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Roj: STS 451/2011
Id Cendoj: 28079130062011100000
Court. Supreme Court. Litigation Chamber
Seat: Madrid
Division: 6
Number of appeal: 4201/2006
Number of judicial decision:
Procedure: APPEAL TO THE SUPREME COURT
Rapporteur: LUIS MARIA DIEZ-PICAZO
GIMENEZ Type of Judicial Decision: Ruling

Summary

FINANCIAL LIABILITY OF THE ADMINISTRATION. ASPIRIN AND REYE'S SYNDROME CONDITION OF THE MEDICAL KNOWLEDGE IN THE MOMENT OF THE FACTS.

RULING

In Madrid, fifteen of February of two thousand and eleven.

Having regard to this appeal to the Supreme Court, in the Third Chamber, Sixth Division of the Supreme Court established by the persons written on the margin, with the number 4201/06, before which the judicial decision depends on, lodged by representation before the court of Mr. Rogelio against the ruling of June 29 2005 mentioned in the appeal 482/03, by the Fourth Division of the Litigation Chamber from the central court at Madrid. Respondent QUÍMICA FARMACÉUTICA BAYER S.A., and the Treasury Counsel in the representation that is held.

FACTUAL BACKGROUND

FIRST.- The lodged ruling has the procedural part of the following content: "WE RULE.- 1 - WE DISMISS the Litigation Chamber lodged by Mr. Rogelio and Ms. Catalina, against the Judicial Decision of the Ministry of Health and Consumers (Ministerio de Sanidad y Consumo) of May 16 2003, to which it contracts, according to law. 2.- With no order to pay costs."

SECOND.- Notified the aforementioned ruling, the representation before the court of Mr. Rogelio, presented by written before the Fourth Division of the Litigation Chamber from the central court at Madrid preparing the appeal to the Supreme Court against this court. By notification, the Chamber prepared in time and shape the appeal to the Supreme Court, giving notice before the Supreme Court.

THIRD.- Received the procedural steps before this Court, the respondent attended to this Chamber and lodged the announced appeal to the Supreme Court, expressing the reasons and claiming the Chamber: "... to estate that the judicial decision from May 16 2003 of the Ministry of Health and Consume is not in true form of law and overturns it; it also estates that the plaintiff has the right to be compensated for the damages suffered and jointly and severally indemnified by both defendants; establishing the quantity of the indemnification in EUR 1,698,304, or, in the case the criteria of the growth in the amount of the evaluation when formulating the action, in EUR 1,132,203; establishing that the quantity of indemnification must be updated to the date in which this procedure is finished according to CPI; and also to establish the imposition of the costs to the defendants and, consequently, to order the defendants to pay to the plaintiffs the quantity of the indemnification updated according to CPI plus legal interests, plus costs."

FOURTH.- Interposed and admitted the appeal to the Supreme Court by this Chamber, it was give notice to the respondents concerned so that in the period of thirty days, they formalized notice of intention to defend, made by the Treasury Counsel objecting to the appeal to the Supreme Court and claiming this Chamber: “to announce a decision by which the appeal will be rejected, to confirm entirely the lodged ruling

and to impose the costs to the respondents."

In addition, the representation before the court of the Química Farmacéutica Bayer, S.A., in its notice of intention to defend claims the Chamber: "... will give ruling rejecting in its totality the appeal to the Supreme Court, on the express order for procedural costs derived from the appeal to the respondents."

FIFTH.- Fulfilled such procedure, the procedural steps concluded, fixing for voting and ruling the hearing on February 8 2011, in which it took place, having observed the legal formalities referred to the procedure.

Recorder: Mr. Luis María Díez-Picazo Giménez, Judge of the Chamber.

LEGAL REASONING

FIRST.- The present appeal to the Supreme Court is lodged by the representation before the court of Mr. Rogelio, who acts on behalf of his disabled son Mr. Anibal, against the ruling of the Litigation Chamber (4th Division) of the central court at Madrid on June 29 2005.

The facts of this case are the following: In the summer 1982, as a lactant, it was given to Mr. Anibal aspirin in the hospital Reina Sofía de Córdoba, so as to fight against a respiratory disease with fever. After he developed the Reye's syndrome, which is a kind of mental retardation. Attributing the disease to the administration of the aspirin, his parents presented a suit of financial liability from the Administration for a poor sanitary assistance, which was rejected by judicial decision of the Ministry of Health and Consume on May 16 2003. So they appealed to the jurisdiction, where its indemnification claim was rejected by the ruling that is now appealed against. The ruling does some factual statements: A) According to the present conditions of the science, it is known that the administration of aspirin to children can cause, in a statistically small number of cases, the Reye's syndrome; but it is also known that this rare disease, can be contracted also by other causes. B) Although the text of the ruling is not absolutely clear and categorical in this point, it seems to accept that the cause of the Reye's syndrome contracted by Mr. Anibal is the aspirin given in the hospital Reina Sofía de Córdoba when he was a lactant. C) It was only in 1986, when both in the United States and in Europe, it was adopted the decision that the patient information leaflet of the compounds of aspirin must warn of the risk of contracting the Reye's syndrome. According to these deliberations, the appealed ruling concludes that it is applicable art. *141.1 LRJ-PAC,* because of being facts "that could not been anticipated or avoided according to the condition of knowledge of the science or of the technique in the moment those facts appeared"; what means that the action of the sanitary administration was adjusted to the *lex artis*.

SECOND.- This appeal to the Supreme Court is based on three reasons, among them the first is formulated under the protection of letter c) from art. 88.1 LJCA and the two to under the protection of letter d) of the same legal precept: in the first, it is pleaded incongruent and a lack of motivation; in the second reason, it is pleaded irrational assessment of the evidence, because of understanding that the appealed ruling denies the connection of the cause between the administration of the aspirin and the Reye's syndrome contracted by Mr. Anibal; and in the third reasons, it is pleaded infringement of the constitutional and legal precepts that control the financial liability of the Administration.

In addition to the reasons supported in the appeal to the Supreme Court, the appellant focus his argumentative efforts in showing that even from 1980 it was known within the medical community that the administration of aspirin to children can cause the Reye's syndrome, which explains that the action examined in this ruling about the sanitary administration was not adjusted to the *lex artis*.

THIRD.- The first and second reasons of this appeal to the Supreme Court must be immediately rejected. In this appealed ruling there is no sign of incongruity nor lack of motivation: it decides the claim formulate by the appellant, doing a careful exam of all the factual and legal aspects of the case. It is possible to disagree with it, but it is a formally irreproachable ruling.

There is not any pretended irrational assessment of the evidence referring to the causal connection. As it was said before, the appealed ruling does not claim definitively that it was the administration of aspirin in the summer of 1982 what produced the Reye's syndrome to Mr. Anibal; but the truth is that the reason why it rejects the indemnification claim is not the absence of causal connection, but the observance of the *lex artis*. In other words, regarding to the practiced evidences, the Court of instance concludes that, apart from any other deliberation, the condition of the medical knowledge in

that time did not made necessary to know that the administration of aspirin to children could cause the Reye's syndrome.

FOURTH.- In the third reason of the appeal to the Supreme Court it is propounded the main question: if in 1982 a competent specialist in medicine must know that the administration of aspirin to children can cause the Reye's syndrome. The Court of instance, after a rigorous exam of the practiced evidences, it gives a negative answer. It is worth reproducing the following fragment of the appealed ruling.

Indeed, the Spanish Medicines Agency (Agencia Española del Medicamento) has reported in the dossier (page 15 and next, and page 384 and next) that the connection between the use of acid acetylsalicylic and the development of the RS is nowadays accepted around the world, but until that moment there were some disputes based on the lack of scientific evidence: the first studies were published at the beginning of the 80s (the defendant refers to the researches already done in the CDC of Atlanta between 1978/80), but the scientific evidence given by them was considered too unstable, so the regulatory authority of drugs in the United States concluded in 1982 that more studies were necessary, although an informative program related to this matter began and, between 1982 and 1985 several studies which supported the connection between ASA/RS were published, so in 1986 both the American sanitary authorities and the European ones (after the intervention of the Committee on Proprietary Medicinal Products for Human Use, community advisory body), added the correspondent information to the warning about RS in the patient information leaflet of the medicinal products for human use with ASA. In Spain, the Dirección General de Farmacia y Productos Sanitarios published the circular 22/86 on August 18, where there is all the information about that patient information leaflets of medicinal products for human use with ASA (pág. 17 and 18 expte.) must contain.

The appealed ruling shows that, if before 1980 there were studies in the sense indicated by the respondent, in 1986 the obligation to report about the referred inherent risk to the administration of aspirin to children was officially established. It cannot be denied the fact that this is a rational assessment of the evidences and so, as the facts here examined happened in 1982, the conclusion about the non-infringement of the *lex artis* by the sanitary Administration is correct.

In particular, knowing the importance of the present matter, this Chamber has used the faculty given by *art. 88.3 LJCA* and has examined the whole evidential material annexed to the referred actions. This lets remark a fact that, although it does not appear in the appealed ruling, it confirms the conclusion reached by this one: It was in 1982 when the supreme American sanitary authority, taking into account the studies started in 1980, began to recommend —in any case to order— some diligence in the use of aspirin with children. This means that in 1982, just the year when the facts of this case took place, there was no established knowledge within the medical community about the connection between the administration of aspirin to children and the Reye's syndrome.

For all this, the third reason of this appeal to the Supreme Court must be dismissed.

FIFTH.- According to art. 139 LJCA, the complete dismissal of the appeal goes with the order to pay costs to the appellants. Adjusting to the criteria usually followed by this 6th division,
the costs are fixed in a maximum of a thousand five hundred Euros with regard to the legal fees from each respondent.

WE RULE

We rule against the appeal to the Supreme Court lodged by representation before the court of Mr. Rogelio against ruling of the Litigation Chamber (4th Division) of the central court at Madrid from June 29 2005, with order to pay costs to the appellant up to a thousand five hundred Euros with regard to the legal fees from each respondent.

So, for this ruling, we take this position, we order it and we sign it.

PUBLICATION.- The previous ruling is read and published by His Honour Mr. Justice Luis María Díez-Picazo Giménez, in the Chamber holding a public hearing in same day of its date, of which, as Secretary, I certify.