T R I B U N A L D E GRANDE I N S T A N C E D E P A R I S

J U G E M E N T
due September 11, 2019

N° RG 19/56082 - N ° P o r t a l i s 352J-W-B7D-CQ CVO

NO.: 1/FF

Court date: June 20, 2019

in summary proceedings (article 487 of the Code of Civil Procedure) before the Tribunal de Grande Instance de PARIS, composed of :

Florence BUTIN, Vice-Chairwoman
Nathalie SABOTIER, First Deputy Vice-President
Gilles BUFFET, Vice-Chairman

Assisted by **Fabienne FELIX**, acting as clerk,

in the matter of :

BAYER INTELLECTUAL PROPERTY GMBH
Alfred Nobel Strasse 10
40789 MONHEIM-AM-RHEIN (GERMANY)

BAYER ANIMAL HEALTH GMBH
Kaiser-Wilhelm-Allee 20
51373 LEVERKUSEN (GERMANY)

represented by Laetitia BENARD, lawyer at the PARIS bar - #J0022

à :

S.A. CEVA SANTE ANIMALE
10 avenue de la Ballastière
33500 LIBOURNE

represented by Maître Benoît STROWEL and Maître Amandine METIER, members of the PARIS Bar - #P512

DEBATES

At the hearing of10 July 2019 chaired by **FlorenceBUTIN**, Vice-President, held in public

THE COURT

THE DISPUTE

The German pharmaceutical and chemical group BAYER is active in the research and development of pharmaceuticals, consumer health products, crop protection products and animal health products. It claims to be the world leader in this sector, with a presence on all 5 continents.

BAYER INTELLECTUAL PROPERTY GMBH, which is responsible for protecting the intellectual property rights of the BAYER Group, is the owner of European patent EP 2164496 - hereinafter EP'496 - entitled *"Formulations containing triazinones and iron",* the application for which was filed on May 21, 2008 under priority of German patent application no. 102007025908 of June 1, 2007. The EP 496 patent was granted on April 12, 2017, and has been maintained in force by the regular payment of annuities.

Patent EP 496 concerns formulations containing triazinone compounds - such as toltrazuril - and iron compounds such as iron (III) dextran, for the treatment of coccidiosis and iron deficiency states in farm animals, especially piglets.

On January 11, 2018, CEVA SANTE ANIMALE (hereinafter CEVA) filed an opposition against patent EP 496 on the grounds that the subject matter of claims 1 to 17 would extend beyond the contents of the application as filed, that the invention would not be set out clearly and completely enough for a person skilled in the art to be able to carry it out and, finally, that the patent would lack inventive step. The preliminary opinion of the Opposition Division is dated October 4, 2018.
By decision dated May 16, 2019, the opposition was rejected after oral proceedings and the patent maintained in its version as granted. CEVA has appealed against this decision, which it considers unfounded.

BAYER ANIMAL HEALTH GMBH (hereinafter BAYER AH), which has held a license to exploit patent EP 496 since June 18, 2019, has filed a marketing authorization application for a veterinary product named BAYCOX IRON®, consisting of a combination of toltrazuril and an iron (III) dextran complex as active substances, and on March 21, 2019, the Comité pour les spécialités pharmaceutiques à usage vétérinaire issued a positive opinion recommending the granting of marketing authorization for the veterinary speciality BAYCOX IRON 36 mg/ml + 182 mg/ml injectable suspension.
On May 20, 2019, this authorization was granted for the territory of the European Union, and the product began to be marketed in France on June 13, 2019.

The French CEVA SANTE ANIMALE group, represented in France by CEVA ANIMALE SA, is a major player in this field and the leading veterinary laboratory in France, now ranked 6th worldwide. It is present in 42 countries, with 13 research and development centers, 21 production sites and more than
3,000 employees worldwide. Its activities focus on research, development, manufacturing, marketing and sales of pharmaceutical products and vaccines for companion animals, poultry, ruminants and swine.

CEVA has developed an injectable formulation - aqueous suspension
- having as active ingredients a combination of toltrazuril and iron (III) dextran, used in a pharmaceutical preparation indicated for the treatment of coccidiosis and anemia in piglets.

On November 10, 2017, CEVA sent BAYER IP a letter stating, under the terms of Article L. 615-9 of the French Intellectual Property Code, of its intention to market *"an injectable veterinary formulation containing a combination of toltrazuril and iron (III)-dextran complex derivatives as active ingredients (...) used for the preparation of a pharmaceutical product to be authorized for the treatment of coccidiosis and anemia in piglets"*, under the FORCERIS ® brand name, specifying that once launched, these production activities would be carried out on French territory and would be preparatory to the product's forthcoming marketing in several European countries and the rest of the world. The company stated that it considered the above-mentioned activities to be outside BAYER's monopoly, as the scope of protection conferred by patent EP 496 was clearly limited to oral formulations and their use for the oral treatment of coccidial infections and iron deficiency, and therefore did not preclude the production and marketing of an injectable formulation.

On December 18, 2017, BAYER IP replied that this letter did not seem to meet the conditions set out in the aforementioned Article L. 615-9, so that the starting point for any action for a declaration of non-infringement would not have begun to run, and that it did not agree with CEVA's interpretation of the claims, the wording of which, as described, reproduced claim 11 of the EP 496 patent.

In a deed dated December 26, 2017, BAYER IP served an interlocutory injunction on CEVA SANTE ANIMALE, seeking an injunction under fine *"to manufacture, hold, import, offer for sale and sell on national territory, pharmaceutical preparations consisting of a combination of toltrazuril and an iron(III)-dextran complex, in particular for the treatment of anemia and coccidiosis in piglets, and any other pharmaceutical formulation falling within claims 1, 11 and 13 of European patent EP no. 2,164,496"*.

These requests were rejected by an order issued on April 5, 2018, on the grounds that the imminent marketing of the disputed product had not been established by the aforementioned letter of November 10, 2017 alone, and that in the event of subsequent therapeutic application of a substance or composition, the results mentioned in a patent serve to assess the technical contribution of the latter and therefore its validity, but also, as a necessary prerequisite for determining its scope, in the case in point, all the examples are devoted to the oral preparation of the combination of triazinones of formula (II) or (III) and polysaccharide iron (III) polynuclear complex compounds for administration to piglets, and *"the only problem to be solved in the patent is the preparation of this juxtaposition of two already known active principles for treatment in oral form, so that the feature omitted in claim 1 will pose a problem with regard to the validity of the EP 496 patent"*.

By bailiff's deed dated January 31, 2018, CEVA SANTE ANIMALE simultaneously served a writ on BAYER IP for a declaration of non-infringement, seeking a ruling that the planned manufacturing and marketing activities did not fall within the scope of protection conferred by patent EP 496. This procedure is registered under no. RG18/1633. In its pleadings no. 1, served on October 29, 2018, the company opposed the inadmissibility of the action and, in the alternative, asked the court to rule that CEVA's veterinary compositions at least reproduce claims 1, 8, 9, 10, 11, 13 and 14 of European patent no. 2,164,496, without at this stage making any claim for damages or compensation.

Following the opinion of the Comité pour les spécialités pharmaceutiques à usage vétérinaire issued on February 21, 2019 concerning the veterinary product FORCERIS 30 mg/ml + 133 mg/ml injectable suspension for piglets, a centralized marketing authorization has been issued for the product "FORCERIS - TOLTRAZURIL / GLEPTOFERRON".

On May 16, 2019, BAYER IP's Dutch counsel sent a letter of formal notice to CEVA instructing it to refrain from launching, advertising for sale, offering and delivering the FORCERIS® product in Europe and/or the Netherlands, a country in which preliminary injunction proceedings have been initiated by the BAYER companies.
A hearing was scheduled for August 27, 2019 before the LA HAYE court.

Similar proceedings have also been initiated by the BAYER Group in Italy and Denmark.

CEVA SANTE ANIMALE has indicated its decision to temporarily suspend the marketing of the veterinary product FORCERIS® first in the Netherlands - in an e-mail dated May 19, 2019 - and then in Germany, In a letter dated June 4, 2019, CEVA SANTE ANIMALE undertook to refrain from marketing *"medicinal products based on a formulation containing toltrazuril and iron (III) in the form of Gleptoferron as active ingredients",* subject to the possibility of terminating this obligation at any time without cause by giving BAYER two months' notice.

In France, BAYER IP was authorized to carry out an infringement seizure on the premises of CEVA in Libourne (33), in accordance with two orders issued on May 17, 2019 by the president of the panel hearing the case on the merits. These operations took place on May 20, 2019, and on the same day, the seizing party was authorized by the president of the 3rd chamber, 3rd section, which issued the order, to summon BAYER IP for the purpose of obtaining measures to preserve the confidentiality of certain items.

On May 21, 2019, CEVA served an interlocutory injunction on BAYER IP, asking the court to rule that the information protected as a business secret should be placed in escrow pending a decision on the merits of the case concerning the infringement of patent EP 496, and to order the seizing party not to make use, either in France or abroad, of the seizure-infringement report if the list of export countries it contained was not redacted, in France and abroad, if the list of export countries contained in the report was not redacted, and in the alternative, appoint an expert to examine the information under seal and determine which of it could be disclosed. These requests were partially granted by an order issued on June 7, 2019, the bailiff being authorized to open the seals (with the exception of the seal constituting appendix 5 of the minutes, relating to commercial documents internal to the CEVA company) without organizing a sorting expert appraisal.

Against this backdrop, by writ of summons issued to CEVA SANTE ANIMALE on June 20, 2019, the terms of which were repeated and orally supplemented at the hearing on July 10, 2019, BAYER INTELLECTUAL PROPERTY GMBH and BAYER ANIMAL HEALTH
request the court to :

Having regard to articles 485, 488 and 493 of the Code of
Civil Procedure, Having regard to article 138 of the
European Patent Convention;
Having regard to articles L. 613-3, L. 615-1, L. 615-7 and L. 615-5-2 of the French Intellectual Property Code ;
Having regard to European patent no.
2,164,496; Having regard to the order
of April 5, 2018 ;

ORDER AND JUDGE that CEVA SANTE ANIMALE has infringed or is about to infringe European patent no. 2164 496 by manufacturing, exporting, offering, marketing, using and possessing the FORCERIS® product for the aforementioned purposes;

PROHIBIT CEVA SANTE ANIMALE, until May 21, 2028 inclusive, from manufacturing, importing, exporting, transshipping, offering for sale, placing on the market, using and holding for the aforementioned purposes, pharmaceutical compositions reproducing European patent no. 2,164,496, subject to a fine of 1,000 euros per package manufactured, imported, exported, transshipped, offered for sale, marketed, used or held, whatever its form of packaging, from the date of service of the order to be issued;

ORDER the company CEVA SANTE ANIMALE to recall and/or withdraw from the distribution networks any veterinary composition manufactured, imported, exported, transshipped, offered for sale, marketed, used and held for the aforementioned purposes, reproducing European patent no. 2 164496, under a penalty of 500 euros per package not recalled or not withdrawn from the distribution networks, starting 48 hours after the date of notification of the decision to intervene;

CONDEMN CEVA SANTE ANIMALE to pay BAYER INTELLECTUAL PROPERTY GMBH provisional damages in the amount of 986,950.36 euros, as compensation for the infringement committed until the end of May 2019, unless otherwise perfected;

CONDEMN CEVA SANTE ANIMALE to pay BAYER ANIMAL HEALTH GMBH provisional damages in the amount of 1,982,928.98 euros, as compensation for the infringement committed until the end of May 2019, unless the amount is to be perfected;

AUTHORIZE BAYER INTELLECTUAL PROPERTY GMBH and
BAYER ANIMAL HEALTH GMBH to request that any veterinary composition reproducing European patent no. 2 164 496 be handed over to any bailiff of their choice, at the sole expense of CEVA SANTE ANIMALE, in order to prevent their introduction into commercial circuits and the continuation of acts of infringement and consequently to :
- authorize BAYER INTELLECTUAL PROPERTY GMBH and BAYER ANIMAL HEALTH GMBH to have any bailiff of their choice carry out the actual seizure of any veterinary composition reproducing European patent no. 2,164,496 on the premises of CEVA SANTE ANIMALE and at any other location where operations reveal the presence of infringing products, so that these products can be kept under the bailiff's supervision in any appropriate storage location;

- authorize the bailiff to be assisted by a police officer or any representative of the police force, who may proceed even outside his district, and by any expert of the choice of BAYER INTELLECTUAL PROPERTY GMBH or BAYER ANIMAL.
HEALTH GMBH, other than the plaintiff's subordinates;
- authorize the bailiff to be assisted by a locksmith, a computer specialist or any other person in his office;
- authorize the bailiff to continue, if necessary, his operations beyond the end of the first day; in this case, authorize the bailiff to affix seals to the relevant products and, in general, to affix any seals or other means with the aim of preserving, safeguarding and conserving any veterinary composition reproducing European patent EP 2 164 496 to be seized in the premises of the seizure;
- authorize the bailiff to be assisted by a handler, packer and driver for transporting the seized products and authorize the bailiff to bring any means of transport to the seizure site.

ORDER CEVA SANTE ANIMALE, under fine, to
10.000 euros per day of delay after a period of eight days from the date of notification of the decision to intervene, to communicate all documents or information held by CEVA SANTE ANIMALE in order to determine the origin and distribution networks of the veterinary compositions reproducing European patent no. 2164496, and in particular (i) the names and addresses of manufacturers, wholesalers, importers and other previous holders of these products, (ii) the quantities produced, imported, marketed, delivered, received or ordered, and (iii) the price and other benefits obtained for these infringing products;

ORDER CEVA SANTE ANIMALE to communicate to BAYER INTELLECTUAL PROPERTY GMBH and BAYER ANIMAL HEALTH GMBH, in writing and in an appropriate form (divided into quarters of the calendar year), the accounting documents, certified by an auditor, indicating the extent of the aforementioned acts of infringement committed by CEVA SANTE ANIMALE under a penalty of
10,000 euros per day of delay after a period of eight days from the date of notification of the decision to intervene;

ORDER the publication of the entire decision, at the exclusive expense of CEVA SANTE ANIMALE, in the form of a PDF document reproducing the entire decision and accessible via an apparent hypertext link located on the home page of CEVA SANTE ANIMALE's website, regardless of the address from which the website is accessed, the title of the link being, in the appropriate language:
"The President of the Tribunal de Grande Instance de PARIS has ordered a provisional injunction prohibiting CEVA from marketing in France veterinary products for the simultaneous treatment of anemia and coccidiosis in piglets, in infringement of the rights of Bayer Intellectual Property GmbH, and ordering the latter to pay the provisional sum of €[to be completed] in compensation for the corresponding damages".
in a font size of at least 20 (twenty), for a period of 6 (six) months, within eight days of notification of the decision to intervene and subject to a penalty of 5,000 euros per day of delay;

DECLARE that the Chairman will be competent to rule, if necessary, on the liquidation of penalty payments;

CONDEMN the company CEVA SANTE ANIMALE to pay to the company BAYER INTELLECTUAL PROPERTY GMBH and the company BAYER
ANIMAL HEALTH GmbH. the sum of 200,000 euros pursuant to article 700 of the French Code of Civil Procedure, with the exception of the amount to be paid in full;

ORDER the company CEVA SANTE ANIMALE to pay all costs and expenses, which may be recovered directly by Laetitia BENARD, attorney-at-law, in accordance with article 699 of the French Code of Civil Procedure.

By submissions filed and orally developed at the hearing on July 10, 2019, CEVA SANTE ANIMALE asks the interim relief judge to:

Having regard to article 771 of the Code of Civil Procedure,

DECLARE that it does not have jurisdiction and invite the BAYER Group companies to appeal to the juge de la mise en état hearing the dispute on the merits (3rd Chamber, 3rd Section, RG 18/1633);

Having regard to articles 122 and 488 of the French Code of Civil Procedure, article 1355 of the French Civil Code, and articles L615-2 and L. 615-3 of the French Intellectual Property Code, if the president of the court considers himself competent :

DECLARE BAYER IP GmbH's claims inadmissible due to the res judicata effect of the order issued on April 5, 2018;

DECLARE BAYER ANIMAL HEALTH, a non-exclusive licensee, inadmissible to bring an action for interim injunction;

In the alternative, **REJECT** all the claims of BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH;

ORDER BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH, *jointly and severally,* to pay the sum of
200,000 to CEVA SANTE ANIMALE ;

ORDER BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH *jointly and severally* to pay all costs and expenses, which will be recovered in accordance with article 699 of the French Code of Civil Procedure.

At the hearing, BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH added that in view of the new circumstances that had arisen since this decision, they were requesting that the summary order issued on April 5, 2018 be set aside and that the provisional measures requested be granted.

The case was argued on July 10, 2019 and adjourned to September 11, 2019.

By e-mail dated July 24, 2019, BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH have, without further ado
having been previously authorized, communicated to the summary jurisdiction, on the one hand, the reasoned decision of the EPO Opposition Division dated July 16, 2019 and its translation into French and, on the other hand, an order issued *ex parte* by the Patent Section of the Barcelona Commercial Court on July 17, 2019, ordering CEVA SANTE ANIMALE SA and CEVA SALUD ANIMAL to refrain from manufacturing, offering,

marketing, using or importing the drug FORCERIS suspension for injection, subject to the payment of a bond payable by the plaintiff.

As these two decisions were communicated in conditions that enabled the defendant to submit any observations it considered useful, which it did in an e-mail sent to the summary jurisdiction on July 25, 2019, there is no reason to exclude them from the proceedings, the reopening of which nevertheless did not appear necessary insofar as they are not based on new facts or arguments that would not have been debated in the context of the present proceedings.

REASONS FOR THE ORDER :

1- Jurisdiction of the interim relief judge and admissibility of claims:

CEVA maintains that, in application of article 771 of the French Code of Civil Procedure, the juge de la mise en état hearing the action on the merits pending before the 3rd section of the 3rd chamber - RG 18/1633, in which the question of CEVA's implementation of the claims of patent EP 496 is raised - has sole jurisdiction to hear the request for a preliminary injunction. It considers that the BAYER companies acted out of pure procedural opportunism, in order to avoid a more distant hearing date and to reserve the possibility of appealing against the decision to be taken, which is all the more obvious given that a previous request for injunction based on the same title had previously been rejected.

The defendant then argues that the res judicata effect of the summary proceedings order of April 5, 2018 precludes the admissibility of BAYER IP's claims under article 1355 of the French Civil Code, in view of the identity of the parties - in the case of BAYER IP - of the subject matter and finally of the cause of action, insofar as the grounds for the action are also the same. She recalls the provisions of article 488 paragraph 2 of the French Code of Civil Procedure, under which a summary judgment having the force of res judicata may only be modified or set aside in the event of new circumstances for which no justification is given.

Lastly, it considers that the action brought by BAYER AH is identically inadmissible under article L. 615-2 of the French Intellectual Property Code, since the latter is a non-exclusive licensee of the rights to European patent no. 2164496 under a contract governed by French law and dated June 18, 2019.

In response to these arguments on jurisdiction, the BAYER companies point out that no pre-trial judge has yet been seized of the infringement action, for which the writ of summons has not yet been served, that they have not filed a counterclaim in the action for a declaration of non-infringement, for which there are no specific facts alleged and discussed, and that, pursuant to article 812 of the French Code of Civil Procedure, motions relating to ongoing proceedings are submitted to the president of the chamber to which the case has been assigned.
It adds that jurisprudence accepts that in the event of an action for nullity of a title, the pre-trial judge is not competent to order measures based on the infringement of the rights it confers, provided that no counterclaim for infringement has been lodged.

On admissibility, the plaintiffs point out that the summary order of April 5, 2018 refusing to issue the requested injunctive relief is based solely on the absence of proven imminent infringement, and that the absence of likelihood of the alleged infringement is raised only *"as a matter of superfluity"*, in view of the scope of the patent and the consequences this could have on its validity.

On that note,

1°- competence :

Article 771 of the French Code of Civil Procedure stipulates that when the claim is lodged after the judge has been appointed, the pre-trial judge has sole jurisdiction, to the exclusion of any other court formation, to :
1. Ruling on procedural objections, requests made pursuant to article 47 and incidents terminating the proceedings;
2. Allocate a provision for the trial ;
3. To grant an advance to the creditor when the existence of the obligation is not seriously disputable;
4. Order all other provisional measures, including conservatory measures, with the exception of provisional seizures, mortgages and pledges, as well as modify or supplement, in the event of new facts, measures that have already been ordered;
5. Order, even ex officio, any investigative measure.

There is no dispute as to the principle that the pre-trial judge of the panel hearing an action on the merits is empowered to hear applications for interim measures relating thereto, notwithstanding the existence of the procedure provided for in article L. 615-3 of the French Intellectual Property Code.

The declaratory action for a declaration of non-infringement provided for in Article L.615-9 of the French Intellectual Property Code enables an economic operator to bring an action before a court to determine whether or not the industrial operation he is planning falls within the scope of the title identified as likely to impede it. Under this procedure, the patentee can bring a counterclaim for infringement - which has a sufficient link with the initial claims - provided that the activity in question is not limited to mere preparations.

In this context, however, BAYER IP cannot be reproached for having sought authorization to carry out infringement seizures from the president of the panel hearing the action for a declaration of non-infringement, as required by article 812 paragraph 3 of the French Code of Civil Procedure, which refers generally to *"requests relating to pending proceedings"*, nor for having initiated an infringement action by way of a separate writ of summons within the time limit prescribed by article R.615-3 of the French Intellectual Property Code. of the French Intellectual Property Code.

Lastly, the fact that this new proceeding could not be joined to the first, due to the lack of placement of the document issued, is the result of a procedural strategy which, however opportunistic, should not be sanctioned, as it does not constitute a flagrant breach of the principles of fairness governing civil proceedings.

The objection of lack of jurisdiction raised by CEVA cannot therefore be accepted.

2°- admissibility of applications :

Article 1355 of the French Civil Code states that *"res judicata applies only to that which is the subject of the judgment.*
The thing claimed must be the same; the claim must be based on the same cause; the claim must be between the same parties, and made by and against them in the same capacity".

And according to article 488 paragraph 2 of the Code of Civil Procedure*, "a summary order does not have the authority of res judicata in the main proceedings.*
It can only be modified or withdrawn in summary proceedings in the event of new circumstances".
Finally, under the terms of Articles L.615-2 of the French Intellectual Property Code, infringement proceedings are brought by the patent owner. Unless otherwise stipulated in the license agreement, the beneficiary of an exclusive right of exploitation may bring an action for infringement if, after formal notice, the patent owner fails to do so.

The defendant rightly invokes the identity of parties, cause of action and object of the present action for interim injunction, which is moreover accepted by the BAYER companies, who orally supplemented their claims by requesting that the order previously issued be set aside.

The requests for prohibition and subsequent measures, which are admissible in the presence of new elements constituted by the start of marketing of the litigious products and the maintenance by the EPO Opposition Division of the patent as granted, will therefore be examined on the basis of article 488 of the Code of Civil Procedure.

BAYER AH, which has been found not to benefit from an exclusive license and, above all, was not a party to the summary proceedings initially brought, will be declared inadmissible.

3- <u>merits of the requests for prohibition and other interim measures</u> :

BAYER points out that CEVA has launched a major advertising campaign and disclosed the future packaging of its product, the imminent marketing of which has been confirmed by numerous third-party publications in the European trade press. Given the outcome of the oral proceedings before the EPO, the company has decided not to organize a promotional information event in the Netherlands on May 21, 2019.
It points out that the difference between the solution according to the patent and the closest prior art lies in the fact that, on the one hand, the administration of the iron complexes is directly linked to that of the triazinone, and on the other, that the two compounds are combined in a single formulation.
It points to the absence in the patent of any explicit or implicit mention that methods of administration other than oral would be outside the scope of the invention or unsuitable for the formulation of the claimed veterinary compositions, and that the scope of the title is inaccurately limited by the defendant to examples or preferred embodiments.

It argues that a claim whose meaning and scope are clear cannot be interpreted as including a limiting feature allegedly deriving from the content of the description.

On the validity of the patent, it is essentially argued that :
-the subject matter of claim 1 does not extend beyond the contents of the application as filed, since the corresponding embodiments were originally described as alternatives in said claim;
-the plausibility criterion associated with analysis of sufficiency of description only applies to claims for new therapeutic applications, whereas the present case concerns a product claim;
-The EP 496 patent provides the information needed to reproduce the claimed formulations;

-assuming that the plausibility criterion referred to by CEVA is applicable, it would be concluded in this case that the content of patent EP 496 makes it plausible that the claimed formulations are simultaneously effective in treating coccidiosis and anaemia in animals;
-The EP 496 patent is based on an inventive step in that, although triazinone derivatives such as toltrazuril and the complex iron(III) compounds claimed had been known for more than 17 years prior to the priority date of the EP 496 patent, no one had ever considered combining these two compounds into a single formulation, and such a combination is in no way suggested by the prior art documents cited by CEVA, which, on the contrary, discouraged the person skilled in the art from developing a formulation comprising both triazinones and iron compounds, since it was generally accepted that such a combined formulation would not meet the mode of administration adapted to each of these two active substances.

Lastly, BAYER considers that EP 496 is clearly infringed by the formula used in CEVA's FORCERIS® veterinary medicine, in that toltruzaril is a triazinone - and more specifically a triazinetrione - which is covered by claim 1, and gleptoferron is a polynuclear iron(III)-polysaccharide complex compound, which is also covered by claim 1, gleptoferron is a polynuclear iron(III)-polysaccharide complex compound, which is also covered by claim 1, it being noted that CEVA itself admits this, acknowledging that the only difference between its composition and that of claim 1 is its injectable nature.

The CEVA company concludes that the requests for interim measures should be rejected on the two grounds that :

1°- the validity of the patent is not established, in that the administration of the two substances toltrazuril and iron complex, although separate, was part of the routine protocol in force before the priority date of European patent no. 2,164,496, implemented at the birth of piglets, and the BAYER company cited an alleged problem justifying combining them in a single formulation, when in fact the aim was to overcome disadvantages linked not to the formulations used but to the product's mode of administration. The administration of toltrazuril and iron as opposed to iron alone was already known in the prior art, and the tests carried out showed no additional beneficial effect of the formulation combining the two active ingredients. The invention covered by EP 496 is therefore no more than the juxtaposition of known means, without any additional - synergistic - effect to those already identified, and if the scope of the patent covers formulations administered other than orally, then the invention is insufficiently described.

2°the reproduction of claims no. 1, 8, 9, 10, 11, 13 and 14 of European patent no. 2,164,496 is not plausible, since the entire description of the patent tends to demonstrate that the formulation sought is an oral formulation, to which all the examples refer, and which was constantly mentioned by the patentee to justify the contribution of the invention in the context of the grant procedure not only before the EPO but also before the Canadian and Indian offices, whereas FORCERIS ® is intended for parenteral administration, the numerous disadvantages of which are highlighted by the patent in question. CEVA adds that the monopoly attached to a patent can only reflect the technical contribution it claims to make.

Lastly, and in the alternative, the CEVA company contests the method of calculation on which the provisional claims for compensation are based.

On that note,

Article L. 615-3 of the French Intellectual Property Code stipulates that any person entitled to bring an action for infringement may apply to the competent civil court for an interim injunction to order, if necessary under penalty, against the alleged infringer or the intermediaries whose services he uses, any measure intended to prevent imminent infringement of the rights conferred by the title, or to prevent the continuation of allegedly infringing acts. The competent civil court may also order any urgent measures on request when circumstances require that such measures not be taken adversarially, in particular when any delay would be likely to cause irreparable harm to the plaintiff. Whether seized in summary proceedings or on petition, the court may only order the measures requested if the evidence, reasonably accessible to the plaintiff, makes it likely that his rights are being infringed or that such infringement is imminent.
The court may prohibit the continuation of the allegedly infringing acts, make them subject to the lodging of guarantees intended to ensure the claimant's possible compensation, or order the seizure or delivery into the hands of a third party of products suspected of infringing the rights conferred by the title, to prevent their introduction or circulation in commercial channels. If the claimant demonstrates circumstances likely to jeopardize the recovery of damages, the court may order the seizure of the alleged infringer's movable and immovable property, including the freezing of bank accounts and other assets, in accordance with common law. In order to determine which assets may be subject to seizure, it may order the communication of banking, financial, accounting or commercial documents, or access to relevant information.
It may also award the claimant an advance when the existence of his or her loss is not seriously disputable.

In summary proceedings or on application, the court may make enforcement of the measures it orders subject to the plaintiff's lodging of guarantees intended to ensure possible compensation of the defendant if the infringement action is subsequently found to be unfounded or the measures annulled.
When the measures taken to put an end to an infringement of rights are ordered before any action is taken on the merits, the plaintiff must, within a time limit set by regulation, either take civil or criminal action, or lodge a complaint with the public prosecutor. Failing this, at the request of the defendant and without the latter having to state the reasons for its claim, the measures ordered are cancelled, without prejudice to any damages that may be claimed.
The interim relief judge hearing such applications must assess the seriousness of the arguments put forward in defense, which are likely to concern the materiality of the infringement and the validity of the patent, and evaluate the proportion that exists between the contestation of the alleged infringement and the provisional measures requested, with regard to the risks incurred by each of the parties.

A challenge to the title itself should only be examined if there is, on the one hand, a proven imminent infringement and, on the other hand, a probable infringement.

1°- On the imminent infringement or the existence of allegedly infringing acts :

In a press release dated April 25, 2019 (BAYER Exhibit 22), CEVA announced the launch of FORCERIS *"the first authorized injectable combination of gleptoferron and toltrazuril in Europe"*.

The BAYER companies have also submitted an extract from the database of the Association Interprofessionnelle d'Étude du Médicament Vétérinaire, showing that 520 units (vials) of FORCERIS suspension injectable 100 ml and 810 units of 250 ml were sold in May 2019 (BAYER Exhibit 60).

CEVA does not dispute the fact that it has begun marketing its products in France.

The first condition required by the provisions of the aforementioned article L.615-3 of the French Intellectual Property Code - i.e. the imminence or proven implementation of the allegedly infringing acts in the territory protected by the patent - is therefore fulfilled.

2°- On the likelihood of the alleged infringement :

It is stated in the patent description that the invention relates to formulations containing triazinones and iron compounds (iron salts and complex compounds), according to claim 1, which are suitable for simultaneously combating coccidiosis and iron deficiency states in animals ([0001]), in the context of intensive livestock farming.

In this context, young piglets are particularly prone to protozoan infections such as coccidiosis, on the one hand, and to iron deficiency, on the other - due to their rearing conditions and rapid growth - which must be combated by prophylactic treatments and rebalanced by external supplements, it being specified that the recommended minimum blood hemoglobin value is 90 g/l ([0005], line 16).
The effects of toltrazuril against coccidia are well known and reported in numerous publications. Various methods of oral administration of this substance are also described. It is stated ([0012]) that the disadvantages of these treatments are the heavy workload required by oral administration, and the stress experienced by the animals during handling.

For the treatment of anemia, there are a number of iron preparations available, differing in the type of compound used, its mode of administration and bioavailability ([0013]). Oral preparations of type (I) iron salts are common and well-known. Compounds from the second group (II) are also used. The third group of compounds, administered mainly parenterally and to a lesser extent orally, mainly concerns iron(III)-dextran, iron(III)-hydroxide-polymaltose, iron(III)-sucrose and sodium iron(III) gluconate complex in sucrose solution ([0016]). It is stated that *"these iron compounds are used almost exclusively in the production of injectable preparations for human or veterinary medicine"* and that *"in veterinary medicine, however, a few rare preparations intended for oral administration are also used"* ([0018], lines 11 to 13). It is further stated that *"the extent of precipitate formation and hydrolysis of the iron core under the influence of gastric acid, on the one hand, and the stability of the complexes in acidic reducing media, on the other, are decisive points for bioavailability in the case of oral administration"* (line 19 to 24). These considerations lead to the conclusion *that "the doctrine that Fe(3+) compounds are not suitable in general*

for oral administration, in particular polynuclear compounds such as iron (III)-dextran" ([0019]). It is added that *"a further reason for the doubts expressed about the oral use of polynuclear Fe (3+) complexes, in particular iron (III) -dextran, is the special absorption pathway of ß -FeO (OH) complexes in the intestinal tract"*.
"This transfer mechanism is only effective in the first few hours of birth *(*according to the available literature, up to 24 hours after birth for optimum efficacy, and possibly on the 2nd day of life - [0020] lines 5 to 17 on page 13 of the translation), with efficacy being greatly reduced after 72 hours.

For oral iron preparations, a dosage of 100 to 200 mg of active iron per piglet and dose unit is recommended for sufficient efficacy, with only the higher dose allowing a single dose ([0021]).
To avoid the complications described above when applied orally, it is customary in pig breeding to administer polynuclear iron (III) complexes by intramuscular injection, usually on the 3rd day after birth. However, this also has a number of disadvantages, such as local lesions, heart muscle disorders and a lowered immune system ([0022], [0023]).

It is concluded from the foregoing ([0024]) that at the date of filing of the patent, the methods available for the treatment of anemia in piglets each have disadvantages, namely:
-In the case of oral administration, the bioavailability is lower, and although better results are observed with iron (III), it should ideally be administered within the first 10 hours of life;
-For intramuscular administration, treatment 1 to 3 days after birth gives similarly good results, but generates the aforementioned side effects and lesions.

For parallel treatment of coccidiosis with toltrazuril, the options are :
-Oral administration of iron (III)-dextran on day 1, followed by oral administration of toltrazuril on day 3;
-oral administration of toltrazuril suspension on day 3, and administration of an injectable formulation of iron(III)-dextran, with the disadvantages described.

The descriptive part of the patent goes on to state ([0025]) that it would therefore be advantageous to have preparations *"which would make it possible to combine the two options without the disadvantages described, i.e. without the harmful side effects while at the same time having a high and reliable efficacy. A suitable preparation could, for example, be a formulation of the active substance toltrazuril and iron(III)-dextran for oral administration to piglets within 1 to 3 days of birth.*

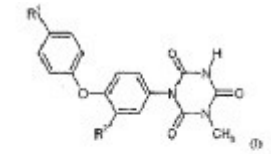
Preparations that should combine both options must, however, meet a series of conditions:
- sufficient quantity of active substance: in one dose unit, there must be a quantity of an anticoccidium sufficient for pharmacological efficacy, usually 20 to 70 mg, e.g. 30 mg, 44 mg or 50 mg of toltrazuril, and at least 100 mg, better still at least 150 mg, preferably 200 to 250 mg active iron (corresponding, for example, to 400 to 600 mg polynuclear iron (III) complex) for anemia prophylaxis - corresponding to the recommended dosages of 20 mg toltrazuril/kg body weight and 200 mg active iron per piglet. This corresponds to a concentration of 2 to 7% m/V of 1' anticoccidium and 10 to 25
% m/V active iron in the formulation (it being understood that % m/V represents the mass of the component concerned in g per 100 ml volume).

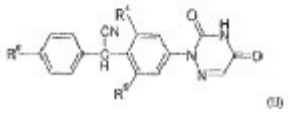
- *low dosage volume for oral administration: for suckling pigs, for example, a dosage volume of around 1 ml is optimal, since with much higher volumes, complete absorption by piglets is often not guaranteed. Larger quantities of liquid often leave the mouth or are vomited.*
- *appropriate consistency"* in that the viscosity must be suitable for syringes or drug guns so that it can be swallowed, but does not leave the animal's mouth after administration.
- quality of the formulation and its efficacy when administered over a longer period after birth;
- sufficient anemia prophylaxis in the case of single administration, since the quantity of iron to be administered in the low-dose volume of the combined preparation must be sufficient to cover the iron requirement of piglets after a single administration under normal rearing conditions.

According to the patent, *"the combination of triazinones and iron preparations in a suitable formulation has not yet been described".*
" ([0026]).

It consists of the object of claim 1, worded as follows:

1. Formulations containing triazinones of formulae (I) or (II)





dans lesquelles

R^1 représente R^3-SO_2- ou R^3-S-,
R^2 représente alkyle, alcoxy, halogène ou $SO_2N(CH_3)_2$ et
R^3 représente halogénoalkyle,
R^4 et R^5 représentent, indépendamment l'un de l'autre, hydrogène ou chlore et
R^6 représente fluor ou chlore,

ou leurs sels physiologiquement acceptables
et des composés complexes polynucléaires de fer (III)-polysaccharide.

Claims 2 to 12 - product - and 13 to 17 - use - being as follows:

2. Formulation according to claim 1, containing 1-30% (W/V), preferably 3-7% (W/V), triazinone.

3. Formulation according to any one of the preceding claims, the dispersed triazinone having a particle size d(v,90) less than or equal to 30 µm, preferably d(v,90) less than or equal to 20 µm and particularly preferably d(v,90) less than or equal to 10 µm.

4. Formulation according to any of the preceding claims, with an iron compound concentration of 10% (W/V) to 30% (W/V) active iron, preferably 11.4% (W/V) to 25% (W/V), but particularly preferably 20% (W/V) to 25% (W/V).

5. Formulation according to any one of the preceding claims, having a viscosity-measured by forming an average value from values measured at shear rates of 128 s-1 and 256 s-1 with a cone/plate arrangement of a rheometer - in a range from 10 to 2500 mPa.s, preferably in a range from 20 to 1500 mPa.s.

6. Water-based formulation according to claim 1.

7. Formulation according to claim 1, containing at least one polyhydric aliphatic alcohol.

8. Formulation according to any of the preceding claims, containing a polynuclear iron(III)-polysaccharide complex compound, the polynuclear iron core of which consists of ß-FeO(OH) units and which contains polysaccharide molecules in the remainder of the coordination sphere.

9. Formulation according to claim 8, containing a polynuclear iron(III)-polysaccharide complex compound selected from: iron(III)-dextran, iron(III)-hydroxy-polymaltose/iron(III)-dextrin and a non-stoichiometric compound of polynuclear ß-FeO(OH) and sucrose and oligosaccharides.

10. Formulation according to any of the preceding claims, containing, as triazinone, a triazinetrione.

11. Formulation according to any one of the preceding claims, the triazinone being toltrazuril and the polynuclear iron(III)-polysaccharide complex compound being iron(III)-dextran.

12. Formulations according to any one of claims 1 to 11, containing one or more constituent substances.

13. Use of formulations according to any of the preceding claims for the preparation of medicaments.

14. Use according to claim 13 for the preparation of medicaments for the simultaneous treatment of coccidial infections and iron deficiency states.

15. Use according to claim 13 or 14 for the preparation of medicaments for oral treatment.

16. Use according to claim 15 for the preparation of medicaments for the oral treatment of suckling pigs.

17. Use according to claim 15 for the preparation of medicaments for the oral treatment of piglets during the period from birth to 10 days after birth, preferably during a period from birth to 3 days after birth.

According to CEVA, the scope of the patent necessarily means that it does not cover a product administered other than orally. It bases its argument in particular on the aforementioned passages of the description, it being further observed that :

-paragraph [0035] gives examples of toltrazuril dosages *"for oral administration"* depending on the animals treated;
-the examples of preparations cited in paragraph [0040] - solutions, suspensions, pastes or gels - are intended for oral administration;
-the iron compounds and concentrations mentioned in [0047] are *"commonly used in oral formulations"*.
-paragraph [0050] specifies that the quantity of formulation to be used per administration depends on the respective quantities of triazinone and iron to be administered, and that it is desirable for volumes *"to be relatively small, easily administered per os",* i.e. orally;
-paragraph [0051] recommends a viscosity suitable for the oral route;
-Paragraph 67 emphasizes that *"the particularly preferred formulations according to the invention enable piglets to be treated orally in such a way that a sufficient supply of iron to piglets in the first four weeks of life can be obtained with a single oral administration"*.

Finally, there are 7 examples of preparations ([0073] to [0092]), all of which are described as intended for oral administration.

The results reported in the descriptive part of the patent are clinical trials carried out with the formulations of examples 2 and 3, on 270 piglets divided into 4 groups treated 3 days after birth. The two formulations administered orally according to Example 2 - one prepared from iron(III) dextran powder - and Example 3 - the other prepared from an iron(III) dextran solution - achieved a hemoglobin value of over 9g/ml on days 7, 14 and 21.

It is concluded ([0097]) that *"it can therefore be demonstrated that the single oral administration of 200 mg of active iron from iron(III)-dextran in combination with toltrazuril in the formulations according to the invention provides surprisingly - contrary to general doctrine and the current state of the art - good prevention of anemic deficiency symptoms in suckling pigs, even when administered on the 3rd day after birth", with* the formulations proving just as effective against coccidiosis according to the research carried out.

The first question to be addressed, prior to that of the apparent validity of the title invoked, is the scope of patent EP 496, which BAYER maintains protects a product independently of its mode of administration.

Article 69 of the EPC states that *"the scope of protection conferred by the European patent or by the European patent application shall be determined by the claims. However, the description and drawings shall serve to interpret the claims"*.

According to Article 1 of its Interpretative Protocol, this text *"must not be interpreted as meaning that the scope of protection conferred by the European patent is determined within the narrow and literal meaning of the text of the claims, and that the description and drawings serve only to dispel any ambiguities that may be concealed in the claims. It must not*

moreover, be interpreted as meaning that the claims serve only as a guideline and that protection also extends to what, in the opinion of a person skilled in the art who has examined the description and drawings, the patentee intended to protect. Article 69, on the other hand, must be interpreted as defining a position between these extremes which ensures both fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties". Article 2 further provides that *"in determining the scope of protection, due account shall be taken of any element equivalent to an element indicated in the claims".*

According to BAYER, these provisions do not allow us to see in claim 1 an implicit limitation that its wording does not suggest.
She argues that if a particular feature is essential to define the subject matter of the claim and must therefore be included in its wording, this implies demonstrating that the protection conferred is too broad, resulting in a ground for invalidity which precisely was not upheld by the Opposition Division in its decision of May 16, 2019, so that patent EP 496 cannot be limited to a particular embodiment of the invention disclosed only in the description.

Finally, it points out that only claim 15 relates to the use of formulations for the preparation of medicinal products for oral treatment.

In the preliminary opinion of October 4, 2018 (Exhibit BAYER 13) the Opposition Division states that:
- there is no inadmissible broadening of the first claim by deleting the reference to Fe(II)- or Fe(III)-based compounds of classes a), b) or c), to refer only to *"polynuclear iron(III)-polysaccharide complex compounds"*;
- the patent is sufficiently disclosed with respect to the formulations claimed under claim 1 or with respect to the use for the preparation of medicaments (claim 13), in view of the 7 formulations according to the invention which enable the person skilled in the art to reproduce it;
- whichever document is chosen as the closest prior art, the difference between claim 1 and the disclosure of these documents is still that the claimed formulation contains two components, toltrazuril and an iron-based preparation; yet it is provisionally credible that there are at least the following technical effects for this difference: improved efficacy of iron supplementation and piglet weight gain (based on the patent in dispute, [95] and table 5 on page 31 of this document; D29, in particular tables 8/page 8 and 4/page 6); improved pharmacokinetics (based on document A33, page 9, table 5 as well as document A34) and simplification of treatment by reducing the number of working steps;
- the problem to be solved by the patent is defined as the availability of improved formulations for pig breeding, and it is provisionally credible that the patent solves this problem in view of the data it contains;
- the solution of the problem within the meaning of the patent involves an inventive step, in that none of the documents examined as the closest prior art contains any reason to expect an improvement in the pharmacological profile of the toltrazuril-Fe (III)-polysaccharide polynuclear combination, that the spatially close disclosure of toltrazuril and Fe- dextran in A1 or of toltrazuril and iron-based preparations in A3 is
"Finally, the sequential administration scheme practiced for years is an indicator of the non-obviousness of the formulation, so that this common formulation shows a technical effect beyond the simple lightening of work by two steps in one.

The reasoned decision of July 16, 2019 dismisses the objection of insufficient description with regard to parenteral formulations, which it claims the skilled person can easily make from aqueous solutions intended for the disclosed oral uses, and that furthermore *"the patent is not conceptually limited to oral formulations",* which is reflected in the structure of the claims presenting oral administration as a particularly preferred embodiment.

The inventive step is assessed independently of the mode of administration of the formulations described and results, according to the Opposition Division, on the one hand from the simplification of the treatment regimen and, on the other hand, from the demonstration of a technical effect of the claimed combination - the improvement of iron supplementation in piglets - *"when the two active ingredients are administered at a single time at a later point in time in a single formulation"*. The validity of claim 1 is therefore not examined from the perspective of a protection that would be limited to orally-administered formulations.

As CEVA rightly points out, and as illustrated above, the entire description and the examples of formulations presented refer to oral administration of the combined treatment.

The prior art described in the patent states that, at the priority date, it was taken for granted that iron (III) compounds were generally unsuitable for oral administration due to their absorption mechanisms, which could limit their bioavailability - or at least make it uncertain as it depends on multiple factors - and that to be sufficiently effective, treatment had to be given within two days of birth, corresponding to the delay between birth and the so-called *"intestinal closure"* phenomenon, which refers to a blockage of the mucosa after the absorption phase of immunoglobulins and antibodies provided by the sow's colostrum.
To avoid the disadvantages of reduced bioavailability and time delay, it has been known to use injectable treatment on day 3 of birth.

After listing the major disadvantages of this method of administration, and pointing out that piglets must also be treated against coccidiosis - generally orally - between the 3rd and 5th day of birth, the descriptive part of the patent concludes that it would be advantageous to have preparations *"capable of combining the two options without the disadvantages described"* these two options being as mentioned above:

1°-successive administration of iron (III) compound on day 1, followed by toltrazuril on day 3, both orally;

2°-concomitant - but separate - administration of the two treatments on day 3, iron compound by injection and oral toltrazuril.

The technical problem described by the patent is therefore the absence of formulations available in the prior art enabling piglets to be treated against coccidiosis and anaemia simultaneously, which the person skilled in the art was deterred from doing because the appropriate time of administration of each treatment to ensure its efficacy was not the same. However, if we consider administration by injection, this problem does not arise in the same terms since, as noted in the description, in this case the iron compound is effectively absorbed and can be administered on day 3 at the same time as toltrazuril.

The patent also points out that the active substances in the triazinone group are generally administered orally.

Thus, the aim of the formulations according to the patent is to treat piglets effectively against coccidiosis and iron deficiency in a single operation and by means of oral administration.

It was either the absence of a common treatment window, or the difference in administration methods, which prevented the two active substances concerned from being combined in a single formulation.
In its search for formulations that would ensure the efficacy of oral anemia treatment on the third day, in order to avoid the parenteral route and its known negative consequences, BAYER carried out tests that brought out the unexpected effect noted by the Opposition Division in its finding of inventive step, namely that in such a combination, even when administered orally, iron (III) remains sufficiently effective from day 3 onwards. Beyond this specific context of oral administration, the company does not demonstrate - nor does it claim to do so - that its combination formula is more effective than taking the two products separately.
In view of what was already known, i.e. that even on the 3rd day parenteral administration of iron (III) was sufficiently effective and could still be used, notwithstanding its major drawbacks, the solution provided by the patent lies in the effect of a combination formula which, although administered orally on the 3rd day, surprisingly makes it possible to treat anemia effectively.

The data mentioned for administration by intra-muscular injection are given in the table of results for the comparative clinical trials presented in the patent. They show that on day 7, the 67 piglets treated with oral formula 2 reached a hemoglobin level of 10.05 g/100ml, while those treated with an injection had a level of 9.75 g/100ml. These levels were respectively 11.37 and 12.84 on day 14 and 10.78 and 12.61 on day 21, which is satisfactory given the recommended threshold of 9g/100ml by reference to which the state of anemia is defined independently of its visible symptoms.

It is this surprising effect obtained through oral administration, and not through an injectable route whose alternative use on the 3rd day is known but clearly not recommended, that is highlighted and that the patent was intended to protect.

It should also be noted that this scope of protection was asserted by BAYER in the context of the grant proceedings for the same title before the Canadian Patent Office, indicating on June 9, 2015 in response to the examiner's report, whose attention is drawn to the fact that
"the present formulation is related to addressing two problems simultaneously. One of which is to arrive at an orally administrable formulation, the other being that this formulation thereby allows for the treatment of anemia in animals that are affected by coccidiosis even via the oral route (being biased in the prior art per seto be the less reliable route even in otherwise healthy animals - see D5 above)".

It is also pointed out that *"the presently claimed invention does provide a non-obvious formulation over the art cited. Moreover, as it clears from pages 10 and 11 of the application, providing an oral formulation that can be used to adress both anemia and coccidiosis is clearly advantageous over problems associated with the monotherapy, such as the use of non-oral formulations and divided administration times"* (CEVA exhibit 17.3).

The issued Canadian version of the patent relates to *"an oral formulation"*. (CEVA exhibit 17-4).

Before the Indian Office, it was also argued that the invention was intended to provide *"means of simultaneously treating iron deficiency and coccidiosis by one (oral) route of administration"* (CEVA exhibit 18).

It is clear from all the foregoing that the arguments put forward by CEVA in support of its position that the scope of protection conferred by patent EP 496 does not extend to a combination administered by injection, appear sufficiently serious that, in view of the respective risks incurred by each of the parties, the provisional injunction should not be granted, notwithstanding the lack of precision as to the method of administration of the product claimed in claim 1, as read in the light of the description and in particular the definition of the technical problem posed and the solution proposed by the invention.

As a result, the summary order issued on April 5, 2018 does not need to be reported or modified.

BAYER INTELLECTUAL PROPERTY and BAYER ANIMAL HEALTH, the losing parties, will bear the costs and must be ordered to pay the CEVA company, which had to incur irreducible costs, compensation under Article 700 of the French Code of Civil Procedure, which the context of the dispute justifies setting at 100,000 euros.

Please note that this order is subject to provisional execution by operation of law.

THEREFORE

THE COURT

Ruling publicly by judgment made available at the clerk's office, contradictory and in first instance,

ADMITS to the debates the elements communicated by the parties during the deliberations, namely :
E-mail from BAYER INTELLECTUAL PROPERTY dated July 24, 2019 and 4 attachments (decision of the Opposition Division dated July 16, 2019 in German and translation, decision of the Commercial Court of Barcelona in Spanish and translation);
- e-mail from CEVA SANTE ANIMALE dated July 25, 2019;

DISMISSES the plea of lack of jurisdiction raised by CEVA in favor of the juge de la mise en état of the 3rd chamber, 3rd section hearing case n°RG 18/1633 (action for declaration of non-infringement initiated by CEVA);

RULES that the claims based on the probable infringement of patent EP 496 and seeking to revoke or reform the order of April 5, 2018 in light of the new circumstances presented by BAYER INTELLECTUAL PROPERTY, are admissible;

DECLARE BAYER ANIMAL HEALTH's action inadmissible;

DECLARES that there are no grounds for amending or rescinding the summary order issued on April 5, 2018;

DISMISSES BAYER INTELLECTUAL PROPERTY's claims in their entirety;

ORDERS BAYER INTELLECTUAL PROPERTY GmbH and BAYER ANIMAL HEALTH GmbH to pay CEVA SANTE ANIMALE SA the sum of 100,000 euros under article 700 of the French Code of Civil Procedure;

ORDERS BAYER INTELLECTUAL PROPERTY GmbH and BAYER ANIMAL HEALTH GmbH *jointly and severally* to pay the costs;

REMINDS that this decision is automatically subject to provisional execution.

Paris, September 11, 2019

The Clerk, The President,

Fabienne FELIXFlorence BUTIN