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JUDICIAL
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section

JUDGMENT
rendered on September 11, 2020

NO. RG 17/10421
N° Portalis
352J-W-B7B-CK7K

MINUTE

Summons dated:
March 29, 2017

APPLICATIONS

ELI LILLY AND COMPANY
Lilly Corporate Center
IN 46285
INDIANAPOLIS (UNITED STATES)

LILLY FRANCE 24
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CS 50004
92521 NEUILLY SUR SEINE CEDEX

represented by Maître Stanislas ROUX-VAILLARD of PARTNERSHIPS HOGAN LOVELLS (PARIS) LLP, avocats au PARIS bar, checkroom #J0033

DEFENDERESSES

FRESENIUS KABI FRANCE
5 place du Marivel
92316 SEVRES

FRESENIUS KABI GROUPE FRANCE
5 place du Marivel
92316 SEVRES

represented by Maître Elisabeth BERTHET-MAILLOLS of SELAFA PROMARK, lawyers at the PARIS bar, courtroom #R0162

Enforceable copies
delivered on :

COURT COMPOSITION

Carine GILLET, Vice-President
Laurence BASTERREIX, Vice-President
Elise MELLIER, Judge

assisted by Alice ARGENTINI, Clerk

DEBATES

At the public hearing of July 01,
2020

JUDGMENT

Delivered publicly at the clerk's office Contradictory
in the first instance

Eli Lilly and Company, an American pharmaceutical company founded in 1876, has developed a drug marketed under the brand name AlimtaoR, for the treatment of two types of lung cancer (malignant pleural mesothelioma and non-small-cell bronchial cancer), whose active ingredient is a compound called pemetrexed, belonging to the antifolate class of therapeutic agents against cancer.

Antifolates are used in the chemotherapy treatment of cancerous tumors, to inhibit tumor growth by affecting the cells' ability to divide and by interfering with certain enzymes involved in cell replication, which are part of the folate metabolic pathway, which accelerates tumor growth. However, antifolates do not distinguish between cancerous and healthy cells, and affect both, leading to serious side-effects for patients, including lethal ones. Although considered promising anticancer agents and the subject of research since the 1950s, few have been brought to market, due to their high toxicity and the difficulty of controlling it.

The active ingredient pemetrexed (an antifolate which is not at issue in the present proceedings) was developed by Eli Lilly and patented under EP 677 on December 10, 1990 as a compound in the drug AlimtaoR, but has been little exploited, given its severe adverse effects.

On June 15, 2001, Eli Lilly filed a patent application (EP 508) under the U.S. priorities of June 30, 2000, September 27, 2000, and September 27, 2001.
April 18, 2001, granted on April 18, 2007, entitled "*composition comprising an antifolate and a methylmalonic acid reducing agent".*
Patent EP 508 will expire on June 15, 2021. The patent relates to the combined administration of AlimtaoR/pemetrexed with vitamin B12 and, optionally, folic acid, to treat two types of lung cancer, reducing 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 the EPO on December 27, 2010, following opposition from TEVA.
To be administered, the drug is presented in acid or salt form (neutral pharmaceutical forms of the active part of a drug), composed of the active part of the compound pemetrexed or pemetrexed anion, combined with two sodium counterparts (cation) or
"pemetrexed disodium".

Lilly France, an Eli Lilly subsidiary, markets AlimtaÖR in France.

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

Believing that this generic drug infringed their rights, Eli Lilly and Lilly France, by deed dated March 29, 2017, brought an action before this court against Fresenius Kabi France and Fresenius Kabi Groupe France 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 AlimtaoR, the LILLY companies report that they have obtained prohibition measures in the UK, Switzerland, Italy, Germany, Sweden, Austria, Finland, Denmark, Portugal, Spain and the Netherlands, as well as outside Europe (with the exception of an isolated first-instance decision by the District Court of The Hague on June 19, 2019 against FRESENIUS KABI, which has been appealed).

The patent has also been declared valid by the EPO in opposition proceedings, by the District Court of The Hague and its Japanese and American equivalents, as well, except for a first instance decision by the German Federal Patent Court (Bundespatentgericht), which declared the German part of the patent invalid, which has since been overturned by the German Federal Supreme Court on July 07, 2020 (as notified by the parties by emails of August 03, 2020).

The Lilly companies served their final pleadings on October 4, 2019, in which they request the court to
And by application of the aforementioned texts and in view of the documents communicated, a list of which appears in the schedule appended to the present summons,

— To declare the claims of Eli Lilly and Lilly France admissible and well-founded;

— To say and judge that

-Fresenius Kabi France and Fresenius Kabi Groupe France have committed acts of direct infringement 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 holding Fresenius Kabi Pemetrexed for the aforementioned purposes,

-Fresenius Kabi France and Fresenius Kabi Groupe France have infringed the claims of the French part of European patent EP 1 313 508 by supplying or offering to supply Fresenius Kabi Pemetrexed in France,

Therefore

— Prohibit Fresenius Kabi France and Fresenius Kabi Groupe France, directly or indirectly, from manufacturing, offering, putting on the market, using, importing, exporting, transshipping or holding 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 enabling the claims of European patent EP 1 313 508 to be reproduced, subject to a fine of 5.000 euros per vial from the date of notification of the judgment,

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to recall all French stocks of Pemetrexed Fresenius Kabi or any other product that reproduces the claims of European patent EP 1 313 508, subject to a fine of 5,000 euros per vial from the date of notification of the judgment,

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to compensate Eli Lilly for the loss it has suffered as a result of the infringement of its rights to the French part of European patent EP 1 313 508, and therefore to pay Eli Lilly the sum of 10,000,000 euros in provisional damages and interest, with the possibility of further compensation, as detailed below,

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to compensate Lilly France, as the operator of the AlimtaoR specialty in France, for the entire loss it has suffered, and therefore to pay Lilly France the sum of 30,000,000 euros in provisional damages, with the possibility of further compensation, as detailed below;

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to produce all documents and information required to assess the damage suffered by Eli Lilly and Lilly France, in particular :

-the names and addresses of manufacturers, wholesalers, importers, exporters, transshippers and other holders of these products,

-quantities stored, produced, imported, exported, transshipped, marketed, delivered, received or ordered, along with delivery dates and prices,

-the relevant product brands and all product identifiers such as product designation, item name and serial number,

-the gross margin on the sale of Pemetrexed Fresenius Kabi and any other preparation that reproduces the claims of patent EP 508
-the names and addresses of customers of Fresenius Kabi France and Fresenius Kabi groupe France, since April 1 2012 until the date of judgment, and
This is subject to a fine of 5,000 euros from the date of notification of the judgment, with the court reserving the right to liquidate the fine directly,

— To declare and rule that this procedure of communication of information and rendering of accounts will be conducted under the control of the juge de la mise en état, with the Court remaining seized of the dispute so as to be able, once the rendering of accounts has been completed, to rule on the amount of the claims for compensation made by Eli Lilly and Lilly France,

— Referral of the pre-trial proceedings on the determination of damages to the mise en état, to enable monitoring and control of the communication and rendering of accounts procedure, and for subsequent conclusions by Eli Lilly and Lilly France on the damages claimed by them,

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to send to each of the customers to whom it has offered for sale, sold or delivered infringing products the following letter by registered mail with acknowledgement of receipt under penalty of 5,000 euros per day of delay per customer from the date of notification of the judgment to intervene
"IMPORTANT
Dear [...]
We are obliged to inform you that the Tribunal de Grande Instance de Paris, by decision of [...], has ruled that the supply or offer to supply the Pemetrexed Fresenius Kabi speciality constitutes an act of infringement of patent EP 1 313 508 and that this product may therefore not be sold, delivered, used, offered for sale or kept in stock in France. We hereby request that you return all the above-mentioned products in your possession as soon as possible. We will immediately reimburse you for the purchase price and any costs incurred in returning these products.
The companies Fresenius Kabi France and Fresenius Kabi Groupe France "

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to send Lilly's counsel copies of the letters sent to its customers, subject to a fine of 5,000 euros per day of delay from the date of notification of the judgment,

— To declare and rule that the court will have jurisdiction over the liquidation of the penalty payments it has ordered, in accordance with article L.131-3 of the French Code of Civil Enforcement Procedures,

In any case,

— Dismiss the counterclaims of Fresenius Kabi France and Fresenius Kabi Groupe France,

Order provisional execution of the judgment notwithstanding appeal and without security;

— Order Fresenius Kabi France and Fresenius Kabi Groupe France to pay Eli Lilly and Lilly France, jointly and severally, the sum of 403,459.51 euros under article 700 of the French Code of Civil Procedure, with the right to claim damages,

— Finally, order Fresenius Kabi France and Fresenius Kabi Groupe France to pay all costs of the proceedings, which will be awarded to Maître Stanislas Roux-Vaillard, pursuant to article 699 of the French Code of Civil Procedure.

FRESENIUS Kabi France SAS and FRESENIUS Kabi Groupe France SASU served their writings No. 7 electronically on October 02, 2019, asking the court to
Having regard to articles L.613-3, L.613-4, L.613-9, L.614-12 and L.615-2 of the French Intellectual Property Code,
Having regard to articles 43, 52, 54, 56, 69, 83, 84 and 123 (2) and 138 (1) a), b) and c) of the European Patent Convention,
In view of article 1240 of the French Civil Code,
Having regard to articles 31, 32-1, 122 and 700 of the Code of Civil Procedure,

In limine litis
— Declare LILLY FRANCE's claims inadmissible, In any event :

— Declare the action brought by ELI LILLY AND COMPANY and LILLY FRANCE against FRESENIUS KABI GROUPE FRANCE inadmissible,

As a result,
Exonerate FRESENIUS KABI GROUPE FRANCE,

In any case,

Main purpose,
Note that the scope of the French part of patent EP 1.313.508 B1 does not extend to the FRESENIUS KABI Pemetrexed product,

As a result,
— To declare that FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE have not infringed the French part of European patent EP 1.313.508 B1,

In any case,
— To declare that FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE have not committed any act of unfair competition,

As a result,
— Dismiss ELI LILLY AND COMPANY and LILLY FRANCE's respective claims for infringement and unfair competition,

In the alternative,
— Declare all the claims of the French part of patent EP 1.313.508 B1 invalid on the grounds of insufficient description,

— Declare all the claims of the French part of patent EP 1.313.508 B1 invalid for extension beyond the application as filed,

— Declare all the claims of the French part of patent EP 1.313.508 B1 invalid for lack of inventive step,

— Order the transcription of the judgment to intervene in the National Register of Patents at the INPI, at the request of the chief clerk of the court,

In all cases,
— Dismiss all ELI LILLY AND COMPANY and LILLY FRANCE claims,

In any case,
Order ELI LILLY AND COMPANY and LILLY FRANCE jointly and severally to pay FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE the sum of 5 million euros (five million euros) for unfair competition;

Order ELI LILLY AND COMPANY and LILLY FRANCE jointly and severally to pay FRESENIUS KABI FRANCE and FRESENIUS KABI GROUPE FRANCE the sum of 404,420 euros (four hundred and four thousand four hundred and twenty euros) under article 700 of the French Code of Civil Procedure,

Order ELI LILLY AND COMPANY and LILLY FRANCE jointly and severally to pay all the costs of the proceedings, to be recovered in accordance with article 699 of the French Code of Civil Procedure.

The proceedings were closed by order of October 17, 2019 and the case set for oral argument on March 26, 2020. As this hearing has been cancelled due to the health situation in France since March 17, 2020, consideration of the case has been postponed to July 1er 2020.

In accordance with the provisions of article 455 of the French Code of Civil Procedure, reference is made to the aforementioned pleadings of the parties, for the presentation of their respective claims and the arguments developed therein.

REASONS FOR DECISION

I - on patent EP 1313508

— On patent presentation

Patent EP 1313 508 belonging to Eli Lilly, which was filed on June 15, 2001 under the U.S. priorities of June 30, 2000, September 27, 2000 and April 18, 2001, and which was granted on April 18, 2007 and maintained as granted by EPO decision of December 27, 2010, upon opposition by TEVA, is entitled
This is a "composition comprising an antifolate and a methylmalonic acid reducing agent". It concerns combined administration of the drug AlimtaoR/ pemetrexed disodium with vitamin B12 and optionally folic acid to treat two types of lung cancer.

According to the description in the booklet, antifolates are antineosplastic agents designed to block cancer cell proliferation, studied for around 50 years and a standard component of effective chemotherapy regimens for malignancies [page 1 lines 11-13, lines 14-15], which inhibit key folate-requiring enzymes involved in cell replication [page 2 lines 1 et seq.] Several antifolate drugs are currently under development [page 2 lines 11-12; lines 1 et seq, lines 20 et seq.], including pemetrexed disodium (Eli Lilly's AlimtaoR), which inhibits several enzymes (such as thymidylate synthase (TS), dihydrofolate reductase (DHFR) and glycinamide ribonucleotide formyltransferase (GARFT)).However, the harmfulness of antifolates [page 7 lines 11 to 22] and the inability to control this, and subsequently their efficacy, is a major obstacle to the administration of these substances and has led to the abandonment of their clinical development [page 1, lines 4-5, pages 2 lines 24-25 and 29- 30]. To modulate the toxicity of antifolates, without however succeeding in eliminating all harmfulness, folic acid or nutritional compositions (vitamin B12, folate and vitamin B6 supplements) can be administered (US patent no. 5,217,97, EP patent A 0546870: vitamin A supplements), but toxicity remains a major concern [page 3 lines 8 et seq.] and the ability to lower cytotoxic activity would constitute a major advance [page 4 line 1-2].

To offset these severe side effects, the patent description states that it was found, surprisingly and unexpectedly, that undesirable toxic effects could be significantly reduced by an agent such as vitamin B12, which lowers methylmalonic acid, a predictor of toxic manifestations [page 8 lines 27 et seq.], 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 disease, but not for treating antifolate toxicity), combined with antifolate drugs, significantly reduces the latter's toxicity [page 4, lines 3 et seq].

The substances may be administered in any order, or simultaneously as a single composition or two separate compositions, or sequentially, preferably in the following order: vitamin B12, then folic acid, if appropriate, then antifolate [page 7 lines 28 et seq., page 8 lines 1 to 15, page 11 lines 28 et seq.] 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 have been carried out on female nude mice with mammary carcinoma [page 12 lines 25 et seq., to page 16 lines 1 to 10] and on cancer patients [page 16 lines 11 et seq., pages 17 to 21], demonstrating a reduction in drug toxicity without adversely affecting tumor activity.

The patent comprises 14 claims, of Swiss type (second medical use of a known compound) and of product (R12 to R14), worded as follows:
" 1. *Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy to inhibit tumor growth in mammals to which 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 folate-binding protein-binding agent selected from folic acid, ï6R)-5-methyl-5,6,7,8,-tetrahydrofolic acid and ï6R)-5-formyl-5,6,7,8,-tetrahydrofolic acid or a physiologically acceptable salt or ester thereof. "*

" 3. *Use according to claim 2, wherein the binding agent to the folate-binding protein 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 drug, vitamin B12 or pharmaceutical derivative thereof and, optionally the folate-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 vitamin B12 or the pharmaceutical derivative thereof."*

" 8. *Use according to any one of claims 1 to 7, wherein the medicament is to be administered after the folate-binding protein binding agent."*

" 9. *Use according to any one of claims 2 to 8, wherein the medicament is to be administered after pretreatment with vitamin B12 or a pharmaceutical derivative thereof, followed by folic acid."*

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

" 11. *Use according to any one of claims 2 to 10, wherein the folate-binding protein-binding agent is to be administered orally in the form of 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 folate-binding protein-binding agent selected from the group consisting of folic acid, ï6R)-5-methyl-5,6,7,8,-tetrahydrofolic acid and ï6R)-5-formyl-5,6,7,8,-tetrahydrofolic acid, or a physiologically acceptable salt or ester thereof, in the form of a combined preparation for simultaneous, separate or successive use in the inhibition of tumor growth. "*

" 13. *The product of claim 12, wherein the vitamin B12 or pharmaceutical derivative thereof is vitamin B12, cobalamin or chlorocobalamin and, where appropriate, the folate-binding protein-binding agent is folic acid."*

" 14. *The product of claim 12, wherein the vitamin B12 or pharmaceutical derivative thereof is vitamin B12 or hydroxocobalamin and, optionally, the folate-binding protein-binding agent is folic acid."*

Thus, according to the description, the invention relates generally to use in the manufacture of a medicament, for combined administration of a pemetrexed antifolate and vitamin B12, alone or in combination with folic acid, to reduce the toxicity of antifolate medicaments and to inhibit tumor growth [page 5, lines 7 et seq. and 10 et seq.] and in particular on 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 antifolate active ingredient pemetrexed, without affecting its therapeutic efficacy.

The "man of the trade" is a multidisciplinary team comprising an oncologist with specialist knowledge and a pharmacologist with experience in the use of antifolates for tumor treatment.

- 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 principle of the antifolate pemetrexed, without adversely affecting its therapeutic efficacy, by using a combination of pemetrexed, in whatever form, with vitamin B12, each of which was already known at the priority date. This is a combination of two distinct means, which constitutes the essential means of the invention, whose primary technical function or effect is to achieve the desired dual result. The form of pemetrexed used to enable its administration by infusion is totally irrelevant, since only the anion of pemetrexed, which has a therapeutic effect but is also responsible for the undesirable effects, produces a technical effect, the counter-ions having no technical effect in solving the technical problem, so that the choice of salt is of no consequence whatsoever, as the skilled person knows perfectly well. Thus, the person skilled in the art is able to understand that the "pemetrexed disodium" referred to in the claims is synonymous with "pemetrexed".

The Lilly companies point out that the scope of protection conferred by the patent is not limited to the literal wording of the claims, and must be determined even in the absence of ambiguities in the claims, in accordance with Article 69 of the European Patent Convention (EPC) and its interpretative protocol, and must be extended to the equivalents of the claimed invention.
During the patent examination, the term
The term "antifolate" initially used in the main claim of the patent as filed was replaced by the term "pemetrexed", to exclude other antifolates not envisaged by the patentee and to remedy a lack of clarity, but also to overcome a possible objection to novelty and inventive step (as certain documents in the prior art referred to antifolates other than pemetrexed). Secondly, the examiner raised a purely formal objection on the grounds of added matter, without however raising any lack of inventive step, since "pemetrexed" is a chemical compound distinct from "pemetrexed disodium", which is referred to in the patent application, so that in the claims, the term "pemetrexed" has been replaced by "pemetrexed".
The term "pemetrexed disodium" refers to the preferred mode of the invention. However, the examination procedure before the EPO has no impact on the assessment of the scope of the patent; it is merely a factual element taken into consideration, especially as the Lilly companies, although they modified the content at the examiner's request, did not intend to limit the scope of the patent, either implicitly or explicitly. The modification made is purely formal, to make up for an addition of matter, which constitutes a formal requirement, and not to counter objections based on the prior art. It has no effect on the substance of the patent's inventive contribution. This modification has no impact on the assessment of infringement by variants or equivalence, except to deprive this theory of any effect. The consultations produced by their opponents (Professors Michel VIVANT and Jacques RAYNOUARD) are irrelevant.

The defendants, for their part, consider that because the claims are clear and not open to interpretation, and are drafted in the form of a specific rather than a general plea, and in view of the limitations imposed during the grant procedure, and having regard to the requirement of reasonable legal certainty for third parties and fair protection for the patentee, the scope of the patent is strictly limited to "pemetrexed disodium" alone, to the exclusion of all other products, in particular other salts of the molecule, The scope of the patent is strictly limited to "pemetrexed disodium" alone, to the exclusion of any other product and in particular of other salts of the molecule. A claim limited to a single salt form of a product cannot apply to "all other derivatives thereof", and the patentee can only receive a monopoly for the enrichment that his invention has actually brought about. Furthermore, the theory of equivalents is not applicable in a case such as this, where the title is restrictively worded and the added characteristic (disodium salt and not its equivalents) constitutes an essential element, necessary for the validity of the patent.

The FRESENIUS companies superfluously argue that the attitude and limitations voluntarily adopted by the applicant during the grant procedure, which constitute a waiver by the applicant and without which the patent would be invalid, must be taken into account in order to ensure consistency between the examination and the validity of the patent.
In response to the arguments put forward by Eli Lilly, the defendants add that the lack of novelty in the function of the means is not the only exception to the application of the doctrine of equivalents; case law precedents limiting the scope of a patent to salts specifically mentioned in the description are applicable; that the claimed invention is not pioneering and cannot confer broad protection if the claims are drafted in restrictive terms; that the claims relate not to a product but to a specific use, and the invention does not constitute a new and inventive (and therefore patentable) combination. It cannot be argued that only the pemetrexed anion is responsible for the activity and could function with any salt other than the disodium salt, as the "inventive concept" here is limited to the disodium salt alone, excluding the doctrine of equivalents, even though this argument was never developed before the EPO in the patent itself, and "inventive concept" or "underlying technical problem" are notions foreign to patent law.

On that note,
According to Article 84 of the EPC, *"The claims define the subject matter of the protection applied for. They must be clear and concise"* and under Article 69 of the EPC, "*the scope of the protection conferred by the European patent or by the patent application shall be determined by the claims. However, the description and drawings [which determine the subject matter of the patent] serve to interpret the claims".*
Interpretation is carried out in accordance with Article 1 of the Interpretative Protocol, reconciling the imperatives of equitable protection for the patentee and a reasonable degree of legal certainty for third parties, along a middle path, excluding any extreme interpretation, without stopping at the literal and narrow meaning of the text of the claims, and without considering that the claims only serve as guidelines of what the patentee intended to protect. According to Article 2 of the same protocol, when determining the scope of a patent, "account shall be taken of any element equivalent

to an element indicated in the claims".

It thus serves not only to determine the actual 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 the light of the description and drawings, and also, where applicable, in consideration of elements taken from the examination file during the grant procedure, such as the modifications made and the arguments put forward by the patentee, which constitute factual elements to be considered among others.

In this case, even though the patent claims refer only to "pemetrexed disodium", for use in combination with vitamin B12, for the treatment of certain lung cancers, the patent description refers generally to the administration o f an "antifolate" (page 4, line 20) or to "antifungal agents".
We refer to "antifolate drugs" (page 4 line 27, page 5 line 2 and line 7) and in particular to "pemetrexed disodium antifolate" (page 5 lines 15-16), indicating that "antifolate" or "antifolate drug" is "pemetrexed disodium AlimtaoR" as manufactured by Eli Lilly & Co (page 8 lines 21 to 23) and used in the clinical trials listed in the patent. Those skilled in the art will know that the active part of the pemetrexed active ingredient is the anion (which is responsible for both therapeutic effects and undesirable side-effects), which combined with vitamin B12 (and possibly folic acid), will comprise
without stopping at the literal wording of the claims, that the invention lies in the combined administration of the active ingredient, in whatever form, with the other substances claimed in the patent.
This interpretation is in line with the principles set out above, and does not take into consideration not only elements that are not part of the patent (such as the wording of the proprietor's other patents, which, unlike the present patent, refer to the same active ingredient and "its pharmaceutically acceptable salts", the applicant's experience in patent matters, or his status as a pharmaceutical manufacturer), but also elements arising from the administrative granting procedure. Indeed, since a patent is a title that stands on its own, the examination procedure before the patent office, whose convening as a mere interpretation tool is optional, has no effect on the scope of the patent, and binds neither the judge nor the patentee. The behaviour of a patentee who has acquiesced to an examiner's request for amendment cannot be construed as an admission that could be binding on the court, and has no effect whatsoever on the scope of the claim. It does not constitute acquiescence or renunciation on its part, nor can it be considered as a statement of position, a fortiori as in the present case, when Lilly intended to refer to a preferred mode of realization, without manifesting any intention of modifying the scope of its title, Even if it had not put forward any arguments to the contrary to the examiner, an amendment for the purpose of adding matter under Article 123 §2 of the EPC is not intended to compensate for prior art likely to call into question the validity of the patent, and is merely a matter of form. The amendment for addition of matter is not such as to prevent the patentee from invoking infringement by equivalents, since it is a condition of form, relating to the substance of the inventive contribution and the literal content of the specification, which prevents the patentee from adding an element that could not be deduced directly and unambiguously from the patent.

This has no impact whatsoever on the scope of protection conferred. Conversely, with regard to the assessment of the scope of the patent, the aforementioned article 69 of the EPC requires that equivalents be considered. It follows from this that an addition of matter during the grant procedure does not preclude 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 folic acid) has a new function (i.e. the reduction of toxic effects without affecting therapeutic efficacy), unless the doctrine of equivalents is rendered ineffective. The consultations carried out by Professors Vivant and Raynard on behalf of the defendant companies not only address the concept of legal certainty, on the assumption that Eli Lilly has expressly renounced the "other salts" and therefore cannot reintroduce what it has excluded, but also the fact that this author has previously argued that the conditions of form are only of minor importance.
For the first, the claims are of "stewardship interest" and do not require "the same amount of development", and for the second, the patent applicant's voluntary choice of claim wording, which has no impact on the scope of the patent, are of no use in resolving the present dispute.

It follows 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 advocated 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 being of any importance. The scope of the patent therefore extends to all pharmaceutically acceptable forms of pemetrexed (salt or other), used in combination with the other two substances.

II - **Inadmissibility of claims**

The defendants argue that LILLY FRANCE's claims are inadmissible, since the plaintiff, who is presented as a mere "distributor" or "operator", is not the owner of the patent and is not the licensee of Eli LILLY, the owner of the patent, while the facts invoked as unfair competition are not distinct from those of infringement.
Kabi Groupe France is asking to be dismissed from the case, as none of the acts of infringement can be held against it, in view of its business activity as shown on its Kbis.

Lilly FRANCE states that it exploits the Alimta specialty in France, as can be seen from the entries in Vidal, and that it is suing the defendants whose actions have prevented it from distributing the patented specialty, thereby causing it its own damage, on the grounds of unfair competition, which is distinct from that of infringement, without there being any need to produce a licensing agreement, which in any event is a substantive issue and not an objection.

On that note,
— on the admissibility of Lilly FRANCE's claims

The plaintiff's claims are based on unfair competition, pursuant to article 1240 of the French Civil Code, and are not made in her capacity as licensee of the patent owner, so that the provisions of article L613-9 of the French Intellectual Property Code, which determine the admissibility of a licensee's action for infringement, do not apply.
The objection raised must therefore be rejected.

— Fresenius Kabi Group France's exclusion from liability

This company is involved in "*the acquisition of shareholdings in any form whatsoever in all companies and the management of all its shareholdings and all commercial, industrial, financial, movable or immovable property transactions directly or indirectly related thereto"*. The broad financial description of the defendant's activities, which is in any case indicative, does not rule out its indirect involvement in and benefit from the co-defendant's activities, given that although the British company FRESENIUS KABI ONCOLOGY Plc is the holder of a marketing authorization, issued by the European Medicines Agency, the generic drug designates Fresenius Kabi France as the marketing authorization holder in France, and Fresenius Kabi Groupe France is domiciled at the same address.
There is therefore no serious reason to disqualify Fresenius Kabi Group France.

III-on counterfeiting

Eli LILLY argues that the generic drug distributed by the defendants constitutes a direct infringement by reproduction of the product whose use is literally recommended in the EP 508 patent, since all the essential features of the invention are reproduced therein, regardless of the modification of form, material or arrangement, through the use of a distinct salt, indicating that the addition of a characteristic during the grant procedure (targeting pemetrexed disodium), for formal reasons and not to overcome a ground for invalidity of the patent, does not render it essential. In this case, the acid or disodium variant is secondary, and it is the combination of substances that constitutes the essential feature, as it is new and inventive.

The generic drug also constitutes a direct infringement by equivalence, since the combination of means provided for in the patent, which constitutes the essential means, is new, and the product distributed by the defendants, consisting of a combination of means of different structure, but fulfilling the same overall function with a view to achieving a similar result, is equivalent and therefore infringing. The same applies even if the disodium salt means were considered essential, and the doctrine of equivalents is not intended to be set aside when the means is used in a different form, provided that the patent covers the function and not just the form of the means, and that this function is not already known in the prior art.

According to the Lilly companies, infringement by literal and equivalent means is also constituted, as the conditions set out in Article L. 613-4 of the French Intellectual Property Code have been met.

The FRESENIUS companies reply that there is no literal direct infringement, as all foreign jurisdictions have ruled, because the allegedly infringing product is distinct from the claimed product, insofar as the essential element relating to the disodium salt is not reproduced and the claimed combination is neither new nor inventive. The patent specification in no way suggests that a person skilled in the art should use another salt, and even less so tromethamine diacid, which is rarely used for intravenous administration. Moreover, FRESENIUS has obtained a patent for this molecule in Europe and the United States, without being accused of a lack of inventive step. As regards direct infringement by equivalence, this is excluded and cannot be invoked by the patent holder, firstly because of the restrictive wording of the patent, and secondly, in the absence of the inclusion in the allegedly infringing product of the specific element linked to the shape of the active ingredient, which it designates as essential, as it was added during the grant procedure, for the sole purpose of obtaining the grant of the title. Finally, the combination in question, and therefore its function, is not patentable.

The conditions for infringement by supply of means, invoked in a manner totally contradictory to direct infringement, have not been met. It cannot be considered that after dissolution in the patient's body, only the pemetrexed anion would remain, when it 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, pointing out that the medical profession has a strict obligation to respect the AMM of the Fresenius drug, recommending dilution in glucose, so that the risk of substitution by sodium chloride is unlikely.

On that note,
— direct counterfeiting by reproduction or equivalent

Direct infringement presupposes the use 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 is admissible when the essential similarities are reproduced notwithstanding secondary differences.
In the present case, given the scope of the patent, and while the formal modification during the grant procedure does not confer any essential character on the modified element, as it was not a condition for the grant of the patent, as stated above, the essential means of the invention consists in the combined application of the active principle pemetrexed, in whatever form, with vitamin B12 or its other derivatives, and possibly with folic acid or its other derivatives.
Frésenius' generic drug is composed of the same active ingredient, pemetrexed, and its administration must be combined, as recommended in EP 508, with vitamin B12 and folic acid. It is therefore irrelevant that the allegedly infringing compound uses a diacid solution to enable administration, since this does not provide any particular technical effect.

A number of possible counter-ions, other than sodium, in free acid form or in the form of a number of well-known acceptable pharmaceutical salts. The absence of evidence invoked by the defendants for the use of this particular salt, classified in 10th position among frequently used salts, which is a criterion of validity of an invention and not of characterization of infringement, or the fact that Frésenius has obtained patents (EP 768 and US9,421,207) on this form of salt, are irrelevant.
The variant involving the use of a different salt is entirely secondary. Pemetrexed Fresenius Kabi is administered according to the intended use of the invention, and is designed to treat the same cancerous conditions, with the same technical effect. It has been authorized as a generic of the reference drug
Infringement by reproduction is characterized.

Once direct infringement by reproduction has been established, in view of the scope of the patent as determined, there is no need to consider infringement by equivalence.

— counterfeiting by supply of means

These claims become moot once direct infringement has been established.

IV- Invalidity of the patent

In the alternative, in the event of infringement being declared, FRESENIUS companies are seeking the invalidation of claims 1 and 2, and subsequently of dependent claims 3 to 14, of the patent, on the grounds of extension beyond the scope of the application, inadequate description and lack of inventive step.
They maintain that the documents in the prior art at the priority date and/or the general knowledge of the person skilled in the art enabled him to arrive at the invention with obviousness.
The defendants point out that the combination of pemetrexed and folic acid to remedy the toxicity of the antifolate is known (Patent US 5,217,974, Worzalla and Jackman - Lilly's exchanges with the European Medicines Agency (EMEA) for the marketing authorization application for AlimtaoR), without any prejudice to the use of folic acid. It was also documented that the toxicity of pemetrexed is correlated with high homocysteine levels, which could be reduced by vitamin B12 and folic acid, enabling the person skilled in the art to envisage the use of vitamin B12, which is harmless. The combination of these teachings clearly enabled the person skilled in the art to arrive at the solution recommended in the patent. On July 17, 2018, the German Federal Patent Court declared the patent invalid.

Eli Lilly concludes that the patent's invalidity claims should be dismissed for lack of inventive step, stating that there was no evidence at the priority date of a therapy combining pemetrexed with vitamin B12; that none of the documents cited, whose number alone is suspect, contain any reference to vitamin B12 and a combination with pemetrexed. On the contrary, there was a prejudice against the use of vitamin B12, which

would have an accelerating effect on tumor cell division, a prejudice that the patent overcame. The documents invoked were not combined, and some were not even consulted. The Jackman anthology is a collection of articles, of which two chapters concern an antifolate and only one relates to pemetrexed, the other referring to vitamin B12, and later Hammond studies did not advocate the use of folic acid (which would, on the contrary, diminish the efficacy of pemetrexed). The Niyikiza study, considered by the EPO, demonstrates that pemetrexed toxicity is not correlated with the marker of vitamin B12 deficiency. The Scott paper (antifolate cycle) is irrelevant. The alleged correlation between homocysteine levels and pemetrexed toxicity does not mean that homocysteine is the cause of toxicity, and that vitamin B12 is all that is needed to lower levels. The IBIS document refers to a different antifolate for the treatment of a different condition (rheumatoid arthritis). The Hammond paper, on the other hand, suggests that folic acid supplementation reduces the therapeutic efficacy of pemetrexed.
The Lilly companies add that the complaints of insufficient description and undue extension beyond the scope of the application have not been substantiated; that the patent does not extend its subject matter and is not speculative, since the scope of the patent does not cover all antifolates, but other variants of pemetrexed disodium; that the assessment and substantiation of infringement has no effect on the validity of the patent. The undue extension can only result from a modification introduced into the specification, and cannot result from the court's assessment of the scope of the title or of the MA (which combines both vitamin B12 supplementation and folic acid). The same applies to the sufficiency of the description. Furthermore, the trials mentioned in the patent also concern the combination of pemetrexed and vitamin B12 alone.

On that note,
The European patent is declared invalid by a court decision, for the reasons set out in article 138 § 1 of the EPC, including insufficient description (b/), extension beyond the application (c/) and if the invention is not patentable, and in particular lacks inventive step (a/ and article 56 of the same text).

<u>on extension beyond the application and insufficient description</u>

In the present case, the extension of the patent beyond the application is not characterized, since the patent was amended during the grant procedure to add matter, to conform to the patent description and claim "pemetrexed disodium", expressly referred to in the description, as a particular mode. The invention is also sufficiently described insofar as the teachings of the patent, described and documented by tests, including in relation to the combination referred to in claim 1 (pemetrexed and vitamin B12 alone), enable the invention to be implemented. In any case, these grievances cannot be characterized in the light of the interpretation mechanisms used by the court to determine the scope of the patent and to characterize infringement, by variants or equivalence.

— lack of inventive step

According to Article L. 611-14 of the French Intellectual Property Code, "an *invention is considered to involve an inventive step if, for a person skilled in the art, it does not clearly derive from the state of the art. If the state of the art includes documents mentioned in the third paragraph of article L.611-11, they are not taken into consideration when assessing inventive step."* In order to assess inventiveness, it is necessary to determine whether, having regard to the state of the art, a person skilled in the art, in view of the problem which the invention is intended to solve, and avoiding any a posteriori analysis, would have obtained the technical solution claimed by the patent by using his professional knowledge and carrying out simple operations. Inventive step is defined in terms of the specific problem faced by the person skilled in the art, and is assessed on the date of priority (in this case, 2000).

The problem to be solved is how to reduce the cytotoxicity of pemetrexed antifolate, without affecting therapeutic efficacy. The argument to the contrary put forward in 2004 by Eli Lilly to the European Medicines Agency, in order to obtain marketing authorization, is not relevant to assessing the inventiveness of the contested patent, apart from the fact that it does not form part of the state of the art, since it post-dates the claimed priority date, and has no connection with the inventive step.

The Jackman document (Frésenius exhibits n°97, 128, 132) from 1999, is a reference work consisting of a series of articles written by researchers in the field of folate biochemistry, of which chapter 8 (Frésenius exhibits n°97 and 132) concerns MTA LY231514 or pemetrexed, where it is stated that the combination of this "classic antifolate" with folic acid supplementation provides an excellent dose/antitumor response relationship and that "these data suggest that folate supplementation not only modulates toxicity, but also slightly improves the antitumor response of MTA". Reference is made to the 1997 Worzalla study on folic acid-supplemented mice. Chapter 12 deals with a separate antifolate (lometrexol), noting that folic acid supplementation normalizes the dose/response to tumor activity, and recommends the use of adequate amounts of vitamins B12 and B6, "which can greatly influence the severity of toxicity observed". The Adlei and Crips articles concern 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 aims of the invention.

However, apart from the fact that it is by no means certain that the person skilled in the art interested in pemetrexed would also have consulted the article devoted to another antifolate, having distinct mechanisms of action and not having an inhibitory effect on the same enzymes, and that it therefore does not appear that vitamin B12 supplementation in combination with pemetrexed was suggested, Subsequent studies (HAMMOND I and II) carried out on human subjects totally qualify these considerations, insofar as it appears that folic acid supplementation attenuates toxicity and even improves tumor response, but nevertheless requires the use of higher doses of pemetrexed, with the following effects

potential risks of other adverse effects (a significant number of patients have renal insufficiency).

Thus, as the defendants suggest, the Jackman document cannot be considered to be the most relevant prior art, since it compiles articles dating back to 1997, while later studies published before the priority date qualify these findings.

Furthermore, Professor Ann Jackman herself (Exhibit HL nos. 61 and 61 bis), states that the Worzalla study, involving mice, is not transposable to humans; that other articles contemporary with the priority reported concerns about the decreasing efficacy of antifolate co-administration with folic acid, and that the scientific community in 2000 was "reluctant to use folic acid in co-administration with antifolates in general, and pemetrexed was no exception". At that time, therefore, there was no serious incentive to combine folic acid administration with pemetrexed in humans.

As far as vitamin B12 supplementation is concerned, the Niyikiza document shows no link between methylmalonic acid (a specific marker of vitamin B12 deficiency) and pemetrexed toxicity, so that a person skilled in the art would have concluded that vitamin B12 was not involved in the toxicity observed. The other documents cited (patent EP 0595.005, Clarke, Brönstrup, Murray, Brattstrom, Ubbink: Fresenius exhibits no. 53, 76, 79, 104,129), relating to homocysteine levels in the body, unrelated to anti-cancer therapy and antifolates, are irrelevant.
The 1999 Scott document (Fresenius exhibits 98 and 116) describes the role played by folates and vitamin B12 in the biochemical process of human cell life, in DNA formation and in the transformation of homocysteine into methionine. It does not specifically concern the treatment of cancer, belongs to the field of nutritional research, and in no way teaches the use of vitamin B12 to reduce the toxicity of pemetrexed.

Furthermore, in 1999, the Vidal (HL part no. 50) issued a contraindication to the use of vitamin B12 for the treatment of malignant tumors, due to the action of this vitamin on the growth of tissues with a high cell multiplication rate. Patent WO 96/8515, dated September 13, 1995, suggested that total vitamin B12 deprivation (or depletion) could be useful in the treatment of cancer and other disorders characterized by uncontrolled cell growth (HL exhibits no. 56 and 56 bis). As suggested by the Lilly companies, there were therefore objectively motivated reasons not to use vitamin B12 in chemotherapy treatments.

This analysis is further confirmed by both Professor Bruce A. CHABNERle and by Professor Jackman, who concludes that "co-administration of vitamin B12 was not on the radar of the antifolate community in 2000", (HL exhibits no. 74 and 74 bis).

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

Thus, there is no reason to believe that a person skilled in the art, seeking to solve the specific problem of the patent, in its two branches, would have used any of the numerous documents cited, alone or in the combinations suggested, and would have arrived with obviousness at the solution recommended in the patent, it being emphasized that the invention comes after several decades of unsatisfactory scientific research, to meet a long-proven need and constitutes an undeniable technical advance.

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

V **- remedial measures**

The plaintiffs, seeking compensation for the damage caused by acts of counterfeiting and unfair competition, which have disrupted distribution in France due to the marketing of Fresenius Kabi's pemetrexed product, are seeking a ban on manufacturing, offering and marketing the counterfeit product, use the counterfeit drug, recall the products, confiscate and destroy them, require Fresenius Kabi to provide information to its customers, provide information within the framework of the right to information (manufacturers, quantities stocked, produced, imported, gross margin, names and addresses of customers, etc.), as well as measures to prevent counterfeiting....), as well as provisional damages of 10,000,000 euros and 30,000,000 euros respectively.

The FRESENIUS companies dispute the 40% royalty rate requested, which appears manifestly disproportionate. They contest the validity of Lilly France's claims, based on facts identical to those of the infringement, and in any event the resulting loss, which is unjustified as regards the loss of sales and the alleged erosion of AlimtaÖR's price. They conclude by rejecting the claims for additional compensation (product recall and advertising measures), and for the right to information, the data being public.

On this
The infringement of Eli Lilly Company's intellectual property rights generates, by the very fact of the infringement, a loss which the Fresenius companies are required to compensate.
Notwithstanding the absence of a licensing agreement, Lilly France, in its capacity as distributor of the products on French territory, has suffered economic and commercial damage of its own, distinct from that caused by the acts of infringement which it does not claim, as a result of the introduction on the market of the generic drug at issue, which has damaged its business and organization, the defendants' faults, although arising from the same facts, constitute distinct faults with regard to each of the plaintiffs and give rise to distinct losses on distinct grounds, which must be compensated.

The economic loss suffered by Eli Lilly, the patent holder, is assessed on the basis of the increased royalties it would have been able to expect if it had granted authorization to its adversaries. With regard to the number of 100 mg (20,742) and 500 mg (46,862) vials sold, as shown by publicly available data from the Groupement pour l'Elaboration et la Réalisation des Statistiques

(GERS) and the sales thus generated, and in application of a royalty rate increased by 25%, it appears justified to allocate, on a provisional basis, an indemnity of 8 million euros as compensation for its losses.

Compensation for the economic loss suffered by Lilly France as a result of the acts of unfair competition, limited to lost profits, taking into account the differences between the face price published in the Official Journal and the price actually paid after conventional and commercial discounts, and the erosion of the price of AlimtaOR, inexorable independently of any marketing of generics and only partially attributable to the defendants, will be provisionally set at the sum of 20 million euros.

The request for the right to information, as provided for in article L. 615-5-2 of the French Intellectual Property Code, which is broader than the data available through the aforementioned GERS, is well-founded and will be ordered within the limits set out in the operative part of this decision, and in particular from the date on which generic MA was obtained in July 2016 (and not from April 1er 2012 as stated), the parties will be required to exploit this information between themselves, if necessary within the framework of a confidentiality agreement, and to determine the damages between themselves, failing which they will be required to refer the matter back to the court for resolution.

Now that the court has ruled on the question of infringement, it is appropriate to grant the supplementary request for a ban for the future, in accordance with the terms set out in this decision, without however ordering the recall from the circuits of the products already with the wholesalers, as this measure appears disproportionate, given that the Lilly companies did not make the procedural choice of requesting a preliminary injunction and thus allowed the acts to continue for the duration of the proceedings.

Nor does the measure of communication to customers appear justified or proportionate, since the defendants will in any case have to explain to their customers the forthcoming disruption of all supplies as a result of the prohibition measure.

VI **- counterclaim by the Fresenius companies**

The Fresenius companies allege wrongful conduct on the part of the owner, resulting from the dissemination to third parties, unjustified by the fact that the third parties had been made aware, by letters dated January 31, 2017, of fragmentary and non-objective imputations of infringement facts against them, without mentioning decisions not yet overturned which were favorable to them, and claim that the plaintiffs should be jointly and severally ordered to pay the sum of 5 million euros.

The Lilly companies claim that this claim should be rejected.

On that note,
The disclosure by one company of information likely to discredit another, and in particular the disclosure of the existence of legal proceedings, constitutes an act of disparagement, unless the information in question relates to a subject of general interest and has a sufficient factual basis, and provided that it is expressed with a

certain degree of restraint.

In this case, on January 31, 2017 (Frésénius exhibit no. 40), Lilly France sent a letter to two companies, but which federate numerous healthcare establishments, informing them of the property rights it held until 2021, indicating that it considered its patent valid and that it would act accordingly to defend its rights, if a laboratory planned to market a generic of Alimta in France, and that various procedures were already underway in Europe.

In addition to being general, measured and objective, the comments do not refer to any company by name, particularly Frésenius. The wrongful disclosure of information to the prejudice of the defendants is therefore not characterized and the claims in this respect will be rejected.

VII - on other requests

The Fresenius companies, who are unsuccessful, shall bear their own costs and pay those incurred b y Stanislas Roux-Vaillard, lawyer.
Pursuant to the provisions of Article 700 of the French Code of Civil Procedure, the party required to pay the costs, or failing this, the losing party, is ordered to pay a sum in respect of costs incurred and not included in the costs, taking into account the fairness or economic situation of the party ordered to pay.
The Fresenius companies will be ordered to pay the Lilly companies the sum of 350,000 euros in irreducible costs.

The circumstances of the case justify provisional execution, which appears necessary and compatible with the nature of the case.

THEREFORE

The Court, ruling publicly, by contradictory judgment, made available at the clerk's office and at first instance,

Declares that Lilly France is entitled to bring an action for unfair competition,

Rejects Fresenius Kabi Groupe France's request for exclusion from liability,

Dismisses the Fresenius companies' claims for invalidity on the grounds of insufficient description, extension beyond the scope of the application and lack of inventive step, of the claims of the French part of patent EP 1 313 508, held by Eli Lilly,

Declares that Fresenius Kabi France and Fresenius Kabi Groupe France have committed acts of infringement by reproducing the entirety of the claims of the French part of European patent EP 1 313 508, by manufacturing, offering, placing on the market, using, importing, exporting, transhipping, or holding for the aforementioned purposes, Pemetrexed Fresenius Kabi,

Prohibits Fresenius Kabi France and Fresenius Kabi Groupe France, directly or indirectly, from manufacturing, offering, putting on the market, using, importing, exporting, transshipping or holding for the aforementioned purposes, supplying, delivering or offering to supply, on French territory, to a person other than those authorized to exploit the invention, Pemetrexed Fresenius Kabi, or any other product enabling the claims of European patent EP 1 313 508 to be reproduced, within 15 days of notification of this decision, subject to a fine of 700 euros per vial,

Rejects the request for recall and destruction of stocks in France of Pemetrexed Fresenius Kabi in commercial channels,

Orders Fresenius Kabi France and Fresenius Kabi Groupe France jointly and severally to pay Eli Lilly the provisional sum of 8,000,000 euros in damages for the infringement of the French part of European patent EP 1 313 508, as compensation for its loss,

Orders the parties jointly and severally to pay Lilly France, in its capacity as operator of the AlimtaoRen France speciality, the provisional sum of 20,000,000 euros in damages, to be applied against compensation for its loss resulting from the acts of unfair competition,

Orders Fresenius Kabi France and Fresenius Kabi Groupe France to inform Eli Lilly and Lilly France, if necessary within the framework of a confidentiality circle to be set up between them, under a fine of 500 euros per day of delay, after a period of two months from the date of service of the judgment to be handed down.

-the names and addresses of manufacturers, wholesalers, importers, exporters, transshippers and other holders of these products,
-quantities stored, produced, imported, exported, transshipped, marketed, delivered, received or ordered, along with delivery dates and prices,

-the relevant product brands and all product identifiers such as product designation, item name and serial number,

-the gross margin on the sale of Pemetrexed Fresenius Kabi and any other preparation that reproduces the claims of patent EP 1 313 508

-the names and addresses of customers of Fresenius Kabi France and Fresenius Kabi groupe France, from July 22, 2016 to the date of delivery of this judgment,

The parties agree to assess the final loss suffered by the plaintiff companies on an amicable basis. Failing agreement, the most diligent party will refer the dispute to the court for a decision,

Declares that there are no grounds for disclosure to customers of Fresenius Kabi France and Fresenius Kabi Groupe France,

Declares that the court reserves jurisdiction over the liquidation of the penalty payments,

Dismisses the counterclaims of Fresenius Kabi France and Fresenius Kabi Groupe France,

Orders provisional execution,

Order Fresenius Kabi France and Fresenius Kabi Groupe France jointly and severally to pay Eli Lilly and Lilly France the total sum of 350,000 euros under article 700 of the French Code of Civil Procedure,

Order Fresenius Kabi France and Fresenius Kabi Groupe France to pay the costs,

Authorizes Maître Stanislas Roux-Vaillard, attorney-at-law, to recover directly from the defendants any costs he has advanced without having received a provision, pursuant to article 699 of the French Code of Civil Procedure.

Done and judged in Paris on September 11, 2020

The ClerkThe Chairman