

FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE
COUR D'APPEL DE PARIS
Division 5 – Chamber 2
DECISION OF 6 JULY 2012
ON THE REQUEST FOR SUBMISSION
OF A PRIORITY QUESTION ON CONSTITUTIONALITY

(No. 193, 13 pages)

Docket Number: **12/05718 (PQC)**

Decision referred to the *cour d'appel*: order of 27 January 2012 – Judge in charge of the case preparation - *tribunal de grande instance de Paris* 3rd Chamber 3rd Section – Docket No. 09/17355.

CLAIMANTS IN THE REQUEST FOR SUBMISSION OF THE PQC

SAS LABORATOIRES NEGMA

represented by its legal representative,

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

represented by Ms Anne-Laure GERIGNY of the firm SELARL RECAMIER, attorney-at-law, member of the Paris Bar, courthouse box: K0148,

assisted by Mr Louis DE GAULLE of the firm SELAS DE GAULLE FLEURANCE & Associés, attorney-at-law, member of the Paris Bar, courthouse box K 035.

DEFENDANT IN THE REQUEST FOR SUBMISSION OF THE PQC:

SAS BIOGARAN

represented by its legal representatives,

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

represented by Mr Dominique OLIVIER, attorney-at-law, member of the Paris Bar, courthouse box: L0069,

assisted by Mr Arnaud CASALONGA of the firm SELAS CASALONGA, attorney-at-law, member of the Paris Bar, courthouse box: K0177.

COMPOSITION OF THE COURT:

Pursuant to the provisions of Articles 786 and 907 of the French Civil Procedure Code, the case was discussed on 1 June 2012, in public hearing, the attorneys-at-law not being opposed to it, before Mr Eugène LACHACINSKI, President, Judge in charge of the report and Mr Benjamin RAJBAUT, Presiding Judge of the chamber.

These Judges gave an account of the oral pleadings during the deliberation of the Court, composed of:

Mr Eugène LACHACINSKI, President,

Mr Benjamin RAJBOUT, Presiding Judge of the chamber,

Ms Sylvie NEROT, Judge.

Court Clerk during the discussion: Mr NGUYEN.

MINISTÈRE PUBLIC^{TN} to whom the case was previously submitted and represented during the discussion by Mr WOIRHAYE, Advocate-General, who made his opinion known.

DECISION:

After hearing both parties,

- the decision was made available at the Court Clerk's office, the parties having been previously notified in accordance with the requirements laid down in the second subparagraph of Article 450 of the French Civil Procedure Code.

- signed by Mr Eugène LACHACINSKI, President, and by Mr NGUYEN, Court Clerk present when the decision was pronounced.

MADAUS AG filed European patent EP 0 520 414 on 24 June 1992, claiming German priority No. 412 09 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;

LABORATOIRES MEDIDOM 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 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 gélule* and *Diacérine REF 50 mg gélule* were generic drugs of the product ART 50 mg 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 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 de 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;

By way of a bailiff's act dated 5 February 2009, LABORATOIRES NEGMA then summoned BIOGARAN to appear in preliminary proceedings before the *tribunal de grande instance de Strasbourg*, to enjoin it, under penalty, from distributing, manufacturing or marketing the generic pharmaceutical products;

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 distributing the ART 50

^{TN}The *Ministère public* is composed of public servants representing the State and the public interest in the judicial process. It has an advisory role and is independent from the parties. The *Ministère Public* is under the control of the Minister of Justice.

generic pharmaceutical products and ordered the recall within 48 hours of all the ART 50 generic pharmaceutical products;

In an additional pleading dated 13 March 2009 before the *tribunal de grande instance de Paris*, BIOGARAN requested that the *tribunal* 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 generic drugs granted in an order in preliminary proceedings on 10 March 2009;

BIOGARAN appealed the order of the Judge ruling in preliminary proceedings of the *tribunal de grande instance de Strasbourg*;

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 de Strasbourg*;

In an order dated 17 November 2009, the Judge in charge of the case preparation of the *tribunal de grande instance de Paris* ordered the severance of the proceedings under docket No. 08/17625 and No. 09/17355;

In an order dated 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 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 de Strasbourg* referred the matter before the *tribunal de grande instance de Paris*.

In a decision dated 31 March 2010, the *tribunal de grande instance de Paris* held that claim 14 of the French designation of European patent EP 0 520 414 was invalid for lack of novelty;

In a decision of 30 June 2010, the *cour d'appel de Paris* affirmed the 31 March 2010 judgment;

In a decision dated 22 June 2010, the *cour d'appel de Colmar* reversed the injunction and the recall ordered by the Judge ruling in preliminary proceedings of the *tribunal de grande instance de Strasbourg* in light of the judgment handed down by the *tribunal de grande instance de Paris* on 31 March 2010;

In a decision dated 10 September 2010, the *cour d'appel de Paris* confirmed that the *tribunal de grande instance de Paris* had jurisdiction to rule on BIOGARAN's claims for compensation;

In a distinct pleading dated 15 July 2011, LABORATOIRES NEGMA raised a priority question on constitutionality relating to 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 21 October 2011, the Judge in charge of the case preparation of the *tribunal de grande instance de Paris* dismissed the request for submission to the *Cour de cassation* of a priority question on constitutionality and referred the matter and the parties in particular to the hearing of 8 November 2011;

In a judgment of 27 January 2012, the *tribunal de grande instance de Paris*:

- held that BIOGARAN's claims are well-founded,
- held that Article 31 of the French Act of 9 July 1991 is applicable in the case of a preliminary injunction in intellectual property,
- held that there is no reason to directly apply the provisions of Article 9 § 7 of the Guideline dated 29 April 2004 and Article 50 § 7 of the "TRIPS" agreement,

- held 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 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?*”
- 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 of Strasbourg* and that it therefore has to compensate for the harmful consequence thereof;
- accordingly, orders LABORATOIRES NEGMA to pay the sum of €2,997,567 to BIOGARAN in compensation for the damage sustained due to the recall and the preliminary injunction from marketing the following ART 50 generic pharmaceutical products:
 - *Diacérine BIOGARAN 50 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 LABORATOIRES 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 Civil Procedure Code,
- orders BIOGARAN to pay the sum of €40,000 to LABORATOIRE MEDIDOM pursuant to the provisions of Article 700 of the French Civil Procedure Code,
- 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 in damages to BIOGARAN;

Having regard to the appeal lodged by LABORATOIRES NEGMA on 27 March 2012 against the order issued on 21 October 2011 by the Judge in charge of the case preparation of the *tribunal de grande instance de Paris* and against the judgment handed down on 27 January 2012 by the *tribunal de grande instance de Paris*;

Having regard to the pleading filed on 2 May 2012 in which LABORATOIRES NEGMA requests that the Court:

- reverse the order of the Judge in charge of the case preparation of 21 October 2011,
- hold admissible the following priority question on constitutionality which it raises in the context of the dispute against BIOGARAN:

Do the provisions of Article 31 subparagraph 2 of the French Act of 9 July 1991 which establish a strict liability system in favour of the debtor of the enforcement of a provisionally enforceable title, prejudice the rights and freedoms guaranteed by the Constitution should the patent on the basis of

which an injunction has been issued by the Judge ruling in preliminary proceedings under the provisions of Article L. 615-3 of the French Intellectual Property Code be subsequently revoked on the merits (or should the action for infringement be rejected on the merits):

1° - more specifically do they violate **the principle of equal of treatment of individuals**, when the patent holder who intends to bring infringement proceedings is subjected to more obligations (in particular the demonstration of fault and a non-controllable risk of being held liable in the case of failure without fault of his infringement action on the merits) than the defendant in the action, who enjoys a strict liability to the detriment of the patent holder, an imbalance which leads to the better treatment of the individual who deliberately freed himself from the obligations deriving from a patent which was in force at the time of the infringing exploitation, than of the legitimate owner of the intellectual property right.”

2° - even more specifically do they violate the right to **access the courts**, since the disputed provisions establish disproportionate, totally unpredictable and dissuasive penalties for the owner's right to exercise his intellectual property right legitimately and without fault”.

3° - and finally, even more specifically, do they violate the **intellectual property right**, since the disputed provisions dissuade the intellectual property right holder from exercising one of the essential prerogatives of his right (the right to restrain and its corollary, the right to bring infringement proceedings).

- hold that it is necessary to refer to the *Cour de cassation*, for submission to the *Conseil constitutionnel*^{NT}, the priority question on constitutionality,
- postpone the decision concerning the costs;

Having regard to latest pleading filed on 25 May 2012 in which BIOGARAN requests that the Court:

- hold that the priority question on constitutionality is devoid of substance,
- hold that there is no reason to refer it to the *Cour de cassation*;

Having regard to the written opinion of the *Ministère public* dated 7 May 2012;

WHEREUPON, THE COURT,

The party which alleges that a legislative provision prejudices the rights and freedoms guaranteed by the Constitution, must, pursuant to the provisions of Article 126-2 of the French Civil Procedure Code, submit this issue in a separate, reasoned document, failing which it will be inadmissible; the Judge may raise the objection of inadmissibility of his own motion;

Therefore, the request lodged by LABORATOIRES NEGMA, which complied with the provisions of the above-mentioned article, is admissible;

Article 23-2 of ordinance No. 58-1067 of 7 November 1958 lays down three requirements concerning the admissibility of the priority question on constitutionality;

- 1° *The contested provision is applicable to the dispute or to the proceedings, or forms the basis of the action,*

BIOGARAN lodged a claim before the *tribunal de grande instance de Paris* for compensation of the damage suffered assessed at €8,282,213 and €500,000 for the harm caused to its image, pursuant to the provisions of Article 31 of French Act No. 91-650 of 9 July 1991 which provides for a strict liability

^{NT} The *Conseil constitutionnel* is the highest constitutional authority in France. It was established by the Constitution of the Fifth Republic on 4 October 1958, and its duty is to ensure that the principles and rules of the Constitution are upheld.

owing to the enforcement of the 10 March 2009 order by the President of the *tribunal de grande instance of Strasbourg*, but also pursuant to Article 1382 of the French Civil Code owing to manoeuvres on the part of LABORATOIRES NEGMA and MEDIDOM which it considers to be wrong;

Since the criticised legislative provisions are directly applicable to the dispute between NEGMA and BIOGARAN, the review of the priority question on constitutionality by the Court is therefore admissible;

-2° The contested provision has not already been declared constitutional in the grounds and the operative part of a decision of the Conseil constitutionnel, except where there has been a change in circumstances,

Besides, under the provisions of Article 126-5 of the French Civil Procedure Code, the Judge is not obliged to submit a priority question on constitutionality contesting, for the same reasons, a legislative provision which has already been referred to the *Cour de cassation* or the *Conseil constitutionnel*;

The parties agree that until now no priority question on constitutionality relating to French Act No. 91-650 of 9 July 1991 and in particular the enforcement of Article 31 subparagraph 2 thereof, is nor has been submitted to the *Cour de cassation* or the *Conseil constitutionnel*;

Since this second requirement is fulfilled, the appeal lodged with the *cour d'appel* on 27 March 2012 by LABORATOIRES NEGMA against the 21 October 2011 order of the Judge in charge of the case preparation of the *tribunal de grande instance de Paris*, is valid;

-3° The question is not devoid of substance;

The dispute between LABORATOIRES NEGMA and BIOGARAN concerns the legal consequences resulting from the enforcement of a decision in preliminary proceedings which ordered provisional measures which, after being implemented by the liable party, were revoked by an affirming decision handed down after a period of time during which the prohibited products could not be publicly distributed thereby causing, according to BIOGARAN, considerable commercial and financial damage;

LABORATOIRES NEGMA points out that the right to a patent, which is an intangible right *in rem*, recognised both at national and community level and which confers to its holder a legal monopoly for a limited period, has, as a corollary, the essential right for its holder to prohibit third parties from marketing, using, importing or holding products protected by the patent;

It indicates, by referring to the decision of the *Conseil constitutionnel* of 10 June 2009 (2009-580 DC Rec. P. 107) that among the new fields extending the scope of property, there is the right for the holders of copyrights or related rights to benefit from their intellectual property rights and to protect them within the framework defined by the law and France's international undertakings;

It adds that to make this legal monopoly effective, the law grants the patentee a specific and fast prohibition procedure, the conditions of which are defined in Article L. 615-3 of the French Intellectual Property Code derived from the French Act of 29 October 2007 and adopted at the instigation of the European Union (Article 9 of Directive 2004/48/EC on the enforcement of intellectual property rights) and international bodies (Articles 48 and 50 of the 1994 TRIPS agreement), although it remains silent on the consequences of invalidation on the merits of the intellectual property title on the basis of which the preliminary injunction was ordered;

However, it points out that the request for guarantees lodged by BIOGARAN with the Judge ruling in preliminary proceedings of the *tribunal de grande instance de Strasbourg* were intended to ensure potential compensation to the defendant if the infringement action were to be subsequently held unfounded or if the cancelled measures were expressly rejected;

It explains that under Article 31 of the 9 July 1991 Act, compensation of the defendant without demonstration of any fault or abuse on the part of the patentee or his licensee requesting the injunction therefore amounts to:

- placing anyone infringing a patent, while the title must be presumed valid until it is revoked, in a

more favourable situation than that of the patent holder himself or his licensee,

- likening a patentee's essential prerogative, namely his right to prohibit which can be asserted against anyone, to an act carrying a very high risk of triggering a mechanism of strict liability, which becomes dissuasive and thereby reduces the patentee's access to the courts.

- negating the patentee's essential prerogative while the legislator intended, with the provisions laid down in Article L. 615-3 of the French Intellectual Property Code, to strengthen the fight against infringement, which the provisions of Article 31 subparagraph 2 of the 9 July 1991 Act dissuade from committing, as they create a risk of liability for the patentee and prejudice the intangible property right of which the patentee is the holder;

LABORATOIRES NEGMA also argues that the principle of equality of all individuals before justice, which has constitutional value, is ignored insofar as the defendant in an infringement action benefits from a more favourable system than the patentee who holds a title which he is entitled to assert against any alleged infringer since he can obtain compensation for the damage which he may have suffered as a result of the legitimate infringement action by not providing evidence of the fault committed by the claimant in the action;

LABORATOIRES NEGMA explains that the alleged infringer can determine the level of risk he is taking and adjust it according to the evolution of the case, contrary to the patentee or his licensee who does not control the level of risk since such a risk depends on the duration of the proceedings leading to the revocation of the patent or to the finding of absence of infringement of the patent as well as of the volume of infringing production and the profit margins made by the infringer during that period;

Therefore, the extension of the proceedings due only to the defendant in the action will worsen the damage suffered and will justify his request for substantial damages;

According to LABORATOIRES NEGMA, the consequence of the strict liability system instituted by Article 31 of the 9 July 1991 Act in favour of the alleged infringer, initial defendant in the preliminary injunction action, is a denial of the principle that individuals should be treated equally despite the many decisions issued by the *Conseil constitutionnel* (No. 75-56 DC of 23 July 1975, No. 2010-15/23PQC of 23 July 2010, NO. 2011-112 PQC of 1 April 2011, No. 2011-190 PQC of 21 October 2011);

It also considers that there is an unjustified imbalance in the demonstration of the fault between the patent holder who must demonstrate the existence of the infringement or its likelihood under Article L. 615-3 of the French Intellectual Property Code and the alleged infringer who, considering himself retrospectively harmed by the provisional measures ordered, will benefit from a compensatory regime without having to demonstrate any fault committed by the claimant in preliminary proceedings;

It further considers that the application of Article 31 of the 9 July 1991 Act directly violates the right of the patent holder to bring legal proceedings by not allowing him any legal failure during proceedings aiming at enforcing his rights;

It also points out that Article 31 of the 9 July 1991 Act ignores the constitutionally recognised right of the patent holder to effectively have access to the courts since the text dissuades him from initiating an action against an alleged infringer on the basis of a patent;

The provision of this article also violates, in LABORATOIRES NEGMA's opinion, Article 16 of the 1789 Declaration of the Rights of Man and of the Citizen because the implementation of a strict liability system applicable to the patent holder acting in compliance with it, restricts his right to initiate an action by creating to his detriment a form of presumption of fault, while the person initiating a legal action is at fault only if the defendant provides evidence that the patentee has acted wrongfully;

LABORATOIRES NEGMA also invokes the violation of the provisions of Article 17 of the 1789 Declaration of the Rights of Man and of the Citizen protecting the property right which include intellectual

property rights as held by the *Conseil constitutionnel* in the decisions of 27 July 2006 (No. 2006-540 DC) and 10 June 2009 (No. 2209-580 DC, Rec. P 107); no reason of public interest can justify the violation of the property right which the patent holder is entitled to claim;

It alleges that the protection granted by Article 31, subparagraph 2 is not necessary with regard to the enforcement of the orders granted on the basis of Article L. 615-3 of the French Intellectual Property Code since the provisional measures implemented by the provisional legal decision tend to protect the lawfulness of the title, namely the patent, when the rights are likely to be infringed; the *erga omnes* invalidity of the patent cannot justify a violation of the property right since the violation of this right does not result from the action initiated by BIOGARAN, but from the fact it is prevented from protecting its property right which legally existed and was presumed valid;

It finishes by adding that the consequence of BIOGARAN's voluntary enforcement of the 10 March 2009 order in preliminary proceedings was to automatically engage its strict liability by simply having initiated a preliminary action under of Article L. 615-6 of the French Intellectual Property Code;

This having been set out, LABORATOIRES NEGMA requests that the following question be submitted to the *Conseil constitutionnel*:

Do the provisions of Article 31 subparagraph 2 of the 9 July 1991 Act prejudice the rights and freedoms which are guaranteed by the *Constitution*, in particular:

- the equality of treatment of individuals,
- the right of access to the courts,
- the right to intellectual property,

when applied to provisional measures ordered under Article L. 615-3 of the French Intellectual Property Code on the basis of a patent which was subsequently revoked or held not infringed;

It must be pointed out that the Court only rules on the substance of the question posed by LABORATOIRES NEGMA and on the appropriateness of referring such a priority question on constitutionality to the *Cour de cassation*;

In order to justify the relevance of the question posed, BIOGARAN contends that the *Conseil constitutionnel* does not have jurisdiction to rule on this question insofar as the *Cour de cassation* should first decide on the interpretation to be given to the Article 31 subparagraph 2 of the of 9 July 1991 Act in order to establish an interpretation, in settled case law, conferred to this legal text;

This argument devoid of relevance will consequently be dismissed;

Article 31 of the French Act No. 91-650 of 9 July 1991 in its version derived from the 21 April 2006 ordinance provides that:

“Subject to the provisions of Article 2191 of the French Civil Code, the enforcement may be carried out to the end under a provisionally enforceable title. 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”;

This provision directly stems from Article 50 item 7 of the World Trade Organization agreements on the trade-related aspects of intellectual property rights dealing with trade (TRIPS) duly signed by France and published in the *Journal Officiel* by decree No 95-1242 of 24 November 1995 which provides:

“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 these measures”.

This provision was applicable directly in France as long as a Community provision did not use it;

Yet Article 9 item 7 of Directive 2004/48 EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights is identical to this provision which has been transposed to Article L. 615.3 of the French Intellectual Property Code, which provides that:

“The court, in preliminary or ex parte proceedings, may condition the implementation of the measures it has ordered on the furnishing of security by the claimant to ensure, if necessary, the claimant’s compensation if the infringement proceedings are subsequently held unfounded or if the measures are void”.

It results from this text that although a guarantee may be granted to the defendant so that he is assured of being compensated if the action initiated against him by the claimant were to fail, it would be illogical and especially unfair to envisage this compensation only in favour of the defendant who obtained such a guarantee and to ignore the request for compensation made by the defendant who would not have asked or obtained this guarantee when the provisional measures were ordered against him;

Equality of treatment of individuals invoked by LABORATOIRES NEGMA would be, in this case, plainly violated;

Consequently, there exists, contrary to LABORATOIRES NEGMA’s allegation, a legislative coherence between the provisions of Article L. 615-3 of the French Intellectual Property Code and those of Article 31 of the 9 July 1991 Act which does not violate the equality of treatment of individuals but on the contrary, re-establishes the balance of rights and ensures compliance with the constitutionally protected principle of equality.

It is undeniable that patent is presumed valid and that LABORATOIRES NEGMA was therefore entitled to bring preliminary proceedings on the basis of patent EP 520 414 against BIOGARAN;

But it is also well-established that the enforcement of a provisionally enforceable decision always occurs at the risk of the person who requested it;

And LABORATOIRES NEGMA cannot argue as it does that the principle of equality of all individuals before justice, which is constitutional, is ignored in this instance since the defendant in an infringement action does not benefit, contrary to what is being alleged, from a more favourable regime than the patent holder;

That the compensation of the damage suffered by the alleged infringer by exempting him from providing evidence of the fault committed by the claimant in the action is only the counterpart of the right available to the person having the capacity to bring infringement proceedings to implement the provisions laid down in Article L. 615-3 of the French Intellectual Property Code which must be so while keeping in mind the risks assumed in the case of the failure of the initiated action;

It is also vain to contend as LABORATOIRES NEGMA does that the alleged infringer can determine the level of risk and adjust it according to the evolution of the case, contrary to the patentee or its licensee who does not control the level of risk since such a risk depends on the duration of the

procedure leading to the revocation of the patent or to the finding of absence of infringement of the patent as well as of the volume of infringing production and the profit margins made by the infringer during that period;

In fact, the risk invoked is part of the procedural contingencies which the person who is entitled to bring infringement proceedings must take into account and keep in mind when initiating an action based on the provisions of Article L. 615-3 of the French Intellectual Property Code;

LABORATOIRES NEGMA also argues that these provisions violate Article 16 of the 1789 Declaration of the Rights of Man and of the Citizen because the implementation of a strict liability system applicable to the patent holder acting in compliance with it restricts his right to initiate an action by creating to his detriment a form of presumption of fault, while the person initiating a legal action is at fault only if the defendant provides evidence that the patentee has acted wrongfully;

But LABORATOIRES NEGMA cannot validly contend as it does that there is an unjustified imbalance in the demonstration of the fault between the patent holder who must demonstrate the existence of the infringement or its likelihood under Article L. 615-3 of the French Intellectual Property Code and the alleged infringer who, considering himself retrospectively harmed by the provisional measures ordered, will benefit from a compensatory regime without having to demonstrate any fault committed by the claimant in preliminary proceedings;

The patent is presumed to be valid as long as the defendant in the infringement action has not demonstrated that the said patent does not deserve the claimed protection;

And the burden of proving an infringement always lies with the holder of the intellectual property right or the successor in title who asserts this right against the alleged infringer;

Since the burden of proof lies with both parties, the patent holder's duty being to provide evidence of the existence of acts of infringement whereas the alleged infringer's duty is to demonstrate the absence of acts of infringement, LABORATOIRES NEGMA cannot therefore contend that there is an imbalance between the parties as to the burden of proving the fault;

The fact that the defendant did not demonstrate the fault committed by the person who, having the capacity to bring infringement proceedings, lodged a claim on the basis of the provisions of Article L. 615-3 of the French Intellectual Property Code, must be assessed on the basis of the exceptional prerogative which is granted by the law to the claimant to request that the Judge order provisional measures likely to have far-reaching consequences if they are not legally founded;

Therefore, LABORATOIRES NEGMA cannot contend that the application of Article 31 of the 9 July 1991 Act directly violates the patent holder's right to bring proceedings by not allowing legal failure during an action to protect his rights and by not allowing him access to courts since it dissuades him from initiating an action against an alleged infringer on the basis of a patent;

This interpretation seems erroneous since the implementation of the provisions of Article L. 615-3 of the French Intellectual Property Code aiming to prevent any imminent infringement of the rights conferred by the title or to stop alleged acts of infringement from continuing is left to the discretion of the person who has the capacity of bringing infringing proceedings for which he is liable, this right to bring proceedings having its corollary in the fourth paragraph of the above-mentioned article as well as in Article 31 of the French Act of 9 July 1991;

Contrary to what is contended, the patent holder is therefore not deprived of his right to access the courts so as to enforce the rights related to his title since he can always bring proceedings on the merits of the infringement and obtain compensation for the damage allegedly caused by the alleged infringer without necessarily having had recourse to the provisions of Article L. 615-3 of the French Intellectual Property Code;

It follows that the provisions of Article 615-3 mentioned above must be implemented advisedly and with considerable caution, as the claimant in the action must be certain that the patent which he asserts against the alleged infringer is legally and technically valid and strong or that the acts of infringement for which he holds the alleged infringer liable, are, with a high degree of probability, founded;

The claimant must assume this risk which must be assessed, since the victim of provisional measures unfairly ordered cannot remain dependent on this risk without obtaining compensation should the action initiated against him on the merits be not founded;

And as mentioned above, this criticised legal provision does not constitute a violation of the right to initiate an action of the person who has the capacity to bring infringement proceedings since it does not prohibit him from issuing a summons to appear in court under Article L. 615-3 of the French Intellectual Property Code but it merely makes him aware, by giving him a sense of responsibility, of the risk involved by an action which may be considered later as foolhardy;

LABORATOIRES NEGMA can neither invoke the provisions of Article 17 of the Declaration of the Rights of Man and of the Citizen by sustaining that the consequence of the application of Article 31 of the 9 July 1991 Act is to dissuade the holder of the intellectual property right from using one of the essential prerogatives of his right, which is the very negation of this property right and of the legal monopoly which it confers to its holder;

It must be noted that the provisional measures ordered under Article L. 615-3 of the French Intellectual Property Code are intended to prevent any imminent infringement of the rights conferred by the title or to stop the alleged acts of infringement from continuing;

Consequently, Article 31 subparagraph 2 of the 9 July 1991 Act will produce its effects if such measures could not be justified by:

- the non-existence of alleged acts of infringement, no violation of the property right could then be invoked by the patent holder,
- the title which was used as the basis for the infringement action and the provisional measures is revoked, the consequence being that there cannot be violation of the property right of the patent holder owing to the absolute effect of the decision to revoke the patent (L. 613-27 of the French Intellectual Property Code), with the result that the asserted patent must be considered as having never existed legally, *ab initio*;

And BIOGARAN rightly points out that the property right is not absolute and that the constitutional protection of the property right is only exercised in presence of an infringement or a restriction which is so serious that it distorts the meaning and the scope of this property right;

Yet in this instance, LABORATOIRES NEGMA which carried on, at its own risk, the enforcement of the provisional measures ordered on the basis of its intellectual property right does not demonstrate the deprivation or misuse of its property right which would allow it to invoke the constitutional protection of the property right;

It follows that the question which LABORATOIRES NEGMA wishes to refer to the *Cour de cassation* so that it can be submitted to the *Conseil constitutionnel* is for each of the three arguments cited – equal treatment of individuals, right to have access to the courts, violation of the intellectual property right – devoid of substance;

ON THESE GROUNDS

Affirms the order issued on 21 October 2011 by the Judge in charge of the case preparation of the *tribunal de grande instance de Paris*,

Holds that the priority question on constitutionality is devoid of substance,

Holds that there is no need to refer it to the *Cour de cassation*

Order LABORATOIRES NEGMA to pay the costs of these proceedings.

THE COURT CLERK

THE PRESIDENT