Extract from the December 2, 2016 PI decision rendered by TGI Paris (France) in the pregabalin case

# On the claims of WARNER LAMBERT formulated before the judge hearing interlocutory proceedings

Article L615-3 of the French Intellectual Property Code provides: "Any person having capacity to act for infringement may seize the competent civil court hearing interlocutory proceedings seeking an order, if necessary subject to a fine, against the asserted infringing party or intermediaries whose services are used, for any measure intended to prevent imminent violation of rights conferred by the title or to prevent the continuation of the asserted infringement...

Seized with an interlocutory application or petition, the court may order the measures sought only if the evidence reasonably accessible to the claimant renders it probable that its rights have been infringed or that said infringement is imminent."

WARNER LAMBERT asserts that the defendant companies would commit infringement by supply of means by knowingly and in bad faith marketing generic Pregabalin as a proprietary medicine protected by patent EP 061, in the knowledge that, given their obligation of substitution, pharmacists will supply generic Pregabalin, including for the protected proprietary medicine, that information sent to municipal and hospital pharmacists and physicians is inadequate to prevent infringement and finally, that this is demonstrated by the fact that the market share for generic Pregabalin, that is 16.2%, is largely exceeded by the total sales of the generics manufacturers.

The defendant companies respond that WARNER LAMBERT cannot collectively criticise them for infringement by supply of means, that it must prove for each defendant, commission of the criticised acts, which it fails to do, that they have complied with all prescriptions on limiting sales of Pregabalin exclusively to those indications for which they have obtained a market authorisation, specifying said specialisms on the instructions for use enclosed with the product and that they have informed municipal and hospital pharmacists and physicians that Pregabalin may not be substituted when used to treat neuropathic pain.

They dispute the method of calculating the market share of generic Pregabalin of 16.2% notably given the panel of physicians selected to this end and given that WARNER LAMBERT confuses references to hospital and municipal use which refers respectively to capsules and packs.

Finally, they maintain that the legislation adequately prevents any substitution when the generic medicine protected for a second therapeutic use co-exists with proprietary medicines which have entered the public domain on the ground that physicians are informed and may stipulate on the prescription that the proprietary medicine is not eligible for substitution but above all, given that a medicine prescribed for an indication not authorised by the market authorisation is not eligible for reimbursement.

The interlocutory judge may rule on disputes brought before him challenging the measures sought and said challenges may concern the validity of the right itself which is the case here; it then falls to the judge to assess the serious or otherwise nature of the challenge and to assess proportionality of the challenge of the defendants to the violation asserted by the

claimants and to adopt, having regard to the risks incurred by both parties, a decision on whether or not to prohibit marketing of the generic.

In this case, the defendants opted not to dispute the validity of patent EP 061 prior to marketing their generic Pregabalin, but rather to directly obtain a limited market authorisation for the purposes of entering the market for the two indications in the public domain. Hence, first of all, a ruling must be pronounced on the existence of probable infringement, that is whether the conditions for marketing Pregabalin constitute infringement by supply of means of patent EP 061 of WARNER LAMBERT, prior to assessing, if necessary, the challenges against patent EP 061 except as concerns MYLAN since the court of first instance has pronounced a decision on the merits rejecting the grounds for annulment.

# The legislation on generic medicines:

Article 11 of EC Directive 2001/83 amended by EC Directive 2004/27 establishing the Community Code on medicines for human use:

"For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included."

- Its transposition as article R.5121-29-2 of the French Public Health Code:

"When informed by the holder of a market authorisation for a medicine granted pursuant to paragraph 1), 2) or 3) of article R.5121-28, prior to marketing of the medicine or the proprietary medicine concerned, given that for some of the indications, pharmaceutical forms or dosages of the proprietary medicine or the reference medicine, the intellectual property rights have not expired, the general manager of the agency will delete from the resume of the product characteristics of the medicine or the authorised generic medicine, pursuant to paragraphs 1), 2) or 3) of article R.5121-28, the parts referring to said indications, forms or dosages."

- Article 3.3 b) of EC Regulation No. 726/2004:
- "3. A generic medicinal product of a reference medicinal product authorised by the Community may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC and Directive 2001/82/EC under the following conditions:
- (a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC or Article 13 of Directive 2001/82/EC;
- (b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed; and
- (c) the generic medicinal product is authorised under the same name in all the Member States where the application has been made. For the purposes of this provision, all the linguistic versions of the INN (international non-proprietary name) shall be considered to be the same name."

## *Infringement by supply of means*

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

- 1) In the absence of consent of the patent holder, the supply or offer to supply, in French territory, to a person other than those authorised to commercially exploit the patented invention, of means for use in the territory of the invention with reference to an essential element thereof, if the third party knows or when the circumstances make it obvious that said means are capable and intended for said use, is also prohibited.
- 2) The provisions of paragraph 1 do not apply when the means for use are products which are widely available on the market, unless a third party incites the party to whom it supplies to commit acts prohibited by article L.613-3.
- 3) Persons authorised to carry out commercial exploitation pursuant to paragraph 1 does not include those carrying out the acts referred to in a, b and c of article L.613-5

Infringement is not assessed subjectively but exclusively objectively, since the Intellectual Property Code does not acknowledge the concept of good faith in such matters.

In this case, claims 1 and 3 of patent EP 061 are prepared in the Swiss form which is the only authorised form given the prohibition on patenting a known molecule under CEB 1973.

The claims are considered as process claims and not product claims, such that the defendant companies cannot be charged with supply of means permitting the use of the process in French territory.

It should be observed that the defendant companies import the pre-prepared medicine, that is already manufactured and do not supply any means for preparing the medicine. They are not criticised for manufacturing the medicine in French territory.

Contrary to the asserted case law of the EPO which does not have jurisdiction to rule on acts of infringement since such matters are outside the scope of its remit which is exclusively to grant or otherwise patents; any act for the marketing of a medicine protected by a patent for a second therapeutic use cannot be analysed as the supply of means.

Even assuming that supplying to pharmacists, the sole persons authorised in France to dispense medicines [since even online websites for the sale of medicines must be linked to a pharmacy], could constitute the supply of means allowing using Pregabalin for the treatment of neuropathic pain, it is established for all the defendant companies that they restricted the market authorisation to unprotected indications and clearly stated same on the instructions for use included in the packaging and finally and above all, conducted an extensive information campaign addressed to pharmacists and prescribing physicians who were notified concerning all sales of the new Pregabalin generic, of the precautions to be adopted when prescribing the proprietary medicine.

If pharmacists are considered as third parties, it appears that they are perfectly well-aware of the information supplied; pharmacists are particularly well-informed third party professionals aware they may not supply Pregabalin in its generic form except for the two conditions, epilepsy and general anxiety.

It could indeed be assumed that given the flow of information concerning said generics, as a precautionary measure, pharmacists tend to supply only the *princeps* to avoid any charges of infringement.

In consequence, the conditions of article L.613-4 1 are not satisfied.

Concerning the second paragraph, it may be accepted that a medicine is a general consumer product, even if its distribution is regulated given the dangerous nature of certain molecules, notably in combination with others.

But on the other hand, it cannot be admitted that the defendant companies incited pharmacists or physicians to substitute generic Pregabalin for the *princeps* in the case of prescriptions for neuropathic pain when the latter spontaneously and fairly informed pharmacists that the market authorisation was limited to the two indications, epilepsy and general anxiety, given that this widespread information campaign generated significant costs for them.

The conditions of article L.615-4 2 are not satisfied hence it is not necessary to define the market share "reserved" to generic Pregabalin, a percentage which would require a decision on the merits concerning its calculation, the panel of physicians selected and whether the references concern capsules or packs.

What is more, the Intellectual Property Code does not define the concept of collective infringement of a patent and it is the responsibility of the person asserting infringement to establish the acts which it ascribes to each of the parties in causing not its loss, but which constitute infringement.

Several persons may be complicit in the same act of infringement if they participate at different stages in said infringement.

Concerning direct infringement, the manufacturer then the wholesaler, then the person storing the products who has custody thereof, then the vendor may all by their actions become complicit in the same infringement.

In this case, the defendant companies holding the market authorisation each import the medicine Pregabalin for which they have obtained a market authorisation and fixed the price.

For example, SANOFI FRANCE imports the product manufactured outside France and distributes it via its own network of sales representatives and wholesalers.

BIOGARAN itself manufactures the Pregabalin for which it is obtained a market authorisation and does not procure the medicine from SANOFI FRANCE. It sells its Pregabalin through its own network.

It cannot be claimed and it is not proved that these companies - which are competitors on the medicines market – are or were complicit in carrying out the same infringement. It does not suffice to rely on infringement of the same patent against the various independent economic players to establish that they were complicit in causing the same damage.

And moreover, in this case, no joint and several order may be pronounced against them.

In this case WARNER LAMBERT simply, after defining the market share dedicated to generic Pregabalin on the basis of statistics collected by GERS – on some occasions relating to individual capsules and on others to full packs - without regard to the different dosages and

on the basis of a panel of physicians of which the composition is to say the least questionable, affirmed that all sales of generic Pregabalin constitute a form of collective infringement.

Nor can it be maintained that the French regulations on prescription and substitution automatically result in infringement of patent rights in the case of a second therapeutic use of a given molecule which is protected, whereas previous indications for the same molecule are in the public domain.

In fact, WARNER LAMBERT has means to notify the administrative authorities pursuant to article 51211-14-3 of the Public Health Code which provides that: "A company which commercially exploits a pharmaceutical proprietary medicine contributes to satisfactory use of the latter by ensuring notably that its proprietary medicine is prescribed in compliance with its market authorisation referred to in article L. 5121-8 and, if applicable, temporary use recommendations referred to in article L. 5121-12-1, its temporary authorisation for use, referred to in article L.5121-12, its registration referred to in articles L.5121-13 or L.5121-14-1, its authorisation referred to in article L.5121-17.

It shall adopt all the information measures it deems appropriate for the attention of health professionals according to the fourth part of this Code if it observes prescriptions which do not comply with proper use of the proprietary medicine as defined in the first paragraph and shall promptly notify the French Agence nationale de sécurité du medicament et des produits de santé."

The documents exhibited during the discussions demonstrate that Pfizer, representing WARNER LAMBERT simply sent letters to ANSM, CESP and HAS:

- \* PFIZER PFE France wrote to ANSM on 27 July 2015 expressing concern about the imminent placing on the market exclusively of SANDOZ GMBH PREGABALINE GMBH and the real risk it believed of this proprietary medicine being prescribed and issued for protected indications of the molecule; it recalled its rights and requested ANSM to keep it informed of actions it intended to implement to prevent the supply of generics for the patented indication by setting out the measures adopted in other countries; in its letter it referred to the letter of 12 June 2015 to the company SANDOZ FRANCE.
- \* On 23 October 2014 PFIZER PFE France wrote to the COMITÉ ECONOMIQUE DES PRODUITS DE SANTÉ to recall the rights it held over patent EP 061 for the reference proprietary medicine marketed under the trademark LYRICA.

It exhibited the information letter of 16 July 2015 sent to it by this body stating that the SANDOZ laboratory (... sic PFIZER Limited) has solicited a request for its proprietary medicine PREGABALINE SANDOZ GMBH and that the latter had confirmed it was authorised to market it without infringing the company's rights.

\* On 12 October 2015 PFIZER PFE France wrote to HAUTE AUTORITÉ DE LA SANTÉ and COMITÉ ECONOMIQUE DES PRODUITS DE SANTÉ under terms similar to the letter of 27 July 2015 sent to ANSM.

Pfizer France representing WARNER LAMBERT sent a letter to ANSM on 7 December 2015 and 15 January 2016 but did not remind ANSM or CESP or HAS of the placing on the market of other generic "Pregabalin".

It only did so vis-à-vis ANSM after a period of six months, on 29 June 2016 immediately prior to initiating the interlocutory proceedings in August 2016.

On 8 December 2015 it sent a letter to which HAS responded on 18 December 2015 (exhibits B6-1) stating that the information disseminated was sufficient having regard to the existing legal texts.

It sent a letter to CEPS of which the mission is to fix the price of medicines, which replied on 3 November 2015 that it did not have competence in this area.

All the letters sent to HAS and ANSM refer exclusively to the dispute with the SANDOZ companies.

In letters dated 7 December 2015, it sent a copy of the interlocutory ruling of 26 October 2015 to the *Ordre national des médecins* and the pharmacists' equivalent body for more extensive dissemination of information provided by the SANDOZ companies; it sent new letters on 25 January and 4 April 2016 to the *Ordre des pharmaciens* which replied that the information already disseminated appeared adequate and on 10 December 2015 and 3 February 2016 to the *Ordre national des médecins*; the latter indicated it would include the item on the agenda of an imminent meeting.

In the same way, although the possibility of substitution of a generic for the *princeps* is encouraged by the legal texts, this option is subject to conditions and provides an option for physicians to indicate that the prescribed medicine cannot be substituted and for pharmacists, depending on the circumstances, to refrain from substituting the generic medicine for the *princeps* medicine.

Finally, an indication not included in the directory is not eligible for reimbursement; hence Pregabalin prescribed by a physician for a protected indication is not eligible for reimbursement.

These provisions adopted by the medical professionals are adequate to protect the indication which is protected by patent.

In fact, if Pregabalin is prescribed as an anti-epilepsy treatment always in combination with another treatment for epilepsy, the pharmacist may substitute the generic for the *princeps*.

If Pregabalin is prescribed for general anxiety, a non-protected indication but not eligible for reimbursement, the pharmacist may also substitute the generic for the princeps.

Finally if Pregabalin alone is prescribed (without another anti-epilepsy treatment and without the statement 'not eligible for reimbursement') or with the words 'not to be substituted' the pharmacist cannot substitute the generic for the *princeps*.

In the event of doubt, the pharmacist is authorised to question the patient to establish the reasons for the prescription and if there is a concern about breaching medical confidentiality, it is recommended talking to the patient in the privacy area which must be provided at each pharmacy.

In this case WARNER LAMBERT simply assumes that physicians prescribe generic Pregabalin to treat neuropathic pain, whereas use of Pregabalin for this indication remains protected and in the same way assumes that pharmacists are failing to comply with the regulations in force by supplying generic Pregabalin for the protected indication.

It does not adduce the slightest proof that health professionals are failing to comply with the legislation in force, other than by asserting a collective infringement not provided by the legal text and, moreover, not established.

Concerning measures seeking to structure the market share of each generic manufacturer having regard to the overall market share of generic Pregabalin:

In addition to the figure of 16.2% for the global market of Pregabalin which WARNER LAMBERT allocates to generic Pregabalin - itself the subject of serious dispute - it appears that the claims as proposed are contrary to European and domestic legislation and that a judge cannot in consequence order such measures.

In fact, article 101 paragraph 1 of the TFEU provides:

- "1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:
- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development, or investment;
- (c) share markets or sources of supply;
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts."

# Article L.420-1 of the French Commercial Code provides that:

"Any concerted actions, agreements, express or tacit understandings or coalitions are prohibited, including via the direct or indirect intermediary of a company a member of a group located outside France, if the object or possible object is to prevent, restrict or falsify competition on a market, if they seek to:

- 1. Limit access to the market or restrict free competition by other undertakings;
- 2. Hinder the fixing of prices by operation of the free market, by artificially favouring their increase or reduction;
- 3. Limit or control production, market outlets, investment or technical progress;
- 4. Share out markets or sources of procurement"

Regarding the exchange of information, the European Commission considers (Guidelines on applicability of article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements):

"Communication of information among competitors may constitute an agreement, a concerted practice, or a decision with the object of fixing prices or quantities. Such types of information exchanges will normally be considered and fined as cartels (...).

Information exchanges between competitors of individualised data regarding intended future prices or quantities should therefore be considered a restriction of competition by object."

Finally, concerning distribution agreements, the Competition Authority stated that "agreements on the sharing out of markets are considered by the competition authorities (...) as without justification and are therefore included in the most serious cases" (Cf. Decision No. 05-D-65 of 30 November 2005 on practices observed in the mobile phone sector).

By requesting that the defendants should jointly comply with a global sales ceiling of 16.2% of units sold (even assuming this figure is valid), WARNER LAMBERT requested the interlocutory judge to create an agreement by imposing measures that would constitute practices prohibited by European and French competition law if occurring between competitors, that is an exchange of sensitive information on sales volumes, distribution of volumes and therefore, directly or indirectly on customers and finally the splitting of market shares among the generic companies.

If executed by the defendant companies, these measures would require reaching an understanding on the monthly volumes allocated to each player operating in the Pregabalin market, to offer the claimants the required guarantee that the global ceiling would not be exceeded.

In consequence, the claims of WARNER LAMBERT before the interlocutory judge must be rejected in full.

## On the counterclaims

BIOGARAN, SANOFI and ZENTIVA, TEVA SANTÉ, ARROW GENERICS, HCS BVBE and KRKA France and EG LABO sought damages and interest for abusive proceedings against the claimant companies.

The exercise of a legal action constitutes in principle a right and becomes an abuse which can justify damages and interest exclusively in the event of malicious intent, bad faith or gross negligence equivalent to wilful misconduct pursuant to article 1382 of the French Civil Code.

In this case, it appears clear on reading the ruling that WARNER LAMBERT, PFIZER PFE France and PFIZER Limited summonsed the defendant companies without specifying the complaints against each of them, thus evading extensive work so they could seek an order for collective measures of which the unlawful nature is manifest having regard to the legislation on anti-competition practice and whereas they were perfectly well aware that none of the

defendants had infringed their rights by supply of means since the interlocutory judgement of 26 October 2015 - which they did not appeal – had already ruled this point.

WARNER LAMBERT, PFIZER PFE France and PFIZER Limited moreover never seized the court of first instance with a claim founded on infringement and notably in the petition seeking the annulment of their patent in the form of counterclaims.

The abusive character derives from the instrumentalisation of the court which was seized solely with a view to obtaining a decision justifying their claim that the existing legislation is inadequate to protect a second therapeutic use when the first indication has entered the public domain, that is not at all established that the legislation on non-substitutable medicines which are non-reimbursable affords sufficient protection by physicians and pharmacists of patented rights.

However, the claims of BIOGARAN, SANOFI and ZENTIVA, TEVA SANTÉ, ARROW GENERIQUES and EG LABO must be rejected, in default of establishing the existence of a loss other than that incurred as legal costs for their defence.

Nor are there grounds for pronouncing a civil fine against WARNER LAMBERT, PFIZER PFE France and PFIZER Limited pursuant to article 32-1 of the Code of Civil Procedure. TEVA SANTÉ which has not suffered a loss is unfounded in seeking publication on the website of the claimant companies or in newspapers, since these measures are intended to provide supplementary compensation

What is more, a publication measure pronounced as an interlocutory order is totally disproportionate.

Finally, the claim of TEVA SANTÉ for reimbursement of the costs for informing pharmacists and physicians is unfounded since by sending said mailings, TEVA SANTÉ merely fulfilled its obligations pursuant to article L.613-4 of the Intellectual Property Code.

This obligation does not derive from an obligation imposed by WARNER LAMBERT and is not a consequence of the proceedings initiated before the interlocutory judge.

The claim of TEVA SANTÉ should also be rejected.

## On the other claims

The conditions are satisfied to award SANDOZ, SANDOZ GmbH, GENERICS UK LIMITED, MYLAN, ZENTIVA KS, SANOFI AVENTIS FRANCE, HCS BVBA, KRKA FRANCE and ARROW GENERIQUES the amount of €0,000 paid jointly and severally by WARNER LAMBERT, PFIZER PFE France and PFIZER Limited pursuant to article 700 of the Code of Civil Procedure.

The conditions are satisfied to award BIOGARAN, TEVA SANTÉ and EG LABO – LABORATOIRES EUROGENERICS the amount of €100,000 paid jointly and severally by WARNER LAMBERT, PFIZER PFE France and PFIZER Limited pursuant to article 700 of the Code of Civil Procedure.

The claim for costs filed by ZENTIVA and SANOFI is unfounded before the interlocutory judge, since this provision of article 699 of the Code of Civil Procedure is intended to apply only when representation by counsel is mandatory.

#### FOR THESE REASONS

Adjudicating at a public hearing, by the making available at the registry, by a judgement pronounced after trial and at first instance

# On the partial withdrawal of the petition and action of WARNER LAMBERT, PFIZER PFE France and PFIZER Limited against RANBAXY:

**SAYS** that the withdrawal of the petition and action of WARNER LAMBERT, PFIZER PFE France and PFIZER Limited against RANBAXY PHARMACIE GENERIQUES is completed;

In consequence,

**RECORDS** the extinguishing of the claim and the declining of jurisdiction of the interlocutory judge in the dispute heard during the interlocutory proceedings between WARNER LAMBERT, PFIZER PFE France and PFIZER Limited exclusively for the company RANBAXY PHARMACIE GENERIQUES;

**SAYS** that each of the parties will pay the legal costs incurred in the context of this dispute pursuant to article 399 of the Code of Civil Procedure.

#### On the procedural objections

**REJECTS** the claim for annulment of the summons served by WARNER LAMBERT, PFIZER PFE France and PFIZER Limited on 9 August 2016 on TEVA SANTÉ.

**REJECTS** the objection of lack of jurisdiction formed by SANOFI FRANCE and ZENTIVA KS in favour of the pre-trial judge of the Paris Court of First Instance, 3<sup>rd</sup> Chamber, 3<sup>rd</sup> Section;

# On the inadmissibility:

**DECLARES** the claims of WARNER LAMBERT, PFIZER PFE France and PFIZER Limited inadmissible against SANDOZ and SANDOZ GmbH, given the authority of *res judicata* of the judgement pronounced on 26 October 2015.

**DECLARES** the actions of PFIZER FRANCE and PFIZER Limited brought together with WARNER LAMBERT inadmissible;

**REJECTS** the ground for inadmissibility asserted by BIOGARAN given criticisms of the administrative authorities;

**REJECTS** the grounds for inadmissibility asserted by TEVA SANTÉ against WARNER LAMBERT;

## On the claims of WARNER LAMBERT, PFIZER PFE France and PFIZER Limited:

**REJECTS** all claims of WARNER LAMBERT for infringement by supply of means against GENERICS UK LIMITED and MYLAN, ZENTIVA KS and SANOFI AVENTIS FRANCE, HCS BVBA, KRKA FRANCE, BIOGARAN, TEVA SANTÉ, EG LABO – LABORATOIRES EUROGENERICS and ARROW GENERIQUES since he probability of infringement is not established.

# On the counterclaims:

**REJECTS** the claims of BIOGARAN, EG LABO, TEVA SANTÉ, ZENTIVA KS, SANOFI FRANCE, ARROW GENERIQUES, HCS BVBA and KRKA France in their claims for damages and interest for abusive proceedings;

**REJECTS** the claims of TEVA SANTÉ for a civil fine, judicial publication and reimbursement of the costs of informing municipal and hospital pharmacists and physicians;

**REJECTS** the claim of ARROW GENERIQUES for a civil fine;

**ORDERS** WARNER LAMBERT, PFIZER PFE France and PFIZER Limited jointly and severally to pay SANDOZ, SANDOZ GmbH, GENERICS UK LIMITED, MYLAN, ZENTIVA KS, SANOFI AVENTIS FRANCE, HCS BVBA, KRKA FRANCE and ARROW GENERIQUES the amount of €0,000 each pursuant to article 700 of the Code of Civil Procedure;

**ORDERS** WARNER LAMBERT, PFIZER PFE France and PFIZER Limited jointly and severally to pay BIOGARAN, TEVA SANTÉ, EG LABO – LABORATOIRES EUROGENERICS an amount of €100,000 pursuant to article 700 of the Code of Civil Procedure;

**REJECTS** the claim for costs formed by SANOFI FRANCE and ZENTIVA KS;

**RECALLS** this judgement is enforceable by provision;

**ORDERS** WARNER LAMBERT, PFIZER PFE France and PFIZER Limited jointly and severally to pay costs.

Done in Paris, 2 December 2016

The Clerk The President

Noémie DUGAY Marie-Christine COURBOULAY