

BARCELONA COURT OF APPEAL

ATTORNEY MONTAÑA MORA, MIQUEL
ELI LIGLly AND COMPANY LIMITED
LABORATORIOS NORMON, S. A.
Ref. : 3119 Proceedings 37/09/3^a

SECTION FIFTEEN
PROCEEDINGS NO. 37/2009-3^a
REQUEST FOR THE OPPOSITION OF INTERIM INJUNCTIONS No. 651/2007
(INTERIM INJUNCTIONS PROCEEDINGS No. 236/2007 and 699/2007)
COMMERCIAL COURT NO. 1 OF BARCELONA

COPY

RULING No. 111/2010

PROCURATORS ASSOCIATION OF BARCELONA
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Article 151.2 L.E.C. 1/2000

Senior Judges

Ms MARTA RALLO AYEZCUREN
Mr LUIS GARRIDO ESPA
Mr JORDI-LLUIS FORGAS I FOLCH

In Barcelona, on the twenty-eighth of June of 2010.

Section Fifteen of this Court of Appeals has heard as an appeal the request for opposition to the interim measures adopted without the defendant's preliminary hearing as proceedings no. 651/2007, deriving from interim injunctions proceedings no. 236/2007 and 699/2007, brought before Commercial Court No. 1 of Barcelona. This request was filed by LABORATORIOS LESVI, S.L., RATIOPHARM ESPAÑA S.A., QUALIGEN, S.L. and LABORATORIO STADA, S.L., represented by the procurators Federico Barba Sopena and directed by the lawyer Miquel Vidal-Quadras Trias de Bes; by KERN PHARMA S.L., LABORATORIOS CINFA, S.A., LABORATORIOS ALTER S.A., ALTER GENÉRICOS, S.A., LABORATORIOS FARMALTER, S.A., FARMAPROJECTS S.A. and GALENICUM HEALTH S.L., represented by the procurator Ignacio López Chocarro and under the direction of the lawyer Javier Huarte Larrañaga, and by LABORATORIOS NORMON, S.A., represented by the procurator Francisco Javier Manjarín Albert and assisted by the attorney Juan Pedro Medina López, against the defendant and applicant of the interim injunctions, ELI LILLY AND COMPANY LIMITED and LILLY, S.A., represented by the procurator Ángel Quemada Cuatrecasas and assisted by the lawyer Miquel Montaña Mora. They are pending before this Court as a result of the remedy of appeal filed by LABORATORIOS NORMON, S.A. against the ruling handed down by said Court on 31 July 2008.

BACKGROUND FACTS

FIRST. The court order of the ruling dated 31 July 2008 reads as follows "*COURT ORDER: AGREE to the confirmation of the interim injunctions adopted in proceedings of the third of August of two thousand and seven (proceedings 236.2007F) and fifth of December of the same year (proceedings 6993.2007), dismissing the opposition prepared in proceedings 651.2007F and 106.2008F*".

It was clarified by a ruling dated 17 September 2008 by adding to the court order that express sentencing of costs was not necessary.

SECOND. Remedies for appeal were lodged against the above-mentioned decision, on the one part, by the procedural attorneys of the defendants LABORATORIOS LESVI, S.L. RATIOPHARM ESPAÑA, S.A., QUALIGEN S.L. and LABORATORIO STADA S.L. and on another, the defendants KEN PHARMA, S.L., LABORATORIOS CINFA S.A., LABORATORIOS ALTER, S.A., ALTER GENÉRICOS S.A., LABORATORIOS FARMALTER S.A., FARMAPROJECTS S.A. and GALENICUM HEALTH, S.L., and another, LABORATORIOS NORMON, S.A., which were given leave to proceed. The party which applied for the interim injunctions presented several writs of opposition to the respective appeals.

The other appellants' remedy of appeal against the ruling in question is being heard in Appeals File 36/2009. In this File, no. 37/2009, the appeal of LABORATORIOS NORMON, S.A. has been heard.

THIRD. Once the Rulings were received and the corresponding File (together with File 37/2009) was opened in the Court, a date was subsequently set for the hearing, which was held on 3 February 2010.

Senior Judge Mr LUIS GARRIDO ESPA wrote for the opinion on behalf of the Court.

POINTS OF LAW

FIRST. The appealed ruling of 31 July 2008 jointly decided on the requests for opposition (recorded under numbers 651/2007 and 106/2008) which were brought forth by the defendants described above against the ex-parte interim injunctions adopted by rulings issued on 3 August 2007 (interim injunctions proceedings no. 236/2007) and 5 December 2007 (proceedings no. 699/2007). The parties affected by the injunctions are grouped under three attorneys and defence lawyers: on one side, LABORATORIOS LESVI, S.L. RATIOPHARM ESPAÑA, S.A., QUALIGEN S.L. and LABORATORIO STADA, S.L.; on another side, KERN PHARMA S.L., LABORATORIOS CINFA, S.A., LABORATORIOS ALTER S.A., ALTER GENÉRICOS S.A., LABORATORIOS FARMALTER S.A., FARMAPROJECTS S.A. and GALENICUM HEALTH S.L.; and separately, LABORATORIOS NORMON S.A.

Such rulings of 3 August and 5 December 2007 successively agreed, in accordance with the Spanish Patent Act (*Ley de Patentes*) ("**LP**"), to grant interim injunctions of abstention or inhibition, under the category of prohibition, to prevent the marketing generic drugs consisting of pharmaceutical compositions of *olanzapine* with regard to certain defendants (LABORATORIOS NORMON S.A. among them) that had recently obtained an set sale price and reimbursement by the Interministerial Price Commission adhering to the Ministry of Health and Consumer Affairs after having previously obtained the relevant

marketing authorisations for said generic drugs, thereby preventing their imminent placement on the market with the infringement of the patent that protects the active ingredient. The measures are extended to other defendants who are prohibited from acquiring from the rest of the defendants marketing authorisation for such generic olanzapine drugs for which the administrative body has established a price.

We decide herein the remedy of appeal lodged by LABORATORIOS NORMON S.A against the above-mentioned ruling that dismissed its opposition to the two rulings that adopted similar measures (the appeals lodged by the rest of the defendants was processed in File 36/2007, in which a resolution was handed down on this same date).

SECOND. The injunctive relief was agreed at the request of ELI ILLY LIMITED and its licensee LILLY S.A., in order to preventatively and anticipatorily protect its principal aims for prohibition and cessation based on the imminent infringement of patent ES 2.078.440 (Spanish validation of patent EP 454.436), which protects in its claims 1 to 4 a procedure to obtain the active ingredient olanzapine and in its claim 5 any pharmaceutical composition that contains olanzapine and excipients.

This patent, applied for before the European Patent Office on 24 April 1991 and granted on 13 September 1995, is known by this court as a result of our judgments of 17 January 2008 (File 368/2007) and 27 March 2009 (File 315/2008), in which we have acknowledged the enforceability in Spain of claim 5 mentioned above, which protects olanzapine as a product by application of Articles 27.1 and 70.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), since its entry into force.

Although a first application for interim injunctions for the prohibition to market was dismissed by the Judge (Ruling of 18 May 2007) because holding applications for authorisation filed before the Spanish Drug Agency was deemed insufficient evidence of an imminent infringement, the injunctions were subsequently granted *ex parte* by the aforementioned rulings of 3 August and 5 December 2007, once the complainant had stated and accredited that on 6 July and 8 November of that year, once the authorisation had been granted by the Spanish Drug and Healthcare Products Agency (*Agencia Española de medicamentos y productos sanitarios*) "AEMPS", the Ministry of Health had proceeded to set a price for such olanzapine generic drugs, which (and it was thus evaluated by the court in light of the concurrent circumstances in respect of being the last administrative step prior to being able to market) constitutes serious evidence that such drugs will be placed on the market without respecting the term of validity of the patent right, which expires in April 2011. The measures were finally agreed pursuant to Article 134.1 of the Spanish Patent Act (amended by Law 19/2006, of 5 June), according to which "*those [measures] which duly assure the complete effectiveness of the potential verdict which will be issued in due course, and in particular the following: 1) The cessation of all acts that violate the applicant's right of the or their prohibition, when there is rational evidence to assume the imminence of such acts*" may be adopted as interim injunctions.

The rulings of 3 August and 5 December 2007 and later on 31 July 2008 were thorough in justifying the admissibility of the injunctions in response to the obstacles and defence that the defendants raised. Of said reasons of opposition we shall focus below on those reproduced by the remedies of appeal which we decide herein.

THIRD. LABORATORIOS NORMON SA alleges the following reasons for challenging this ruling:

- a) LILLY S.A. lacks *locus standi* as a non-exclusive licensee of said patent, in accordance with Article 124 LP.
- b) The inexistence of *fumus boni iuris* because Article 52.1.b) LP protects the obtaining of the administrative authorisation to market generic drugs and the stage at which the price is set, and therefore does not constitute *per se* an act that violates the patent.
- c) The inexistence of imminent infringement since the proceedings to include the authorised generic drug in the pharmaceutical provisions of the Spanish Healthcare System and to setting a price are initiated *ex officio*.
- d) The inexistence of *periculum in mora* assumes the undertaking to not launch the olanzapine generic onto the market “*until one of the premises established in Law arises*”.

FOURTH. The first reason for challenging the ruling is completely ineffective and irrelevant in this court since, although the non-exclusive licensee's lack of *locus standi* is considered, the injunctions should not be lifted because of it, given that they are postulated and sustained by the patent-holder, who jointly litigates with the non-exclusive licensee. As regards the rest, if we have issued a pronouncement for injunctive purposes regarding the *locus standi* of the non-exclusive licensee that acts jointly with the patent-holder, the grounds of the appealed ruling appear correct to us in light of the first subsection of Article 124.1 LP and section 3 thereof.

FIFTH. 1) The appealed ruling and the rulings that adopted the interim injunctions had reasoned, from the perspective of the *fumus boni iurus* requirement and, in some aspects, from within the context of the *periculum in mora* requirement, the appropriateness of the injunctive protection of prohibition as relevant evidence of the imminence of the infringement, starting with the objective data of the marketing authorisation application and subsequent price attainment, as the latter step is the one which concludes the administrative procedure and places the defendants, LABORATORIOS NORMON S.A. among them, in a position to market the generic olanzapine drugs at any time.

The Senior Judge indicated that this evidence is qualified bearing in mind that in the corresponding application for a price authorisation, the sale forecasts, the cost of raw material, personnel and other costs are offered as parameters to be evaluated when setting the recommended retail price. These parameters vary over time, which allows it to be inferred that the setting of the price precedes a moment very near to the effective marketing since, in other circumstances, (if the effective marketing is delayed), there is a risk that the set price has no correlation with these values that would ensure the expected profit margin with the risk of selling at a similar price or even less than the cost of production: “*if the laboratory has no intention of marketing the product, it constitutes a maxim of experience that makes no sense to allow the price to be set in accordance with the parameters that will undergo variations, normally increases, until the effective marketing date and will determine a sale or loss or with margins other than those desired*”, the appealed ruling reasons.

The Senior Judge bears in mind that if the procedure for setting a sale price is not initiated at the request of the generic drug laboratories, but rather *ex officio* by the administrative body, nevertheless, pursuant to Article 91 of Spanish Law 29/2006, of 26 July, on guarantees and rational use of drugs and healthcare products, once the administrative body requests from the holder of the authorisation the proposed drug price in order to decide on its inclusion in the pharmaceutical services of the Spain's National Healthcare Service (*Sistema Nacional de la Salud*) ("*SNS*"), and in this step the owner of the marketing authorisation has the possibility of suspending said administrative procedure at any of its stages, such that it does not constitute an unavoidable process. The Senior Judge concludes in response to the defendants' arguments that "*The allegedly intended difficulty deriving from the suspension of the administrative process at that point in order to not include the product in Spain's National Healthcare Service with the consequent loss of subsidies is not difficult because it does not waive it, but rather it is simply a delay in the time which entails the actual suspension*".

Likewise, the Senior Judge of the Commercial Court considers for these purposes that few days after issuing the ruling dated 3 August 2007, the newspaper "El Global" published an article (on 9 September 2007) which noticed the imminent placement on the market of the first generic olanzapine drugs (this document appears in the court documentation).

And the judge explains that it is not that the setting of the price infringes the patent *per se*, but rather it constitutes, for the reasons mentioned above, qualified or powerful evidence of the imminent infringement, bearing in mind the following objectives: "*The complainant will not have the right to consider the described use a violation, but it does have the right because it is granted to it by Article 134 LP, to prohibit those that may entail an imminent infringement (...)*".

II) We substantially agree with this reasoning when assessing the existence of *rational evidence in order to entail the imminence* of the infringing behaviour, whether the presupposition of the *fumus boni iurus* in reference to the main aim of cessation in the prohibition category, or whether as an integral factor of the provisional *periculum in mora* requirement, since the indicated circumstances provide evidence of an intense degree of likelihood of imminent marketing upon the completion, once the retail price of the generic olanzapine is set (which will be included in the pharmaceutical services of the Social Security and be financed with public funds), of the administrative steps needed to be able to begin commercially exploiting them.

It is not debated that despite the *ex officio* initiation of this last step, the owner of the authorisation must present the corresponding price-setting application by means of the appropriate proposal justifying parameters such as manufacturing costs, sales forecasts for the two previous years, the expected profit margin, and must attach invoices for the acquisition of raw materials, which determines the establishment of a laboratory sale price in accordance with those factors, the variation of which would have repercussions on the business's profits between the date on which the offer or proposal is presented and the effective marketing. This correlativity is an indication more than it is significant, as explained in the appealed ruling, in order to presume the imminent marketing, without waiting for the patent to expire (which will take place in April 2011) or an unappealable judgment which decides on the nullity or unenforceability of claim 5 of the patent in the proceedings currently underway. And for these purposes, LABORATORIOS NORMON S.A. and the other defendants, rather than

requesting the suspension of the procedure to include their generic drugs in the SNS, for which they are expressly authorised, made the price offer or proposal.

The suspension should not produce the loss of rights as nothing prevents the owner from seeking the resumption of the proceedings, without any additional consequence other than the inherent temporary delay. It must be borne in mind that the patent expires in April 2011; that the cassation appeal against the judgment of this Court of 17 January 2008 (corresponding to File 368/2007) has been admitted by virtue of Spanish Supreme Court Ruling of 7 July 2009, and that the administrative authorisation would expire in three years as from the time it is obtained without initiating the marketing (Article 21.4 of Law 29/2006). All of this reveals that the price offer made by the defendants to have it set by the administrative body seeks imminent marketing without waiting for the patent to expire or for the final judgment to be handed down in the procedure (or procedures) in which the unenforceability of claim 5 is sought.

As the complainant indicates, unless the appellant herein launches its generic product whilst the patent is in force, the marketing authorisations would have expired by the expiry date of patent ES 2.078.440, which constitutes significant evidence of the imminent infringement.

III) Furthermore, we agree that the detection of the imminence of the infringing conduct must be based on objective criteria since otherwise the injunctive relief (and, when all is said and done, the main intention to prohibit) would be at the mercy of the deliberate statements of the victim by simply expressing that it does not intend to place the infringing product on the market despite having already obtained or finalised the administrative marketing authorisations.

The announced undertaking that the generic drugs are not going to be marketed “*until one of the premises established in Law applies*” is, as warned by the complainant, vague and inaccurate. And in any case the detection of the imminence of the infringement must not be based on subjective criteria when: the stated intention may be rectified at any time, the preparatory acts carried out place the party affected by the measure in a situation in which it is able to market the product at any time and its procedural position is to oppose a measure that guarantees that it will not carry out any conduct in such a way that expresses that it has no intention of carrying it out.

IV) Lastly, it is irrelevant here that the establishment of the price does not constitute *per se* or may not constitute an infringement of the patent right pursuant to article 50 and 52.1 .b) of the LP. The appealed ruling does not grant interim protection because it considers that the obtaining of a price constitutes an infringement of the patent right, but rather it deems this act and the intervention of the defendants therein, as significant evidence of the imminent marketing of the generic drugs of those affected by said administrative act.

With the above we hereby provide a complete response to the alleged grounds for appeal.

SIXTH. By dismissing the appeal, the costs must be imposed on the appellant (Article 398.1 in relation to 394.1 LEC).

In light of the above-mentioned legal provisions, those alleged by the parties and any other relevant and applicable legislation,

COURT ORDER

We hereby dismiss the appeal lodged by the attorneys for LABORATORIOS NORMON, S.A. against the ruling issued on 31 July 2008, imposing the procedural costs on the aforementioned appellant.

A certificate of this ruling will be issued and sent to the original Court for the relevant purposes together with the referred proceedings.

No extraordinary appeals may be lodged against this ruling in accordance with the Final Sixteenth Provision of the LEC.

Thus by virtue of our Ruling do we the Senior Judges pronounce, order and sign.