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## *COUR D'APPEL DE PARIS*

## Division 5 – Chamber 2

## DECISION OF 31 JANUARY 2014

(№ 023, 19 pages)

Docket number: **12/05485.**

Decision referred to the *cour d'appel*: Judgment of 27 January 2012 - *Tribunal de grande instance de PARIS* 3rd Chamber 3rd Section - Docket № 09/17355.

**APPELLANT:**

**SAS LABORATOIRES NEGMA**

represented by its legal representatives,

having its registered office located at 10 rue Paul Dautier 78140 VELIZY VILLACOUBLAY,

represented by SELARL RECAMIER Avocats Associés, through Mr Benoît HENRY, attorney-at-law, member of the PARIS bar, courthouse box: K0148,

assisted by Mr Louis DE GAULLE of SELAS de GAULLE FLEURANCE & Associés, attorney-at-law, member of the PARIS bar, courthouse box: K0035.

**RESPONDENT:**

**SAS BIOGARAN**

represented by its legal representative,

having its registered office located at 15 boulevard Charles de Gaulle 92700 COLOMBES,

represented by Mr Dominique OLIVIER, attorney-at-law, member of the PARIS bar, court room: L0069,

assisted by Mr Arnaud CASALONGA and Ms Marianne GABRIEL of the law firm CASALONGA, attorneys-at-law, members of the PARIS bar, courthouse box: K0177.

**COMPULSORY RESPONDENT[TN]:**

**LABORATOIRE MEDIDOM**

represented by its President,

having its registered office located at 44 Enetriederstrasse 6060 SARNEN (SWITZERLAND),

represented by Mr François TEYTAUD, attorney-at-law, member of the PARIS bar, court room: J125,

assisted by Mr Silvestre TANDEAU de MARSAC of the law firm FISCHER TANDEAU de MARSAC SUR & Associés, attorney-at-law, member of the PARIS bar, courthouse box P 147.

**COMPOSITION OF THE *COUR D'APPEL*:**

[TN] Laboratoire Medidom, party to the first-instance proceedings, did not appeal the judgment of the *tribunal de grande instance de Paris* dated 27 January 2012, but Biogaran lodged a cross-appeal for the finding of its liability, thus obliging Laboratoire Medidom to become party to the appeal proceedings.

The case was discussed on 5 December 2013 in public hearing before the *cour d'appel* composed of: Ms Marie-Christine AIMAR, Presiding Judge,

Ms Sylvie NEROT, Judge,

Ms Véronique RENARD, Judge,

who deliberated.

**Court Clerk** during the discussion: Mr Truc Lam NGUYEN.

**DECISION**:

After due hearing of the parties,

- pronounced publicly by making the decision available at the Court Clerk's office, the parties having been previously informed under the conditions provided in the second subparagraph of Article 450 of the French Civil Procedure Code,

- signed by Ms Marie-Christine AIMAR, Presiding Judge, and Mr Truc Lam NGUYEN, Court Clerk present when the decision was pronounced.

Having regard to Articles 455 and 954 of the French Civil Procedure Code,

Having regard to the order of the judge in charge of the case preparation of the *tribunal de grande instance de Paris* dated 21 October 2011,

Having regard to the judgment of 27 January 2012 handed down by the *tribunal de grande instance de Paris* (3rd chamber 3rd section),

Having regard to the appeals lodged on 23 and 27 March 2012 by Laboratoires Negma against both decisions,

Having regard to the order for consolidation of both appeal proceedings dated 24 May 2012,

Having regard to the decision of this *cour d'appel* division 5-2 dated 6 July 2012,

Having regard to the order of the judge in charge of the case preparation dated 14 March 2013,

Having regard to the decision of this *cour d'appel* handed down on 20 September 2013 on a judgment referred to it,

Having regard to the last pleading of Laboratoires Negma, the appellant, dated 18 November 2013,

Having regard to the last pleading dated 20 November 2013 of Biogaran, the respondent to the main appeal lodged by Laboratoires Negma, the appellant to the cross-appeal lodged against Laboratoires Negma and the appellant to the cross-appeal lodged against Laboratoire Medidom,

Having regard to the last pleading of Laboratoire Medidom, compulsory respondent to the cross-appeal lodged by Biogaran, dated 18 November 2013,

Having regard to the closing order dated 21 November 2013,

**WHEREUPON, THE *COUR D'APPEL*,**

Express reference is made to the appealed judgment and the parties' pleadings for a more detailed statement of the facts at issue and the proceedings.

It will simply be recalled that:

On 24 June 1992, Madaus AG filed European patent EP 0 520 414 claiming German priority № 412 09 89. This patent was granted on 13 March 1996 and its French translation was published in the *Bulletin officiel de la propriété industrielle* on 14 June 1996. It relates to a process for the preparation of diacetylrhein having a degree of purity making it suitable for use in pharmacies and having a total residual content of undesirable aloe-modin derivatives inferior to 20 ppm (parts per million) as well as diacetylrhein that may be produced by this process and a pharmaceutical composition containing this compound.

An exclusive licence under this patent was granted to Laboratoire Medidom and registered in the French patent register on 16 July 2001, before the patent was assigned to it by an act registered in the French patent register on 19 December 2006.

Laboratoire Medidom granted a licence, whose nature is disputed, for France to Laboratoires Negma according to an act registered in the French patent register on 2 February 2007; Laboratoires Negma marketed a pharmaceutical product named "*ART 50*", an anti-arthritis drug for long-term treatment.

On 21 January 2006, Biogaran filed three applications for marketing authorisation for the products named "*Diacéréine*"; on 4 and 9 September 2008, it obtained three marketing authorisations for the products named "*Diacérine Biogaran 50 mg gélules"*, "*Diacérine SET 50 mg gélules"* and "*Diacérine 50 mg Gélules"* and it marketed them as of 6 July 2010; the products are entered on the list of the refundable drugs.

On 4 September 2008, Laboratoires Negma itself applied for and obtained a marketing authorisation for its generic product under the name "*diacétylrhéine Negma 50 mg*".

On 7 October 2008, Laboratoires Negma sent Biogaran a letter, in which it argued that the products *Diacérine SET 50 mg gélules* and *Diacérine REF 50 mg gélules* were the generic drugs of the product *ART 50*, which it exploits on the French market, a product covered by patent EP 0 520 414, of which it is the exclusive licence-holder, and informed it that it would prevent the marketing of these products by any appropriate action and it took various administrative steps to suspend and revoke the MAs and their registrations on the list of the refundable drugs.

On 12 December 2008, Biogaran sued Laboratoire Medidom and Laboratoires Negma before the *tribunal de grande instance de Paris* for invalidity of claim 14 of the French designation of European patent EP 0 520 414 for lack of novelty and, in the alternative, for lack of inventive step.

On 5 February 2009, Laboratoires Negma sued Biogaran before the judge of the preliminary proceedings of the *tribunal de grande instance de Strasbourg* to stop the distribution, the production and the marketing of the generic pharmaceutical products, under penalty, on the basis of claim 14 of patent EP 520 414.

By an order of 10 March 2009, the judge of the preliminary proceedings enjoined Biogaran from marketing and distributing the generic pharmaceutical products ART 50, under a penalty of 30,000 euros per recorded infraction and per day and ordered the recall of all the ART 50 generic pharmaceutical products within 48 hours.

Biogaran lodged an appeal against this order before the *cour d'appel de Colmar*.

On 13 March 2009, by way of a supplementary pleading filed before the *tribunal de grande instance de Paris*, Biogaran requested that the court order Laboratoires Negma to pay it an interim payment to the sum of 2,000,000 euros in compensation for the damage suffered from the injunction from marketing the generic drugs, which was pronounced by an order in preliminary proceedings dated 10 March 2009.

On 27 March 2009, Laboratoires Negma sued Biogaran on the merits for infringement before the *tribunal de grande instance de Strasbourg*.

On 16 April 2009, Laboratoires Negma sued Biogaran for calculation of the penalty before the *tribunal de grande instance de Strasbourg*, which dismissed its claim according to the order of 2 June 2009.

On 10 July 2009, the judge in charge of the case preparation of the *tribunal de grande instance de Paris* dismissed the plea of lack of jurisdiction to rule on the claim for compensation raised by Laboratoires Negma, by reason of the injunction from marketing the generic drugs, in favour of the judge ruling on the enforcement.

On 17 November 2009, at Biogaran's request, the judge in charge of the case preparation of the *tribunal de grande instance de Paris* ordered the separation of proceedings № 08/17625 and № 09/17355 relating to the validity of the patent and the other claims respectively.

On 10 December 2009, the judge in charge of the case preparation of the *tribunal de grande instance de Strasbourg* referred the proceedings relating to the infringement of the generic drugs to the *tribunal de grande instance de Paris*.

On 31 March 2010, the *tribunal de grande instance de Paris* pronounced the invalidity of claim 14 of the French designation of European patent EP 0 520 414 for lack of novelty, with provisional enforcement.

On 30 June 2010, the *cour d'appel de Paris* affirmed the judgment of 31 March 2010 pronouncing the invalidity of this claim.

On 22 June 2010, the *cour d'appel de Colmar* reversed the injunction and recall measures ordered by the judge of the preliminary proceedings of the *tribunal de grande instance de Strasbourg*.

On 10 September 2010, the *cour d'appel de Paris* affirmed that the *tribunal de grande instance de Paris* had jurisdiction to rule on Biogaran's claims for compensation.

On 11 February 2011, Laboratoires Negma and Laboratoire Medidom's plea of lack of jurisdiction in favour of the judge ruling on the enforcement was dismissed by an order of the judge in charge of the case preparation.

On 15 July 2011, before the *tribunal de grande instance de Paris*, Laboratoires Negma raised a priority question on constitutionality relating to the application of Article 31 subparagraph 2 of French Act № 91-658 of 9 July 1991 reforming the enforcement civil procedures in the case of a preliminary injunction if the judge holds that there is a likelihood of infringement of an intellectual property right, which would breach the ownership right guaranteed by the constitution.

**By way of an order of 21 October 2011**, which is appealed, the judge in charge of the case preparation of the *tribunal de grande instance de Paris* dismissed the new claim for the submission of a priority question on constitutionality to the *Cour de cassation*, relating to the constitutionality of Article 31 subparagraph 2 of the French Act of 9 July 1991 regarding the intellectual property law and referred the cause and the parties to the court ruling on the merits.

**By way of a judgment of 27 January 2012**, which is appealed, the *tribunal de grande instance de Paris*:

- held Biogaran's claims admissible,

- held that Article 31 of the French Act of 9 July 1991 applies in the case of preliminary injunction measures in matters of intellectual property,

- held that there is no reason to apply the provisions of Articles 9 § 7 of the Directive of 29 April 2004 and Article 50 § 7 of the TRIPS Agreement directly,

- held that in the absence of doubt about the interpretation to be given to the aforementioned provisions of the Directive of 2004, there is no reason to submit the following question to the Court of Justice of the European Union for a preliminary ruling:

*"Should Articles 3 and 9 of the Directive dated 29 April 2004, derived from the 'TRIPS' Agreement of 15 April 1994, providing interim measures of a proportionate and deterrent nature, be interpreted in the sense that they go against a national regulation, the effect of which is to introduce a strict liability of the holders of intellectual property rights resorting to interim measures to enforce their right?",*

- held that Laboratoires Negma enforced at its own risk the order handed down on 10 March 2009 by the President of the *tribunal de grande instance de Strasbourg* and that it therefore has to compensate for the resulting harmful consequences,

- accordingly, ordered Laboratoires Negma to pay the sum of 2,997,575 euros to Biogaran as compensation for the damage suffered from the recall and the preliminary injunction from marketing the following ART 50 generic pharmaceutical products:

* *Diacérine Biogaran 50 mg gélules CIS 6 793 610 6,*

* *Diacérine Ref. 50 mg 6 gélules CIS 6 480 333 9,*

* *Diacérine Set 50 mg 6 gélules CIS 6 211 751 2,*

- dismissed all of Biogaran's claims against Laboratoire Medidom,

- dismissed Biogaran's claims based on Article 1382 of the French Civil Code against Laboratoires Negma,

- ordered Laboratoires Negma to pay the sum of 200,000 euros to Biogaran pursuant to Article 700 of the French Civil Procedure Code,

- ordered Biogaran to pay the sum of 40,000 euros to Laboratoires Negma pursuant to Article 700 of the French Civil Procedure Code,

- ordered the partial provisional enforcement of the decision on the irrecoverable costs and Laboratoires Negma being ordered to pay damages to Biogaran up to the sum of 1,500,000 euros.

**On 6 July 2012 the *cour d'appel*, division 5-2, held that the priority question on constitutionality is not serious and that there is no reason to submit it to the *Cour de cassation*.**

On 14 March 2013, the judge in charge of the case preparation dismissed Laboratoire Medidom's claim for the inadmissibility of the cross-appeal lodged against it by Biogaran and, by a decision of 20 September 2013, the *cour d'appel* held inadmissible the request submitted by Laboratoire Medidom to reverse this order.

**Laboratoires Negma, the appellant,** requests in its last pleading of 18 November 2013 that the *cour d'appel*:

- affirm the judgment in that it dismissed Biogaran's claims for Laboratoires Negma's fault liability,

- reverse the judgment on the other provisions,

- accede to the plea of inadmissibility drawn from the lack of jurisdiction of the 3rd Chamber of the *tribunal de grande instance* pursuant to Article L. 111-10 of the French Enforcement Civil Procedure Code,

- hold that the first-instance judges exceeded their power justifying the annulment of the judgment,

- hold that the first-instance judges violated the right to a fair trial provided in Article 6-1 of the European Convention for the Protection of Human Rights and Fundamental Freedoms by ruling in the same panel as

that which pronounced the revocation of a patent,

*in the alternative,*

- hold and judge that Article L 111-10 of the French Enforcement Civil Procedure Code cannot apply in the case of preliminary injunction measures in matters of intellectual property,

- if there is some doubt on the interpretation to be given to the provisions of Article L. 615-3 of the French Intellectual Property Code, seize the Court of Justice of the European Union with the following question for a preliminary ruling:

"*Should Articles 3 and 9 of the Directive dated 29 April 2004, derived from the 'TRIPS' Agreement of 15 April 1994, providing interim measures of a proportionate and deterrent nature, be interpreted in the sense that they go against a national regulation, the effect of which is to introduce a strict liability of the holders of intellectual property rights resorting to interim measures to enforce their right?*

*If the question is answered by no, does Article 9.7 of the Directive of 29 April 2004, which authorises the judicial authorities to grant an appropriate compensation for any damage suffered from the protective measure if it is found later that there was no violation or threat of violation of an intellectual property right, only refer to the case of non-infringement or does it extend also to the case of a subsequent revocation of the intellectual property right in dispute?*

*If the appropriate compensation of the party having been the subject of a preliminary injunction measure covers the case of the retroactive revocation of the asserted property right, does Article 9.7 of the Directive of 29 April 2004 oppose a national regulation requiring, with this respect to this appropriate compensation, a restitution by equivalence to the victim, which is meant as covering both the damage intrinsic to the injunction measure, but also the extrinsic damage such as the operating loss or the loss of use suffered during the entire period of injunction?*"

*in any case,*

- dismiss all of Biogaran's claims,

- order Biogaran to pay the sum of 250,000 euros to it pursuant to Article 700 of the French Civil Procedure Code,

- in the very alternative,

- hold and judge that the preliminary injunction lasted from 13 March 2009 to 31 March 2009,

- hold and judge that the assessment of Biogaran's damage cannot exceed the sum of 598,000 euros,

- if the capacity as exclusive licensee is denied to it, hold and judge that Laboratoire Medidom alone is liable for the damage suffered by Biogaran from the preliminary injunction of 10 March 2009.

**Biogaran, the respondent, the appellant to the cross-appeal and the appellant to the cross-appeal lodged against Laboratoire Medidom,** requests in its last pleading of 20 November 2013 that the *cour d'appel*:

- dismiss Laboratoire Medidom's claim for a stay of the proceedings,

- reverse the judgment in that it dismissed its claims lodged against Laboratoires Negma,

- giving a new ruling,

- hold and judge that Laboratoires Negma and Laboratoire Medidom, by their manoeuvres, committed distinct faults having contributed to the damage suffered by Biogaran and involved their liability,

- order both companies jointly and severally to pay it the additional sum of 7,884,646 euros as main claim or, at least, the sum of 5,072,220 euros in the alternative as compensation for the loss of profits by reason of the preliminary injunction from marketing its products,

- order Laboratoires Negma to pay it the additional sum of 500,000 euros as compensation for the harm caused to its image,

- order both companies jointly and severally to pay it the additional sum of 150,000 euros pursuant to Article 700 of the French Civil Procedure Code,

- affirm the judgment on the other provisions.

**Laboratoire Medidom, the compulsory respondent to the cross-appeal,** requests in its last pleading of 18 November 2013 that the *cour d'appel*:

- stay the proceedings pending a final decision in the proceedings before the *Cour de cassation* against the decision of 20 September 2013,

- in the alternative, hold inadmissible the cross-appeal lodged against it by Biogaran,

- dismiss Biogaran's claims against it,

- in the very alternative, affirm the decision in that it dismissed all of Biogaran's claims against it,

- order Biogaran to pay it the sum of 150,000 euros pursuant to Article 700 of the French Civil Procedure Code.

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**On the claim for a stay of the proceedings:**

Laboratoire Medidom, in its last pleading of 18 November 2013, after having already filed a pleading on the merits on 24 December 2012, requests that the proceedings be stayed pending the outcome of the proceedings before the *Cour de cassation*, which it brought on 23 October 2013.

However, this appeal does not suspend the enforcement of the criticised decision and Laboratoire Medidom enjoyed long periods of time in which to file a pleading on the merits to dispute the merits of the claims lodged against it, so that there is no reason to accede to this claim for a stay of the proceedings, which would excessively delay the outcome of this case, which was subject to numerous procedural issues raised late and designed to delay.

**On the admissibility of the cross-appeal lodged by Biogaran against Laboratoire Medidom:**

Laboratoire Medidom argues that this appeal is inadmissible as it does not originate in the main appeal with respect to its limited nature and on the grounds that the claims lodged against it are different from those lodged against the main appellant.

Biogaran argues that this appeal is admissible as the judge in charge of the case preparation rightly held.

According to Article 547 of the French Civil Procedure Code, all the parties in first instance may be respondents.

Article 550 of the same Code sets forth that a cross-appeal against the main appellant or a compulsory respondent may be lodged in any case even if the party lodging it would have exceeded the legal time limit to lodge main claims.

Biogaran, the respondent to the main claims, is entitled to lodge a cross-appeal against Laboratoire Medidom, which is not present on appeal, but which was party to the first-instance main proceedings and against which it had lodged claims for a finding of liability.

Furthermore, the declaration of main appeal lodged by Laboratoires Negma on 27 March 2012 indicates that a total appeal for the annulment or the reversal of the judgment handed down on 27 January 2012 by the *tribunal de grande instance de Paris* 3rd Chamber, 3rd Section and, in its last appeal pleading, this company requests in particular that the *cour d'appel* affirm the judgment in that it dismissed Biogaran's claims for Laboratoires Negma's fault liability and reverse the judgment regarding the other provisions, so

that it be a general appeal regarding the provisions that are even indirectly against it, for instance the issue of Laboratoire Medidom's liability. Biogaran is threatened by the main appeal proceedings since it considers that the manoeuvres carried out jointly by both companies caused it one and the same damage for which it has claimed compensation since the beginning of the proceedings, jointly and severally against them, so that it has a new interest in lodging an appeal against Laboratoire Medidom.

This interest is all the more manifest given that, according to it, it would have had confirmation, since the referred judgment, of an element on which it relied and which relates to the fact that Laboratoires Negma was not an exclusive licensee under the patent at issue.

Consequently, this cross-appeal against Laboratoire Medidom is admissible and the plea of inadmissibility lodged by Laboratoire Medidom should be dismissed.

**On Laboratoires Negma's and Laboratoire Medidom's liability and the validity of the judgment:**

* On Laboratoires Negma's strict liability:

Biogaran argues that Laboratoires Negma is strictly liable to it because of the enforcement of the order in preliminary proceedings authorising the injunction and recall measures.

Under Article L. 111-10 of the French Enforcement Civil Procedure Code, *"the enforcement on the basis of a provisionally enforceable right may be carried out until it is completed. The enforcement is carried out at the risk of the creditor, who shall restore the debtor's rights in kind or by an equivalent, should the right be subsequently modified."*

In the present case, Biogaran enforced the preliminary injunction and recall measures authorised by an interim order of 10 March 2009 on the basis of claim 14 of patent EP 0 520 414, which had been the subject of an invalidity action since 12 December 2012 brought by the opposing party and of another invalidity action brought previously in 2007 by a third company.

The event giving rise to the obligation of compensating for the consequences of this enforcement carried out at Laboratoires Negma's risk is constituted by the enforcement of the interim order resulting from its service, by the reminder sent on 20 March 2009 to Biogaran and by its summons for calculation of the penalty.

Laboratoires Negma raises in vain the lack of jurisdiction of the *tribunal de grande instance de Paris* to rule on this action based on Article L. 111-10 of the French Enforcement Civil Procedure Code in favour of the judge ruling on the enforcement with respect to the provisions of Article L. 213-6 of the French Judicial Organisation Code, which provides that *'"the judge ruling on the enforcement deals exclusively with the difficulties relating to the enforceable titles and the disputes, which rise in case of enforcements, even if they relate to the merits of the law unless they do not fall within the jurisdiction of the courts of the judicial order"*, since this plea of lack of jurisdiction, which, admittedly, is based on the general principle of civil liability regarding the jurisdiction of the judge ruling on the enforcement to hear the action for liability following the enforcement of the order in preliminary proceedings at issue, was dismissed by an order of the judge in charge of the case preparation of 10 July 2009 affirmed by a decision of this *cour d'appel* of 10 September 2010 and by an order of the judge in charge of the case preparation of the *tribunal de grande instance de Paris* dated 11 February 2011, which was not appealed.

It should be noted in addition that, in the present case, it is not a question of enforcement or protective measures within the meaning of Article L. 213-6 of the French Judicial Organisation Code since the respondent enforced the order spontaneously in a dispute that falls within the exclusive jurisdiction of the *tribunaux de grande instance* according to Article L. 615-17 of the French Intellectual Property Code.

The exclusive jurisdiction of the judge of the enforcement provided in Article R. 121-4 of the French Civil

Procedure Code relates only to its field of action limited to the difficulties in enforcement of the decisions or the interim measures that he ordered and the harmful consequences that may result therefrom.

As a result, the claim for the annulment of the judgment lodged by Laboratoires Negma for excess of power is not founded as the *tribunal* settled the dispute within the framework of its material jurisdiction.

To dispute the validity of the judgment, Laboratoires Negma argues that it would not be fair for the same judges to give a ruling first in the proceedings for the revocation of the patent and then on the compensation.

However, nothing prohibits the same judge from ruling successively on the merits and the issues related to each other, which, on the contrary, is provided by the French Civil Procedure Code itself for ancillary, additional and counter claims...; otherwise, it would require systematically separating the trial between, first, proceedings for infringement with the examination of the appraisal of the validity of the asserted right and, second, proceedings for the compensation for the resulting consequences.

The separation of the proceedings in first instance between the action for the validity of the patent and Biogaran's additional claims for liability and the defendants' counterclaims did not modify the nature of this dispute, which could have been judged globally by the same judges.

This dispute on the validity of the judgment, which is no more founded than the previous one, should be dismissed.

In the alternative, Laboratoires Negma continues its dispute by indicating that the provisions of Article L. 111-10 of the French Enforcement Civil Procedure Code cannot apply to preliminary measures ordered on the basis of Article L. 615-3 of the French Intellectual Property Code as this first Article can only apply to enforcements, which is not the case here, while only the special action in preliminary proceedings for injunction provided in this Article was brought.

But it is established that aforementioned Article L. 111-10 applies as it is justified, as in the present case as recalled above (service of the order, reminder, summons for calculation of the penalty), that the creditor of the obligation showed its intention to continue the provisional enforcement of the decision unambiguously.

Laboratoires Negma adds that the preliminary proceedings for injunction provided in Article L. 615-3 of the French Intellectual Property Code, which constitutes a specific procedure, leads to applying a specific compensation procedure based on the demonstration of a fault.

But this Article, which provides, in these last subparagraphs, the possibility of subjecting the enforcement of the ordered measures to the deposit of guarantees to ensure the possible compensation of the opposing party if the infringement action is later judged unfounded and, regarding the measures annulled, the possibility of the payment of damages if the action on the merits is not brought within the required time limits, does not provide a specific limited compensation, contrary to the appellant's allegations on the implementation of the preliminary proceedings for injunction, and the general principle of the right to total compensation for the damage suffered, if its reality is justified, should consequently apply.

This Article, which mentions the possible damage, relates to that resulting equally from fault liability and strict liability, with no restriction being introduced by these provisions.

Laboratoires Negma argues also that the revocation of the patent does not make it possible to challenge the prior decisions. But the decision at issue was purely interim and was reversed, hence, when it was finally judged, as in the present case, that no infringement act could be reproached to Biogaran, it can bring an action for liability against the author of this inappropriate enforcement, without introducing any discrimination between citizens before the law; on the contrary, this action re-establishes the freedom of

exercising its rights by the person who suffered from the effects of this challenged enforcement.

This action for restoration in kind or by an equivalent of the rights of the debtor harmed by the enforcement of the obligation, which was later annulled, is only the consideration for the exceptional prerogative granted by the law to the claimant to seek the order of preliminary measures hindering free trade, at its own risk.

As a result, Biogaran's claim for the application of Article L. 111-10 of the French Enforcement Civil Procedure Code is admissible and founded.

Laboratoires Negma requests that three questions be asked to the Court of Justice of the European Union for a preliminary ruling:

1st question: request that the CJEU determine if the provisions of the Directive of 29 April 2004 derived from the TRIPS Agreement should be interpreted in the sense that they go against the acknowledgment by a national regulation of strict liability while it tends to provide a high level of protection of the intellectual property rights and appropriate and adequate compensation if the injunction measures were taken abusively;

It maintains that the phrase "*possible compensation*" mentioned in Article L. 615-3 of the French Intellectual Property Code supposes the prior demonstration of a fault.

But it has been indicated above that this Article did not exclude the application of strict liability and the provisions of the aforementioned Directive, which provide that the judicial authorities are authorised to grant appropriate compensation for any damage caused by the measures, are unequivocal and need no interpretation.

2nd question: ask the CJEU if Article 9.7 of the Directive of 29 April 2004 only refers to the case of non-infringement or if it extends to the case of the revocation of the patent.

It argues in that respect that the revocation of the patent is not included in the events giving rise to the compensation provided in Article 9.7 of this Directive and Article L. 615-3 of the French Intellectual Property Code.

But both provisions, which are clear, need no interpretation; appropriate compensation is provided in this case.

Article L. 615-3 of the French Intellectual Property Code refers to the case when, as in the present case, the infringement action is unfounded or the measures are annulled while Article 9.7 of the Directive of 29 April 2004 refers to the same circumstances: *'"the cases when it is found later that there was no infringement of an intellectual property right"* either because the right was revoked or because there is no infringement.

3rd question: ask the CJEU if the possible compensation of the alleged infringer, against whom an injunction was wrongly ordered, provided in Article 9.7 of the aforementioned Directive, should be limited to the expenses incurred for the enforcement of the measure or should include the loss of profits in the marketing that was aborted during the injunction period.

But, as Biogaran emphasises, these provisions need no interpretation as they make no distinction: "*In cases where the preliminary measures are abrogated or will stop to apply by reason of any action or omission from the claimant, or in cases where it is founded later that there was no infringement or threat of infringement of an intellectual property right, the judicial authorities are authorised to order the claimant, at the defendant's request, to grant the latter appropriate compensation for any damage caused by these measures."*

Consequently, there is no reason to accede to these unfounded claims.

Laboratoires Negma requests that the *cour d'appel* hold by interpretation that the aforementioned

Article L. 111-10 can only make available an action for fault liability, unless the presumption of validity of the granted patents and Article 6 § 1 of the European Convention for the Protection of the Human Rights is ignored.

However, there is no reason to interpret a clear text and to add elements contrary to the law.

The presumption of validity of a patent, like any presumption, may be disputed when the patent is asserted to hinder the free trade of a competitor, which is guaranteed by Article 4 of the French 1789 Declaration of the Right of Man and of the Citizen, otherwise a disproportionate protection is granted to the patent.

Laboratoires Negma, which used the possibilities of seizing the courts to enforce its rights and to enjoy the two-tier judicial system in multiple ways when it was unsatisfied with the decisions, is not in any position to argue that the provisions of the European Convention for the Protection of the Human Rights were violated.

Laboratoires Negma argues wrongly that the application of Article L. 111-10 of the French Enforcement Civil Procedure Code is subject to the application of a fault and the *tribunal* applied this Article rightly following the enforcement of the injunction measures claimed and obtained by it in the preliminary proceedings for injunction in matters of patent and held that Biogaran's claim for compensation for the negative effects resulting therefrom is admissible and founded.

* On Laboratoires Negma's and Laboratoire Medidom's fault liability:

On the basis of Article 1382 of the French Civil Code, Biogaran claims for a finding of liability of Laboratoires Negma and Laboratoire Medidom, which, according to it, have committed an abuse of proceedings by their delaying manoeuvres and their intention to cause harm.

Biogarant argues in this respect that these companies carried out various blocking manoeuvres to reserve a monopoly on diacetylrhein, although it fell within the public domain:

- by intervening unusually in the prosecution procedure of the generic drug by its letters of 11 March 2008, 28 May 2008 and 13 August 2008, by requesting analyses of the active ingredients, delaying the grant of the marketing authorisation, by pressing the AFSSAPS to see the content of aloe-modin reduced, which caused an increase in the production cost of the active ingredient, while it itself had placed products with higher rates on the market,

- thus by obliging its competitors to make these modifications; it wanted their product to fall within the scope of claim 14,

- by delaying the grant of the MAs for two and a half years,

- by lodging (Laboratoires Negma) requests in preliminary proceedings for a suspension and annulment of the marketing authorisations before the *Conseil d'État*, which were dismissed, by persisting before the AFSSAPS after the grant of the MAs and by bringing preliminary proceedings for the record by a court-appointed expert of the facts in dispute on 21 October 2008, which are still in progress,

- by seizing the President of the CEPS on 15 January 2009 with an appeal for reconsideration of his/her decision on the price set for *Diacérine Biogaran*, which was refused, and by disputing this decision before a court.

Biogaran continues and argues that, with Laboratoire Medidom's complicity, Laboratoires Negma asserted its capacity as exclusive licensee to obtain preliminary injunction measures while it is not the company designated by licence № RCS 410.102.008; the company registered under № RCS 306 094 053 is different and itself is not an exclusive licensee since Pharma 2000, which is not a sub-licensee contrary to Laboratoires Negma and Laboratoire Medidom's allegations, also enjoys a licence, which it has exploited since 2007.

It adds that, by a letter of convenience from Laboratoire Medidom, which acknowledges that it has the capacity of exclusive licensee, Laboratoires Negma could sue Biogaran in preliminary proceedings in Strasbourg in the short term while the *tribunal de grande instance de Paris* had been seized earlier, that Laboratoires Negma's registered office is in Vélizy and that of Biogaran in Colombes and while the launch of the product was national.

Both companies multiplied the procedural issues afterwards to delay the outcome of the case so that 20 court decisions were handed down in addition to the administrative appeals.

Biogaran also argues that, as early as 30 January 2009, Laboratoires Negma sent a letter to all the pharmaceutical wholesalers and distributors leading them to believe that its rights were allegedly acknowledged by a court, which constitutes a real pressure on them; then, sent a second letter to the wholesalers and pharmacists on 2 February 2009, in the same words as the first one; then, sent them a letter on 13 March 2009 informing them of the content of the order pronouncing the injunction measures without indicating that this decision was temporary.

It deduces that all these unfair manoeuvres contributed directly to the damage that it suffered.

Laboratoires Negma argues that it committed no fault in the defence of the patent under which it was the exclusive licensee and for which it paid royalties, which Laboratoire Medidom confirms, and that it took necessary and reasonable steps, since the launch in 2010 of the generic drugs had disastrous economic and social consequences for its company.

It indicates that it is not liable for the prosecution periods of the marketing authorisations in the AFSSAPS, which is an independent institution, that Biogaran faced by reason of its inability to produce *ab in initio* a *Diacerin* identical to that of the proprietary medicine.

The dialogue that it started with the AFSSAPS was legitimate since it is the MA-holder for the proprietary medicine and the choice of procedure made by Biogaran.

However, it results from all the elements mentioned, justified by Biogaran and recalled above that, by its multiple interventions, which were acknowledged and claimed with the administrative authorities, which were moved in a memorandum filed with the *Conseil d'Etat* under the pretext of guaranteeing health security, then, once the authorisations were granted by their systematic disputes in court, then by the multiplication and accumulation of procedural issues, its summons for infringement before the *tribunal de grande instance de Strasbourg* with no real basis before that court - judicial disputes that were dismissed - the sending to resellers and pharmacists of letters denigrating Biogaran indirectly, by this delaying strategy and these manœuvres, Laboratoires Negma went beyond the legitimate defence of its interests to block the peaceful development and marketing of its competitor's products unfairly and knowingly while its patent was already attacked and it could not ignore that the only change in the purity degree was a factor of fragility as diacerin was already in the public domain.

These wrongful manœuvres for misusing the judicial paths degenerated into an abuse of proceedings and caused direct damage to Biogaran, both financial and moral, vis-à-vis its partners.

Laboratoires Negma maintains that Biogaran contributed to the creation of its damage by wrongful acts.

It reproaches it for having launched its drugs at its own risk and having only taken the patent into consideration four years before its expiry and not as soon as it was granted on 13 March 1996.

But Biogaran, which was created on 9 May 1996 after the grant of the patent, brought its action for invalidity of the patent before Laboratoires Negma brought its action in preliminary proceedings for injunction and marketed its products only when it was convinced, thanks to its own developments, of the

invalidity of claim 14 of the patent, whose validity had been disputed since 2007.

Contrary to Laboratoires Negma's allegations, it is not justified that Biogaran had recourse to an inappropriate administrative procedure for the grant of MAs for generic drugs, which is furthermore contradicted by the terms of the memoranda drafted by the AFSSAPS in the procedures for administrative disputes.

Furthermore, it is not demonstrated that Biogaran made contradictory statements during the proceedings, which, in any case, would have had no consequence on the damage it incurred.

Laboratoires Negma is not in a position to reproach Biogaran for not having requested that the *cour d'appel de Colmar* hear the case on a fixed day while its requests for accelerated proceedings is justified and that, furthermore, Laboratoires Negma multiplied the procedural issues to delay the outcome of this case excessively.

Laboratoires Negma and Laboratoire Medidom establish no fault imputable to Biogaran that could contribute to the creation of its damage.

On the contrary, as Laboratoires Negma is the only one to initiate these acts, its presentation in its capacity as exclusive licensee - a capacity that Laboratoire Medidom has expressly acknowledged since the beginning - and the position within the Whockardt France group of the different companies of the group, which makes compatible the payment of royalties by Pharma 2000, which appears as its sub-licensee through the acts, directly to Laboratoires Negma, without disqualifying this exclusive nature, which is, furthermore, expressly mentioned in its contract duly published in the French patent register, lead to the fact that no fault is established against Laboratoire Medidom.

Reversing the judgment partially in this respect, the action for fault liability brought by Biogaran against Laboratoires Negma should be held founded and the judgment should be affirmed in that it dismissed its action for fault liability brought against Laboratoire Medidom.

**<u>On the remedies</u>:**

Biogaran claims the payment of the sum of 8,282,213 euros, all taxes excluded, for the period from 18 March 2009 to 30 June 2010, the date upon which the order pronouncing the injunction measures was reversed.

Biogaran is justified in claiming the entire compensation for its damage by an equivalent directly linked to Laboratoires Negma's failures for the period corresponding to the injunction measures, to which it remained subject under penalty, notwithstanding the revocation in March 2010 of the patent claim, that is, until 30 June 2010, contrary to the opposing parties' allegations. The observations of the audit firm Mazars dated 26 July 2013 do not oppose a legal appraisal.

It bases itself on the report by the independent expert, the audit firm Deloitte, which examined the accounting data, most of which were certified by an auditor and a chartered accountant, like the contracts, sales data and forecasts, to which a study performed by Smart Pharma Consulting, specialised in pharmaceutical market studies, dated 19 May 2010 and 17 March 2011 is attached.

Laboratoires Negma and Laboratoire Medidom criticise the study performed by Smart Pharma on the grounds that its manager had allegedly worked for Servier International and lacked objectivity.

However, this study is based on objective elements and no established impartiality is demonstrated while Laboratoires Negma, behaving in the very manner it reproaches its adversaries, produces a report to the contrary, drafted by JNB Développement, written by Ms Caroline Delaitre Bonnin, Laboratoires Negma's

former manager of regulatory affairs.

In its first report drafted on 19 May 2010, the audit firm Deloitte had formulated hypotheses from a sample established by four criteria of choice explained in its study, then updated the assessment of the damage by limiting the panel of products comparable with the Biogaran products, by interviewing managers and directors of companies competing with Biogaran to establish the extent of the period of exclusivity that this company would have enjoyed if the preliminary injunction had not been ordered, by taking into account the real sales data of the different laboratories in the market.

It assessed the damage by taking into account the loss of the incremental profit margin relating to the lost sales and the additional costs incurred by the company.

It checked the consistency between the formulated hypotheses with respect to the data in the market, explaining and illustrating its work with graphics.

Consequently, this expert delivered a complete and serious work that can be used as a base for the assessment of the damage suffered by Biogaran.

It emerges therefrom that Biogaran:

- incurred expenses for the recall of the products (108,413 products) between 23 January and 12 March 2009, their return, their storage, their re-processing, and expenses for preparation and delivery, which were not re-invoiced: 397,576 euros,

- suffered a loss of profits: loss of incremental profit margin when exploitation of this drug was halted, corresponding to the turnover less the production and marketing charges without deducting the marketing and advertising costs, which are fixed costs incurred regardless of the production volume, and after deduction of the sales commissions and the taxes of variable nature: a total loss of 7,775,504 euros, a partial loss of 109,142 euros on the delay in the marketing which is certain and directly linked to the loss of exclusivity.

The latter are assessed by taking into account the fact that Biogaran would have been in a position of exclusivity from March 2009 to June 2010 in the absence of an established intention of marketing this generic drug from the competitors, which marketed it only after the final revocation of the patent, as noted on competitors' similar products, while it had exploited the drug in exclusivity before the injunction measures between 23 January 2009 and 10 March 2009.

The purchase by Mylan of the active ingredient in December 2008 does not establish its intention to market these products immediately, which it did not do, requesting the registration of the drug on the list of refundable drugs only in June 2010, since Biogaran itself acquired the active ingredient several months before in May 2008 before marketing its product.

In addition, two directors of companies in direct competition with Biogaran certify that they were not able at that time to market the generic drug at issue.

It is not established that the absence of marketing of the generic drugs by the competitors is directly linked to the injunction order and that in the absence of the order they would have marketed this generic drug, while it should be recalled that Biogaran was the only one to market it when the injunction measures were ordered and that only Mylan and Teva, which started the marketing after the invalidity of the patent was affirmed, did not market this drug before either for their own reasons (Mylan) or because they were not in a position to do so due to a lack of MA (Teva).

Furthermore, in March 2009, Laboratoires Negma defended its patent and could not market generic drugs without contradicting itself.

By calculating the penetration rate of the Biogaran generic drug based on the penetration rate for the real one calculated in February 2009, i.e., 16.1%, then over the period of time from March 2009 to June 2010 by analogy with comparable products, which are relevant due to their ease of substitution, the audit firm Deloitte assessed a loss of 1,738,441 boxes, i.e. a penetration rate of 16.1%, which corresponds to the 16.4% calculated in February 2009.

The firm fixed the net selling price of the drugs at the sum of 7.967 euros by taking into account a 17% discount rate calculated on the basis of the accounting document and establishes the turnover lost at the sum of 13,766,491 euros.

The cost price of a box as certified by the auditors and the invoices produced amounts to the sum of 3.0141 euros, i.e. a total of 5,239,835 euros.

The incremental profit margin rate was consequently fixed by this expert at 56.5%, which would correspond to that recorded by the company in 2010 and 2011.

All these elements are based in particular on the real manufacture and distribution invoices and accounting exhibits transmitted by Biogaran, certified by the auditor.

Because of the injunction measures, Biogaran lost a competitive advantage as mentioned above.

By taking into account the market of Diacereine over the period from July 2010 to December 2011, the assessment of the penetration of the generic drugs and the assessment of Biogaran's market share if it had enjoyed exclusivity until June 2010, Smart Pharma indicated that this company would have marketed 93,875 more boxes, accordingly representing a loss of turnover of 193,514 euros, i.e. a loss of the incremental profit margin of 109,142 euros.

It emerges from all these elements that Biogaran suffered damage of 7,884,646 euros due to Laboratoires Negma's acts according to this report.

However, as Laboratoires Negma and Laboratoire Medidom relevantly emphasise, the auditor, who certified some figured data, did it only on the basis of those produced by Biogaran by checking their consistency while he specified that he carried out neither audit nor survey on the consequences of the withdrawal. Moreover, Biogaran has never produced the analytical accounts, which had been requested in vain since 14 October 2010 and which make it possible to check a part of the Deloitte report's data.

Furthermore, they justify by many probative documents without being contradicted seriously on this issue that the pharmacists' back margins are in practice much higher (20% to 35%) than the legal ceiling of 17%. They rightly point out regarding the variable costs that the transportation costs were not taken into account, which is acknowledged, and that the structure of the group of companies should be taken into account as Biogaran has no employees or production costs and subcontracts its work.

Consequently, it is reasonable considering all these elements to fix the damage suffered by Biogaran from Laboratoires Negma's wrongful manoeuvres at the sum of 3,500,000 euros after correction of the Deloitte report's data.

Consequently, reversing the judgment partially, Laboratoires Negma should be ordered to pay this sum.

The measures of recall and the injunction from marketing the products with an incomplete and partial communication from Laboratoires Negma to the detriment of Biogaran harmed its image and discredited it in particular with the professionals of the sector at issue.

Consequently, Laboratoires Negma should be ordered to pay the additional sum of 150,000 euros to Biogaran as compensation for the damage suffered in this respect.

Equity commands granting Biogaran the sum of 30,000 euros to be borne by Laboratoires Negma in addition to the sum already granted in first instance on the basis of Article 700 of the French Civil Procedure Code and to dismiss Laboratoires Negma's claim lodged in this respect.

The court expenses will be borne exclusively by Laboratoires Negma, which fails, and will be collected by the attorneys-at-law of the case under the conditions of Article 699 of the French Civil Procedure Code.

**ON THESE GROUNDS,**

Dismisses the claim for a stay of the proceedings lodged by Laboratoire Medidom,

Holds admissible the cross-appeal lodged by Biogaran against Laboratoire Medidom,

Dismisses the claims for referral to the Court of Justice of the European Union lodged by Laboratoires Negma,

Dismisses all of Laboratoires Negma's claims,

Reverses the judgment partially in that it dismissed Biogaran's action for fault liability against Laboratoires Negma and on the amount of the compensations granted to Biogaran,

Consequently,

Holds that Laboratoires Negma is strictly liable for distinct acts on the basis of Article L. 111-10 of the French Enforcement Civil Procedure Code and Article 1382 of the French Civil Code,

Orders Laboratoires Negma to pay the sum of 3,500,000 euros to Biogaran as compensation for its financial damage and that of 150,000 euros as compensation for the harm caused to its image,

Orders Laboratoires Negma to pay the additional sum of 30,000 euros to Biogaran pursuant to Article 700 of the French Civil Procedure Code,

Affirms the referred judgment regarding the other provisions,

Orders Laboratoires Negma to pay the court expenses, which will be collected by the attorneys-at-law of the case under the conditions of Article 699 of the French Civil Procedure Code.

The Clerk The Presiding Judge