TRIBUNAL DE GRANDE INSTANCE DE PARIS

■

ORDER IN PRELIMINARY PROCEEDINGS
handed down on 26 October 2015

Docket №:
15/58725

BF/№:1

Summons of:
13 October 2015

by **Marie-Christine COURBOULAY, Vice Presiding Judge** of the *tribunal de grande instance de Paris*, acting through delegation of powers from the Presiding Judge of the *tribunal*,

assisted by **Rachid BENHAMAMOUCHE, Court Clerk**.

CLAIMANTS

WARNER-LAMBERT COMPANY LLC, ***a company incorporated under the laws of the United States of America***
235 EAST 42ND STREET
NEW YORK, NY 10017 USA
UNITED STATES OF AMERICA

PFIZER LIMITED, ***a company incorporated under English law***
Ramsgate road Sandwich KENT CT13 9NJ
UNITED KINGDOM

S.A.S. PFIZER PFE FRANCE
23-25 avenue du docteur Lannelongue
75014 PARIS

represented by Ms Laetitia BENARD, attorney-at-law, member of the PARIS Bar - Courthouse box #J0022

DEFENDANTS

S.A.S. SANDOZ
49 avenue Georges Pompidou
92300 LEVALLOIS PERRET

represented by Mr Denis SCHERTENLEIB, attorney-at-law, member of the PARIS Bar - Courthouse box #A0948

SANDOZ Gmbh, ***a company incorporated under Austrian Law***
Biochemiestrasse 10, 6250 kundl
62000 AUSTRIA

represented by Mr Denis SCHERTENLEIB, attorney-at-law, member of the PARIS Bar - Courthouse box #A0948

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DISCUSSION

At the hearing of **19 October 2015**, held publicly, presided by **Marie-Christine COURBOULAY, Vice Presiding Judge**, assisted by **Rachid BENHAMAMOUCHE, Court Clerk**,

FACTS AND PARTIES' CLAIMS

Parties

WARNER-LAMBERT was acquired by PFIZER INC. in 2000, unifying two of the companies in the pharmaceutical industry.

The PFIZER group owns one of the most extensive portfolios of products and medicinal products promoting well-being and the prevention, treatment and cure of illnesses in a wide range of medical fields.

One of PFIZER's leading drugs is marketed under the Lyrica® brand: its active ingredient is pregabalin.

PFIZER LIMITED is the holder of a centralised marketing authorisation ("MA") in the European Union for the Lyrica® drug.

PFIZER PFE FRANCE, the group's French subsidiary, exploits the MA for the Lyrica® drug, which it sells in France.

The Sandoz group is active in a number of medical fields, including the field of pain treatment.

SANDOZ GmbH was granted two centralised MAs on 19 June 2015 according to the abridged procedure, entitling it to claim benefit of the clinical trials conducted for the reference drug. The first one covers the three indications specified for LYRICA; the second one is restricted according to the "carve out" mechanism to a single indication covering epilepsy and generalised anxiety disorder called "GAD".

Thus, the indication for the neuropathic pain treatment has been carved out.

The generic version of Lyrica® is marketed by SANDOZ under the name PREGABALINE SANDOZ GMBH.

The leaflet does not include the indication covered by Patent EP 061, it only refers to epilepsy and generalised anxiety disorder called "GAD".

PREGABALINE SANDOZ GMBH was added to the list of reimbursable drugs for patients covered by the French State health system by the Decree of 27 August 2015, and was allocated a price and a reimbursement rate.

The only drug listed as a reimbursable drug is the drug indicated for the treatment of epilepsy.

The dispute

European patent № 0 641 330 was filed on 18 May 1993 by NORTHWESTERN UNIVERSITY, subject to the priority of US patent application № 886,060. It expired on 18 May 2013. It covered the pregabalin compound as such. The validity of this patent has never been challenged.

On 21 May 2005, NORTHWESTERN UNIVERSITY was granted SPC № 04C0031, based on European patent № 0 641 330, and the above-mentioned centralised MA EU/1/04/279/001-025 of 6 July 2004 for the Lyrica® branded drug.

SPC № 04C0031 covered pregabalin. Its expiry was effective on 18 May 2013.

Therefore, pregabalin, the active ingredient of Lyrica®, was covered by European patent № 0 641 330 and SPC № 04C0031, which have now expired.

European patent EP 061 was filed on 16 July 1997 by WARNER-LAMBERT, subject to the priority of US patent application № 19960022337 P filed by Mr Singh.

This patent derives from international application WO 98/003167. It claims priority from US patent application US 22337P whose filing date is 24 July 1996.

ORION CORPORATION filed opposition with the EPO on 27 February 2004.

On 10 June 2005, the Opposition Division rejected the opposition.

On 23 September 2014, WARNER-LAMBERT filed a request for the limitation of patent EP 061 with the EPO. This centralised limitation was granted on 21 November 2014 and published in European Patent Bulletin № 2015/04 of 21 January 2015.

Patent EP 061 was maintained in force by the regular payment of the annual fees. It is due to expire on 16 July 2017.

It is a second medical use patent because it discloses the use of pregabalin, already known for the treatment of convulsions, for the preparation of a pharmaceutical composition for the treatment of pain.

Patent EP 061 comprises 14 claims, covering various types of pain. The first three claims are worded as follows:

Claim 1:
"*Use of (S)-3-(aminomethyl)-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain*."

Claim 2:
"*Use according to claim 1, wherein the pain is inflammatory pain*."

Claim 3:
"*Use according to claim 1, wherein the pain is neuropathic pain*."

Only claims 1 and 3 are invoked by LAMBERT WARNER.

The European Commission granted LYRICA® a marketing authorisation for the first time on 6 July 2004 (Centralised MA № EU/1/04/279). The LYRICA® MA was initially granted for two indications, namely the treatment of peripheral neuropathic pain in adults and as an adjunctive therapy in adults for the treatment of partial epileptic seizures with or without secondary generalisation.

The MA was then extended to two other indications: the treatment of generalised anxiety disorder (also called "GAD") in adults on 20 March 2006 and the treatment of central neuropathic pain on 7 September 2006.

To date, the Summary of Product Characteristics[TN] for LYRICA® refers to the following three indications:
* neuropathic pain (an indication for which it has been listed as a reimbursable drug): "Lyrica is indicated for the treatment of peripheral and central neuropathic pain in adults";
* epilepsy (also an indication for which it has been listed as a reimbursable drug): "Lyrica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation"; and
* generalised anxiety disorder (an indication for which it has not been listed as a reimbursable drug): "Lyrica is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults."

LYRICA® is available in capsules of 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg, and as a 20 mg/ml oral solution.

These three indications for pregabalin are covered by the same so-called "global" MA for LYRICA® because each new indication requires authorisation as a "variation" of its MA, according to Regulation (EC) № 1234/2008.

The variations are classed according to importance and whether the application requires an in-depth examination: the addition of a new therapeutic indication is classed as a "major type II variation" requiring an in-depth examination by the relevant authority, in this case the European Medicines Agency, or EMA.

The starting point for data regulatory protection periods, which prohibits applications for generic and commercial exclusivity MAs

[TN] The original French court order makes a reference to the "*rémunération de la copie privée*", which appears to be an error as this refers to a tax in favour of copyrights works. From the context, the correct reference appears to be the "summary of product characteristics".

and prevents the marketing of generic drugs, is the granting date of the initial MA in the EU.

LAMBERT WARNER estimates that, in 2014, LYRICA® prescriptions for the treatment of pain represented about 88 % of the total sales of LYRICA® (including 72 % for neuropathic pain). LYRICA® prescriptions for the treatment of epilepsy and generalised anxiety disorder represented about 1% of LYRICA® sales each.

SANDOZ GmbH was granted two MAs on 19 June 2015, one for a generic of the LYRICA® branded drug named PRÉGABALINE SANDOZ, including the three LYRICA® indications and the other - in dispute - for a drug named PRÉGABALINE SANDOZ GmbH with the neuropathic pain treatment indication carved out of the SmPC.

Accordingly, the company has authorisation to market PRÉGABALINE SANDOZ GMBH only in the treatment of epilepsy and generalised anxiety disorder.

It only mentioned these two indications in the leaflet enclosed with the drug packaging.

PREGABALINE SANDOZ GMBH was added to the list of reimbursable drugs for patients covered by the French State health system and approved for use by local authorities and public services, and was allocated a price and a reimbursement rate by the Decree of 27 August 2015.

Numerous letters were exchanged between Pfizer and SANDOZ from April 2015 to October 2015.

LAMBERT WARNER discovered that the drug PRÉGABALINE SANDOZ GMBH was marketed in pharmacies in France by instructing a bailiff to draft two purchase reports on 8 October 2015; a pharmacist was handed a prescription for pregabalin and dispensed a box of PRÉGABALINE SANDOZ GMBH.

It also found that SANDOZ had purchased advertising space in the daily *Le Quotidien du pharmacien,* which stated in that its prospective market was worth 144 million euros.

Considering that this mention of a prospective market exceeded the market share available to generic drug manufacturers, i.e. a market excluding prescriptions for use in the treatment of neuropathic pain, LAMBERT WARNER, PFIZER Limited and PFIZER PFE France served summonses in preliminary proceedings with an emergency motion, on 13 and 14 October 2015, and upon authorisation from the President, on Sandoz GmbH and Sandoz France, for measures to be taken to inform health professionals, to limit the sales of PRÉGABALINE SANDOZ GMBH and for publication measures.

Situation in other countries

Germany

The Hamburg Regional Court, ruling in preliminary proceedings, enjoined several generic pregabalin manufacturers from proposing discount agreements to health insurance organisations and from taking part in invitations to tender which do not exclude the indication for pain treatment.

Spain

Since the authorisation of the first pregabalin generic drugs at the beginning of 2015, at least 11 of the 17 Spanish regional health authorities, representing 85 % of the Spanish market, have taken steps to ensure the protection of the PFIZER patent.

Most of these regions, like the Balearics and Galicia, have issued recommendations to health professionals notifying them of the Pfizer patent and informing them that generic pregabalin is not authorised for use in treating neuropathic pain and, accordingly, its cost for this use will not be reimbursed.

Murcia and Catalonia have stressed that prescriptions must be written in accordance with the drug SmPCs (without more details). Other regions, like Madrid, have adopted recommendations asking doctors to prescribe LYRICA® by reference to the brand name for the treatment of pain.

Italy

In August 2015, AIFA, the Italian Drug Agency, posted on its website a communiqué concerning the prescription of pregabalin in the treatment of neuropathic pain for the attention of prescribers, stating that:

* as the use of pregabalin in the treatment of neuropathic pain is covered by a patent due to expire on 15 July 2017, the cost of pregabalin generics is not reimbursed by State health insurance if used in treating neuropathic pain;
* for the treatment of neuropathic pain, an indication which is protected by the patent, doctors should only prescribe LYRICA® and not a generic pregabalin;
* for all other indications (GAD and epilepsy), which are not protected by a patent, doctors can prescribe any available pregabalin composition.

On 16 September 2015, AIFA published a second directive concerning prescription and dispensation practices for pregabalin-based drugs, aimed at prescribers and pharmacists (the first communiqué was only targeted at prescribers).

Denmark

On 25 June 2015, the Commercial and Maritime Court pronounced a provisional injunction against Danish pharmacies, enjoining them from dispensing a generic of the LYRICA® drug for the pain treatment indication.

United Kingdom

By an order of 26 February 2015, supplemented by a judgment of 2 March 2015, the High Court of Justice ordered the National Health Service (NHS) to issue guidance to ensure that doctors prescribed pregabalin for the treatment of pain using the Lyrica® brand name and not the international non-proprietary name. No appeal was lodged against this decision and it must also be noted that generic drug laboratories involved in the proceedings in the UK have not challenged the order requiring such guidance to be issued.

The NHS guidance to doctors and pharmacists is worded as follows:
"*When prescribing pregabalin for the treatment of neuropathic pain to patients you should (so far as reasonably possible):*
a) prescribe by reference to the brand name Lyrica®; and
b) write the prescription with only the brand name "LYRICA", and not the generic name pregabalin or any other generic brand. […]

When dispensing pregabalin, if you have been told that it is for the treatment of pain, you should ensure, so far as reasonably possible, that only Lyrica®, the branded form of pregabalin, is dispensed. […]"

The guidance advises that a notice or advice box containing the following wording should be added to electronic prescription systems: "*if treating neuropathic pain, prescribe LYRICA® (brand) due to patent protection. For all other indications, prescribe generically.*"

In a judgment of 10 September 2015, the High Court of Justice held Patent EP 061 invalid for insufficient disclosure.

Claims

LAMBERT WARNER, the holder of patent EP 061, PFIZER Limited, the MA holder, and PFIZER PFE France, which markets Lyrica in France, requested that the Judge ruling in preliminary proceedings:

Having regard to Articles L. 613-3, L. 613-4, L. 615-1, L. 615-3 and Article L. 615-5-2 of the French Intellectual Property Code;
Having regard to European patent № 0 934 061;

Hold that SANDOZ GMBH and SANDOZ SAS infringed claims 1 and 3 of European patent № 0 934 061 by offering, putting on the market and

importing drugs including pregabalin in their composition for the treatment of neuropathic pain, reproducing the characteristics of these claims.

Enjoin SANDOZ GmbH and SANDOZ from manufacturing, offering, putting on the market, using, importing, exporting, transhipping or holding for the aforementioned purposes, any drug including pregabalin in its composition until 16 July 2017, in excess of 10.24% of the units (capsules) of pregabalin sold in France in the preceding month, it being for the claimants to supply updated data on unit (capsule) sales of pregabalin each month to SANDOZ GmbH and SANDOZ SAS. Every three months, the above percentage of pregabalin units relating to non-patented indications will be adjusted based on updated data on the market share spread per indication, supplied by the claimants to SANDOZ GmbH and SANDOZ SAS. This injunction will be subject to a penalty of €1,000 (ONE THOUSAND EUROS) per infringing capsule manufactured, imported, exported, transhipped, offered for sale, sold, used or held, from the date of service of the judgment to be handed down, in excess of 10.24% of the units (capsules) of pregabalin sold in France per month.

Order SANDOZ GmbH and SANDOZ SAS to recall and/or withdraw from distribution channels, including pharmacies, any pharmaceutical product reproducing the protected characteristics, i.e. those protected by claims 1 and 3 of European patent № 0 934 061, that they have manufactured, caused to be manufactured, imported, exported, transhipped, offered for sale, sold, used or held for the aforementioned purposes, in excess of 10.24% of the units (capsules) of pregabalin sold in France, subject to a penalty of €1,000 (ONE THOUSAND EUROS) per infringing capsule not recalled or withdrawn, to be effective 48 hours after the date of service of the judgment to be handed down.

Enjoin SANDOZ GmbH and SANDOZ SAS from taking part in invitations to tender relating to pregabalin unless such invitations to tender are exclusively and specifically restricted to epilepsy and generalised anxiety disorder, subject to a penalty of €100,000 (ONE HUNDRED THOUSAND EUROS) per invitation to tender not exclusively and specifically restricted to epilepsy and generalised anxiety disorder in which SANDOZ GmbH and SANDOZ SAS would take part.

Order SANDOZ GmbH and SANDOZ SAS to issue a letter to the French College of Physicians and to all prescribing doctors registered with the College of Physicians, stating that:
"In a ruling dated [XX], the President of the tribunal de grande instance de Paris *(first instance court) ordered SANDOZ GmbH and SANDOZ SAS to notify you of the following:*
PREGABALINE SANDOZ GMBH is a generic drug based on the LYRICA® branded drug. LYRICA® is indicated in the treatment of neuropathic pain, epilepsy and generalised anxiety disorder.

By virtue of European patent № 0 934 061, which covers the use of pregabalin in the preparation of a pharmaceutical composition for treating pain, due to expire on 16 July 2017, SANDOZ has removed the indication for pain from the summary of product characteristics of PRÉGABALINE SANDOZ GMBH so that PRÉGABALINE SANDOZ GMBH is only

authorised for the treatment of epilepsy and generalised anxiety disorder. Therefore, it may neither be prescribed nor dispensed for pain treatment. Contrary to the statements made in our advert in Le Quotidien du pharmacien*, the prospective market for PRÉGABALINE SANDOZ GMBH is not worth 144 million euros but, at best, 6.16 million euros.*

Accordingly, in compliance with the ruling of the Presiding Judge of the tribunal de grande instance de Paris *dated [XX], SANDOZ requests that you prescribe only by reference to the brand name LYRICA® where the drug is to be used to treat pain and that, in your prescriptions, you state 'not to be substituted'.*

Concerning the indications relating to the treatment of epilepsy or generalised anxiety disorder, prescriptions must continue to use the international nonproprietary name (INN), according to Article L. 5121-1-2 of the French Public Health Code."

Order SANDOZ GmbH and SANDOZ SAS to send a letter to the French College of Pharmacists and to all pharmacists registered with the College of Pharmacists, stating that:
"In a ruling dated [XX], the Presiding Judge of the tribunal de grande instance de Paris *(first instance court) ordered SANDOZ GmbH and SANDOZ SAS to notify you of the following:*
PRÉGABALINE SANDOZ GMBH is a generic drug based on the LYRICA® branded drug. LYRICA® is indicated in the treatment of neuropathic pain, epilepsy and generalised anxiety disorder.

By virtue of European patent № 0 934 061, which covers the use of pregabalin in the preparation of a pharmaceutical composition for treating pain, due to expire on 16 July 2017, SANDOZ has removed the indication for pain from the summary of product characteristics of PRÉGABALINE SANDOZ GMBH so that PRÉGABALINE SANDOZ GMBH is only authorised for the treatment of epilepsy and generalised anxiety disorder. Therefore, it may neither be prescribed nor dispensed for pain treatment. Contrary to the statements made in our advert in Le Quotidien du pharmacien*, the prospective market for the drug PRÉGABALINE SANDOZ GMBH is not worth 144 million euros but, at best, 6.16 million euros.*

Accordingly, in compliance with the ruling of the President of the tribunal de grande instance de Paris dated [XX], SANDOZ requests that you prescribe only by reference to the brand name LYRICA® where the drug is to be used to treat pain.

In this context, we would remind you that pharmacists have a duty to keep themselves abreast of a patient's condition in the light of their duty to advise and assist when dispensing medicines, as provided in the national agreement organising the relationship between pharmacists holding dispensary licences and the State health insurance authority.

Where the drug is to be used in the treatment of epilepsy or generalised anxiety disorder, pharmacists retain the right to substitute a generic for the LYRICA® branded drug".

Order SANDOZ GMBH and SANDOZ SAS to send the following statement to hospitals with respect to invitations to tender for pregabalin and pain in which SANDOZ GmbH and SANDOZ SAS would have taken part, subject to a penalty of €10,000 (TEN THOUSAND EUROS) per late day, after a period of eight days after the date of service of the judgment to be handed down:
"With regard to the public tender procedure / agreement that you have initiated / entered into with us covering the indication for the treatment of pain, we hereby notify you that we are not (or no longer) able to bid / supply you because this market is exclusively reserved to PFIZER's LYRICA® product until 16 July 2017. We are only entitled to participate in public tenders / agreements that offer an absolute guarantee that they are not aimed at procuring pregabalin for the treatment of pain".

Order SANDOZ GmbH and SANDOZ SAS to inform third parties purchasing their PRÉGABALINE SANDOZ GmbH generic drugs that this drug cannot be prescribed or dispensed for the treatment of pain and to inform them that they cannot supply such generic drugs to third parties unless they can guarantee that this restriction will be respected[TN] and provide evidence thereof to the applicants.

Order SANDOZ GmbH and SANDOZ SAS not to use advertising materials not expressly restricted to the epilepsy and generalised anxiety disorder indications, including sales figure information, subject to a penalty of €100,000 (ONE HUNDRED THOUSAND EUROS) for each non-complying advert still accessible after the date of service of the judgment to be handed down;

-Order the publication of the entire judgment, exclusively at the costs of SANDOZ GmBH and SANDOZ, in the form of a PDF document reproducing the entire decision and available via a visible hyperlink on the homepage of the website of SANDOZT GmBH and SANDOZ, regardless of the address for acceding this website, the title of the link being, in the appropriate language:
"The tribunal de grande instance de Paris *has issued an order in preliminary proceedings enjoining SANDOZ GmbH and SANDOZ SAS from supplying in France drugs containing pregabalin for the treatment of pain, which would constitute an infringement of PFIZER's rights. PRÉGABALINE SANDOZ GMBH may only be prescribed and dispensed for the treatment of epilepsy and generalised anxiety disorder"*
in a font of at least 20 (twenty) points for 6 (six) months, within eight days as of the service of the judgment to be handed down and under a penalty of €5,000 (FIVE THOUSAND EUROS) per day of delay.

-Authorise WARNER-LAMBERT LLC and PFIZER PFE France to publish the same declaration on the medium of their choice:
"The tribunal de grande instance de Paris *has issued an order in preliminary proceedings enjoining SANDOZ GmbH and SANDOZ SAS from supplying in France drugs containing pregabalin for the treatment of pain, which would constitute an infringement of PFIZER's rights. PRÉGABALINE SANDOZ GMBH may only be prescribed and dispensed for the treatment of epilepsy and generalised anxiety disorder"*

[TN] The passage "that this restriction will be respected" seems to be missing from the original French court order and was added in the translation

Order SANDOZ GmbH and SANDOZ SAS, under a penalty of €10,000 (TEN THOUSAND EUROS) per day of delay after a period of eight days as of the day of service of the judgment to be handed down, to disclose all documents or information held by SANDOZ GmbH and SANDOZ SAS to determine the origin and distribution channels of pharmaceutical compositions reproducing the characteristics protected by claims 1 and 3 of European patent № 0 934 061, including (i) the names and addresses of manufacturers, wholesalers, importers, proprietors and other prior owners of these products; (ii) the quantities produced, imported, sold, delivered, received or ordered and (iii) the prices and other benefits received in consideration for the infringing products.

Hold that the Presiding Judge will have jurisdiction to rule, if necessary, on the calculation of the penalties he will have set.

Order SANDOZ GmbH and SANDOZ SAS to pay the claimants €200,000 (TWO HUNDRED THOUSAND EUROS) pursuant to Article 700 of the French Civil Procedure Code.

Order SANDOZ GMBH and SANDOZ, jointly and severally, to pay all the costs.

Recall that the decision to be handed down will be provisionally enforceable as of right.

At the hearing, the claimants reiterated their claims and submitted their arguments orally.

They claimed that patent EP 061 was valid and was neither insufficiently disclosed, because a sufficient number of tests and experiments had been carried out at the patent application stage, nor lacked an inventive step, because a person skilled in the art would logically be interested in the new anti-convulsion drugs for the treatment of neuropathic pain but nothing would prompt him to take a particular interest in PRÉGABALINE.

They claimed to have acquired the patent rights from the inventor, the only person entitled to apply for a patent in the United States, and an employee of Davis Research, at the filing date, as US legislation is fairly similar to the French provisions applicable to inventions made in the performance of the employee's duties. Accordingly, there is no basis for challenging the assignment of the priority right and, therefore, the ability to assert another PFIZER Limited patent with respect to novelty.

They explained why SANDOZ was committing a direct infringement of claims 1 and 3 of Patent EP 061, in particular:

* the respective sizes and special characteristics of the markets for the various indications;

* the reference by SANDOZ to the patented indication in its promotional and marketing activities,

* the failure by SANDOZ to take any steps with regard to the French authorities to prevent the infringement of Patent EP 061;

* SANDOZ's deceptive tactics, showing its determination to market its generic drug for the patented indication.

In their pleading presented orally at the hearing, SANDOZ GmbH and SANDOZ SAS requested that the judge ruling in preliminary proceedings:
Hold that preliminary proceedings are not justified.
Dismiss all of the claimants' claims.
Order the claimants, jointly and severally, to pay Sandoz 100,000 euros pursuant to Article 700 of the French Civil Procedure Code, Order the claimants to pay all the legal costs pursuant to Article 700 of the French Civil Procedure Code.
In the alternative, Prescribe any additional information measure targeted at health professionals that the Judge ruling in preliminary proceedings will consider necessary; postpone the proceedings for a hearing at a later date to verify that the additional information measure has been duly conducted.
In the further alternative, if a legal limitation on the sales of Prégabaline Sandoz should be imposed, Limit such sales to 31% of the total market for Prégabaline in France, the size of the market to be updated, *inter partes*, every three months.

They argued that the aim of the system of issuing marketing authorisations to generics manufacturers only for pharmaceutical compositions in the public domain is to allow the marketing of the molecule for indications that are no longer protected and thus to avoid placing generics manufacturers in a position where they are infringing rights; that they only intended to market PRÉGABALINE SANDOZ GmbH for two indications: epilepsy and GAD; that, for this purpose, they removed all reference to treatment for neuropathic pain from the leaflet and, more importantly, notified the claimants of their intention to restrict their product to these indications, informed health professionals, doctors, pharmacists and wholesalers that their generic drug could not be prescribed for neuropathic pain because the indication was protected by the PFIZER Limited patent.

They further specified that the marketing information published in *Le Quotidien du pharmacien*, indicating a prospective market worth 144 million euros was in line with the indications of PRÉGABALINE SANDOZ GMBH and could not be misleading to pharmacists who do not necessarily know the size of the pregabalin market.
They denied any direct infringement as well as any contributory infringement by supplying means.

Finally, they challenged the validity of the patent for insufficient disclosure because the mentioned tests do not in any way demonstrate a treatment for neuropathic pain, but only a pain treatment, due to a lack of inventive step because numerous documents establish that it has been known since 1949 that anticonvulsants may have an effect on the treatment of pain; that the two new effective anticonvulsants discovered in the 1990s are pregabalin and[TN];
that the first one was patented before a MA was granted, while the second one was not patented for this indication, but was tested by

[TN] Word missing (probably “gabapentin”).

practitioners who quickly made it known that the drug was effective in treating neuropathic pain; that clinical trials were conducted, resulting in the grant of a MA for NEUROTIN; that this proves that testing PRÉGABALINE as a pain treatment was obvious, which deprives the asserted claims of any inventive step.

As regards Patent EP 061, they added that no evidence had been adduced to prove that the inventor had assigned his priority right to his employer and that, accordingly, the claimants cannot assert it, and that the patent granted for the treatment of inflammatory pain for the same molecule combined with kaolin can be asserted as regards novelty.

They pointed out that Patent EP 061 has been challenged on the merits by MYLAN so that it could market pregabalin for the three indications in the MA.

At the 19 October hearing, SANDOZ suggested, with the agreement of the ANSM[TN] , that they should publish a new advert, clearly informing doctors, respecting their freedom to prescribe and the interests of patients, that, if they prescribe pregabalin for the treatment of pain, they would be infringing PFIZER's rights under the claimants' Patent EP 061; that to avoid such a risk, all they needed to do was to indicate in their prescriptions "LYRICA, not to be substituted"; and informing pharmacists that, if a doctor fails to state the indication for which the Lyrica is prescribed, they should enquire as to the doctor's intention and should not replace the Lyrica with PRÉGABALINE SANDOZ GmbH because doing so would infringe WARNER LAMBERT's patent rights.

It was agreed that the wording of the advert, to be approved by an ANSM committee that meets only once a quarter, could be agreed by the parties and, if the parties did not reach agreement, they could refer the matter back to the Judge ruling in preliminary proceedings the following day; that if the ANSM gave rapid approval for the publication of the amended information or an early date for a decision on the advert, SANDOZ would alert the Judge ruling in preliminary proceedings, at the same time as the claimants, during the deliberation period.

On Tuesday, 20 October, the parties indicated that they had reached an agreement on the wording of the corrected statement to health professionals; SANDOZ FRANCE specified that the ANSM had considered that this was an information notice, not an advertisement, and that, as such, it did not require ANSM approval, a position that it had already adopted in relation to the first notice back in the summer.

SANDOZ informed the Judge ruling in preliminary proceedings and Pfizer that it agreed to provide information to a wider group of health professionals, in particular hospital doctors and pharmacists not targeted by the previous letter; that they would reissue their mailing using Celtipharm, but with a larger database; that using this method, the corrective message would reach almost all pharmacists; and that they were willing to send out another mass mailing through another company suggested by the claimants with a wider doctor database; that they accepted including geriatricians and rheumatologists in the list of doctors,

[TN] The French agency for drug and health products safety

without acknowledging, at this stage, that Patent EP 061 protects all forms of pain treatment.

The case was adjourned until 26 October at 11:00 a.m. for verification of the emails dispatched by SANDOZ.

At this hearing, SANDOZ proved by producing exhibits № 46 and 47 that the corrected information had been sent out to around 100,000 health professionals over three working days, at a cost of more than 40,000 euros using Celtipharm and IMS, in the following sectors:
high street pharmacists, hospital pharmacists, GPs, rheumatologists, neurologists, psychiatrists, anaesthesiologists, oncologists, diabetes specialists, geriatricians and orthopaedic surgeons.

The claimants persisted in their claims with respect to the information to be issued to the College of Physicians and College of Pharmacists, the changes to the advert in *Le Quotidien du Pharmacien*, the limitation of the supply of PRÉGABALINE SANDOZ GmbH to a market share of no more than 14% and the injunction from submitting bids in public tender procedures relating to PRÉGABALINE SANDOZ GmbH in the treatment of pain.

SANDOZ replied that it had only provided this additional information in such a short time to provide more comprehensive information to drug prescribers and dispensers but that they denied committing any infringement and, in the alternative, they challenged the validity of the patent.
They added that they did not believe that the court had the power, especially not in summary proceedings, to limit the supply of PRÉGABALINE SANDOZ GmbH to the market share percentage requested by the claimants.

WHEREUPON

On the requests lodged before the Judge ruling in preliminary proceedings

Article L 615-3 of the French Intellectual Property Code provides: *"Any person with authority to bring an action for infringement may, in preliminary proceedings, request that the competent civil court order, under a penalty of a daily fine if necessary, against the alleged infringer or intermediaries whose services he uses, any measure aimed at preventing an infringement about to be committed against rights conferred by the intellectual property right or aimed at stopping any further allegedly infringing act.*
The competent civil court may also order ex parte urgent measures when the circumstances require that such measures should not be taken in the presence of both parties, in particular when any delay would be likely to cause irreparable damage to the claimant."

It is alleged that, although apparently complying with the duties of a generics manufacturer with benefit of a restricted MA, SANDOZ is committing a direct infringement, as a main claim, and a contributory infringement by supplying means, in the alternative.

Therefore, the Judge ruling in preliminary proceedings needs to rule on the objections to the requested measures and these objections may relate to the validity of the patent itself, which is the case here; the Judge ruling in preliminary proceedings will then decide whether the objections are genuine and will evaluate the defendants' denial of the infringements alleged by the claimants against the claims lodged by the said claimants and then decide, assessing risks on both sides, whether or not to prohibit sales of the generic composition.

The infringement itself is disputed on the grounds that, as the patent contains a "Swiss form" claim, i.e. a process rather than a product claim, there can be no proven direct infringement, and that the evidence is no more compelling for a case of contributory infringement by supplying means.

In this case, as SANDOZ chose not to challenge the validity of Patent EP 061 before marketing its PRÉGABALINE SANDOZ GmbH, but rather to apply for a restricted MA, which it was granted, to enter the market for the two indications now in the public domain, the Court will first rule on whether there is a plausible infringement, i.e. whether or not the conditions of marketing of Pregabalin Sandoz GmbH infringe WARNER LAMBERT's Patent EP 061, before considering, if necessary, the challenges to patent EP 061

On the alleged infringement

On the "direct" infringement by exceeding the market share relating to the indications included in the restricted MA.

Pfizer argues that, in 2014, prescriptions of LYRICA® for the treatment of pain represented about 88% of the total sales of LYRICA® (72 % of which were for the treatment of neuropathic pain); that the drug's use for treating epilepsy and generalised anxiety disorder represented only about 1% each of total sales of LYRICA®; that this data was supplied by IMS, a reputable, independent supplier of medical data, based on data from a sample group of doctors.
It indicates that the latest data shows a level of market share already acquired by PRÉGABALINE SANDOZ GmbH since its market launch, which proves that a direct infringement has been committed.
It adds that SANDOZ's determination to acquire a greater market share than available is clear from the advert published in *Le Quotidien du pharmacien* because this advert states that the prospective market is worth about 144 million euros, which is the entire pregabalin market if calculated at the generic drug price.

SANDOZ essentially disputes that there can be no case of direct infringement because it is a process claim and the allegations of infringement are not being made against the manufacturer but against the distributor; it disputes that the market share figures given by Pfizer are based on data supplied by IMS because they have been reworked by the claimants using an unreliable method of calculation; that the percentage of prescriptions for unidentified indications was systematically added to the pain treatment figures so that the free portion of the market share available to generic manufacturers is not 14%, as claimed by Pfizer, but 30%.
Sandoz argued that the reference to a prospective market worth 144 million euros was not an admission of their determination to conquer the entire pregabalin market, which is worth an estimated 144 million euros, but an unnecessary comment made by their sales department; that an infringement must be assessed objectively and not subjectively, so that intentions have no part to play in the appraisal.

Whereupon:

Article L. 613-3 of the French Intellectual Property Code provides:
"*The following shall be prohibited, save consent by the owner of the patent:*
a)Making, offering, putting on the market, using (Act № 2014-315 of 11 March 2014, Art 6) ,importing, exporting, trans-shipping a product which is the subject-matter of the patent, or importing or stocking a product for such purposes;
b)Using a process which is the subject matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the owner of the patent, offering the process for use on French territory;
c)Offering, putting on the market, using, importing, exporting, trans-shipping the product obtained directly by a process which is the subject matter of the patent or stocking a product for such purposes.

It is established that the conditions in subparagraphs a and b of Article L. 613-3 of the French Intellectual Property Code are not applicable to the present case since subparagraph a) relates to a product claim and since subparagraph b) relating to a process invention can only be asserted against the manufacturer.

In the case of (c), it should be established whether the offer for sale by SANDOZ FRANCE of the product obtained using the process and manufactured outside France, and the import of that product by SANDOZ GmbH, are in breach of the conditions of (b).

It is not disputed that SANDOZ GmbH was granted a "carved out" MA by the European Medicines Agency to market pregabalin to treat the epilepsy and GAD indications, but not to treat neuropathic pain; that SANDOZ SANDOZ has been selling PRÉGABALINE SANDOZ GmbH in France since the end of September 2015; and that it sent the following information letter to doctors (more than 30,000) and pharmacists (more than 19,000) by e-mail:

"Information about Prégabaline Sandoz GmbH

In the near future, Sandoz will be launching its Prégabaline Sandoz GmbH® generic on the market pursuant to the grant of a marketing authorisation for this drug.

Prégabaline Sandoz GmbH® is indicated:
• as an adjunctive therapy in adults in the treatment of partial epileptic seizures with or without secondary generalisation.

• in the treatment of Generalised Anxiety Disorder (GAD) in adults.

Please be informed that Prégabaline Sandoz GmbH® is not indicated in the treatment of neuropathic pain insofar as this indication is protected by a patent owned by Warner-Lambert Company LLC (a Pfizer Group company).

Therefore, for reasons associated with the patent protection, Sandoz has decided not to market a prégabaline-based drug for the treatment of neuropathic pain and this indication is not included in the Summary of Product Characteristics for Prégabaline Sandoz GmbH®

You will be notified by Sandoz, should this position change.

The products concerned are:
Prégabaline Sandoz GmbH ® 25 mg, capsule
Prégabaline Sandoz GmbH ® 50 mg, capsule
Prégabaline Sandoz GmbH ® 75 mg, capsule
Prégabaline Sandoz GmbH ® 100 mg, capsule
Prégabaline Sandoz GmbH ® 150 mg, capsule
Prégabaline Sandoz GmbH ® 200 mg, capsule
Prégabaline Sandoz GmbH ® 300 mg, capsule

These compounds have been granted generic MAs based on Lyrica® 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg and 300 mg, capsule, dated 16 June 2015, and are awaiting registration in the list of generic drugs maintained by the ANSM.

To avoid infringing the patent rights, you should only prescribe / dispense Prégabaline Sandoz GmbH® for indications that do not include the treatment of neuropathic pain.

The claimants do not dispute that the marketing of PRÉGABALINE SANDOZ GmbH for the two indications disclosed in its leaflet infringe their patent EP061.

On the issue of the "rights-free" market share, it should be recalled that, although free trade is the rule, the medicines market is governed by regulatory provisions authorising the marketing, and that Pfizer is entitled to a monopoly based on its patent EP061.

None of the parties have challenged the data supplied by the IMS.

The data are based on data sourced from 1190 doctors, GPs (400) and specialists (790, not including geriatricians). The panel doctors use the International Statistical Classification of Diseases (ICD 10) codes in their prescriptions.

However, the exhibits validly produced in court by Pfizer are the result of work carried out by its departments, transforming raw IMS data associated with a particular code for each disease

treated by pregabalin into data assigned to the various indications in the global MA.

The IMS document defines the following level 1 categories: epilepsy, other conditions, pain, psychiatry and unspecified, then in a more detailed table, the pain sub-categories.

In this case, it is not possible to understand how the ICD categories have been applied to incorporate some pain indications into the general neuropathic pain category that should not be included in this category.

Accordingly, the figure of 86 % to 88 % of the level 1 category relates to pain in general.

However, although Pfizer only has a MA for the treatment of neuropathic pain, this action is based on Patent EP061, particularly claims 1 and 3, relating to the use of pregabalin in the preparation of a pharmaceutical composition for the treatment of pain and, more particularly for the treatment of neuropathic pain.

Consequently, PFIZER's Patent EP061 covers pain treatment in the broad sense even if only one MA was issued for the treatment of neuropathic pain, so that PRÉGABALINE SANDOZ GmbH cannot be marketed for pain treatment in general.

Although Lyrica may have been used by practitioners for a much broader range of pain, therefore outside the MA, this is not a relevant factor to an infringement claim (it is a public health matter).

Accordingly, the reference market to take into account with regard to the asserted claims is the global pain treatment market, i.e. 86 % of the pregabalin market, although, at this stage, Sandoz's objection that the patent cannot offer valid protection for all pain treatments should not be overlooked.

It would appear from the data provided by GERS[TN], the veracity of which has not been challenged, that, in week 41, i.e. 3 weeks after its market launch, PRÉGABALINE SANDOZ GmbH achieved a market share of 16.96 %, i.e. 2.96 % above the authorised market share threshold.

Accordingly, doctors have prescribed and pharmacists have dispensed PRÉGABALINE SANDOZ GmbH in excess of the market share reserved for treatments other than pain relief, i.e. they have prescribed and dispensed it for an unauthorised indication.

However, in assessing whether or not SANDOZ FRANCE can be held liable for infringement, it should be verified whether the company has complied with its obligations because it holds a MA for two indications that are not patent-protected.

In fact, only an offer for sale or marketing, and for SANDOZ GmbH and SANDOZ FRANCE, an import of PRÉGABALINE SANDOZ GmbH manufactured by SANDOZ (LEK) in Slovenia, contravening claims 1 and 3 of Patent EP061, can constitute an act of infringement according to the provisions of Article L. 613-3 (c) cited above.

[TN] *Groupement pour l'Élaboration et la Réalisation des Statistiques* (Statistics Preparation and Production Group)

As stated above, the obligations imposed on a generics manufacturer selling a drug for which it has been granted a MA solely for indications that are in the public domain, where the active substance is still protected for another indication (in this case the treatment of pain in the very broad sense of the term, by a patent, in this instance Patent EP 061) have been honoured because the leaflet refers only to the two indications (epilepsy and GAD) for which SANDOZ GmbH has been granted its MA and because an information letter has been sent to doctors and pharmacists.

The applicants are criticising SANDOZ for not asking the French health authorities to post a communiqué on their website or one targeted at doctors and pharmacists to alert them to the fact that PRÉGABALINE SANDOZ GmbH cannot be prescribed or dispensed for neuropathic pain or pain in general.

However, although they have produced in court the information released and distributed in other European countries on the websites of health authorities or in information letters sent to health professionals, they have not provided information about the process that led to the publication of such information letters, as to whether they were posted online or sent out pursuant to proactive action on the part of SANDOZ, or whether the health authorities did so at their own initiative or at the express request of Pfizer.

In this case, there is no proof that SANDOZ has the possibility of asking the ANSM to put out such a message to doctors and pharmacists, but it is for Pfizer, aware of SANDOZ's applications for MAs, to alert the French health authorities in order to obtain an institutional announcement on the matter.

Finally, it appears from the correspondence between the parties that:

* on 30 April 2015, SANDOZ GmbH wrote to PFIZER Limited “proactively” according to the wording of the letter to reassure it that PRÉGABALINE SANDOZ GmbH will not be indicated as a treatment for neuropathic pain and that it would respect Patent EP 061 at least until it has been cancelled or has expired.

* on 20 May 2015, PFIZER Limited replied that it had noted the undertaking of SANDOZ GmbH and that it wanted information about the market launch of PRÉGABALINE SANDOZ GmbH in the UK.

* in a letter dated 12 June 2015, SANDOZ undertook only to sell PRÉGABALINE SANDOZ GmbH for the indications cited in its MA, only to produce promotional materials for these indications, to send out information notices “to the relevant customers and authorities in the market explaining expressly that the SANDOZ drug was only indicated in the treatment of GAD and epilepsy and should not be supplied for the treatment of neuropathic pain” and encouraged PFIZER Limited to correspond with the appropriate organisations and authorities to ensure that LYRICA would be prescribed and supplied in the treatment of neuropathic pain, specifying that it would join if necessary Pfizer's communications on this subject.

* in a letter dated 27 July, PFIZER Limited's attorneys-at-law requested clarifications from SANDOZ GmbH on the content of the letter

received from the CEPS[TN] on 16 July and enclosed the letter sent to the ANSM the same day.

*on 31 August, SANDOZ GmbH replied that it did not agree with the "free-of-right" market share figures; that it would forward Pfizer the letters addressed to customers and the authorities concerned by the market as soon as they were sent out and that it would have preferred to be warned about the letter sent to the ANSM giving notice of their agreement in order to join in the steps taken by PFIZER PFE France to arrange an institutional information for doctors and pharmacists.

* on 29 September, PFIZER Limited's attorneys-at-law wrote to SANDOZ GmbH's legal officers, expressing their astonishment that:
- they had not sent letters to the CEPS, the ANSM, the HAS[TN], UNCAM[TN], pharmacies and hospitals to prevent PRÉGABALINE SANDOZ GmbH from being prescribed, dispensed, substituted and/or reimbursed for the treatment of neuropathic pain, and that such letters should have been sent out before the market launch of the drug, not afterwards;
- there had been a change in the assessment of the validity of patent EP 061;
- there had been no explanation of the reasons for their disagreement with regard to the market shares;

* on 7 October 2015, SANDOZ GmbH replied that: - the letter of 29 September contained errors; - it had never said that patent EP 061 was valid since it had challenged its validity in Germany and other parties had done the same in France but it had given its undertaking to respect PFIZER Limited's rights until patent EP 061 was held invalid or had expired;
-it had complied with its undertaking, referring in the leaflet only to epilepsy and GAD;
- it had attached to its letter the email sent out to pharmacists and doctors at the beginning of October;
- it considers that it is up to Pfizer to take further steps or to suggest such steps to Sandoz, but with greater clarity and in less general terms.

Further:

* PFIZER PFE France wrote to the ANSM on 27 July 2015 expressing its concern about the upcoming market launch of PRÉGABALINE SANDOZ GmbH and the risk, that it considered very real, of this drug being prescribed and dispensed for the protected indication of the molecule; it set out its rights and asked the ANSM to keep it informed of the actions that it intended to take to prevent the dispensing of generics for the patented indication and gave an account of the measures taken in other countries; in its letter, it mentioned the letter from SANDOZ FRANCE dated 12 June 2015.
Pfizer has not produced the reply from the ANSM.

* On 23 October 2014, PFIZER PFE France wrote to the CEPS to reiterate its rights on patent EP 061 as regards the reference drug sold under the LYRICA brand.
It produces the letter of 16 July 2015 it received from the CEPS stating that the SANDOZ laboratory had solicited an application for its drug PRÉGABALINE SANDOZ GmbH and that the CEPS had confirmed that it was authorised to sell this drug without infringing the rights of PFIZER Limited.

[TN] *Comité Économique des Produits de Santé* (health product economic committee)
[TN] *Haute Autorité Nationale* (national health authority)
[TN] *Union Nationale des Caisses d'Assurance Maladie* (national union of health insurance funds)

* On 12 October 2015, PFIZER PFE France wrote to the HAS and the CEPS in similar terms to its letter of 27 July to the ANSM.

It can therefore be seen that SANDOZ only marketed its product for the indications for which it was granted a MA; it included a leaflet referring only to the two indications epilepsy and GAD; it provided information widely to doctors and pharmacists at the time of the PRÉGABALINE SANDOZ GmbH market launch in an email dispatched at the beginning of October.

Concerning the messages to be sent to the health authorities, it appears that Pfizer sent these messages to alert the authorities to its rights and the need to protect them. It was therefore pointless for SANDOZ to send a similar letter.

It should also be noted that SANDOZ agreed to dispatch a more explicit message to high street and hospital doctors and pharmacists in order to provide details as to how PRÉGABALINE SANDOZ GmbH should be prescribed or dispensed so as not to infringe the patentee's rights.

Therefore, there is not act of direct infringement in this case.

Concerning the advertisement published in *Le Quotidien du pharmacien* on 1 October 2015, it appears that it was approved by the ANSM; that the authorised indications are stated at the top of the page; that at the bottom of the page, it is stated that PRÉGABALINE SANDOZ GmbH has been granted generic MAs based on Lyrica.

The wording of the message is not disputed by Pfizer, which criticises SANDOZ FRANCE, the advertiser, for highlighting “a prospective market worth 144 million euros” in an insert in this advert, which is the value of the entire pregabalin market, and which allegedly shows Sandoz's intention to market its drug for the pain treatment indication.

As SANDOZ FRANCE rightly pointed out, infringement should only be assessed objectively, not subjectively, especially as the French Intellectual Property Code does not acknowledge the notion of good faith in such matters.

Adding the mention “prospective market worth 144 million euros” which is the value of this market, does not imply that SANDOZ FRANCE infringed claims 1 and 3 of Patent EP 061 because its advert contains a clear statement of the treatment indications.

This statement on the value of the market is of no interest to pharmacists, who do not necessarily know the size of the pregabalin market, and it does not encourage them to substitute Lyrica for PRÉGABALINE SANDOZ GmbH which, in any case, is not a relevant criterion to assess whether there has been an infringement, labelled by Pfizer as a direct infringement, i.e. by selling or offering its generic drug for sale within the meaning of Article L. 613-3 of the French Intellectual Property Code.

Although this advertisement, in its published form, announces the arrival of this new generic drug and could well be seen as an offer for sale to pharmacists, at whom it is targeted, it does not contain any wording that may be construed as meaning that the offer for sale is for a use of PRÉGABALINE SANDOZ GMBH to treat pain.

Although it may well be the ambition of SANDOZ to conquer a large share of the pregabalin market - a market valued at around 144 million euros, in which each percentage point is worth 1.5 million euros - and also a share of the pain treatment market, there is no objective evidence that might lead one to believe that it intends to do so before Patent EP 061 expires or is held invalid, as invalidity proceedings initiated by MYLAN are currently pending before the *tribunal de grande instance de Paris*, 2nd Section, 3rd chamber.

Accordingly, there is no plausible case of infringement on the basis of Article 613-3 (c) of the French Intellectual Property Code, especially as throughout the period preceding the market launch and the period after the hearing, SANDOZ agreed to send a message to health professionals and to reissue another more explicit message, drafted in agreement with Pfizer, to those same professionals and to other high street and hospital practitioners.

on the contributory infringement by supply of means

Pfizer argues that importing, putting on the market and offering a drug for sale constitutes an infringement where it is proven that the drug is intended to be used for the treatment of a patented indication; that SANDOZ knows that the generic drug is likely to be used in the treatment of pain; that the circumstances show that PREGABALINE SANDOZ GMBH is intended to be used in the treatment of pain, that SANDOZ knows that the regulatory framework automatically leads to an infringement of the patent.
It adds that the following circumstances: the reference made by SANDOZ FRANCE to the patented indication in its marketing and promotions; the failure by SANDOZ GmbH to take any action as regards the French authorities to prevent the infringement of patent EP 061 and Sandoz's misleading tactics showing its obvious determination to sell the generic for the patented indication, prove that the conditions of Article L. 613-4 of the French Intellectual Property Code are satisfied.

SANDOZ answers that the scope of a “Swiss form” claim, which is the case of the asserted claims, is incompatible with Article L. 613-4 (1) because the physical act constituting the infringement is the preparation of the composition and cannot be the import or sale of a finished product; that only a third party supplying the essential means for the preparation of a pharmaceutical composition to treat pain can validly be accused of such acts of infringement; and that this presupposes that once the means have been supplied on the French territory, the actual infringement, i.e. the preparation of the drug, takes place in France.
It points out that, if the active substance or a precursor thereof is not supplied in France for the manufacture of the drug in France,

there can be no contributory infringement.
It adds that, based on subparagraph 2 of the same article, there can be no infringement where the products supplied are products that are readily commercially available unless the third party induces the person it is supplying to commit the prohibited acts; that, accordingly, the infringement is the physical act of inciting one to use the protected product.

Whereupon:

Article L. 613-4 of the French Intellectual Property Code provides:

1°)It shall also be prohibited, save consent by the owner of the patent, to supply or offer to supply, on French territory, to a person other than a person entitled to exploit the patented invention, the means of implementing, on that territory, the invention with respect to an essential element thereof where the third party knows, or it is obvious from the circumstances, that such means are suitable for putting and are intended to put the invention into effect.
2°)Subparagraph 1 shall not apply where the means of implementation are staple commercial products, except where the third party induces the person supplied to commit acts prohibited by Article L. 613-3.
3°)Persons carrying out the acts referred to in subparagraphs (a), (b) and (c) of Article L. 613-5 shall not be deemed persons entitled to exploit the invention within the meaning of subparagraph 1.

In this case, although Pfizer does not specify which subpararaph of Article L. 613-4 it is relying upon, it is clear, first, from reading its pleading and from oral presentations, and, second, from the "Swiss form" claims involved in this application, that the provisions of subpararaph (1) do not apply because Sandoz does not supply any third party in France with the means to exploit the protected process in France.

Only subparagraph (2) might apply because the drugs in question are products that are readily commercially available.

Thus, it has to be proven that Sandoz induced third parties, in this case doctors and pharmacists, to dispense the product manufactured pursuant to the process and[TN] the provisions of Article L. 613-3 (c) of the Intellectual Property Code.

It cannot be argued that the rules governing the prescription and substitution of medicines will automatically lead to an infringement of the rights of the patent holder in a case where the second medical use of a given molecule is protected when the previous indications for the same molecule are in the public domain.

This dispute relates specifically to the evaluation of the measures to be taken to prevent possible infringements in these circumstances and, in this case, the measures taken by SANDOZ to prevent an infringement of Pfizer's patent EP 061 as a result of the authorised marketing of PRÉGABALINE SANDOZ GmbH for the indications not protected by the patent.
It has been stated above that it is not the responsibility of SANDOZ FRANCE to contact the health authorities directly to alert them to PFIZER Limited's rights on pregabalin for the treatment of neuropathic pain, but that such a step can only be taken by the rights holder; that, moreover, this is why rights holders are notified

[TN] Passage missing. Probably "in breach of".

when a MA is granted to a generic manufacturer, so that the request that the information letter be sent to the College of Physicians and the College of Pharmacists is irrelevant.

Concerning SANDOZ FRANCE's alleged misleading tactics in mentioning the prospective market for pregabalin in its first advert, it has also been stated above that this constituted neither an infringement nor an incitement directed at pharmacists to substitute Lyrica by dispensing PRÉGABALINE SANDOZ GmbH in its place. Therefore, the claim for a modification of the advert published in *Le Quotidien du pharmacien* is also irrelevant.

Finally, it has been noted that the market share apportioned to the generic drug cannot currently exceed 14%; that the measures taken by SANDOZ to prevent infringing prescribing and dispensing of drugs were directed at the health professionals likely to commit such infringements, i.e. doctors and pharmacists; that these measures did not prove adequate because the market share achieved by SANDOZ FRANCE exceeded that share apportioned to the generic drug; that the parties were still in negotiations at the date of the summons; that at the hearing, SANDOZ offered and agreed to remedy these inadequacies by sending out new emails containing a corrected information message to an even wider professional audience, including using a database suggested by the claimants; that Sandoz even acted voluntarily on some of the claims contained in the claimant's summons.

Although SANDOZ agreed to issue more specific information to relevant health professionals, it did so denying that it had committed any act of infringement

In this instance, there has never been any evidence that SANDOZ induced doctors or pharmacists to sell PRÉGABALINE SANDOZ GMBH for the treatment of pain; on the contrary, its behaviour has proved that it informed doctors and pharmacists and even agreed during the hearing to supplement this information at its expense, and also to respect the views of the claimants.

Accordingly, the claims of PFIZER Limited, WARNER LAMBERT and PFIZER PFE France will be dismissed as there is no evidence of any plausible acts of contributory infringement by supplying means.

The conditions are met to grant to SANDOZ the sum of 100.000 euros pursuant to Article 700 of the French Civil Procedure Code.

ON THESE GROUNDS

Ruling publicly by delivery of the decision to the Court Clerk's office, after hearing all the parties and in first instance

Hold that the infringement acts asserted against SANDOZ GmbH and SANDOZ FRANCE by WARNER LAMBERT, PFIZER Limited and PFIZER PFE France on the basis of

patent EP 061 are not plausibly established pursuant to both Article L. 613-3 and Article L. 613-4 of the French Intellectual Property Code.

Consequently,

Dismiss the claims of WARNER LAMBERT, PFIZER Limited and PFIZER PFE France.

Order WARNER LAMBERT, PFIZER Limited and PFIZER PFE France, jointly and severally, to pay SANDOZ the sum of 100,000 euros pursuant to Article 700 of the French Civil Procedure Code.

Order WARNER LAMBERT, PFIZER Limited and PFIZER PFE France, jointly and severally, to pay the costs.

Done in Paris on **26 October 2015**

The Clerk	The Presiding Judge
R. BENHAMAMOUCHE	M.C. COURBOULAY