Court of Appeals of Madrid (Section 32) Judgment of 23 June 2023 ELI LILLY & DAICHI v TEVA & CINFA - ECLI:ES:APM:2023:9288

The new section 32, specialized in IP, of the Madrid Court of Appeals analyses in this judgment several procedural issues of interest that often arise in patent infringement proceedings, such as the standing of the exclusive licensee plaintiff or the preclusion of actions for having previously brought a nullity action against the same patent before another court. In addition, the judgment addresses the liability for damages of the defendants TEVA and CINFA as the first laboratories to launch "at risk" with their generic (infringing) drugs.

**Introduction**

The plaintiff ELI LILLY AND COMPANY is the owner of patent ES2102602, the Spanish validation of European patent EP0584952, whose object is the use of the active ingredient raloxifene and its pharmaceutically-acceptable salts in the preparation of a drug that is helpful in the treatment and prevention of osteoporosis, and of SPC No. 00990002 granted on the basis of that patent (expiration date: July 28, 2012), which extended its term until August 5, 2013.

The co-plaintiff, DAIICHI SANKYO EUROPE GmbH, the exclusive licensee of these titles, marketed the Raloxifene drugs in Spain under the brand name EVISTA® through its Spanish subsidiary DAIICHI SANKYO ESPAÑA S.A.

More specifically, ELI LILLY was marketing Raloxifene drugs in Spain through two different companies, under two different brand names: on the one hand, DAIICHI marketed it as EVISTA® and, on the other, LABORATORIOS ESTEVE under the brand name OPTRUMA®, as the distributor of ELI LILLY.

TEVA was the first pharmaceutical laboratory to launch its generic Raloxifene drug into the Spanish market in May 2011, that is, two years before the expiration of the patent and SPC (August 5, 2013).

As a result, the so-called "homogeneous grouping" comprising the original EVISTA® and OPTRUMA® products and TEVA raloxifene was created in September 2011.

In accordance with the Spanish Medicines Law then in force[[1]](#footnote-1) , this homogeneous grouping required pharmacists to dispense the lowest-priced drug included in the grouping (the so-called "lowest price system"). Following the launching of this first generic drug, DAICHII was forced to reduce the price of EVISTA® in order to align it with that of TEVA.

Months later, CINFA also launched its generic, in January 2012 and, subsequently, other laboratories launched theirs: STADA, SANDOZ, RATIOPHARM, KERN in July 2012; and MYLAN, TECNIGEN and TARBIS in 2013.

In the first instance, Commercial Court No. 7 of Madrid in its Judgment dated February 28, 2022, found the existence of infringement and ordered TEVA and CINFA to pay damages against both the owner ELI LILLY and its exclusive licensee DAIICHI.

**Proof of standing of the exclusive licensee (DAIICHI) to bring an infringement action**

The first issue addressed by the appeal judgment issued by section 32 of the Madrid Court of Appeals was the procedural plea raised by the defendants for the lack of standing of the co-plaintiff DAIICHI SANKYO EUROPE GmbH, the exclusive licensee of the original drug EVISTA®.

The defendants claimed that DAIICHI did not have standing to bring this infringement action, as it had not submitted the complete license agreement with ELI LILLY, nor had it registered the license with the Spanish Patents and Trademark Office (SPTO).

However, the Court considered that the partial submission of the license agreement, which included, among others, the clause relating to the granting of the exclusive license, and the fact that this extract had been checked by a notary public with the original, was sufficient to prove DAIICHI's status as the licensee and to bring an infringement action jointly with the patent owner.

**Preclusion of actions: patent invalidity action previously brought before another court**

Another of the procedural issues addressed by the judgment of the Court of Appeals of Madrid is the preclusion of the nullity action that the defendants TEVA and CINFA had raised as a defense against the patent infringement action.

The question to be resolved by the Court was whether or not, since CINFA and TEVA had already filed a nullity action against ELI LILLY in a previous lawsuit before the Courts of Pamplona, which was rejected, they could now request the nullity of the same patent before the Courts of Madrid.

The Court considered that they could not, in application of the rule on the preclusion of actions of article 400 of the Spanish Civil Procedural Law.

The Court understood that, since the nullity action had been previously dismissed in Navarra, TEVA and CINFA could not in a subsequent litigation before another court reopen the debate on the nullity of the patent, even if the nullity arguments were different. In the words of the Court: "*What is decisive here is that nothing prevented it from having alleged at that time other grounds to try to support the nullity action it was bringing. Failure to do so implied the procedural impossibility of alleging them in the future in accordance with the provisions of Article 400 of the LEC*".

**Claim for damages by the owner/parent company**

As for compensation, the defendants TEVA and CINFA also argued that ELI LILLY, having assigned the exploitation of the patent to its exclusive licensee DAIICHI, could not claim damages, but rather in such a case, only DAIICHI should receive compensation.

However, the Court rejected this argument, understanding that ELI LILLY had “its own compensatory interest" different from that of DAIICHI: "*The owner (...) in addition to its interest in defending the exclusive right, also has an interest in obtaining compensation, since (...) it participates in the result of the exploitation in Spain of the patented invention by supplying the licensee DAIICHI with the product EVISTA® (...). It is out of place to try to question that this co-plaintiff would be harmed by the reduction of sales that could have been caused in Spain due to the infringement of the exclusive right*".

In addition, the Court noted that in the complaint ELI LILLY had already avoid duplicity in the damage’s compensation claim.

For this purpose, ELI LILLY had requested -and this was the criterion accepted by the court- that the damages be quantified according to the criterion of the profit obtained by TEVA and CINFA from the sales of each unit of its generic Raloxifene drugs but limited to all those units which, if they had not been marketed by the defendants, would not have been attributable to DAIICHI's EVISTA® product and, subsidiarily, in the event that DAIICHI's claim for damages was dismissed, what ELI LILLY claimed was the profit obtained by the defendants for all the units of generic drugs marketed by TEVA and CINFA.

**Calculation of damages claimed by the exclusive licensee (DAIICHI) and liability of the first generic laboratory to launch "at risk"**

On the other side, DAIICHI claimed the payment of damages according to the profits it would have foreseeably obtained from the exploitation of the invention had there been no infringement by TEVA and CINFA and differentiating, within this criterion, a direct loss of profits (due to the effects of the reduction of the share and price of its original drug EVISTA®, as we will see below) and an indirect loss of profits (corresponding to the losses derived from the reduction of the net result of its subsidiary DAIICHI SANKYO ESPAÑA, S.A. as a consequence of the infringement).

Regarding direct lost profit, DAIICHI differentiated two main items for the calculation of damages, which it called "effect of (market) share reduction" and "effect of price reduction", respectively.

* "Share reduction effect"

Based on this criterion, the Court had jointly and severally sentenced CINFA and TEVA for the profits that DAIICHI would have obtained from the marketing in Spain of that part of the generic Raloxifene drugs that, had there been no infringement, would have been assumed by the original drug EVISTA®.

In response, the defendant CINFA argued, with respect to the compensation period, that it could not be held liable to pay damages beyond August 5, 2012, the date from which other laboratories (STADA, SANDOZ, RATIOPHARM, etc. which had not been sued) were launching their generic Raloxifene drugs into the market, prior to the expiration date of the patent (August 5, 2013).

In particular, CINFA argued that one could not assume the hypothesis that what TEVA and CINFA sold could not have been sold by the rest of the non-defendant laboratories. According to CINFA, it would be more logical to consider that the other generic companies, and not just DAIICHI, would have sold more product.

However, the Court rejected this approach and considers that the frustrated sales of DAIICHI’s drugs were due to the "at risk" launches of CINFA and TEVA, whose market shares were progressively increasing.

Furthermore, the Court clarifies that the decision not to sue the rest of the generic laboratories is not relevant in this regard because, in the words of the court, "*each subject must respond to the consequences of the infringement committed, even though there may be others who have also infringed the same right*".

In conclusion, the Court considered the criterion that, in the absence of TEVA and CINFA, the drugs sold by the latter would have been marketed by the rest of the laboratories in proportion to their respective market shares (and not by creating a compartmentalization of the market between innovative drugs vs. generic drugs), to be correct. In this way, a part of the sales could have been effectively absorbed by the other generic companies, but another part should in any case be attributed to the sales taken away from the plaintiff.

* "Price reduction effect"

Regarding this second criterion, the first-instance Court had sentenced TEVA -as the first laboratory to have launched “at risk”- for the losses derived from the forced reduction of the price of EVISTA® due to the inclusion of TEVA's generic drug in the so-called "homogeneous grouping" for the active ingredient Raloxifene.

Once again, the Court accepted DAIICHI's thesis and considers that the laboratory that launches at risk and markets the first generic drug (TEVA) forces the price reduction of the original drug and therefore must be responsible for the damages caused during the entire remaining exclusivity period, regardless of whether other generic laboratories join the “homogeneous grouping” later (and before the expiration date of the patent).

Consequently, TEVA was declared responsible for all the lost profits during the entire exclusivity period, since it was the first generic laboratory that caused the reduction of the sales price of the original reference drug.

In a subsidiary scenario, DAIICHI had asked the court that, if it did not share the view that TEVA alone should be liable for all the damages because it was the one that originally triggered it, TEVA and CINFA should be jointly liable for those damages, with liability apportioned according to their respective market shares.

However, the Court ruled out this possibility because it said that, in order to do so, "*one would have had to prove in this litigation that, during the specific relevant period, that is, until the expiration of the exclusive right, there had been successive revisions and precisely decreasing prices, as a consequence of the entry of new generics into the group (which did not occur when CINFA's generic was incorporated), in order to justify that TEVA would have to share in the responsibility for this reason with other parties*".

Therefore, the Court decided to ascribe all the damages to TEVA, as the first generic laboratory and solely responsible for causing the reduction of the sale price (by 40%) of the original drug EVISTA®, since it was the one who, in accordance with the regulatory framework of the pharmaceutical sector then in force in Spain, triggered the formation of the aforementioned "homogeneous grouping", and since it was not proven that the launching of successive generic drugs of Raloxifene by other laboratories would have caused additional drops in the price of EVISTA®.



1. Law 29/2006, of July 26, on the guarantees and rational use of drugs and health products ("Medicines Law") as amended by Royal Decree-Law 9/2011, of August 19, whose Fourteenth Additional Provision provides that a "homogeneous grouping" includes "*the presentations of medicines financed with the same active ingredient(s) in terms of dose, content, pharmaceutical form or grouping of pharmaceutical forms, and method of administration, which may be interchangeable in their dispensing*". [↑](#footnote-ref-1)