T R I B U N A L
D E G R A N D E
I N S T A N C E
O F P A R I S

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3rd Chamber 3rd Section

Docket No.
09/17355

Minutes No.:

Summons of:
23 November 2009

JUDGMENT
handed down on 27 January 2012

CLAIMANT

BIOGARAN SAS, represented by its President, Mr Pascal Briere
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92700 Colombes

represented by Mr Arnaud CASALONGA, SELAS CASALONGA AVOCATS, attorney-at-law, member of the Paris Bar – Court box #K0177

DEFENDANTS

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SWITZERLAND

represented by Mr Silvestre TANDEAU DE MARSAC, SCP FISCHER TANDEAU DE MARSAC - SUR, attorney-at-law, member of the Paris Bar – Court box #P0147

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Represented by Mr Louis DE GAULLE, SELAS DE GAULLE FLEURANCE, attorney-at-law, member of the Paris Bar, Court box #K0035

COMPOSITION OF THE *TRIBUNAL*

Marie SALORD, Vice-Presiding Judge, *signatory of the decision*
Anne CHAPLY, Judge,
Laure COMTE, Judge

assisted by Marie-Aline PIGNOLET, Court Clerk, *signatory of the decision*

DISCUSSION

At the hearing of 8 November 2011, held publicly before Marie SALORD, Anne CHAPLY, reporting judges, who, without opposition on behalf of the attorneys-at-law, held the hearing alone and, after hearing the parties' attorneys-at-law, gave an account of it to the *Tribunal*, pursuant to the provisions of Article 786 of the French Code of Civil Procedure.

JUDGMENT

Pronounced by delivery of the decision to the Court Clerk's office
After hearing both parties
in first instance

THE DISPUTE

Madaus Aktiengesellschaft filed European patent EP 0 520 414 on 24 June 1992, claiming German priority No. 41209 89. This patent filed on 13 March 1996, the translation of which was published in the Industrial Property Official Bulletin on 14 June 1996, relates to a method 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-emodin derivatives inferior to 20 ppm, as well as diacetylrhein that may be obtained by this procedure and a pharmaceutical composition containing this compound.

This patent was the subject of an exclusive licence grant to Laboratoire Medidom, registered in the French patent register on 16 July 2001, before it was assigned to it, by way of an act registered in the French patent register on 19 December 2006.

This company granted an exclusive licence for France to Laboratoires Negma, pursuant to an act registered in the French patent register on 2 February 2007, which marketed a pharmaceutical product named Art 50, an anti-arthritis drug for long-term treatments.

On 4 and 9 September 2008, Biogaran obtained three marketing authorisations for the products *Diacérine BIOGARAN 50 mg gélules, Diacérine SET 50 mg gélules* and *Diacérine REF 50 mg gélules*.

On 7 October 2008, Laboratoires Negma sent a letter to Biogaran in which it argued that the products *Diacérine SET 50 mg gélules* and *Diacérine REF 50 mg gélules* were generic drugs of the product Art 50 mg which it exploits on the French market, a product covered by patent EP 0 520 314 of which it is the exclusive licence-holder, and that it will take all appropriate actions to prevent their marketing.

By way of a bailiff's act dated 12 December 2008, Biogaran served a summons upon Laboratoire Medidom and Laboratoires Negma before the *Tribunal de Grande Instance* of Paris for the invalidity of claim 14 of the French designation of European patent EP 0 524 414 for lack of novelty and alternatively for lack of inventive step. It began marketing its products.

By way of a bailiff's act dated 5 February 2009, Laboratoires Negma then summoned Biogaran to appear in preliminary proceedings with an emergency motion to be heard on very short notice before the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Strasburg, pursuant to Article L. 615-3 of the French Intellectual Property Code, mainly to enjoin it, under penalty, from marketing, arranging to distribute, manufacturing or arranging to manufacture generic pharmaceutical products and to recall these products under penalty.

In an order dated 10 March 2009, the Judge ruling in preliminary proceedings enjoined Biogaran, under a penalty of €30,000 per recorded infringement, from marketing and arranging to distribute the following generic pharmaceutical products of Art 50:
- *Diacérine Biogaran mg gélule* CIS 6 793 610 6
- *Diacérine Ref 50 mg gélule* CIS 6 480 333 9
- *Diacérine Set 50 mg gélule* CIS 6 211 751 2

from manufacturing or arranging to manufacture the following generic pharmaceutical products of Art 50:
- *Diacérine Biogaran mg gélule* CIS 6 793 610 6
- *Diacérine Ref 50 mg gélule* CIS 6 480 333 9
- *Diacérine Set 50 mg gélule* CIS 6 211 751 2

and ordered the recall within 48 hours of all the generic pharmaceutical products of Art 50.

In an additional pleading dated 13 March 2009 before the *Tribunal de Grande Instance* of Paris, Biogaran requested that the *Tribunal* hold that neither claim 14 nor process claims 1 to 13 are infringed, and requested that it order Laboratoires Negma to pay the sum of €2,000,000 to it as an interim payment in compensation for the damage suffered due to the injunction from marketing the above-mentioned generic drugs, that an expert be appointed and that this company be ordered to pay the additional sum of €500,000 to it in compensation for the harm caused to its image.

In a declaration dated 19 March 2009, Biogaran appealed the order of the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Strasburg dated 10 March 2009.

By way of an act dated 27 March 2009, Laboratoires Negma served a summons on the merits for infringement upon Biogaran before the *Tribunal de Grande Instance* of Strasburg.

In an order dated 2 June 2009, the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Strasburg dismissed Laboratoires Negma's request for the calculation of the penalties accompanying the preliminary injunction and the recall of the products pronounced in the order dated 10 March 2009.

In an order dated 17 November 2009, the Judge in charge of the case preparation of the *Tribunal de Grande Instance* of Paris ordered the severance of the case under docket No. 08/17625, maintaining under this docket number the case relating to Biogaran's initial claim for invalidity of claim 14 of the patent and referring under docket number RG 09/17355 Biogaran's additional claims and Negma and Medidom's counterclaims.

In an order dated 10 July 2009, the Judge in charge of the case preparation of the *Tribunal de Grande Instance* of Paris dismissed the plea of lack of jurisdiction raised by Laboratoires Negma.

In an order dated 10 December 2009, the judge in charge of the case preparation of the *Tribunal de Grande Instance* of Strasburg referred the matter before the *Tribunal de Grande Instance* of Paris.

In a decision dated 31 March 2010, the *Tribunal de Grande Instance* of Paris held that claim 14 of the French designation of European patent EP 0 520 414 was invalid for lack of novelty.

In a declaration dated 15 April 2010, Negma appealed this judgment before the *Cour d'Appel* of Paris which, ruling in fast-track proceedings, affirmed it in a decision dated 30 June 2010.

In a decision dated 22 June 2010, the *Cour d'Appel* of Colmar reversed the injunction and the recall ordered by the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Strasburg on 10 March 2009 in light of the judgment handed down by the *Tribunal de Grande Instance* of Paris on 31 March 2010.

In a decision dated 10 September 2010, the *Cour d'Appel*, ruling on the appeal of the order handed down by the Judge in charge of the case preparation on 10 July 2009, affirmed the jurisdiction of the *Tribunal de Grande Instance* of Paris to rule on Biogaran's claims for compensation.

In an order dated 11 February 2011, the Judge in charge of the case preparation dismissed Biogaran's claim for an interim payment.

In an order dated 17 June 2011, the judge in charge of the case preparation dismissed Laboratoires Negma's request for the communication of exhibits.

In a distinct pleading dated 15 July 2011, Laboratoires Negma raised a constitutionality issue as regards the application of Article 31, paragraph 2 of the French Act No. 91-650 dated 9 July 1991 relating to the reform of the civil enforcement procedures which, in the case of a preliminary injunction order on the grounds that the judge holds that an intellectual property right has likely been infringed, breaching the ownership right ensured by the Constitution.

In an order dated 20 October 2011, the judge in charge of the case preparation dismissed the request to refer this issue to the *Cour de Cassation.*

In its latest recapitulative pleading served electronically on 23 September 2011, Biogaran requests that the *Tribunal*:
Considering Article 31 et seq. of the French Code of Civil Procedure, Article 31 of the French Act of 9 July 1991, Articles L 615-1 et seq. of the French Intellectual Property Code, 138, 54 and 56 of the European Patent Convention, 1382 et seq. of the French Civil Code,
Considering the decision handed down by the Cour d'Appel *of Paris on 30 June 2010,*
- Hold Biogaran's claims admissible and well-founded,
- Dismiss all of Laboratoire Medidom and Laboratoires Negma's claims and arguments,
- Hold that Laboratoires Negma enforced provisionally and at its own risk the order handed down on 10 March 2009 by the President of the *Tribunal de Grande Instance* of Strasburg, and that it must therefore compensate for the harm caused,
- Hold that Laboratoires Negma and Medidom, through their manoeuvres, committed distinct faults and engaged their civil liability;
- Accordingly, order Laboratoires Negma and Medidom, jointly and severally, to pay the sum of €8,282,213 to Biogaran in compensation for the damage suffered due to the recall and the preliminary injunction preventing the marketing of its products,
- Order Laboratoires Negma to pay Biogaran the additional sum of €500,000 in compensation for the harm caused to its image,
- Order Laboratoire Medidom and Laboratoires Negma, jointly and severally, to pay the sum of €300,000 to Biogaran pursuant to the provisions of Article 700 of the French Code of Civil Procedure,
- Order Laboratoire Medidom and Laboratoires Negma, jointly and severally, to pay all the costs,
- Order the provisional enforcement of the decision to be handed down, notwithstanding an appeal and without the obligation to provide security.

In its latest recapitulative pleading served electronically on 10 October 2011, Negma requests that the *Tribunal*:

- Hold that Article 31 of the French Act of 9 July 1991 cannot be applied in the case of a preliminary injunction in the field of intellectual property;
- Accordingly, directly apply the provisions of Article 9 § 7 of the Guideline dated 29 April 2004 and Article 50 § 7 of the "TRIPS" agreement.
- In case of any doubt as to the interpretation to be given to the above-mentioned provisions of the 2004 Guideline, refer the following issue to the Court of Justice of the European Union:

"*Should Articles 3 and 9 of the Guideline 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 assert their title?"*

- Dismiss all of Biogaran's claims,
- Order Biogaran to pay the sum of €250,000 to Negma pursuant to Article 700 of the French Code of Civil Procedure,
- Order it to pay all the costs, collected by SELAS de Gaulle Fleurance & Associés pursuant to Article 699 of the French Code of Civil Procedure.

In its latest recapitulative pleading of 12 September 2011, Medidom requests that the *Tribunal*:

- Hold Biogaran's claims inadmissible and unfounded;
- Record Biogaran's withdrawal of all claim based on Article 31 of the French Act of 9 July 1991 against Medidom;
- Dismiss all of Biogaran's claims and arguments;
- Order Biogaran to pay to Medidom the sum of €150,000 pursuant to Article 700 of the French Code of Civil Procedure;
- Order Biogaran to pay all the costs.

The closing order was handed down on 25 October 2011.

GROUNDS

Biogaran claims compensation for damage suffered on two distinct grounds; first, pursuant to Article 31 of the French Act of 9 July 1991 on the reform of the enforcement procedures which provides for a strict liability system, due to the enforcement by Negma of the order of the President of the *Tribunal de Grande Instance* of Strasburg dated 10 March 2009 and, second, pursuant to Article 1382 of the French Civil Code, due to distinct tortious acts committed by Negma and Medidom.

On the strict liability pursuant to Article 31 of the French Act of 9 July 1991

Only Negma is sued on this basis.

Medidom was not party to the proceedings opposing Negma to Biogaran before the judge in the Strasburg preliminary proceedings and, accordingly, did not take part in the enforcement of the order handed down in preliminary proceedings.

Negma argues that Biogaran initially based its claims exclusively on tort liability and that the decision handed down on 10 September 2010 by the *Cour d'Appel* of Paris, to which the issue of the *Tribunal*'s jurisdiction was referred, had affirmed the jurisdiction of the *Tribunal de Grande Instance* of Paris by the very fact that Biogaran did not maintain that the said order had been enforced.

It maintains that the claimant cannot allege, without contradicting itself, that there was no enforcement and then put forward arguments to the contrary; additionally, it argues that estoppel has recently been reaffirmed by the *Cour de Cassation* in a decision dated 20 September 2011, recalling that "*a person may not contradict himself to the detriment of another person*".

It adds that, as early as in the proceedings relating to the first claim, it is incumbent upon the claimant to put forward all the arguments it deems likely to serve as a base for the latter.

However, the *Tribunal* points out that Biogaran has never maintained that Negma was liable in tort for having enforced the order handed down in preliminary proceedings by the President of the *Tribunal de Grande Instance* of Strasburg.

Biogaran always acknowledged that it voluntarily complied with this order and it is precisely because the decision had not been enforced upon it that the *Cour d'Appel* affirmed the jurisdiction of the *Tribunal de Grande Instance* of Paris and held that the enforcement judge had no jurisdiction.

Consequently, Biogaran did not change the legal basis of its claims during the proceedings. It always referred to Negma's strict liability following the enforcement of the order in preliminary proceedings authorising the injunction and withdrawal measures and to the defendants' tort liability of Article 1382 of the French Civil Code for having committed distinct faults.

Consequently, Biogaran is justified in basing its claims on Article 31 of the French Act of 9 July 1991, which provides that "*the enforcement on the basis of a provisionally enforceable title 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 title be subsequently modified"***.

Negma disputes the application of Article 31 of the French Act of 9 July 1991 on the grounds that, applied to intellectual property, it is allegedly contrary to Article 17 of the French Constitution, that it violates the constitutionally protected right to access to a court, that the Community intellectual property law requires setting aside the application of this Article and that, in any case, this Article should be set aside because it obviously fails to take account of Article 6 §1 of the European Convention for the Protection of Human Rights.

Negma does not establish in what capacity Article 31 of the French Act of 9 July 1991, applied to intellectual property rights, could be considered as contrary to the provisions of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, of Article 50.7 of the TRIPS Agreement, of the French Act 2007-1544 of 29 October 2007 since Article 9.7 of Directive 2004/48/EC sets forth that "*where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by those measures"*. These particularly clear provisions are compatible with Article 31 of the French Act of 9 July 1991 and a request for a preliminary ruling is not necessary.

Finally, Article 6 §1 of the European Convention for the Protection of Human Rights refers to the right to a fair trial and provides that "*in the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law"*.

In the present case, Negma was in a position to assert its rights and thus obtained preliminary injunction before the revocation of its title had been pronounced.

Subparagraph 2 of Article 31 of the French Act of 1991 applies to the voluntary compliance by a debtor with an order handed down in preliminary proceedings, which was subsequently reversed.

The legislator, whose ultimate aim in this subparagraph was to reach a state of compliance and not enforcement, wished to give a right to compensation to any debtor, whether the decision handed down was enforced upon or was voluntarily complied with by the debtor.

Deciding otherwise would amount to sanctioning the debtor, who voluntarily complied with a court decision, without having waited for the creditor to enforce the decision upon it.

In the present case, Biogaran is all the more justified in bringing an action on the basis of subparagraph 2 of aforementioned Article 31 as it is not disputed that Negma clearly showed its intention of enforcing the decision since it served the order dated 10 March 2009 on Biogaran on 12 March 2009, sent a letter to it on 20 March 2009 to ensure the provisional enforcement of the order and commenced proceedings for the calculation of the penalty pronounced in the said order.

Even if Biogaran voluntarily complied with the order dated 10 March 2009 as early as 13 March 2009, the fact nevertheless remains that Negma showed its intention of pursuing the provisional enforcement of the decision.

Negma considers that Article 31 of the French Act of 9 July 1991can only be interpreted as establishing a tort liability regime.

However, the *Tribunal* recalls that the interpretation of a text presupposes that the terms employed in the text require interpretation, but the provisions of Article 31 of the French Act of 9 July 1991 clearly state strict liability and require no interpretation.

In the present case, as claim 14 of the asserted patent was held invalid by the judgment of the *Tribunal de Grande Instance* of Paris dated 31 March 2010, the *Cour d'Appel* of Colmar reversed the order dated 10 March 2009.

Consequently, Biogaran is justified in requesting that the *Tribunal de Grande Instance* of Paris restore its rights within the meaning of Article 31 of the aforementioned French Act, it being admitted that the demonstration of a fault committed by Laboratoires Negma is not required, as compensation is imposed by the mere fact that there is enforcement.

As a consequence, Negma should be ordered to restore Biogaran's rights following the enforcement of the order handed down in preliminary proceedings by the President of the *Tribunal de Grande Instance* of Strasburg on 10 March 2009, reversed by the decision of the *Cour d'Appel* of Colmar on 22 June 2010.

On the tort liability

Biogaran alleges that Negma and Medidom committed distinct faults through the fraudulent and intentional organisation and creation of a monopoly on a medicine to the detriment of their competitors, the health system and patients, which makes them liable on the basis of Article 1382 of the French Civil Code.

It reproaches them for:

- dilatory manoeuvres;
- a strategy for blocking the marketing of generic drugs;
- manoeuvres against the grant of marketing authorisations for generic drugs;
- attempts to challenge the decisions of the *Comité Economique des Produits de Santé*[TN] (CEPS);
- having relied on a wrong capacity to bring an infringement action;
- the unfair communication with pharmacists and wholesale distributors;
- the multiplication of dilatory court proceedings.

In this respect, it more particularly reproaches Negma for the pressure it exerted on the AFSSAPS[TN]; Biogaran recalls that it filed its applications for marketing authorisations on 21 January 2006 and only obtained a favourable opinion from the *Commission d'Autorisations de Mises sur le Marché* (French marketing authorisation commission) on 9 July 2008, i.e. more than two and a half years later, compared to a 120-day theoretical time limit at the time of the facts (Article R.5121-35 of the French Public Health Code).

It maintains that Negma intervened with the AFSSAPS at several times during the technical assessment of the marketing authorisation application to exert pressure on this entity in order to see the content in aloe-emodin reduced and to oblige its competitors, in order to comply with this standard, to fall within the scope of claim 14 of the patent.

It adds that Negma then did not hesitate, following the favourable opinion given by the AFSSAPS to Biogaran on 20 December 2007, to challenge the purification process used by Biogaran's manufacturer.

It concludes that, through its acts, Negma delayed the grant of Biogaran's marketing authorisations by two and a half years and seriously damaged its image.

In response, Negma maintains that Biogaran fails to demonstrate the existence of a fault, a damage and a causal link, that the long time taken for the technical assessment of the marketing authorisation application before the AFSSAPS is due to Biogaran's inability to produce *ab initio* diacerein identical to that of the proprietary medicine and that Negma only informed the AFSSAPS of the content of its medicine to verify that the generic drug was in fact bioequivalent.

It maintains that the criticised exchanges between itself and the AFSSAPS are only the consequences of Biogaran's choice to use a derogatory administrative procedure to enjoy a marketing authorisation for a generic drug following a simplified procedure.

It argues that it merely protected the monopoly it enjoyed thanks to its licence contract.

[TN] French economic committee for health products

[TN] The French agency for the safety of health products, which grants, suspends or withdraws marketing authorisations for medicines.

It appears that Negma intervened with the AFSSAPS to inform it that its products had a content in aloe-emodine of 2 ppm, that it modified its manufacturing process several times to reduce aloe-emodine from 900 ppm to 150 ppm in 1993, then to 4 ppm in 1995 and finally to 2 ppm in 2002.

It also requested that the AFSSAPS verify the veracity of the data declared by Biogaran through analyses of the active ingredients.

However, Negma merely used the possibility available to it to present its arguments for both the protection of the monopoly it holds thanks to its industrial property title in force at the time of the technical assessment of Biogaran's marketing authorisation applications and ensuring the sanitary qualities of the generic drug.

None of the letters or the elements developed in the documents produced by Biogaran make it possible to say that Negma exceeded its rights and used unfair manoeuvres.

It is certain that, through its interventions, it managed to convince the AFSSAPS to verify the qualities of the Biogaran products; however, the AFSSAPS is an independent entity, which freely appraises the arguments put forward by the patent-holder.

Consequently, Biogaran produces no probative element regarding any "pressure" exerted on this entity by Negma.

Regarding the time taken for the technical assessment of the marketing authorisation application, if it is certain that, through its requests for verification, Negma took part in the extension of the time needed, it appears that Biogaran had not filed a marketing authorisation application relating to a purified diacerein of 2 ppm and that several applications related successively to a purified diacerein of 500 ppm, then 15 ppm and finally 2 ppm, leading to new tests by the AFSSAPS to verify the identity of the composition, which necessarily extended the time required for the technical assessment.

Regarding the attempts to challenge the decision of the CEPS, Biogaran recalls that, on 5 January 2009, the CEPS set the price of the Biogaran diacerein and registered it in the list of medicines eligible for reimbursement, which authorised its marketing; Biogaran reproaches NEGMA for having lodged an appeal before the President of the CEPS to urge him to reconsider his decision; this appeal was finally dismissed by the *Conseil d'État*[TN] by an order dated 6 March 2009.

Negma replies that it disputed the decision of the CEPS without fraud and in a perfectly justified way.

[TN] The French highest administrative court, which hears the appeals lodged against the AFSSAPS decisions regarding marketing authorisations.

It should be noted that Biogaran justifies no dilatory manoeuvre in the dispute of the CEPS's decision aiming to register the generic version of ART 50 on the list of medicines eligible for reimbursement, it limits itself to maintaining that the appeal in itself constitutes a manoeuvre.

It appears that this appeal was based on an alleged lack of knowledge of the provisions of Article 3 of the framework agreement entered into between the CEPS and the pharmaceutical industry, relating to patent-holders' intellectual property rights.

Negma cannot be reproached for having disputed an administrative decision that it considered as violating its intellectual property rights by using the legal remedies available to any holder of a patent in force.

In addition, the *Tribunal* points out that Biogaran never lodged a claim for abuse of process.

Negma is also reproached for having relied on a wrong capacity to bring an infringement action. More particularly, Biogaran reproaches it for having relied on its capacity as exclusive licensee to obtain preliminary injunction whereas, according to it, it emerges from the contracts and the facts of the case that it is not the company designated by the licence, which itself is not exclusive.

Negma recalls that this issue was already settled by the *Cour d'Appel* of Colmar and that, in any case, it produces the exhibits justifying its capacity as exclusive licensee.

In fact, the *Cour d'Appel* of Colmar held in a decision handed down between the same parties on 22 June 2010, which today is final, that Negma enjoys the capacity of exclusive licensee of Medidom, the holder of the patent in dispute.

Consequently, pursuant to *res judicata*, Biogaran cannot validly maintain that Negma lied about its capacity as exclusive licensee.

Furthermore, Biogaran reproaches Negma for having communicated in an unfair way through the letter that it sent to pharmacists and wholesalers on 30 January 2009, for having made a purposeful reading of the order dated 12 December 2008 of the *Conseil d'État* (dismissing its request in preliminary proceedings for a suspension of the marketing authorisations) to support its claims relating to the scope of patent EP 520 414.

Negma replies that it communicated in well-chosen words and that the *Conseil d'État* had expressly set aside the notion of urgency on the grounds that the intellectual property rights preclude an immediate marketing.

In the letter in dispute, Negma stated that "*furthermore, the* Conseil d'État *recognised in an order dated 12 December 2008 that* [our rights] *conflict with each other, considering that the marketing of generic versions of ART 50 mg could 'only take place at the expiry of the intellectual property rights attached to the original proprietary medicine, on 24 June 2012'"*.

Upon the reading of the order dated 12 December 2008, it emerges that the *Conseil d'État* dismissed the claim for suspension on the particular ground that "*the risks of adverse effects resulting from the use of the generic drugs over a long period may not be revealed before the actual marketing of the authorised generic drugs; consequently, the marketing will only take place at the expiry of the intellectual property rights attached to the original proprietary medicine, on 24 June 2012 (…)"*.

Consequently, if Negma reproduced the part of the grounds of the order that was favourable to it, the words were not distorted and the letter has no defamatory or misleading nature, therefore it is not established that they damaged Biogaran's image.

Finally, Biogaran reproaches Negma for having tried by all procedural means possible to protect its monopoly based on an invalid claim.

Negma replies that, during the proceedings, its position did not vary, that it did not obtain the order in preliminary proceedings in bad faith, that it did not abusively enforce the pronounced injunction measures and that it simply protected its monopoly following its exclusive licence contract, that Biogaran chose to launch its generic product without constituting a strong case in support of its invalidity action beforehand.

Even if it is indisputable that Negma used all the legal remedies possible to defend its monopoly and its industrial property title, the fact nevertheless remains that these remedies drew their lawfulness from the very existence of the patent, which, as long as it has not been the subject-matter of a court decision revoking it, has all the rights attached to such a title.

The *Tribunal* recalls that bringing a court action, in principle, constitutes a right and only turns into an abuse giving rise to a debt of damages based on Article 1382 of the French Civil Code in the case of malice, bad faith or gross error equipollent to deception.

In the present case, such a fault is not established; the *Tribunal* points out that Negma's claims in court were not systematically dismissed, that it never used deceptive manoeuvres to succeed and that, even if some of its actions could sometimes appear as if intended to gain time, the *Tribunal* points out that Biogaran itself delayed the proceedings on multiple occasions. It appears that each party did everything to defend its rights

without ever overstepping the limits of the abuse of right.

More precisely, the fact that claim 14 was later held invalid does not retrospectively transform the legal remedies used into unfair manoeuvres.

The *Tribunal* points out that Biogaran had lodged no opposition before the EPO upon the grant of the patent in 1997 and that it itself took an equally judicial and commercial risk by applying for a marketing authorisation and by launching its generic drug on the market before the expiry of the patent in force and before having sought the invalidity of claim 14.

Finally, Biogaran reproaches Negma for anti-competing practices to prevent it from penetrating the market, which Negma disputes.

The *Tribunal* recalls that such acts respond to a precise legal definition which requires the identification of the reference market making it possible to know the competing companies and to demonstrate a dominant position, which the claimant refrains from doing.

Consequently, no charge against Negma is established and, accordingly, Biogaran's claims against it will be dismissed.

As to Medidom, it disputes having been party to most of the proceedings criticised by Biogaran; it maintains that it never expressly authorised Negma to seek preliminary injunction. Finally, it confirms Negma's capacity as exclusive licensee.

The *Tribunal* finds that Biogaran's charges on the multiplicity of the court and dilatory proceedings do not concern Medidom, as the latter was neither party to the preliminary proceedings before the *Tribunal de Grande Instance* of Strasburg nor the infringement proceedings before the *Tribunal de Grande Instance* of Strasburg. Moreover, it did not participate in initiating the plea of lack of jurisdiction raised by Negma in favour of the enforcement judge.

Since it was held that Negma had committed no fault in this respect, which would have held it liable, *a fortiori,* Medidom cannot be held liable for these proceedings or even for a possible authorisation given to Negma to commence court proceedings to obtain preliminary injunction since, in any case, this could not constitute a fault *per se* thanks to the existence of its intellectual property title.

Finally, it was held that the issue of the capacity as exclusive licensee had been settled and that Biogaran could not question the decision of the *Cour d'Appel* of Colmar on that point.

Thus, it is not established that Medidom committed any fault justifying that it be ordered to pay damages to Biogaran.

Accordingly, all of Biogaran's claims against the defendants based on Article 1382 of the French Civil Code will be dismissed.

On the damage suffered by Biogaran

Biogaran requests that Negma and Medidom be ordered, jointly and severally, to pay to it the sum of €8,282,213, in compensation for the damage suffered due to the recall and the preliminary injunction from marketing its products and that Negma alone be ordered to pay Biogaran the additional sum of €500,000 in compensation for the harm caused to its image.

It explains that the image harm relates to Negma's abusive procedural behaviour as well as to an unfair communication.

First, it was held that the defendants could not be accused of a distinct fault; therefore, the damage done to its image, which directly results from these faults, will not be examined; second, as Medidom was not a party to the proceedings before the judge ruling in preliminary proceedings and as it could not enforce the order which did not involve it, it cannot be held liable for the damage suffered by Biogaran due to the enforcement of this order.

Accordingly, no compensation may be requested from Medidom, regardless of the basis.

There remains the damage directly related to the enforcement of the order handed down in preliminary proceedings and which Negma has to compensate; pursuant to Article 31 of French Act of 9 July 1991, the latter should restore Biogaran's rights in kind or by an equivalent thereof.

Negma asserts that Biogaran's behaviour must be taken into account to reduce its right to compensation, and in particular:
- that it put itself at risk by marketing an infringing product without anticipating the risk of an action for preliminary injunction and without waiting for the outcome of its action for patent invalidity,
- that its defence before the President of the *Tribunal* was not duly carried out as it presented an empty file in support of its request for patent invalidity while it is the one that had set the launch date of the generic and

- that it is responsible for the 18-month period between the order of 10 March 2009 and the decision of the *Cour d'Appel* of Colmar dated 22 June 2010 lifting the preliminary injunction insofar as it appealed the order of 10 March 2009 without requesting that the *Cour d'Appel* examine the matter in fast-track or speedy proceedings.

Negma recalls that the *Cour de Cassation* censured the *Cour d'Appel* of Paris for not having determined, pursuant to Article 31 of French Act of 9 July 1991, whether the debtor had committed a fault tending to reduce or exclude its right to compensation.

Biogaran responds that liability under Article 31 establishes a strict liability and that it cannot be accused of having marketed its product before the patent had been held invalid; according to it, deciding the contrary would amount to making it possible, on the basis of an obviously invalid blocking patent, to neutralise with complete impunity all undesirable competitors for years until the outcome of the proceedings on the merits.

It adds that it cannot be accused of not having requested that the *Cour d'Appel* of Colmar rule in fast-track proceedings while the appeal of an order given in preliminary proceedings is governed by the provisions of Article 910 of the French Code of Civil Procedure according to which Biogaran continuously requested that the case be handled expeditiously by the *Cour d'Appel*; as to Synteco joining these proceedings, it is a third party on behalf of which Biogaran had no power to decide.

Finally, it disputes that "*the prior art documents it submitted at the date of the preliminary injunction (…) could not, by themselves, question the validity of the title in issue*" while it invoked and communicated as of 16 January 2009 patent Proter FR 2 508 789 corresponding to the Friedmann patent which was taken into account by the *Cour d'Appel* of Paris on 30 June 2010 to hold claim 14 of the opposed patent invalid and which was submitted to the discussion in the Synteco proceedings as of 2007.

As regards the first two grounds, neither of them can constitute a compensation-limiting fault, all the more so since Biogaran brings evidence that it tried to obtain a date not too distant for the hearing and that in any case, it did nothing to delay the appeal proceedings.

As regards the exhibits produced in support of Biogaran's defence before the judge ruling in preliminary proceedings, it appears that its file was not empty but that it already contained exhibits which were taken into account in the assessment of the patent invalidity.

Finally, starting the marketing of generic products while there is a patent in force and while the invalidity action has just commenced is not a fault in itself, it merely constitutes risk-taking for the generic drug company based on the assessment that the patent was invalid, which turned out to be the case here.

Accordingly, in the absence of an established fault by Biogaran, the latter is entitled to compensation for the whole of its damage.

On the quantum of the damages

Biogaran claims compensation for the damage which it considers as corresponding to the loss it suffered which, according to it, is composed of the expense it had to incur for the recall of the products put on the market between 23 January and 12 March 2009, then for putting them back on the market and the lost profit allegedly composed of the loss of margin it should have generated if its exploitation had not been stopped.

More precisely, it assesses its damages as:

-for the loss of contribution margin due to the lost revenue between 13 March 2009 and 30 June 2010: €6,739,774

- for the loss of contribution margin due to the delay in the marketing of the *Diacérine Biogaran 50 mg*: €1,011,754

- for the costs borne due to the recall of the diacerein batches put on the market between 23 January and 12 March 2009: €188,813

- for the costs incurred for the retreatment of the diacerein batches in stock required for putting them on the market as of July 2010: €250,644

Biogaran relies on the principle that it would have remained alone on the generic drugs market during the 18 months in question and that this exclusivity situation is proved by the facts.

It argues that it was the only one to market its diacerein generic specialty drug between 23 January 2009 (date of the launch of its specialty drug) and 10 March 2009 (date of the preliminary injunction) and infers therefrom that the preliminary injunction granted against it is not what prevented the other competitors from marketing their products.

It also argues that none of Negma and Medidom's competitors applied with the CEPS to determine the price and reimbursement of their specialty drugs before June 2010, although as of 31 March 2010, the *Tribunal de Grande Instance* of Paris had held claim 14 of the patent invalid notwithstanding the provisional enforcement.

It adds that the fact that Mylan had purchased the active ingredient until February 2009 does not mean that the purchaser was going to manufacture the batches and that its exploitation would be imminent and that it suffices to read the Synteco judgment it submits to understand that Mylan's decision not to market resulted from

Negma's "*letters of threat*", from its applications with the AFSSAPS and the CEPS, and from the appeals lodged before the *Conseil d'État*.

It contends that it is absurd to believe that Negma could have launched a generic drug while it was asserting the patent against its competitors.

It considers that its exclusive position is also confirmed by the telephone conversations held by Smart Pharma with the directors of the competing companies and related in its report.

Finally, it contends that the hypothesis of the exclusivity with regard to the generic drug market is not absurd since there exist numerous actual cases in which exclusivity periods of longer than 18 months can be found.

Negma argues that Biogaran was not the only company to be ready to launch its generic drug; that, first, Negma itself had a MA for its own generic drug, that the Smart Pharma report produced by Biogaran itself admitted that "*Negma could have launched its own generic drug with the hope of limiting Biogaran's penetration"* (an auto-generic drug which, besides, it launched within 5 days following the marketing of the Biogaran generic drug) and that, second, Mylan, Teva and others also had MAs for generic drugs and that less than 20 days had passed in July 2010 before four other generic drugs of the Art 50 were put on the market.

It contends that their fear of also being subject to a preliminary injunction action and their refusal to make false statements with the CEPS are the reasons why they did not launch their generic drugs early 2010.

It adds that there is never an exclusive position benefitting only one generic drug company in the context of products having sales volumes comparable to the diacerein and the list of 13 products produced by Biogaran alleged to have benefitted from an exclusive position during several months was mentioned without any critical analysis by the firm Deloitte in its report No. 2 and was not submitted to Smart Pharma Consulting, that it relates to products (or presentations) and not to molecules, which in addition have very small markets.

It argues that the firm JNG-Développement reviewed these 13 molecules and it emerges that almost all the submitted examples relate to niche markets concerning only one economic player, contrary to the diacerein market.

Finally, it contends that the exclusivity hypothesis is denied by the positioning of Mylan itself which, when asked in December 2008 by Medidom about its interest in bringing an action for patent invalidity action in the proceedings under Docket No. 0708192, submitted

a "*business plan*" in which it expected to obtain as of 2009 a 20% market share on diacerein and, besides, Synteco had supplied Mylan with the active ingredient in industrial quantities as of December 2008.

The *Tribunal* repeats the terms of Article 31 of the French Act of 9 July 1991:

"*The enforcement is carried out at the risk of the creditor, which shall restore the debtor's rights in kind or by an equivalent thereof, should the title be subsequently modified*".

It emerges therefrom that the debtor must be granted compensation restoring it to the situation in which it was, including the predictable consequences of this situation, neither more nor less.

In this case, the subsequently modified title is the order handed down on 10 March 2009 by the President of the *Tribunal de Grande Instance* of Strasburg who had ordered an injunction from marketing Biogaran's generic drug as well as the recall of the products already marketed.

The modification of this title led to the withdrawal of the marketing injunction and the recall; accordingly, one should reason as if no injunction had been ordered and as if there had been no interruption in the marketing of these products.

It is indisputable that at the date of that order, Biogaran was the only generic drug company to market the diacerein and that this marketing had started two months earlier.

Biogaran contends that this market exclusivity would necessarily have continued over the 18 months during which the injunction applied. Its arguments are essentially based on telephone statements made by the competitors to the firm Smart Pharma Consulting and on the idea that it is not absurd for a generic drug company to have market exclusivity.

However, the compensation principle may not be satisfied by approximate hypotheses and extrapolations, insofar as the compensation must be the closest possible to the actual damage.

Since Biogaran contends that it would have remained in an exclusive position during 18 months, it has to prove it, all the more so since it is not disputed that the exclusive position of a generic drug company on a given market is not the most frequent case.

Indeed, even if one may not exclude the possibility that a generic drug company may find itself the only one in a market, it must be noted upon reading the exhibits that, in such case, these are above all niche markets; yet, in this case, the Deloitte report points out the presence of no less than nine generic drug companies on the diacerein market in 2010.

Biogaran alleges that the following question was asked to the interviewed persons, although this cannot be verified by the *Tribunal*:
"On which date would they have launched their generic drug if the Biogaran diacerein had not been withdrawn from the market?"
And the answers given by the persons questioned were typed on page 10 of the Smart Pharma report in the following terms:
According to the external conversations:
- Mylan and Qualimed which obtained their MA in September 2008 could have launched their diacerein in April 2009; as for Actavis, Teva Santé and Winthrop, they could have launched their diacerein in December 2009 but they all preferred avoiding the risk of a litigation and preferred waiting until the appeal decision was handed down in June 2010.
- EG and Arrow, facing a supply problem, could not launch their generic version until November and December 2010".

Biogaran infers therefrom that these competitors decided not to market their products because of personal grounds and not because of the order in preliminary proceedings dated 10 March 2009.

The *Tribunal* points out that the Smart Pharma report submitted by Biogaran merely mentions the transcript of statements made by third parties, that they are brief and not supported by further information.

In any case, if one considers the content of these statements, the fact that certain competitors had decided to wait until the appeal decision before launching the marketing of their products does not establish the absence of a link between their decision and the order dated 10 March 2009.

On the contrary, it appears that some of them had obtained their MA long before and were ready as of 2009 to launch their product; furthermore, as soon as the injunction had been lifted, several generic drug companies marketed their products in the following days, thereby showing that they were technically able to do so.

Therefore, it is clear that it is precisely because of the order handed down in preliminary proceedings against Biogaran that these competitors refrained from doing so and that should this order not have been handed down, they would have launched their products in the 18 months during which Biogaran contends that it would necessarily have been the only company on the market.

Biogaran responds that the fact that the competitors waited until 30 June 2010 to enter the market and not until 1 April 2010 – the day after the judgment of the *Tribunal de Grande Instance* of Paris holding claim 14 of the patent invalid – shows that they had no intention of launching their product earlier and that their decision was not related to the order in preliminary proceedings.

However, the *Tribunal* points out that an appeal had been lodged against both the judgment of the *Tribunal de Grande Instance* of Paris and the order in preliminary proceedings of Strasburg, that the appeal against the judgment handed down by the *Tribunal de Grande Instance* of Paris was examined during the fast-track proceedings and that the decisions of both the *Cour d'Appel* of Colmar and the *Cour d'Appel* of Paris were handed down in June 2010.

Consequently, the argument is not relevant, as the competitors may prefer waiting two more months to have a greater guarantee as to the outcome of the legal proceedings.

Since the possibility is not excluded that at least part of the competitors – five in this case – would have launched their products during that period, Biogaran cannot validly contend that it would necessarily have had market exclusivity.

Consequently, the assessment of Biogaran's damage must take into account the probability that other competitors could have marketed their products during the 2009-2010 period.

Concerning the breakdown of its damage estimate, Negma denies that Biogara suffered a loss of contribution margin but asserts that it merely suffered from a time gap in achieving this margin.

However, Biogaran rightly contends that the margin it did not record between 13 March 2009 and 30 June 2010 is definitively lost and that it will never be able to recover it in addition to the fact that this necessarily modified the margin flow and that the diacerein market is a declining competing market, which changes over time and to its disadvantage.

Concerning the assessment methods used by Smart Pharma Consulting, upon reading the two reports established by this company after an interval of a few months, it appears that the differences which could be noted are due to the possibility for this consulting company to take the actual sales into account in the second report, which it could not do before.

Furthermore, the choice of the relevant similar products made by this consulting company, although criticised by Negma, appears to be probative, all the more so since Negma does not offer more convincing products.

Concerning the established net sale price of a diacerein package, Negma alleges that it is disconnected from the operational realities and that the 17% rate appears to it to be underestimated with regards to market practices; however, it appears that, pursuant to Article L 138-9 of the French Code of the *Sécurité Sociale*[TN], the rebate rate is limited to 17% and that the auditor confirmed the figures communicated by Biogaran and the fact that they tally with Biogaran's internal data.

[TN] The French public welfare system.

Negma also disputes Biogaran's margin rate, assessed at 56.1%. Upon reading the Deloitte report, this 56.1% contribution margin was calculated on the basis of the actual analytical and historical data. This rate is justified and consistent with the 70% margin announced by Negma in its summons on the merits for infringement before the *Tribunal de Grande Instance* of Strasburg.

Accordingly, the *Tribunal* has no objective reason not to consider the figures communicated by Biogaran.

Likewise, the cost price held by Biogaran was confirmed by the auditor and, in its report, Deloitte developed the calculation of the cost price for a 30-capsule package of diacerein 50 mg so that the *Tribunal* considers that, in view of these elements and of the annexes to the report, in an exclusive position, the lost contribution margin between 13 March 2009 and 30 June 2010 was rightly assessed at €7,775,504 and the loss of contribution margin after 30 June 2010 was rightly assessed at €109,142.

Taking into account the fact that this exclusivity is not established for the entire period and that at least five competitors, at some point in time, could have launched the marketing of their products before June 2010 in the absence of the injunction, the *Tribunal* considers a total lost margin of €2,600,000.

Concerning the costs relating to the recall of the diacerein batches and the retreatment of the batches in stock, the sums requested on this ground appear justified by factual elements (suppliers' invoices and customers' credit notes).

As to the assessment of the costs for the retreatment of the diacerein batches in stock consisting in extending the expiry date displayed on the packages with the agreement of the AFFSSAPS, it also results from factual elements (suppliers' invoices).

Consequently, the sums of €188,813 and €208,754 requested on this ground will be considered.

Therefore, in total, Biogaran will be awarded a sum of €2,997,567 in compensation for its damage.

Considering that fact that the prosecuting creditor pursuant to Article 31 of the French Act of 9 July 1991 is Negma, which is the only party involved in the order handed down in preliminary proceedings by the President of the *Tribunal de Grande Instance* of Strasburg, then only Negma will be ordered to pay the sum of €2,997,567 to Biogaran.

On the other requests

Biogaran requests that Medidom and Negma be ordered, jointly and severally, to pay to it the sum of €300,000 pursuant to Article 700 of the French Code of Civil Procedure, and to pay the costs.

Considering the grounds set out herein, only Negma will be ordered to pay the sum of €200,000 to Biogaran on this ground.

It will also be ordered to pay all the costs.

Medidom, against which no order has been pronounced, is well-founded in requesting that Biogaran pay it the sum of €40,000.

The provisional enforcement, in accordance with the grounds set out herein, will be ordered concerning the irrecoverable costs and Negma being ordered to pay €1.500.000 in damages to Biogaran.

ON THESE GROUNDS

The *Tribunal*, ruling by way of a judgment handed down in first instance in the presence of both parties, and by making the judgment available at the Clerk's office on the day the judgment is handed down,

- Holds that Biogaran's claims are well-founded;

- Holds that Article 31 of the French Act of 9 July 1991 is applicable in the case of an interim injunction in intellectual property;

- Holds that there is no reason to directly apply Article 9 § 7 of the Guideline dated 29 April 2004 and Article 50 § 7 of the "TRIPS" agreement;

- Holds that in the absence of doubts on the interpretation to be given to the above-mentioned provisions of the 2004 guideline, there is no reason to refer the following question before the Court of Justice of the European Union:
"Should Articles 3 and 9 of the Guideline 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 assert their title?"

- Hold 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* of Strasburg and that it therefore has to compensate for the harmful consequence thereof;

- Accordingly, orders Laboratoires Negma to pay the sum of €2,997,567 (two million nine hundred ninety seven thousand five hundred sixty seven euros) to Biogaran, in compensation for the damage sustained due to the recall and the preliminary injunction to market the following generic pharmaceutical products of Art 50:
* *Diacérine Biogaran mg gélule* CIS 6 793 610 6
* *Diacérine Ref 50 mg gélule* CIS 6 480 333 9
* *Diacérine Set 50 mg gélule* CIS 6 211 751 2

- Dismisses all of Biogaran's claims against Laboratoire Medidom;

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

- Orders Laboratoires Negma to pay the sum of €200,000 to Biogaran pursuant to the provisions of Article 700 of the French Code of Civil Procedure;

- Orders Biogaran to pay the sum of €40,000 to Laboratoire Medidom pursuant to the provisions of Article 700 of the French Code of Civil Procedure;

- Orders Laboratoires Negma to pay all the costs;

- Orders the partial provisional enforcement of the order which will relate to the irrecoverable costs and Laboratoires Negma being ordered to pay €1,500,000 (one million five hundred thousand euros) in damages to Biogaran.

Ordered in Paris on 27 January 2012

The Presiding Judge The Clerk