pay to the Lilly companies the sum of 350,000 euros by way of discretionary costs.

The circumstances of the action justify that provisional enforcement, which appears to be necessary and compatible with the nature of the case, be ordered.

THEREFORE

The Court, ruling publicly by judgment rendered in the presence of all of the Parties, made available to the Clerk's Office and at first instance,

Declares that it is admissible for the company Lilly France to act based on unfair competition,

Rejects the petition that the company Fresenius Kabi Groupe France be exonerated,

Dismisses the petitions of the Fresenius companies for declaration of invalidity for insufficiency of disclosure, extension of subject matter beyond the content of the application, and lack of inventive step regarding the claims of the French part of Patent EP 1 313 508, of which the company Eli Lilly is the holder,

Rules that the companies Fresenius Kabi France and Fresenius Kabi Groupe France committed acts of infringement by reproduction of the entirety of the claims of the French part of European Patent EP 1 313 508 by manufacturing, offering, marketing, using, importing, exporting, transhipping, or possessing Pemetrexed Fresenius Kabi for the aforementioned purposes,

Enjoins the companies Fresenius Kabi France and Fresenius Kabi Groupe France from directly or indirectly manufacturing, offering, marketing, using, importing, exporting, transhipping, or possessing for the aforementioned purposes, supplying, delivering or offering to supply, on French territory, to any person other than those authorized to exploit the invention, Pemetrexed Fresenius Kabi or any other product making it possible to reproduce the claims of European Patent EP 1 313 508, effective after a period of 15 days counting from notification of the present decision, subject to a penalty of 700 euros per vial,

Rejects the petition to recall and destroy the stocks in France of Pemetrexed Fresenius Kabi in commercial circulation,

Orders the companies Fresenius Kabi France and Fresenius Kabi Groupe France *in solidum* to pay to the company Eli Lilly, as compensation for the damages resulting from infringement of the French part of European Patent EP 1 313 508, the provisional sum of 8,000,000 euros as compensation for damages,

Orders said companies *in solidum* to pay to the company Lilly France, in its capacity as the distributor of the proprietary medicinal product Alimta® in France, the provisional sum of 20,000,000 euros as compensation for damages resulting from acts of unfair competition,

Orders the companies Fresenius Kabi France and Fresenius Kabi Groupe France to inform the companies Eli Lilly and Lilly France, where appropriate within the framework of a circle of confidentiality that will be arranged among them, subject to a penalty of 500 euros per day of delay, when the period of two months after notification of the judgment to be rendered has elapsed, of the following:

- the names and addresses of the manufacturers, wholesalers, importers, exporters, transhippers and other holders of these products,
- the quantities stored, produced, imported, exported, transhipped, marketed, delivered, received or ordered, as well as their delivery dates and price,
- the brand names of the relevant products and all of the elements identifying the products, such as the designation, the article name, and the serial number of the product,
- the gross margin realized on the sale of Pemetrexed Fresenius Kabi as well as any other preparation making it possible to reproduce the claims of Patent EP 1 313 508,
- the names and addresses of the clients of the companies Fresenius Kabi France and Fresenius Kabi Groupe France, from 22 July 2016 until the date of notification of the present judgment,

Rules that the Parties must amicably assess among themselves the final damages of the Plaintiff companies, and if an agreement is not reached, the first party to take action shall apply to the Court ruling on the merits of the case in order to settle the dispute,

Rules that there are no grounds for ordering Fresenius Kabi France and Fresenius Kabi Groupe France to notify their clients,

Rules that the Court reserves the right to enforce the penalties,

Rejects the counterclaims of the companies Fresenius Kabi France and Fresenius Kabi Groupe France,

Orders provisional execution,

Orders the companies Fresenius Kabi France and Fresenius Kabi Groupe France *in solidum* to pay to the companies Eli Lilly and Lilly France the total sum of 350,000 euros pursuant to Article 700 of the Code of Civil Procedure,

Orders the companies Fresenius Kabi France and Fresenius Kabi Groupe France to pay the expenses of the proceedings,

Authorizes Stanislas Roux-Vaillard, Attorney at Law, to directly recover from the Defendants any expenses advanced by him for which he has not received a provision, pursuant to Article 699 of the Code of Civil Procedure.

So done and judged in Paris, 11 September 2020

The Clerk of the Court The Chief Presiding Judge