Roj: **SAP M 9288/2023** - **ECLI:EN:APM:2023:9288**

Cendoj Id: **28079370322023100010**
Body: **Provincial Court**
Headquarters: **Madrid**
Section: **32**
Date: **06/23/2023**
Appeal No.: **10/2023**
Resolution No.: **18/2023**
Procedure: **Appeal**
Speaker: **ENRIQUE GARCIA GARCIA**
Type of Resolution: **Judgment**

Case decisions: **SJMer, Madrid, no. 7, 28-02-2022 (proc. 403/2016), SAP M 9288/2023.**

Thirty-second Civil Provincial Court of
Madrid, Thirty-second Section
c/ Santiago de Compostela, 100, 5ª planta -
28035 Tfno.: 914383466,914383590
Fax:911911411
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N.I.G.: 28.079.00.2-2016/0089300
Appeal 10/2023
Judicial O. Origin: Commercial Court No. 07 of Madrid
Ordinary Proceedings 403/2016 APPELLANTS/APPELLANTS:
ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH
Attorney: Mr. Ángel Quemada Cuatrecasas
Attorney at Law: Mr. Josep Montefusco
Monferrer LABORATORIOS CINFA, S.A.
Attorney: Mr. Aníbal Bordallo Huidobro.
Counsel: Mr. Oriol Ramon Sauri and Mr. Miguel Vidal-Quadras Trias de
Bes TEVA PHARMA, S.L.U.
Procurator: Santiago Tesorero Díaz
Counsel: Mr. Francisco Javier Carrión García de Parada and Ms. Marta González Díaz.

JUDGMENT Nº 18/2023

In Madrid, on the twenty-third day of June of the year two thousand and twenty-three.

In the name of H.M. the King, the 32nd Section of the Provincial Court of Madrid, specialized in intellectual and industrial property, competition and advertising law and composed of the illustrious magistrates Mr. Enrique García García, Mr. Alberto Arribas Hernández and Ms. Mercedes Curto Polo, has seen in

degree of appeal, under roll number 10/2023, the proceedings of proceeding No. 403/2016, coming from the Commercial Court No. 7 of Madrid, relating to Industrial Property, specifically, Patent Law.

ELI LILLY AND COMPANY,DAIICHI SANKYO EUROPE GmbH,LABORATORIOS CINFA, S.A. and TEVA PHARMA,S.L.U. intervened in the second instance as appellants and appellees.
represented by an attorney and defended by a lawyer.

Judge Enrique García García acted as rapporteur, expressing the opinion of the Court.

FACTUAL BACKGROUND

FIRST.- The procedural proceedings were initiated by a writ of claim filed on May 6, 2016 by the representation of ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmgH against LABORATORIOS CINFA, SA and TEVA PHARMA,S.L.U., in which it requested the following:

"BE IT FURTHER DECLARED:

(1) ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH are the owner and licensee, respectively, of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(2) That the generic drugs "RALOXIFENO TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) invade the scope of protection of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(3) That the manufacture, offering, introduction into commerce and use of the generic drugs "RALOXIFEN TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFEN CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) involved, up to and including August 5, 2013, infringement of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(4) That TEVA PHARMA,S.L.U. and LABORATORIOS CINFA, S.A. have carried out acts of infringement of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(5) That TEVA PHARMA,S.L.U. and LABORATORIOS CINFA, S.A. have caused ELI LILLY AND COMPANY and ELI LILLY AND COMPANY to
DAIICHI SANKYO EUROPE GmbH to pay actual damages. ORDER THE

DEFENDANTS TO:

(1) Be and go through the above statements.

(2) To compensate DAIICHI SANKYO EUROPE GmbH according to the criterion of the profits that DAIICHI SANKYO EUROPE GmbH would have foreseeably obtained from the exploitation of the invention in the absence of the infringement of patent ES 2,102,602 and the CCP 009900002 by TEVA PHARMA,
S.L.U. and LABORATORIOS CINFA, S.A., in accordance with the amounts determined during the trial period or, alternatively, in accordance with the amounts determined during the execution phase, applying the bases established in the Judgment.

The following bases shall be used for the calculation of damages:

- Direct quota reduction effect: the additional profits (additional revenues, additional costs) that DAIICHI SANKYO EUROPE GmbH would have obtained from the marketing in Spain of that part of the medicines "RALOXIFENO TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. 72417) marketed or otherwise placed on the market for free or for consideration by the defendants during the term of the patent ES 2.102.602 and the SPC 009900002 which, in the absence of the infringing action, would have been assumed by the original Evista® product.

- Direct price reduction effect: the losses derived from the reduction in the price of Evista® forced by the effective inclusion of the generic drug "RALOXIFENO TEVA coated tablets EFG" (Reg. No. 1067002) in the pharmaceutical benefit of the National Health System, taking into consideration for this purpose:

(i) Evista® units supplied by DAIICHI SANKYO EUROPE GmbH to DAIICHI SANKYO SPAIN,
S.A. at a reduced price, as well as (ii) the Evista® units whose sale was frustrated by the infringing action determined in accordance with the previous section ("direct quota reduction effect"), in the following two periods:

- On a principal basis: between October 5, 2011 and August 5, 2013 (both inclusive)

-In the alternative: between October 5, 2011 and June 12, 2012 (both inclusive).

The difference between the additional unit profit (additional revenues additional costs) earned by DAIICHI SANKYO EUROPE GmbH by supplying each unit of Evista® to DAIICHI SANKYO ESPAÑA, S.A. before and after October 5, 2011.

Indirect loss of profit: the losses of DAIICHI SANKYO EUROPE GmbH arising from the reduction in the net operating profit after tax of its subsidiary DAIICHI SANKYO ESPAÑA, S.A. as a result of the sale by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. of the medicines "RALOXIFENO TEVA comprimidos recubiertos EFG" (No. 1067002) and "RALOXIFENO TEVA comprimidos recubiertos con película EFG" (No. 1067002) and the forced price reduction due to the inclusion of "RALOXIFENO CINFA 60 mg comprimidos recubiertos con película EFG" in the price of "RALOXIFENO TEVA". Reg. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" and the price reduction forced by the inclusion of "RALOXIFENO TEVA comprimidos recubiertos EFG" (Reg. No. 1067002) in the pharmaceutical provision of the National Health System.

The specific bases on which we request that the above items be calculated are those specified, principally and in the alternative, in paragraphs 196 to 202 of the present claim which are reproduced here.

(3) To indemnify ELI LILLY AND COMPANY LTD. According to the criteria of the benefits that TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. have obtained from the exploitation of the invention in Spain during the term of the patent ES 2.102.602 and the CCP 009900002, in accordance with the bases specified principally and subsidiarily in paragraphs 205 to 207 of the present lawsuit and which we hereby reproduce:

- Principally, taking into account only those units of the generic drugs "RALOXIFENO TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" marketed during the term of patent ES 2,102,602 and of the SPC 009900002 that had not already been considered as frustrated sales of the product Evista® for the purpose of quantifying the quota reduction effect suffered by DAIICHI SANKYO EUROPE GmbH.

In the alternative, and in the event that this Court rejects in its entirety, for whatever reason, the preceding petition (2) for condemnation requested by DAIICHI SANKYO EUROPE GmgH taking into account the totality of the units of generic drugs "RALOXIFEN TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFEN CINFA 60 mg film-coated tablets EFG" sold by TEVA PHARMA, S.L.U. and LABORATORIOS CINFA 60 mg film-coated tablets EFG (Reg. No. 1067002). Reg. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" sold by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. during the aforementioned period.

And all of the above, with costs imposed on the defendants."

SECOND.- After following the trial through the corresponding proceedings, the Commercial Court nº 7 of Madrid issued a sentence, dated February 28, 2022, whose decision was as follows:

"I uphold the claim brought by ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH against LABORATORIOS CINFA, S.A. and TEVA PHARMA S.L.U. therefore:

A.- I declare:

(1) ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH are the owner and licensee, respectively, of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(2) That the generic drugs "RALOXIFENO TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) invade the scope of protection of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(3) That the manufacture, offering, introduction into commerce and use of the generic drugs "RALOXIFEN TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFEN CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) involved, up to and including August 5, 2013, infringement of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(4) That TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. have carried out acts of infringement of patent ES 2,102,602 and Supplementary Protection Certificate No. 009900002.

(5) That TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. have caused ELI LILLY AND COMPANY and ELI LILLY AND COMPANY to
DAIICHI SANKYO EUROPE GmbH certain and effective damages. B.-

Condemn LABORATORIOS CINFA, S.A. and TEVA PHARMA S.L.U.:

(1) To be and to go through the above statements.

(2) To compensate DAIICHI SANKYO EUROPE GmbH that would have foreseeably obtained from the exploitation of the invention if there had not been the infringement of the patent ES 2.102.602 and the CCP 009900002 by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. for the following concepts:

1. Direct loss of profits: the following bases shall be used for the calculation of damages:

a. Direct quota reduction effect: Joint and several liability of LABORATORIOS CINFA, S.A. and TEVA PHARMA S.L.U. of the additional benefits (additional revenues, additional costs) that DAIICHI SANKYO EUROPE GmbH would have obtained from the commercialization in Spain of that part of the medicines "RALOXIFENA TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. Reg. 72417) marketed or otherwise placed on the market for free or for a consideration by the defendants during the term of patent ES 2,102,602 and the SPC 009900002 which, in the absence of the infringing action, would have been assumed by the original Evista® product.

The amount of the loss of profit derived from the "quota reduction effect" will be determined by multiplying the following factors:

1. Number of Raloxifene TEVA and Raloxifene CINFA drugs marketed or otherwise placed on the market (for free or against payment) by TEVA and CINFA in the period from May 5, 2011 to August 5, 2013, adjusted according to the percentage attributable to the Evista® product in relation to:

-The number of units sold of ESTEVE's Optruma® product in the period between May 5, 2011 and August 5, 2013; and

-The number of units of generic Raloxifene other than Raloxifene TEVA and Raloxifene CINFA sold as of July 1, 2012 and as of August 5, 2013.

In any case, in the execution of the sentence, the units actually sold by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. must be determined.

2. Profit obtained by DAIICHI as a result of the sale of each additional unit of Evista® in Spain in the period between May 5, 2011 and August 5, 2013.

This calculation shall take into account the net unit margin (euros per unit) that would have been obtained from the sale of each subsequent additional frustrated unit:

INCOME FOR THE YEAR FY201 FY2012 FY2013 Initial selling price 8.15 7.98 6.29 Promafional allowance 5.66 1.91
7.16 Purchase price -3.23 -3.31 -4.51 Sales transport -0.02 -0.02 -0.01 10.51 6.57 7.93

The result will be specifically allocated to TEVA PHARMA S.L.U. or LABORATORIOS CINFA, S.A. according to their respective market shares in each period, in accordance with the Urceda report.

b. Direct price reduction effect: Responsibility of TEVA PHARMA S.L.U. for the losses derived from the reduction of the Evista® price forced by the effective inclusion of the generic drug "RALOXIFENO TEVA comprimidos recubiertos EFG" (Reg. No. 1067002) in the pharmaceutical benefit of the National Health System, taking into consideration the following criteria:

-The units of Evista® supplied by DAIICHI SANKYO EUROPE GmbH to DAIICHI SANYO ESPAÑA, S.A. at a reduced price, plus the units of Evista® whose sale was frustrated by the infringing action to be determined in accordance with the previous section ("direct quota reduction effect"), in the period between October 5, 2011 and December 31, 2011.

The net unit margin (euros per unit) to be taken into account for the price reduction effect calculations is:

LUCRO CESANTE FY2011 FY2012 FY2012 FY2013 Initial selling price 8.15 7.98 5.29 Promotional allowance 5.66 1.91
7.16 Price concept -3.28 -3.31 -4.51 Sales transport -0.02 -0.02 -0.01 10..51 6.57 7.93

In any case, in the execution of the sentence, the units actually sold by TEVA PHARMA S.L.U. must be determined.

-The difference between the additional unit profit (additional revenues additional costs) earned by DAIICHI SANKYO EUROPE GmbH by supplying each unit of Evista® to DAIICHI SANKYO ESPAÑA, S.A. before and after October 5, 2011.

II. Indirect loss of profit: the losses of DAIICHI SANKYO EUROPE GmbH arising from the reduction in the net operating profit after tax of its subsidiary DAIICHI SANKYO ESPAÑA, S.A. as a result of the sale by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. of the drugs "RALOXIFENO TEVA comprimidos recubiertos EFG" (No. 1067002) and "RALOXIFENO CINFA 60 mg comprimidos recubiertos con película EFG" (No. 1067002) and the price reduction forced by the inclusion of "RALOXIFENO CINFA 60 mg comprimidos recubiertos con película EFG" (No. 1067002) in the price of the drugs. Reg. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" and the price reduction forced by the inclusion of "RALOXIFENO TEVA comprimidos recubiertos EFG" (Reg. No. 1067002) in the pharmaceutical provision of the National Health System.

The indirect loss of profit suffered by DAIICHI SANKYO EUROPE GmbH shall be determined according to the following factors:

1. Total operating income of DAIICHI SPAIN for the fiscal years 2011, 2012 and 2013.

2. Increase in such operating income if the "quota reduction effect" and "price reduction effect" calculated in accordance with the preceding bases had not occurred.

(3) To compensate ELI LILLY AND COMPANY LTD. according to the criterion of the benefits that TEVA PHARMA S.L.U and LABORATORIOS CINFA, S.A. have obtained from the exploitation of the invention in Spain during the period of validity of the patent ES 2.102.602 and of the CCP 009900002, according to the following bases:

-Number of units of infringing generic sold by TEVA and CINFA in the term of the ES602 patent and the CCP 009900002 (May 2011 - August 2013) multiplied by the additional profit earned by TEVA and CINFA for each of those units (revenue minus additional costs).

Taking into account only those units of the generic drugs "RALOXIFENO TEVA film-coated tablets EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" marketed during the term of patent ES 2.102.602 and of the SPC 009900002 that had not already been considered as frustrated sales of the product Evista® for the purpose of quantifying the quota reduction effect suffered by DAIICHI SANKYO EUROPE GmbH.

In any case, in the execution of the sentence, the units actually sold by TEVA PHARMA S.L.U. and LABORATORIOS CINFA, S.A. must be determined.

With express sentence to LABORATORIOS CINFA, S.A. and TEVA PHARMA S.L.U. to pay the costs".

THIRD.- By order dated June 6, 2022, an order was issued to clarify and complement the preceding sentence, from the text of which the following pronouncements can be extracted:

"I clarify paragraph (2) 1.b. of the Judgment by establishing that, for the purposes of determining the direct loss of profit due to price reduction, the relevant magnitude to be multiplied by the units affected is that specified in that paragraph of the Judgment as "The difference between the additional unit profit (additional revenue - additional costs) obtained by DAIICHI SANKYO EUROPE GmbH through the supply of each unit of Evista® before and after October 5, 2011."

"(...) the destruction of raloxifene by TEVA PHARMA S.L.U. is certain, in its reality and in its amount, so that this amount should be reduced from the profits of TEVA PHARMA S.L.U. in the sale of raloxifene for the purposes of the indemnity calculation. Thus, the number of units destroyed should be considered as the one established in the judicial expert report in point 5 of Report 3 of 4 Teva's Expert Report".

"(...) we cannot consider the raloxifene refunds claimed by LABORATORIOS CINFA, S.A. to be accredited".

"We consider the deduction of the "Lump sum payment" expense to be correct. However, we agree with the subsidiary argument of ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH so we understand that Mr. Alvaro's calculation is not accurate, since the 5-year period for which he accrues the cost starts on January 1, 2012, when Mr. Alvaro's own report (p. 11) states that the first sale of CINFA took place on January 18, 2012. If the 5-year period were to start on January 18, 2012 (instead of January 1), there would be17 days less cost amortization within the indemnification period (until August 5, 2013), which would imply a lower deductible expense figure of €852.38 (17 days x €50.14/day). Therefore, even if conceptually the "Lump sum payment" is considered deductible (which it is not), it should not be deductible in the figure of 29,080 euros calculated by Mr. Alvaro, but in 28,227.62 euros, resulting in a figure of benefits illicitly obtained by CINFA of 205,542.38 euros.

It is appropriate to clarify the sentence in this way on this point:

I. Direct loss of profits: the following bases shall be used for the calculation of damages:

a) Direct quota reduction effect: Liability of LABORATORIOS CINFA, S.A. and TEVA PHARMA S.L.U. for the additional benefits (additional revenues - additional costs) that DAIICHI SANKYO EUROPE GmbH would have obtained from the commercialization in Spain of that part of the drugs "RALOXIFENO TEVA comprimidos recubiertos EFG" (Reg. No. 1067002) and "RALOXIFENO CINFA 60 mg comprimidos recubiertos con película EFG" (Reg. 1067002) and "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) marketed or otherwise placed on the market for free or against payment by the defendants during the term of the patent ES 2.102.602 and the CP 09900002 which, if the infringing action had not taken place, would have been assumed by the original product Evista®.

"Regarding the correction of the reference to a sentence for indirect loss of profits where the "price reduction effect" for LABORATORIOS CINFA, S.A. is included in the Judgment, we must clarify the following:

Indeed, in the judgment it was stated that the liability of LABORATORIOS CINFA, S.A. for the indirect loss of profits suffered by DAIICHI SANKYO EUROPE GmbH be determined according to the following factors: (...) Increase of said operating result corresponding to the case of not having produced the "quota reduction effect" and - "price reduction effect" calculated according to the preceding bases. The reference to the calculations according to the preceding bases implies with regard to the "price reduction effect", that it is only imputable to TEVA PHARMA S.L.U. and in the times established in the sentence".

"As regards the clarification on a conviction for indirect loss of profits where the "price reduction effect" is limited to the same period as that provided for in Judgment B, (2), b "Direct price reduction effect", we must follow what was agreed above in point 2."

"(...) regarding the opposition of LABORATORIOS CINFA, S.A. to the indemnity claim of ELI LILLY AND COMPANY in accordance with the criterion of the profits that the co-defendants have obtained from the exploitation of the invention, it is accepted the argument that LABORATORIOS CINFA, S.A. which argued in those terms against the claim for compensation to DAIICHI SANKYO EUROPE GmbH for indirect loss of profits derived from the losses derived from the reduction in the net operating result after taxes of its subsidiary DAIICHI SANKYO ESPAÑA, S.A. as a consequence of the infringing sale of the defendants, is accepted, but without greater significance in the argumentation of the judgment."

FOURTH: Publicity and notification of the aforementioned resolution to the litigants, by the respective representatives of TEVA PHARMA S.L.U., LABORATORIOS CINFA, S.A. and ELI LILLY AND COMPANY, and
DAIICHI SANKYO EUROPE GmbH filed appeals which, once admitted by the aforementioned court, were processed in due form.

Once the proceedings before the court were completed, the case was sent to the Provincial Court. Once the matter was referred to the 32nd section, after the latter received the proceedings, it proceeded to the formation of the appeal file, which has been followed in accordance with the procedures foreseen for proceedings of its kind.

FIFTH.- The deliberation, voting and ruling session of the matter by the members of the court was held respecting the order of appointment established in this judicial body. It was held on June 22, 2023.

SIXTH.- In the processing of the present appeal, the legal requirements have been observed.

LEGAL BASIS

FIRST.- The North American entity ELI LILLY AND COMPANY (LILLY) is the holder of patent ES '602 (Spanish validation of the European patent EP '952, whose grant was published by the EPO on May 2, 1997) which has as its object the use of the active ingredient Raloxifene and its pharmaceutically acceptable salts in the preparation of a useful medicine in the treatment and prevention of osteoporosis. It also holds the SPC 009900002, granted on the basis of patent ES '602 and which, following the expiration of the latter (on July 28, 2012), extended its validity - for the product Raloxifene - until August 5, 2013.

DAIICHI SANKYO EUROPE GmbH (DAIICHI), domiciled in Germany, is the exclusive licensee of the ES '602 patent and of the CCP 009900002, DAIICHI, which acts as the European "headquarters" of the Japanese pharmaceutical group of the same name, markets Raloxifene drugs in Spain under the brand name Evista® through its Spanish subsidiary, DAIICHI SANKYO ESPAÑA, S.A. (hereinafter, "DAIICHI ESPAÑA").

The protection conferred by patent ES '602 on the use of Raloxifene was in force until August 5, 2013, when the CCP 009900002 that extended its validity expired. Since then, the use of Raloxifene entered the public domain.

In the case of Raloxifene, LILLY implemented in Spain a commercial system in which two different companies marketed Raloxifene drugs, in parallel, under two different brands. On the one hand, the exclusive licensee DAIICHI, which imported the Raloxifene product in Spain for its subsequent commercialization under the brand name Evista®, through its subsidiary DAIICHI ESPAÑA, a product authorized as "EVISTA 60 mg film-coated tablets" (Reg. No. 98073001). On the other hand, the company LABORATORIOS DEL DR. ESPTEVE, S.A. ("ESTEVE"), which marketed the Raloxifene product under the brand name Optruma002, as a mere distributor of LILLY.

TEVA B.V. - a Dutch company of the group to which TEVA PHARMA S.L.U. belongs - obtained a marketing authorization from the Spanish Agency of Medicines and Health Products (WAEMPS") for its generic product "RALOXIFENO TEVA coated tablets EFG" (Reg. No. 1067002) on October 20, 2010. A few months later - between February 22 and March 20, 2011 - the Ministry of Health, Social Services and Equality set the Laboratory Sale Price ("LVP") of Raloxifene TEVA at 13.22 euros and agreed its inclusion in the pharmaceutical benefit of the National Health System (EFG with authorized price). TEVA PHARMA S.L.U. finally launched the commercialization of Raloxifene TEVA (generic product of Raloxifene) in the Spanish market in May 2011, more than two years before the expiration of the ES '602 patent and the CCP 009900002.

As a result, a "homogeneous grouping" (No. 2634) for Raloxifene medicines authorized in Spain was created in September 2011, in accordance with the regulatory framework for the pharmaceutical sector that was in force, i.e. it included both the original products Evista® and Optiruma® from DAIICHI and ESTEVE and Raloxifene TEVA. This applied to all drugs included in the "homogeneous grouping" (including Evista®) the substitution obligation in the prescription established in article 85 of the Medicines Act, which imposed on pharmacists the obligation to dispense in any case the lowest priced drug included in the "homogeneous grouping" ("lower price system").

With the creation of Pool No. 2634 for Raloxifene, DAIICHI was forced, with effect from October 5, 2011, almost two years in advance of the expiration of the CCP 009900002, to reduce the PVL of Evista® by 40% in order to bring it up to the level of the PVL of Raloxifene TEVA. The risk of not doing so was that, as a result of the application of the so-called "lower price system", it would lose its market share completely.

LABORATORIOS CINFA, S.A. obtained authorization for its generic drug "RALOXIFENO CINFA 60 mg film-coated tablets EFG" (Reg. No. 72417) on September 13, 2011. The PVL and the inclusion of Raloxifene CINFA in the pharmaceutical provision of the National Health System took place in November 2011 and the price set was also 13.22 Euros (excluding VAT), like Raloxifene TEVA, CINFA started marketing Raloxifene CINFA in January 2012, thus joining TEVA, which had been doing so since May 2011.

Subsequently, other laboratories obtained their corresponding authorizations for their respective generics. Specifically, the companies STADA, SANDOS, RATIOPHARM and KERN launched their corresponding generic products in July 2012, followed by MYLAN TECNIGEN and TARBIS during 2013.

SECOND.- The lawsuit filed by LILLY and DAIICHI alleged that the manufacture, importation, use, offering and marketing in Spain of the generic drugs Raloxifene TEVA and Raloxifene CINFA involved, while the ES '602 patent and subsequently the SPC 009900002 were in force (until August 5, 2013), an infringement of the ES '602 patent and its corresponding SPC 009900002, ex article 50 of the Patent Law. Therefore, in addition to requesting the declaration of infringement, pursuant to article 63.1 of the Patent Law, paragraph b), an action for compensation for damages suffered as a result of the same in the period between May 2011 and August 5, 2013 was also brought. It was based on Article 64 of the Patent Law, which imposes on infringers of the rights conferred by a patent the obligation to compensate the damages caused by their actions to the owners of those rights. Because the manufacture, use, offering and commercialization, as well as the possession and importation for such purposes, of the medicines Raloxifene TEVA and Raloxifene CINFA involved - between May 2011 and August 5, 2013 (in the case of TEVA) and between January 2012 and August 5, 2013 (in the case of CINFA) -, an infringement of patent ES '602 and, by extension, of the CCP 009900002.

Several injunctions were sent to the defendants (DOCUMENTS 21, 22 and 25 of the complaint) warning of the infringement of the ES '602 patent and therefore of the CCP 009900002. And they were required to refrain from launching the infringing product on the market, but they did not comply with them.

DAIICHI claimed damages according to the criterion of loss of profit it has suffered as a result of the marketing of the infringing generics of Raloxifene (article 66.2ª of the LP), which included: 1st) the losses suffered by DAIICHI because of the generic Raloxifene TEVA and Raloxifene CINFA units that were sold by the defendants at the expense of the market share of Evista® in the period from May 2011 to August 5, 2013 in which the ES '602 patent and the CCP 009900002 were in force (quota reduction effect); 2º) the consequences of the price drop caused by the triggering of the application of the so-called "lower price system" established in the pharmaceutical sectorial legislation, since the launching on the market of the defendants' generic drugs forced DAIICHI to reduce the price of its drug Evista® by approximately 40%, thus equating it to that of the defendants' infringing generics, in order to avoid being totally expelled from the Spanish Raloxifene market approximately one year and a half before the expiration of the CCP 009900002 (price reduction effect); and 3) the loss of profit suffered indirectly by DAIICHI, in its capacity as parent company of the subsidiary DAIICHI ESPAÑA, insofar as the aforementioned effects of "reduction of quota" and "reduction of price" resulted in a drop in the profit margin of said subsidiary, with the consequent reduction of the consolidated profit of the parent company (indirect loss of profit).

LILLY claimed damages that would be quantified according to the criterion of the profit obtained by the infringing companies TEVA and CINFA from the sales of each unit of Raloxifene TEVA and Raloxifene CINFA (under the protection of article 66.2.a I.P), that is, in a certain way, a kind of unjust enrichment obtained through the exploitation of its generic Raloxifene. However, in order to avoid duplicity with the plaintiff's claim, its main claim was limited to all those units of Raloxifene TEVA and Raloxifene CINFA which, if they had not been marketed by the defendants, would not have been attributable to DAIICHI's Evista® product. In the alternative, in the event that DAIICHI's claim for damages was dismissed, what LILLY was claiming was the profit obtained by the defendants for all the units of generics marketed by TEVA and CINFA.

The legal framework of reference is given by Law 11/1986 on Patents (LP). The subsequent Law 24/2015, of July 24, 2015, is effective after the beginning of the litigation (ninth final provision) and, therefore, the provisions contained therein do not apply to the object of the debate.

The decision of the judge in the first instance, expressed in his judgment and in a subsequent order of clarification/supplement, was to uphold the claim. It rejected the exceptions of lack of standing to sue that were filed against both plaintiffs. It also rejected the plea that, by way of exception, opposed the nullity of the patent and CCP presented in the complaint. It accepted the declaratory action of the infringement of the exclusive right exercised in the lawsuit. It also upheld the action for damages, establishing the basis on which the quantification of the compensation to be paid by the defendants to the plaintiffs should be calculated.

The decision in the first instance has provoked cross appeals from all the procedural parties. We will outline, in a very concise manner, what each of the appellants seeks to obtain in this appeal, without prejudice to the fact that by analyzing each of them in more detail we will have the opportunity to better understand the nuances of each ground of appeal.

TEVA PHARMA S.L. intends that the appealed judgment be overturned and that it be acquitted of all the claims made against it for a very specific reason, to which its appeal has been limited although it supports it with various reasons, although it announced, at the beginning of its brief, its intention to appeal for more reasons, which it did not finally state. In short, it understands that DAIICHI SANKYIO EUROPE GmbH lacked standing to sue it for not having proved its status as exclusive licensee of the patent and the CCP of ELI LILLY AND COMPANY which the latter would have denied, moreover, to the former with its procedural actions.

For its part, LABORAROTIROS CINFA SA argues, as its main argument, that the claims of the EP '952 patent would be affected by the Spanish reservation to Article 167 of the European Patent Convention (EPC) and that, therefore, they should be considered ineffective or invalid, which would seem the possibility of success of the claim for infringement of the corresponding exclusive right. In the alternative, it contests the plaintiff's right to receive any kind of compensation or, failing that, it claims that the basis for its quantification should be reduced by the court. To this end, it disputes DAIICHI's standing to claim it, questioning its status as exclusive licensee of the EP '952 patent and the corresponding SPC. Likewise, the appellant argues that the expert report provided by DAIICHI for the determination of damages (opinion of the economist Mr. Eduardo) is based on a basic document, which is the analytical operating account of the drug Evista® marketed in Spain by that entity, and argues that no one could have validated it. It denies that the co-plaintiff, LILLY, could have suffered any damage and that it could therefore claim any compensation whatsoever in the following cases

in its favor. LABORATORIOS CINFA SA also argues as a ground of appeal against the compensation claimed by DAIICHI for direct loss of profits due to the reduction of the market share for its product that the period to be taken into consideration, as far as it is concerned, should be limited to June 12, 2012 instead of extending until August 5, 2013 (expiration of the patent), as the appealed judgment does. It also argues that when calculating the net profit obtained in the period concerned by the action brought by the plaintiff, a series of product returns should be subtracted, which would have been included by the court expert Mr. Alvaro in his opinion, which were not, however, considered as proven in the first instance (specifically, in the order of clarification/complementation dated June 6, 2022). It stated that it contested, ad cautelam, in the event of an appeal by the opposing party, that it could be held responsible for the price reduction effect of the drug. And, finally, it appealed the imposition of costs that it had suffered in the first instance, because it considered that the claim was partially upheld, so that each party had to bear its own costs.

In turn, the plaintiffs ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH argued in their appeal that the plea of preclusion/substantial estoppel raised by them should be upheld, so that the grounds of ineffectiveness/invalidity of the LILLY patent raised by CINFA based on the effects of the Reservation made by Spain to the EPC should be declared inadmissible ad limine, without the need to enter into the merits of the case. They also asked to replace the table appearing in paragraph B(2) I.a. of the judgment under appeal (p. 75) with table 23 of Mr. Eduardo's opinion, version dated November 3, 2021. With regard to DAIICHI's direct loss of profit item for "price reduction" and the indirect loss of profit item, they requested that they be upheld in accordance with the possibilities that, according to an order of gradation, they set out in their appeal brief. It also claimed that the alleged destruction of 82,007 boxes of the drug Raloxifene Teva in February and March 2013 should not be considered as accredited and that the "lump sum payment" should be excluded as a deductible cost for the purposes of determining the profits unlawfully obtained by CINFA.

THIRD.- Both co-defendants allege in this second instance the lack of standing of the co-plaintiff DAIICHI SANKYO EUROPE GmbH to act due to the infringement of the ES '602 patent on the use of Raloxifene and the CCP certificate 009900002 by virtue of the condition of exclusive licensee of the patent on which the aforementioned co-plaintiff is based. It is reproached for not having provided the written document that would assign it that condition, in a complete way and with the value of such, besides not having registered the license in the SPTO and not having acted as such in the previous litigation that took place in Navarra.

With regard to the existence of a written license, it is crucial to examine the contract of February 27, 2008, between ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH. It should also be borne in mind that DSE PHARMA GMBH also a signatory to the agreement, was taken over by DAIICHI SANKYO EUROPE GmgH in mid-2009, as evidenced by the deed of merger filed in the proceedings (document no. 17 of the lawsuit), thereby acquiring all of its assets, with all its rights and obligations (including those relating to the aforementioned contractual relationship). Well, the aforementioned contract has been partially incorporated to the files, by means of an extract in which some of its clauses are suppressed for reasons of confidentiality (documents nº 18 of the claim and 18 bis of later contribution). But we cannot oppose to its evidentiary effectiveness, since it is stated in the copy provided that it was checked by a notary public and that it coincided in what was reproduced with what was stated in the original in its entirety, as it appears in the notarial act that has been provided as document nº 18 bis of the claim (attached to the previous hearing to correct the deficiencies of the initial document nº 18). This manner of contribution offers sufficient guarantees for the rights of the affected parties to be respected. What is relevant is that the part of the contract concerning the exercise of the rights at stake here has been made available to all those involved for analysis and possible contradiction. Other agreements of purely commercial content are not relevant and their protection against competing companies in the pharmaceutical market makes perfect sense. The handling in court of copies of contracts whose content can only be partially accessed for reasons of confidentiality is a common procedural practice. And the way in which the plaintiff has managed to guarantee confidentiality, through the intervention of a notary public who certifies the coincidence of what is shown with the complete document, we consider reasonable. We do not consider that this modus operandi, even if other possible means of preserving confidentiality were conceivable (in the appeal of one of the parties, Law 1/2019 on Business Secrets is invoked, although it is a body of law that is inapplicable here for temporary reasons), entails the commission of a legal infringement. Moreover, it is even in accordance with the legal provisions, since the non-conforming party could have requested that the document be completed with what might actually be necessary (Article 321 of the LEC) or could have requested the counterparty to show the original (Article 328 of the LEC). But the simple challenge of the documentation does not prevent the court from assessing it according to sound criticism. And we do not appreciate any

There is no compelling reason to question whether the partial excerpt of the license agreement provided is truly transcendent, for the purposes of the present case, of what was stipulated in writing between the patent holder and the licensee.

Well, in the contractual clauses (art. 3.2 and in relation to the preliminary recitals of the contract) explicitly includes the granting of a license that we must consider exclusive ("sole license" in the original English or "sole" as the Spanish translator says) for the exploitation of the licensed patents (among which the protection certificate 9900002 for Spain appears in the list tabulated at the bottom of the contract, in addition to the mentions that are included in relation to the product "Raxofileno" and "Evista"), including the powers of use, sale, promotion, marketing and importation of the product. It is true that the licensor reserved in the contract some exploitation faculties (clauses 3,5 -to manufacture the product for DAIICHI- and 5,8 -for the comarketing agreement with LABORATORIOS DEL DR ESTEVE SA in Spain), but the legislation allowed (as it has continued to do later in the current LP), through an explicit agreement in this respect, that modality within the exclusive license (article 75,6 of the Patent Law 11/1986). Therefore, the recognition of the condition of exclusive license attributed to DAIICHI SANKYO EUROPE GmbH cannot be denied even though, in this case, there is a special stipulation of reservation of exploitation powers in favor of the licensor itself, ELI LILLY AND COMPANY and of the companies of its group indicated therein, ELISA (ELI LILLY SA) and LILLI EXPORT.

As regards the requirement of registration of the license, it is true that article 79 of Patent Law 11/1986 (LP) required in its number 2 that licenses affecting patent applications or patents already granted had to be registered in the corresponding registry (in this case that of the SPTO) and only then would they be effective against bona fide third parties. Likewise, n. 3 of the aforementioned legal provision stipulated that rights over patent applications or patents that had not been duly registered could not be invoked against third parties. Hence, Spanish case law had been stating in certain precedents (judgments of the Supreme Court, 1st Chamber, of October 18, 1995 and January 17, 2001) that the unregistered license only produced effects "inter partes", so that the unregistered exclusive licensee could not act on his own against third parties, relying on it, but should urge the patent owner to act against him.

However, there are significant precedents (the 1st Chamber of the SC, in its judgment of July 11, 2000 and in its order of February 8, 2017, and the 28th section of the PA of Madrid, in its judgment of July 18, 2014) that have been inclined to admit the standing of the unregistered licensee entity that acted jointly with the patent holder, in view of its condition of direct injured party by the infringement of the exclusive right. The presence of the patent owner in the process is what allows the legal protection of the exclusive right (actions for declaration, cessation, removal, etc.) to be effective, with erga omnes scope, and the fact that the unregistered licensee accompanies him as co-plaintiff must be considered justified by his condition of being affected by the infringing action, so that he can receive the compensation that should correspond to me as the lawful exploiter of the patent. This is precisely what is happening in the present case, in which together with DAIICHI SANKYO EUROPE GmbH, to which we have recognized the status of licensee of the patent, the holder of this exclusive right, ELI LILLY AND COMPANY, acts as co-plaintiff.

On the other hand, we do not consider that the co-plaintiffs have shown in other procedural forums (such as before the courts in Navarra) a conduct that could be considered contradictory in nature with the contractual condition that is being assigned to them here. There could have been reasons of mere opportunity that could explain why at a certain moment the patent holder acted without going hand in hand with the licensee acting here, when there was no procedural reason that required the presence of the latter. Moreover, it makes perfect sense that if a dispute had arisen in which the very validity of the patent was being settled, it was the patent holder, who was also the one who was the defendant (so that any other plaintiff could only have come by way of mere voluntary intervention), the one who showed her opposition and defended the effectiveness of the title.

In short, for all the reasons we have explained, we consider that the plea of lack of standing to sue was correctly dismissed. We must therefore dismiss this ground of appeal raised by the co-defendants.

FOURTH. We also note that underlying the debate held in this second instance, in one of the appeals of the defendants and in the other one explicitly, although in the limit of raising new issues, the refusal to admit the legal standing of the owner of the ELI LILLY AND COMPANY patent to claim damages for the infringement of its rights, arguing that, since it would have assigned its exploitation to the exclusive licensee, it should be the latter and not the former the one who would be economically harmed by the reduction of its rights, and not the former.

of the commercialization of the patented product. It is suggested that ELI LILLY AND COMPANY would not have been able to justify that it had suffered any damage or prejudice as a consequence of the infringement of the patent in dispute.

The patent holder, ELI LILLY AND COMPANYin addition to its interest in defending the exclusive right, also has an interest in obtaining compensation, since, as is clear from the document analyzed above, it participates in the result of the exploitation in Spain of the patented invention by supplying the licensee DAIICHI with the product Evista(r) for sale in this country, as stated when granting the license, and also commercializing the Optruma(r) product in Spain, under a comarketing regime, manufacturing and supplying it to ESTEVE, either directly or through the companies of its business group (ELI LILLY SA - ELSA- and LILLI EXPORT), as also referred to in the aforementioned document. Because there is no doubt that this is the scenario that corresponds to the exploitation of the patent in dispute, it is out of place to try to question that this co-plaintiff would be harmed by the reduction of sales that may have been caused in Spain due to the infringement of the exclusive right denounced in the lawsuit. For ELI LILLY AND COMPANY the quantity of the product and the price at which it could be sold in Spain was not indifferent, and the fact is that there was a drop in this respect (the sales revenues of the drugs Evista(r) and Optruma(r) were reduced in Spain in the period concerned by the infringement) at the time when, with the patent in force and its effects extended by the corresponding SPC, the defendant began to market generic drugs that invaded the scope of protection corresponding to the exclusive rights of others. It makes no sense to deny the co-plaintiff ELI LILLY AND COMPANY as it is claimed on the contrary, its status as an injured party entitled to claim the compensation it should be entitled to.

Based on the assumption that this damage has existed, the co-complainant has the power to opt in its claim for compensation in accordance with the legal criterion of quantification (article 66 of the LP) of the loss of profits suffered in the way it considers that best suits its legitimate interest (judgment of the Chamber of the SC No. 263/2017, of May 3 in relation to the subsequent No. 516/2019, of October 3). In this case, the claimant chose to rely on the criterion of the profits unlawfully obtained by TEVA and CINFA through the exploitation of its Raloxifene generics, under the protection of the provisions of article 66.2.a of the LP, and no objection can be raised to this. On the other hand, it was already concerned in the lawsuit to opt for a claim formula that prevented duplicity in the claim, since there were two plaintiffs and each one of them defended its own compensatory interest.

FIFTH.- In the appeal filed by LABORATORIOS CINFA SA, it is argued that the claims of patent EP'952 would be affected by the Spanish reservation to article 167 of the European Patent Convention (EPC) and that, therefore, they should be considered ineffective or null and void. The appellant argues that, although the EP'952 patent was applied for after October 7, 1992, that is, after the expiration of the term of the reservation to article 167 EPC, given that its priority date is July 28, 1992, therefore prior to October 7, 1992, the latter would be applicable. The appellant claims that the reservation would affect the claims of use of pharmaceutical products. Specifically, it argues that the claims of the EP'952 patent are of the Swiss type (use of X, known compound, for the manufacture of a drug for the treatment of Y, new therapeutic use) and that those of that class would be affected by the reservation to article 167 EPC. Thus, according to its approach, the infringement suit brought against it should have been dismissed as the patent on which it is based is null and void.

In the first instance, the judge rejected this exception because he understood that the reservation to patentability should be subject to a restrictive interpretation and, therefore, be limited to chemical or pharmaceutical products as such. Consequently, it would not affect claims of use of pharmaceutical products, as is the case of the plaintiff's title, which would be fully effective in Spain. This solution applied by the judge would be consistent with the even more subtle criterion that the Swiss-type wording, which is undisputed to be the category to which the patent at issue here corresponds, i.e., that which refers to the use of product X for the preparation of a medicine for the treatment of disease Y, is nothing other than a process claim related to the purpose of manufacturing that medicine. In any case, the decision of the judge of the first instance is disputed by the defendant CINFA.

However, before reaching the judgment, during the proceedings, the judge of the first instance also rejected (by orders dated October 23, 2019 and January 29, 2020) the plea of res judicata that the plaintiff, LILLI, raised against the plea of nullity raised in the answer to the claim. If this had been successful, it would have meant that it would not have been necessary for the judge to pass judgment on the aforementioned allegation. The plaintiff now reiterates its argument on appeal, requesting this court to recognize that the judge should have rejected the plea of nullity on procedural grounds, without even having to issue a ruling on the merits in relation to it. This is the first aspect of a legal nature that this court must judge in the second instance. That is to say, we must

to resolve whether the plea raised by CINFA in its main response to the lawsuit regarding the ineffectiveness and invalidity of the claims of the patent ES 2.102.602 and, by extension, of the CCP, was barred by the mandate of article 400 of the LEC, since CINFA and TEVA had previously filed an ordinary lawsuit in Navarra against LILLY, requesting the nullity of this industrial property title, and the result had been adverse, so that they could not raise litigation in this regard again.

The solution to this controversy requires starting from the legal provision. Article 400 of the Civil Procedure Law 1/2000, under the heading "Preclusion of the allegation of facts and legal grounds", establishes in its first paragraph that: "1- When what is requested in the claim may be based on different facts or on different legal grounds or titles, the claim shall contain as many as are known or may be invoked at the time of filing it, without it being admissible to reserve their allegation for a later proceeding...". The second paragraph of the aforementioned precept establishes the consequences that follow the non-observance of the prevention contained in the first paragraph, when it states: "... for the purposes of lis pendens and res judicata, the facts and legal grounds adduced in a lawsuit shall be considered the same as those alleged in a previous lawsuit if they could have been alleged in this one". What this procedural provision means is that it is not possible to go before a court with an argument based on different facts, grounds or legal titles when what is being requested is the same as what was already claimed on a previous occasion, since all the grounds could have already been put forward then and were not. Article 400 of the LEC allows all the facts and grounds or legal titles on which the plaintiff could have based his claim in his first lawsuit, whether or not they had been effectively presented at that time. The preclusion reaches the deductible causes of action, even if they had not been explicitly deduced in that previous litigation.

The explanation for the operation of this procedural principle lies, as stated in case law (Supreme Court decision dated December 30, 2010), in the following justification: "In the essence of the immutability of res judicata is the principle of legal certainty because legal life cannot withstand a continuous renewal of the process. The legal system prefers the preclusive effect of res judicata as a lesser evil in the face of the principle of legal certainty and this preclusive effect is given when the process has been legally susceptible to an exhaustion of the case (STS of September 24, 2003, RC n. 4046/1997), and this preclusive effect is given when the process has been legally susceptible to an exhaustion of the case (STS of September 24, 2003, RC n. 4046/1997). Therefore, this Court has declared that in order to determine the existence of objective identity between the proceedings, what was deduced in the first proceeding must be taken into consideration, as well as what could have been deduced therein (SSTS of June 26, 2006, February 28, 2007, May 6, 2008 and June 17, 2009, RC n.º 2225/2004). Res judicata makes it impossible to raise a problem indefinitely before the Courts of Justice (STS of April 20, 2010, RC n.o 1896/2007), the issue that has already been examined and resolved, has been satisfied and there is no valid reason to deal with it again". Res judicata extends, as case law teaches (Supreme Court judgments of June 26, 2012, March 21, 2011 and June 10, 2002), "to issues that have been implicitly deduced in the claim: res judicata extends even to unadjudicated issues, insofar as not expressly deduced in the process, but which are also covered by res judicata, preventing their reproduction in subsequent proceedings, as happens with complementary petitions to another main one or other deductible issues and not deducted, [....] provided that there is a profound link between them and the main object of the lawsuit, since the maintenance in time of the litigious uncertainty, after a lawsuit where objectively and causally the plaintiff was able to assert all the claims he had against the defendant, breaks the legal guarantees of the threatened party".

The application of this procedural doctrine, which implies the extension of the effects of res judicata to issues that can be deduced in a proceeding and were not deducted, implies that, as the declaration of invalidity of patent ES '602 (Spanish validation of the European patent EP '952) and of the supplementary protection certificate 009900002 was already claimed before the Court of Pamplona (ordinary 477/2009), and that petition was dismissed, the defendant here, which was precisely the defeated plaintiff in that previous litigation, could not in a subsequent litigation try again to resurrect a debate on the nullity of those titles. It matters little that it then decided to base the nullity action on the accusation of lack of inventive step. What is decisive here is that nothing prevented him from having adduced at that time other grounds to try to support the nullity action he was bringing. Failure to do so implied the procedural impossibility of adducing them in the future in accordance with the provisions of Article 400 of the LEC.

It does not constitute an excuse, allowing to avoid such a clear legal consequence, that the defendant intends to claim that it was the judgment of the Court of Justice (CJEU) dated July 18, 2013 (case C 414/11), and the two orders of the same body dated January 30, 2014 that followed (cases C 462/13 and C 372/13), which would legitimize to make use in the second litigation of what it did not oppose in the first one. This court believes it should be clarified that the last two decisions, despite the fact that the defendant/appellant intends to try to make us

On the contrary, they refer precisely to the same type of problem and not to a different one from the sentence that has been mentioned above. Well then, we must point out that, in general, the mere evolution of case law cannot be understood as a new factual situation that enables an attempt to circumvent the effects of preclusion and res judicata in the procedural sphere and more significantly when the frame of reference is that of industrial property (which has little to do with that referring to consumer rights defense proceedings where the CJEU has had to make, exceptionally, efforts of balance to find some fissure against the general procedural rules to safeguard the rights of consumers), exceptionally, efforts of balance have had to be made to find a loophole in the general procedural rules in order to safeguard the protective regime in force there, which is not extensible outside that field). And, in any case, the aforementioned decisions of the CJEU did not imply any change of scenario that would reveal to the defendants that in the second litigation they would have the possibility to argue what they did not have the opportunity to do in the previous one. Because the doctrine on the normative interpretation contained in those decisions refers to cases in which the patents, which had faced a national reservation to the patentability of pharmaceutical products, had been granted and validated in the respective country only with process claims and not product claims, The CJEU concluded that the mere entry into force of TRIPS (Agreement establishing the World Trade Organization - WTO signed in Marrakech on April 15, 1994) did not automatically extend patent protection to the product. The doctrine established did not apply to other types of situations, such as patents applied for under the effects of the reservation, but which also incorporated product claims as such and which, by virtue of the provisions of article 70.7 of the TRIPS, were granted and validated in the corresponding country already including such claims. This is the understanding of the Chamber la of the Spanish Supreme Court in its judgment No. 568/2017 of October 20, 2017 (Escitalopram case). Well, the LILLY patent contained only "Swiss-type" claims (of use procedure) that were already found in addition in the title that was granted and validated in Spain (Article 70.7 TRIPS). Therefore, it is a very different case from the one referred to in the case law of the CJEU on which the defendant wants to rely, in an unjustifiably self-serving manner. It cannot be maintained that with the issuance of these decisions a breach was being opened in a jurisprudential panorama that had been opposed until then, nor that a new jurisprudential doctrine was being established in relation to the Community and international regulations in relation to the exercise of nullity/ineffectiveness actions that could have been unthinkable at the time for the now defendants; nor that this implied a change in the pre-existing situation that would have projected a completely different legal perspective for a case such as the one at issue here. The possibility of having argued the nullity on the grounds that the defendant/appellant CINFA is trying to argue was already conceivable, with the degree of feasibility that one wishes to assign to it, long before it filed its lawsuit in Navarre, in 2009. What happens is that either it simply did not occur to its defense counsel to invoke such a basis for the nullity action or, to which we confer greater probability, it simply dismissed such a possibility. The fact that it was later sued for infringement did not give it the right to resurrect an action, such as the application for invalidity of the patent/protection certificate, which had already been dismissed, with the effect of res judicata. This applies both to what was explicitly alleged therein as grounds for the eventual nullity claimed and to that other possible argumentation which, having had the opportunity to have adduced it as additional grounds for the action brought, was not, however, invoked in due time and form.

The procedural obstacle raised by the plaintiff against the exception of nullity of the patent alleged on the contrary should have been accepted in the first instance. Therefore, in this first aspect, regardless of the position that could be held on the substantive argument that the defendant intended to oppose (which was, in any case, rejected in the appealed decision), the appeal of the plaintiff deserves to be upheld. The plaintiff has the right to dispute the decision on a ruling that was procedurally adverse to it by the court, regarding the plea of res judicata/preclusion, and its reproduction in this second instance means that this court must agree with the plaintiff regarding the fate of this procedural issue.

SIXTH.- It is only in the appeal filed by LABORATORIOS CINFA SA in which it is disputed, from the side of the co-defendant that has been condemned to its payment, the damages awarded in the first instance judgment. It disputes both the one awarded in favor of DAICHI and the one awarded to LILLY. Let us analyze each of the different arguments of this appellant.

First, the appellant argues that the expert report provided by DAIICHI SANKYO EUROPE GmbH for the determination of damages (opinion issued by Mr. Eduardo) is based on a basic document, which is the analytical operating account of the drug Evista(r) marketed in Spain by that entity, and argues that no one could have validated it. The consequence that the appellant assigns to this argument is that the quantification of damages made by the plaintiff DAIICHI should not be accepted and that the claim for damages of this party should therefore be rejected.

This court considers that what has been of utmost interest to meet the burden of proof that was incumbent upon the plaintiff is that the analytical accounts of Evista(r) for the years 2010, 2011, 2012 and 2013 are included in the file as Annex VI of the report of the expert economist Mr. Eduardo. Mr. Eduardo explained during the oral hearing before the judge that he had gone to the head office of the plaintiff company, located in Munich, to personally validate the accounts, for which he interviewed the corresponding personnel, asked for the appropriate explanations and confirmed that the information expressed in these accounts came from the company's systems. These accounts show the allocation of income and expenses made by DAIICHI to the Evista(r) product. We consider as a very relevant fact that the information contained in them has been extracted directly from DAIICHI's accounting systems and that they respond to predefined cost allocation criteria, as can be seen from the opinion of the expert witness Mr. Eduardo expressed during the trial. To this must be added the testimony of the witness Mr. Marino, who has unquestionable knowledge of the matter as he is the financial director of DAIICHI SANKYO ESPAÑA SA and has previously worked in other positions in the accounting department of this company. The employment relationship of this witness with a subsidiary company of one of the plaintiffs, when there is no evidence of any specific interest on his part in this litigation as far as his person is concerned, nor that his personal assets are involved, is not sufficient reason for us to distrust the veracity of his statement on what he has learned in the course of his profession (assessed in accordance with Article 376 of the LEC). This witness had knowledge of his own knowledge, since he was at the beginning of 2012 the accounting manager of DAIICHI SANKYO ESPAÑA SA and also intervened, therefore, as he stated and it is also adjusted to the regulations in force, in the preparation of the accounts of the preceding 2011. Well, his testimony came to be confirmatory of the objectivity and adherence to reality of what is reflected in the aforementioned analytical accounts. His explanations serve to show that it was not information that could have been recreated for retrospective purposes or linked to the preparation of the present litigation, but rather, and this has also been verified by an expert witness (as stated by the court expert Mr. Alvaro), it was those accounts that were the basis for the preparation of the present litigation, and it has also been verified by an expert witness (as stated by the court expert Mr. Alvaro). Alvaro), those accounts were the tool used at the time within DAIICHI to carry out the adjustments of the supply price of the Evista(r) product between the plaintiff parent company DAIICHI SANKYO EUROPE GmbH and its Spanish subsidiary in the years 2011 to 2013, therefore in a temporal context far from the beginning of this lawsuit and ultimately little susceptible to generate suspicions of a possible manipulation of data. Moreover, these analytical accounts match DAIICHI's profit and loss accounts for the years 2011 to 2013, which were audited without any qualification. The expert economist Mr. Eduardo stated that he verified that the analytical accounts reconciled with the company's operating account; the court expert Mr. Alvaro also confirmed at the hearing that DAIICHI's analytical account, supported by the invoicing that was selected for the audit, agreed with the company's profit and loss account.

It is for all these reasons that we consider reasonable the methodology followed to take this documentation as an objective basis for the calculation of the indemnity, because it is with which DAIICHI determined its profits in the past that is relevant to the dispute that is being settled here.

It is, of course, conceivable that additional evidence could have been provided to support the content of the aforementioned analytical accounts, such as, for example, the use of the exhaustive checking operations mentioned by the experts who presented the economic opinions obtained at the request of both defendant entities (Mr. Rogelio or Mr. Salvador). But this court understands that what can be demanded of the plaintiff is that it should make an effort that can be reasonably considered sufficient to demonstrate the facts constituting its claim (article 217.2 of the LEC), not that it should exhaustively exhaust every conceivable possibility to make its evidence more solid and thus anticipate any objection that the opposing party may have an interest in opposing. Precisely, the evaluation of the evidence provided by the parties by the courts covers the intellectual operation by which they can consider that the evidence provided is reasonably sufficient for the accreditation of facts alleged in due time and form. And this is precisely what happens in this case, where we have a documentary support that has allowed the plaintiff's expert witness Mr. Eduardo to follow a working method and reach conclusions that have been supported, at least substantially, by the judicial expert witness Mr. Alvaro.

On the other hand, we find it significant that the appellant CINFA has limited itself to questioning the credibility of the data contained in the analytical accounts, but neither has it provided a calculation with an alternative criterion that could be considered technically reliable, nor has it requested the counterparty to exhibit any kind of complementary documentation to try to support another possible option. Because what can hardly be ignored is that DAIICHI has suffered a loss of profit because it sold fewer boxes of Evista(r) and because those it continued to sell had to do so at a lower price. And in this situation, to claim that the compensation should be zero euros, as the appellant tries to do, limiting itself to criticizing the effort of

the opposing party, without offering a reasonable alternative valuation that could be more moderate offers little procedural merit.

Furthermore what the appellant alleges as inconsistencies in the analytical accounts provided by DAIICHI, which were pointed out by the expert of the respondent CINFA, the economist Mr. Salvador, have received a satisfactory explanation, in the opinion of this court. This reinforces our conviction that the plaintiff's evidentiary effort has gone as far as it was reasonable to demand. Specifically, as regards the evolution of the item of returns and discounts between 2010 and 2013, the drop occurring in the last two is consistent with the characteristics of the pharmaceutical sector and with the fact that in 2012 and 2013 generic drugs were already in commerce (not only those of TEVA and CINFA, which were first, but also those of STADA, SANDOZ, RATIOPHARM and KERN, which would later be followed by others), with the result that the deductions previously applied in accordance with the provisions of RDL 8/2010 in favor of the Public Administration were not necessary. Mr. Marino's testimony also gave an explanation for the upturn in 2011, due to the accounting in the mandatory discount of the so-called sanitary tax, which in the previous year had been computed in general expenses, with many doubts that generated consultation with the auditor for the following year, where its accounting treatment was modified. And as regards the downward evolution of costs below the gross margin, the explanation provided by the expert economist Mr. Eduardo , in his opinion (page 24), allows to understand that DAIICHI stopped investing in the Evista(r) product from 2011 for reasons that can be considered understandable (degree of knowledge that the product already had, proximity of the end of the patent right and reduction of its price since the end of 2011). The witness Mr. Marino completed that explanation, indicating what DAIICHI's alternative commercial effort was focused on in 2011 (drug SEVICAR HCT for the treatment of (hypertension) and referring that the last boost given to Evista(r) was in fiscal year 2012, only during the first months of that year, in which an investment effort was made in primary care doctors' sales representatives, in accordance with the commercial strategy decided at that time in DAIICHI and which would be a modus operandi that would later be abandoned after assessing the results of those initial monthly payments for the year.

On the other hand, it can only be considered reasonable that the expert economist Mr. Eduardo used the cost structure data for the years 2011 to 2013 to recreate the scenario corresponding to a market in which neither TEVA nor CINFA would have been present and thus estimate the profit that should have corresponded to DAIICHI. Because neither the year with the highest relative weight of costs (which was 2012 and not 2010, as wrongly argued by the appellant), nor the expert Mr. Eduardo applied a cost structure of a market with competition to one where there was no competition (as also wrongly argued by the appellant), because since 2012 other generic laboratories other than the two defendants entered the market and the mentioned expert also took into account the incidence of the activity of these others, attributing them a corresponding percentage.

SEVENTH.- LABORATORIOS CINFA SA also argues as a ground of appeal against the compensation claimed by DAIICHI for direct loss of profits due to the reduction of the market share for its product that the period to be taken into consideration, as far as it is concerned, should be limited to June 12, 2012 instead of extending until August 5, 2013 (expiration of the patent), as the appealed judgment does. It defends this because then more generic raloxifene drugs marketed by other laboratories that have not been sued in this litigation would have appeared on the market, since the companies STADA, SANDOZ, RATIOPHARM and KERN launched their products in July 2012 and MYLAN TECNIGEN and TARBIS during 2013. All this occurred before the expiration of the patent, so that the actions of these companies would be in the same situation as the defendants here although they have not also been co-defendants because, according to the appellant, they would be free to raise the plea of nullity, because they would not reach them, given their status as third parties, the effect of res judicata analyzed above. The appellant considers that the criterion that what was sold by TEVA and CINFA could not have been sold by the rest of the laboratories that have not been sued here cannot be assumed. For the appellant, it is not admissible to work with a hypothesis that assumes that if TEVA and CINFA had not been present, these other generic laboratories would have sold the same as in the scenario with the presence of these two, but considers, and tries to support its assertion with the sales data it extracts from the consulting firm IMS HELTH, that in the absence of these two it would be more logical to consider that it would have been the other generic companies, and not precisely DAIICHI, which would have sold more product.

In the first place, and the opposing party is right in this, we do not notice that the appellant used at least with due clarity, this argument in due time and form, that is, in the pleadings phase of the first instance, which does not understand that it was invoked, belatedly, in the final phase of the litigation (that of conclusions, which cannot serve to innovate the object of debate). In any case, in the face of what, at least could be veiled insinuations regarding this argument, this court must point out that it cannot accept the appellant's initial argument, which is to deny relevance for the determination of the damages award to the

sales of Ralixifene that CINFA, as well as TEVA, made as of June/July 2012, when it is an unquestionable fact that these were produced and, therefore, to some extent, contributed to frustrate sales of the plaintiff's product in Spain. The observation of the IMS consulting firm's data also allows to notice that the market share of generic products increased progressively upwards, between 2011 and 2013, which, logically, implied a correlative detriment of the market share of the plaintiff's products. The market shares of CINFA and TEVA also increased in those years, so it is unquestionable that they contributed to the frustration of sales caused to the plaintiff. Therefore, a consequence such as the one predicted by the appellant, which pretends to be exempt from liability since mid-2012, is not acceptable. Furthermore, it is a paradoxical way of defending oneself to assert that the plaintiff has been acquiesced to the consequences of the infringement, since then, for not having sued other entities that could also have been reproached as infringers. If a person infringes another person's exclusive right by his conduct, he is liable for the consequences of the infringement committed by him, even though others may also have infringed the same right. What may be required is that the consequences imputed to the defendant should be in line with those of his actions, but not that he should be exempted from liability because there were others who, like him, may also have infringed the rights of others. In short, the aim is to provide fair compensation to the injured party whose exclusive rights have been infringed, not to favor the impunity of an infringer who has been sued even though there may be other parties who could have been similarly reproached.

Secondly, in order to give a reasonable answer to the most appropriate indemnity treatment to solve a situation of the kind we have described, this court considers logical the criterion followed by the expert economist Mr. Eduardo , which consisted in determining an objective criterion of liability distribution. For this purpose, he used the methodology consisting in assuming that, in the absence of TEVA and CINFA, the units sold by them would have been marketed by the rest of the marketers of raloxifene drugs in a manner proportional to their respective market shares. Thus, it considered that, in effect, a part of the sales could have been absorbed by the other generic companies, but another part should be attributed to what would have been taken away from the plaintiff. This is a criterion that is based on the observation of concrete and real data on the performance of the third generic companies, since they appeared on the market, and not on mere conjectures such as those offered by the appellant. Moreover, the appellant's theory is more objectionable, since, apart from presenting us with a sort of artificial compartmentalization of the raloxifene market into two watertight submarkets (innovative drugs and generic drugs), which is not in keeping with reality, it is revealed as voluntarist in claiming that those third party generic companies, which demonstrated what market share they had been able to achieve in a regime of direct competition, would have the capacity to absorb, in an automatic manner and at all costs, the totality of the sales made by TEVA and CINFA, as if the plaintiff had not also been acting in the market.

EIGHTH.- The appellant CINFA also argues that when calculating the net profit obtained in the period concerned by the action brought by the plaintiff, a series of product returns should be subtracted, which would have been collected by the legal expert Mr. Alvaro in his opinion, which were not, however, understood as proven in the first instance (specifically, in the order of clarification/complementation dated June 6, 2022). The appellant considers that the product returns that it claims were made up to February 2014 should be subtracted, so that the compensation is not calculated on a gross figure, but on a net figure.

In the order issued in the first instance, the judge concluded that there was no evidence, not even circumstantial, of the existence of the aforementioned returns of the drug raxophylline alleged by CINFA. He considered that this type of approach was only based on mere assertions of the parties and was inclined to consider as more solid the argumentation of the opposing party that was adverse to admitting that the mentioned refunds had taken place.

After reflecting on the matter, in view of the evidence provided, this court considers that the judge's decision is well founded and that the allegations of the appeal are insufficient to refute them. The first difficulty faced by the appellant is that it itself alleges that the "logistics of returns" would not allow it to provide the documentation showing the return of the material to CINFA, because it was either paid for by CINFA or compensated by discounts to the customer without return to inventory. Well, if this were so, the appellant could have tried to obtain from them the corresponding documentary evidence reflecting this type of commercial operation, which did not occur. The lack of evidence, which should have been provided by the plaintiff alleging this fact (article 217.3 of the LEC), is obvious and we cannot admit conclusions that, in addition, could go against the commercial logic of companies that, for their own business interests, usually operate with an agile management of their stocks of pharmaceutical products.

In addition Annex VI of the report 4/4 of the judicial expert economist Mr. Alvaro does not contain a document that makes up for the lack of evidence that we have detected, but a mere explanatory note prepared by CINFA itself that he simply annexed to his report, without endorsing its content. Precisely, the conclusion of the aforementioned opinion was unfavorable to be satisfied, with what was made available to him, of the reality of the alleged refunds for the reasons and product that were alleged.

On the other hand, the technical data sheet of the drug Raloxifene CINFA (document No. 12 of the lawsuit) stated that the expiration period was three years. Bearing in mind that the list of CINFA purchase invoices in Annex VIII of Mr. Alvaro's opinion shows that the first of them correspond to November 2011, the expiration would go beyond the period claimed by the appellant as the justification for the withdrawal of the product due, allegedly, to that cause.

We cannot therefore admit this ground of appeal either. The court decision of the first instance deserves to be confirmed in this pronouncement.

NINTH.- The appellant CINFA states that it contests, ad cautelam, in the event that the other party appeals, that it could be held responsible for the effect of the reduction in the price of the medicine. This is not strictly speaking a ground of appeal, since the appellant has not been convicted for this reason and therefore lacks the necessary burden to be able to appeal (articles 448 and 456 of the LEC). It simply intends to anticipate what it fears that the plaintiff may allege in its respective appeal to the extent that this could be detrimental to CINFA. As in fact, as we will see below, the plaintiff has appealed the corresponding judgment, against TEVA and also, in a subsidiary approach, against CINFA, we will refer to the relevant considerations regarding the plaintiff's appeal which is the ideal place to analyze the opposing arguments that CINFA has attempted to raise, improperly, on the occasion of its own appeal and which it has had the opportunity to use, already in a procedurally correct manner, in the opposition proceedings to the appeal of the opposing party.

TENTH.- The appellant CINFA also appeals the imposition of costs it has suffered in the first instance, because it considers that the estimation of the claim was partial, so that each one had to bear its own costs. The appellant draws attention to the fact that in the appealed decision the time to be taken into account for the calculation of the effect of the price reduction has been reduced (which would imply that 82% of the amount attributable to this item would be excluded and would be an amount of more than 6 million euros) and that there are some items to be subtracted from the item of loss of profit due to price reduction (to which it attributes an economic impact of 173,131 and 21,475 euros).

The judge pointed out in the justification of the sentence in costs to the defendants that he considered that his decision implied an estimation of the claim in essence. Precisely, it was precisely because of the clarification that he decided as to the time to be taken into account for the calculation of the effect of the price reduction that he made this clarification. However, it was a decision that affected the co-defendant TEVA, as the other items that CINFA is invoking in its appeal also refer to it.

In any case, there are multiple case law precedents (judgments of the Chamber of the Supreme Court of March 14, 2003, July 17, 2003, January 24, 2005, April 26, 2005, April 6 and 9, 2005, April 6 and 9, 2005, April 6 and 9, 2005, April 6 and 9, 2005, April 6 and 9, 2005).
June 2006, July 9, 2007, March 25 and June 18, 2008 and July 18, 2013, among others) which indicate that in cases of substantial estimation of the claim i.e., obtaining a victory that is not total, but almost complete, within the process, the principle of objective expiration of Article 394.1 of the Civil Procedure Act could be applied, which, in principle, is reserved for decisions that fully uphold the claim. In this way, the rule that would otherwise be followed for decisions involving a mere partial upholding of the claim (article 394.2 of the LEC) is bypassed, which would mean that each party would bear its own and the common ones in half, unless there were merits to impose them on one of them for having acted with recklessness.

The criterion of substantiality in the estimation of the claim implies including, by way of jurisprudence, a margin of certain flexibility in the application of the rule that allows equating, when deciding on the imposition of costs, those other cases that, although not so in their literal sense, imply the achievement of victory over the opposing party in all the most important aspects of what was requested in the claim, to the decisions that fully uphold the claim.

At this point, since it would be a matter, in view of the text of the appeal that we are now analyzing, of analyzing to what extent the plaintiff's claims have been substantially upheld, we consider that it may also be important to take into account that the plaintiff has appealed those parts of the first instance judgment that it considers were not favorable, including the aforementioned time limitation. The outcome of this appeal may have a bearing on the overall assessment of the degree of

The attention that the plaintiff's arguments have ultimately merited. We consider, therefore, that the most prudent thing to do is to postpone our judgment until later, once we have analyzed this other appeal, and then take up again this last motive that has been raised by the aforementioned co-defendant.

ELEVENTH.- The plaintiffs, ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH, also have their reasons to disagree with the decision of the first instance. Apart from reiterating the plea of estoppel/ res judicata against the patent nullity plea, which we have already analyzed, what the plaintiff seeks is that the claims for damages it raised in its complaint should be further addressed. Its allegations refer, on the one hand, to DAIICHI's claim and, on the other hand, to LILLY's request.

As regards DAIICHI's claim for direct loss of profit due to reduction of quota, the appellant requests that the table appearing in section B (2) I. a. of the judgment of the judgment under appeal (page 75 of the judgment under appeal), which comes from the version of January 10, 2019 of the opinion of the economist Mr. Eduardo , which was the one provided at the preliminary hearing, by Table 23 of this expert's opinion, in its version of November 3, 2021 (document n° 15 ter), which was made in view of the definitive data of TEVA's and CINFA's actual sales. Thus, the unit profit margin for 2011 would be 10.83 instead of 10.51.

This court has verified that, in fact, there is in the file the revised copy of the expert witness Mr. Eduardo revising Table 23 of the previous copies of his expert opinion, who had initially taken for his calculations the statistical data extracted from the consulting firm IMS. But once the actual sales data of TEVA and CINFA became available in the file, the expert prepared a revised copy that conformed to them and the plaintiff filed it with the court. The court provided for such presentation and the new version was incorporated into the proceedings by means of a writ of summons dated November 15, 2021, that is, sufficiently in advance of the date scheduled for the trial to take place. At the hearing session held on the following November 22, the plaintiff was advised by the plaintiff, before proceeding to the interrogation of the experts, that there was an updated version of the same and none of the parties, who were asked about it by the judge, put any formal obstacle in this regard. The expert witness, Mr. Eduardo, then ratified this final version.

In the appealed resolution, the judge adopts the table of the opinion of the judicial expert economist Mr. Alvaro, explaining that in fact, what he did was to support the correctness of Mr. Eduardo's opinion. It is true that the opinion of the former was prior to the latest version of the opinion issued by the latter, but we share the appellant/plaintiff's opinion that, in fact, what is important is that the judicial expert opinion came to endorse the calculation methodology followed by the economist Mr. Eduardo. Therefore, we are inclined to believe that it would have been more appropriate for the judgment to have taken into account not only the first two versions of Eduardo's report and Mr. Alvaro's expert opinion, but also the third version of the report prepared by Mr. Alvaro, which was nothing more than a mere revision of the two previous reports, based on real data, and in accordance with their methodology.

This is not a problem that, as the appellee insinuates, could have been solved by clarification or rectification of the judgment (articles 214, no. 2 and 3, of the LEC). Because the judge had opted, whether he was fortunate or not in his choice, for a certain table, explaining where he had taken it from (from the opinion of the judicial expert), and the principle of invariability of judicial decisions (article 214.1 of the LEC) was incompatible with the fact that his decision could be varied, neither ex officio nor at the request of a party, and the discrepancy that could be harbored in this respect by any of the parties should be channeled through the appeal, as has been done. The problem cannot be treated as if it were a rectification of a mere material error, because that is not what it consisted of. Erroneous decisions of the judge such as the one we are analyzing are not corrected by way of clarification, because the problem was not the lack of clarity of the ruling, which in this aspect was clear, nor by way of a request for a material error, because there is no such error when the judge is simply not very accurate in leaning towards certain evidentiary data when adopting his decision. Here it did not happen that one thing was written where, according to the rest of the content of the resolution or the uncontroverted information, another thing should have been written, but simply that the judge explicitly and unequivocally endorsed some economic data without attributing the relevance it deserved to the fact that additional evidence had been provided that allowed him to choose to proceed to its due updating. Only by means of an appeal can this kind of deficiency be corrected. And this court is going to do so in strict compliance with the principles of justice requested (article 216 of the LEC) and procedural congruence (article 218.1 of the LEC) in relation to the scope of what can be reviewed on appeal (article 465.5 of the LEC), which require that we attend to what the appellant submits to appeal; in this case we were requested that the decision of this court should adhere to section B (2) I. a. of the ruling of the appealed judgment (page 75 of the same) and we are going to do so.

TWELFTH.- The plaintiff also states in its appeal, with regard to the claim for compensation for loss of profit in favor of DAIICHI, concerning that caused by the effect of the price reduction, that the judgment should be revised with regard to the compensation period to be taken into consideration in this regard. The lawsuit presented a main scenario (with an alternative A claim only against TEVA for triggering the effect and another B in which it was raised jointly and severally against TEVA and against CINFA as co-generator) in which the loss of profit suffered by DAIICHI should be compensated from October 5, 2011 (the date on which DAIICHI's claim was filed). 2011 (date on which the price reduction of Evista(r) took place) until August 5, 2013 (date of expiration of the CCP) and only as a subsidiary scenario did it claim that it should cover exclusively until June 12, 2012 (date on which generic third parties not sued had already been introduced). In the appealed decision, after having imputed, as requested by the plaintiff (main scenario, alternative A, of its claim) to TEVA to have caused the price reduction of the drug Evista(r), as the generic drug of that defendant was the only one integrated in the Homogeneous Grouping number 2634, on October 5, 2011, however, it assigned it a different consequence than the one predicted in the claim by limiting the compensation period to the period between October 5 and December 31, 2011, because since then other generic drugs also entered the market and would have taken advantage of the situation.

The appellant stresses that the solution applied in the judgment means that neither TEVA nor CINFA is liable for the damages resulting from the reduction in the price of Evista(r) between January 1 and June 12, 2012, when during that period only they marketed the generics. Therefore, the plaintiff claims in its appeal, as its main request, that TEVA should be liable for the loss of profits resulting from the sale of Evista(r) at a 40% lower price during the entire term of the CCP (i.e, between October 5, 2011 and August 5, 2013) for the simple reason that it was the first laboratory to launch a generic raloxifene drug on the market and kept it there, so that its inclusion in the Homogeneous Grouping 2634 forced DAIICHI to reduce the selling price of Evista(r). Thus, TEVA caused an injury that extended to the expiration of the CCP.

Alternatively, if the court does not share the criterion that only TEVA should be liable for all the damage because it was the one that triggered it in origin, the plaintiff requests that TEVA and CINFA be liable for the entire period in which they contributed to the damage (the former since October 5, 2011 and the latter since January 2012) with distribution of liability according to their respective market shares. Alternatively, if the preceding request is not accepted either, it proposes that, at least, it should be compensated for the loss of profits due to price reduction up to June 12, 2012, because from that date only TEVA and/or CINFA can be liable, and both cannot be exonerated from liability, as stated in the appealed decision. And, in the last case, it claims that it should also be recognized the right to be indemnified for this concept insofar as it considers that TEVA itself would have admitted it with a proportional and temporary distribution with the other laboratories that were integrated in the Homogeneous Grouping No. 2634.

This court considers that the price reduction is an effect that the plaintiff has suffered until the expiration of its exclusive right so that the compensation for that reason must temporarily cover until then. Because in a market without competition, as a result of its exclusive right, there would have been no lawful reason for a third party to cause a price drop as a result of its competition. Furthermore, there is a clear party responsible for the drop in Evista's selling price. And this was none other than the first laboratory (TEVA) which, despite the fact that the plaintiff's patent was in force, decided to launch a generic raloxifene drug on the market and then kept it there despite infringing a patent. TEVA's commercial initiative is in direct correlation with the fact that, under the provisions of the regulation in force, a "homogeneous grouping" (No. 2634) was created in September 2011, in accordance with the regulatory framework of the pharmaceutical sector, for the Raloxifene drugs authorized in Spain, that is, both the original products Evista(r) and Optruma(r) of DAIICHI and ESTEVE and TEVA Raloxifene. This applied to all the drugs included in the "homogeneous grouping" (including Evista(r)) the substitution obligation in the prescription established in article 85 of the Medicines Act, which imposed on pharmacists the obligation to dispense in any case the lowest-priced drug included in the grouping ("lower price system"). With the creation of grouping No. 2634 for Raloxifene, DAIICHI was forced, with effect from October 5, 2011, almost two years before the expiration of the CCP 009900002, to reduce the PVL of Evista(r) by 40% in order to bring it up to the level of the PVL of Raloxifene TEVA, otherwise it risked losing, due to the application of the so-called "lower price system", its entire market share.

TEVA is then liable for the loss of profits resulting from the sale of Evista(r) at a 40% lower price during the entire remaining term of the SPC (i.e., between October 5, 2011 and August 5, 2013) because it caused a loss that lasted until the expiration of the plaintiff's exclusive right. The successive generic manufacturers subsequently and gradually incorporated

to a situation already created. Therefore, other responsibilities could be assigned to them in relation to their infringing conduct while the exclusive right of others remained in force, but they could not be reproached for having been the ones who caused this fallout effect, which is linked precisely to the presence of the TEVA product as the first generic product to be introduced on the market. It would have to have been proven in this litigation that, during the specific period that is relevant here, that is, until the expiration of the exclusive right, there had been successive and precisely downward price revisions as a consequence of the entry of new generics into the group (which did not occur when CINFA's was incorporated), so that TEVA could have been justified in sharing the responsibility for this reason with another or other parties. Nothing has been adduced in this respect so that we can here take into consideration that after that initial fall, within the time period in question, a subsequent fall would have occurred as a result of a new downward revision of the price concerned due to the incorporation of some other party involved, for which reason it should have been specified at what time and to what extent it occurred as an unimputable premise in order to be able to introduce some correction in the criterion applied for the imputation of liability to TEVA.

It is true that in Spain it is the State that is in charge of setting the financing price of medicines included in the public provision (Law 29/2006, of July 26, on guarantees and rational use of medicines and health products - later RDL 1/2015, of July 24, which approved the corresponding rewritten text). But the corresponding "homogeneous grouping", which is how the situation is legally called, is formed for each presentation when generic drugs enter the market for the first time, which entails that all drugs with the same active ingredient and presentation are matched at the lowest price. Thus, if a manufacturer has launched a first generic drug on the market when the innovator's patent is still in force, the conduct of the former will end up causing a price drop that is detrimental to the patented product. Therefore, the liability is attributable to the party that, being aware of this, either improperly launches the generic drug on the market or, once it may be aware of the consequence that will occur due to the occurrence of a regulatory adjustment to that effect, persists, in spite of this, in maintaining the improper marketing of what was then the only generic drug on the market. It is the presence of this generic drug on the market that is the determining factor, in the context explained, to explain the fall in the price of the reference drug, so that the demand for liability is justified, and this with the temporal scope that we have readjusted in this second instance.

THIRTEENTH.- The next ground of appeal refers to the indirect loss of profits claimed by DAIICHI. This corresponds to DAIICHI's loss derived from the impossibility of capitalizing the profits that DAIICHI ESPAÑA, a DAIICHI subsidiary company (wholly owned), would have obtained had the defendants' infringing activity not occurred. DAIICHI SPAIN's loss of profits followed the same pattern, one part derived from the loss of market share in favor of the defendants' raloxifene drugs ("quota reduction" effect) and the other part was caused by the reduction in the selling price of the drug Evista(r) that DAIICHI SPAIN was forced to request with effect from October 5, 2011.

The first instance decision is unfavorable to the plaintiff only insofar as, although it admits this item, it limits the period of compensation for indirect loss of profit, as far as its "price reduction" component is concerned, to the period between October 5 and December 31, 2011. The appellant appeals it in a manner linked to the preceding ground of appeal, concerning the judicial decision to limit the period of compensation of the direct loss of profit for "price reduction". The fate of this new ground of appeal should be the same as that of the one concerning the direct loss of profit. The same consequence applied to the former should be extended to the latter.

Therefore, having adopted the solution explained in the preceding legal ground, the appeal is upheld in the same manner as indicated therein. No additional reasoning is required.

FOURTEENTH.- The next ground of appeal raised by the plaintiff refers to the compensation claimed by LILLY and is related to the calculation of the amount of profits obtained by TEVA for the unlawful exploitation of its generic drug raloxifene (until August 5, 2013). What the plaintiff disagrees with is that in the decision of the first instance (clarifying order of June 6, 2022), the destruction of 82,007 boxes of the drug Raloxifene Teva in February and March 2013 has been considered as proven, by way of presumption, and as a consequence, the final quantification of the compensation that should correspond to the plaintiff is going to be reduced.

In the order of June 6, 2022, the court accepted TEVA's approach and considered, under Article 386 LEC, that it could presume that TEVA had proceeded with the destruction of 82,007 boxes of raloxifene.

in January and February 2013, using as evidence: (a) TEVA's accounting, which would accredit that the adverse party had those medicines in its stock; (b) the certification of a third party outside TEVA, a waste treatment company, which would accredit the reality of the destruction of a series of medicines by a certain weight; (c) the accounting deregistration of the stock of raloxifene medicines in TEVA's accounting, which would coincide with internal certifications of the number of medicines affected; and (d) the existence of a legal rule that would oblige the destruction of expired medicines.

The first thing we must point out is that the legal expert, Mr. Alvaro, already warned that he had severe reservations about this item. This was not because he had not been able to physically verify it at the time, which would obviously be an oversimplification of what he had said, but because there were several signs that revealed to him that something did not add up in this respect. It is enough to listen to the explanations given by the aforementioned expert when he was questioned on the matter during the trial, which were quite eloquent; he was not the one to prove or disprove certain facts, so he attributed a quantum to this item as requested, but he exposed the weaknesses he noticed regarding the same without intending to reproach any malicious intent on the part of the parties.

The problem lies, in the opinion of this court, in the fact that the certificates do not make clear which specific medicines were those that would have been subject to destruction. The invoices that should prove it did not indicate that the medicines that were the object of this operation were precisely Raloxifene Teva (Annex X of Mr. Alvaro's Report 3/4). Furthermore, there was a problem of mismatch between the number of kilograms of drugs said to have been destroyed in the invoice issued by the service provider (6,500 kg.) and the number of kilograms of drugs supposedly destroyed provided by TEVA to the expert witness in an Excel file (4,617 kg.). The weight referred to in the certificate for the month of March does not agree with those that TEVA claims were destroyed, as there is a difference of around 2,000 kgs. Likewise, according to the table in section 5.4 of the Report 3/4 of the expert Mr. Alvaro , the vast majority of the raloxifene drugs allegedly destroyed by TEVA were destroyed in the second shipment corresponding to March 2013, so that the certificate does not provide 1 a solid indication to presume the destruction of 82,007 boxes of Raloxifene Teva. On the other hand, the data of the Excel file in which the basis for the cancellation of the stock of raloxifene medicines in TEVA's accounts is supposed to be found also shows a discrepancy between the number of boxes resulting therefrom (81,672 boxes) and the one TEVA claims to have destroyed (82,007 boxes), being not negligible the significant divergence between both which is added to the one already detected regarding the huge difference in weight mentioned above.

Finally, and this is very revealing, we do not see a satisfactory explanation for the fact that in January 2013 the boxes of lot T029, purchased in 2012, were supposedly cancelled due to expiration, when the expiration date of Raloxifene Teva was two years. Frankly, we do not find the destruction of the medicines for alleged expiration only one year after their purchase.

In short, we agree with the appellant that the mere fact that TEVA had a stock of raloxifene drugs accounted for and that a service provider had certified having destroyed a number of kilograms of unidentified drugs, together with the generic legal provision that expired drugs cannot be marketed and must be destroyed, do not constitute evidence with sufficient strength to consider accredited, through the presumptions evidence, the alleged destruction of a large part of the stock of the aforementioned entity. We cannot doubt that TEVA could have destroyed at the time indicated an appreciable volume of medicines that could be out of date, but we do not find sufficiently solid support to be able to affirm that it was precisely the raxophylline, nor to what extent, that would be of interest to take into account here. On the other hand, we cannot find justification for having been placed in this situation, because in the pharmaceutical market the traceability of the product must be guaranteed, so we understand that we are dealing with a fact that should not have been so difficult for the pharmaceutical company concerned to be able to duly demonstrate by means of objective evidence that certain properly identified units had really been destroyed and therefore would not have been in a condition to be marketed. However, the information provided in this regard is indirect, partial and very vague. Everything is too confusing and even contradictory to be able to accept an approach of the defendant that may be opportunistic, self-serving or at least hypertrophied to a degree that we are not able to specify in order to try to undermine the final amount of the compensation that it will have to pay.

It is for all these reasons that also in this aspect we will uphold the appeal of the plaintiff, so that nothing can be deducted for this concept so scarcely diaphanous. We wish to make it very clear here that this court, in line with the requests of the claim and with the criterion applied in the appealed resolution, must limit itself to ruling in this resolution, in line with the work carried out in the first instance,

the basis for the liquidation of the compensation. The translation of the same in the determination of concrete amounts will be, as the litigation has developed, in the phase of execution (article 219 of the LEC).

FIFTEENTH.- The last ground of appeal of the plaintiff regarding the compensation requested by LILLY is related to the calculation of the amount of profits obtained by CINFA for the unlawful exploitation of its generic drug raloxifene (until August 5, 2013). The appellant disagrees with the deduction for its calculation, admitted in the order of June 6, 2022, of the cost consisting of the so-called "lump sum payment", which consisted of a contribution made to defray the costs of a supplier (SYNTHON BV) for product development and preparation of registration documents. The appellant argues that this is a fixed cost that is not related to the infringing activity itself but would have been incurred in order to market the product if it had waited for the expiration of the SPC. Therefore, it argues that it should not be taken into account to reduce the amount of the compensation, because otherwise the structural costs of the defendant would be financed with the unlawful profit obtained to the detriment of the interests of the plaintiff.

This court considers that what must be deducted for the calculation of the indemnity are the operating expenses directly related to the infringing activity. This implies that the costs that would have been necessary to assume directly and exclusively to obtain the benefits linked to the infringing conduct of another's right must be deducted. What will not have to be deducted are the structural costs that are not directly attributable to the exploitation of the good or service concerned by the infringement. We refer to those other indirect costs that cannot be attributed precisely to the exploitation of what has been affected by the infringement, but which form part, in a shared manner, of the support of all the general activity of the businessman.

On the other hand, in the present case there is a peculiarity, which is that the unlawfulness of the defendant's conduct is restricted to a very specific period of time, since after that time the same type of conduct, carried out in the future, became lawful. Carrying out marketing activities of the generic while the exclusive right of the plaintiff was still in force implied infringement of the patent and its SPC, but from the date of expiration of that title, whatever was carried out thereafter was already legal.

In view of this peculiar circumstance, this court considers that the appellant is right when it claims that it is not justified to deduct from the compensation the cost of a license payment to a third party that the defendant CINFA needed to bear, equally and in full, in order to be able to continue its activity after the expiration of the patent. The problem lies in the fact that there is, in effect, a cost that would be common to both the infringing and non-infringing periods, as it was necessary in order to continue marketing after the expiration of the patent. It is not a cost exclusively attributable to the infringing period. Moreover, it was invariable, so we rule out any kind of apportionment according to an accrual of expenses, since the defendant would have had to assume it anyway to continue operating in the way it did after the infringing period (this is clear both from the supporting documentation and from the answer provided by the court expert Mr. Alvaro when, to clarify this aspect, a question was addressed to him in this regard in the second session of the oral trial). Therefore, we consider that, in effect, it does not make sense to deduct for the calculation of the compensation a cost that cannot be exclusively linked to expenses related to the commission of the infringement, since what it would also be financing is the possibility of continuing CINFA's commercial activity beyond the infringing period.

SIXTEENTH.- We return here to the speech corresponding to the fate that the costs of the first instance should deserve. We note that the action for infringement of patent rights brought by the plaintiffs has been successful and that the claim for compensation has also been successful in terms of the acceptance of the items claimed in the lawsuit, which were not quantified, but were identified by the bases that should allow the quantum to be fixed. Moreover, in this second instance, the limitation on the price reduction effect that had been pointed out in the first instance has disappeared in order to assign to it the quality of a substantial estimate, instead of a full estimate, of the claim. In any case, the mere fact that during the course of the proceedings there was discussion as to how to translate into concrete figures the detailed bases indicated in the claim, which does not prevent the final determination of the quantum from being left pending for the execution phase, does not interfere with the fact that what was claimed in the claim, following the outcome of the appeal, should be considered to have been estimated by the judgment resolving the dispute. It is enough to compare what was requested in the claim with what the judicial body is recognizing in its judgment to be able to understand it. Therefore, the application of the principle of objective expiration (article 394.1 of the LEC) to the costs of the first instance is appropriate.

SEVENTEENTH.- The costs of the second instance must be imposed according to the rules contained in article 398 of the LEC. Accordingly, the parties who have had all their claims dismissed will suffer the imposition of costs in accordance with the principle of objective expiration (no. 1 of art. 398 of the LEC). And whoever succeeds in having his appeal upheld, either totally or even in part, will cause the costs of the second instance that correspond to it not to be imposed on any of the parties, since this has been provided for by the legislator for when the decision on an appeal decrees the modification, in some sense, of what was initially decided in the preceding instance (no. 2 of art. 398 of the LEC).

In view of the aforementioned precepts and other concordant provisions of general and pertinent application to the case, this court pronounces as follows

FAILURE

1°.- We uphold the appeal filed by the representation of ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH against the judgment issued by the Commercial Court No. 7 of Madrid in proceeding No. 403/2016 (dated 28/2/2022) and the order of clarification/complementation that followed (dated 6/6/2022) and consequently we order the introduction of the following modifications in what was ruled in the first instance:

a) We revoke the pronouncement regarding the plea of res judicata that the plaintiff filed against the plea of nullity raised in the answer to the claim by LABORATORIOS CINFA, S.A., and, in its place, we uphold the aforementioned plea and decree the dismissal of the proceedings in relation to the express allegation of the defendant;

b) we order the substitution of the table appearing in section B (2) I. a. of the judgment of the appealed judgment (page 75 thereof) for the following:

2011

2012

2013

Initial selling price DS EUROPE to DS_SPAIN

8.15

7,98

5,29

True-up unit adjustment

5.98

1,91

17,16

Total unit selling price 14.13

9,89

12,45

Acquisition price

-3,28

-3,31

-4,51

Sales transportation

-0,02

-0,02

-0,01

Subcontracted expenses

0

0

0

Unit margin

10.83

6,57

7,93

c) regarding the items claimed by DAIICHI as direct loss of profit due to "price reduction" and the item of indirect loss of profit, we establish that the indemnity period for which TEVA PHARMA S.L.U. shall be liable is from October 5, 2011 (date on which the price reduction of Evista(r) occurred) until August 5, 2013 (date of expiration of the CCP);

d) with respect to the compensation claimed by LILLY and for the calculation of the amount of profits obtained by TEVA from the unlawful exploitation of its generic drug raloxifene (until August 5, 2013), we decree that the alleged destruction of 82,007 boxes of the drug Raxofylene TEVA in February and March 2013 should not be considered as proven; and

e) we reject that the item identified as "lump sum payment" constitutes a deductible cost for the determination of the benefits unlawfully obtained by CINFA.

2°.- We dismiss the appeal filed by the representation of TEVA PHARMA S.L.U. against the judgment issued by the Commercial Court No. 7 of Madrid in proceeding No. 403/2016.

3°.- We dismiss the appeal filed by the representation of LABORATORIOS CINFA, S.A. against the judgment issued by the Commercial Court No. 7 of Madrid in proceeding No. 403/2016 and the order of clarification/complementation that followed.

4°.- We confirm the remaining pronouncements of the judgment issued by the Commercial Court No. 7 of Madrid in proceeding No. 403/2016 and the order of clarification/complementation that followed.

5°.- We do not expressly impose the costs derived from the appeal filed by ELI LILLY AND COMPANY and DAIICHI SANKYO EUROPE GmbH.

6°.- We impose to TEVA PHARMA S.L.U. the costs generated by its appeal. 7°.-

We impose to LABORATORIOS CINFA S.A. the costs derived from its appeal.

Return to the party whose appeal has been upheld the deposit he/she would have had to make in order to appeal.

We inform the parties that no ordinary appeal may be filed against this judicial decision. However, we inform them that, if appropriate according to the legal and jurisprudential criteria applicable for the admission of this type of means of appeal, they may have the possibility of filing before this court, within twenty days of its notification, an appeal in cassation and, if appropriate, an extraordinary appeal for procedural infringement, which would be heard by the First Chamber of the Supreme Court.

Thus, by this our Judgment, we pronounce it, we order it and we sign it, the most illustrious magistrates of this court.