Decision STS 3015/2006
Supreme Court

In Madrid, May 9 2006

The Third Chamber of the Supreme Court, Fourth Section, composed by the judges noted at the margin herein, has reviewed the appeal number 4933/2003, filed by the General Council of the Official Colleges of Pharmaceutics, represented by court agent Ramiro Reynolds Martínez, against the decision of the Chamber of Administrative Law of the Superior Court of Justice of Madrid, which decided the appeal before the administrative court number 532/2000, challenging the resolution dated March 8, 2000, issued by the Sub-secretariat of Health and Consumer Affairs, that declined the administrative appeal against the resolution dated November 25, 1999 issued by the General Directorate of Pharmacy and Chemical Products, which authorized the funding by the National System of Health of the medicinal product REBETOL 200 milligrams of 140 hard capsules registered under number EU/1/99/107/002 (c.n. 792200) and REBETOL 200 milligrams 168 hard capsules registered under number EU/1/99/107/002.

The Public Administration is represented herein by the Court agent.

Factual background

First. – In written statement dated April 11, 2000, the General Council of Official Colleges of Pharmaceutics filed an action against the resolution issued by the Sub-secretariat of Health and Consumer Affairs dated March 8, 2000, and after the pertinent proceedings the action was terminated by decision February 4, 2003, which stated: "Dismissing the action filed by the Court agent, Mr. Ramiro Reynolds de Miguel on behalf of the General Council of Colleges of Pharmaceutics, against the resolution of the General Directorate of Health Products issued on November 25, 1999, we declare such resolutions in accordance with the legal system and in consequence, we confirm them. Without ordering the payment of legal costs."

Second. – Once the quoted decision was notified, the party that filed the action, by written statement dated March 24, 2003, expressed its intention to prepare the appeal and by order dated April 7, 2003, the appeal was considered as prepared, and the parties were called before this Chamber of the Supreme Court.

Third. – The appealing party, in the formalization of the appeal, requests the repeal of the appealed decision and to declare that the medicinal product Rebetol, in its several presentations, must be distributed by the pharmaceutical offices, except when dealing with hospital patients.

In the basis of the following motives: "FIRST. – Claim, under the legal basis of article 88.1.d) of the Law of Jurisdiction, of infringement by the decision herein appealed of

article 22, sections 1 and 3 of the Law of Medicines. SECOND. – Claim, also under the legal basis of article 88.1.d) of the Law of Jurisdiction, of infringement by the decision herein appealed of article 103.a) and b) of the General Law of Health."

Fourth. – The Court agent in his opposition statement to the appeal, requests its dismissal.

Fifth. – By order dated March 6, 2006, the vote and decision was set to take place on March 3, 2006.

Chosen to issue the opinion of the Court, Justice Antonio Martí García.

Legal Rationale

First. – The decision herein appealed, dismissed the administrative action and confirmed the contested resolution, referring, in its legal rationale, amongst others, in the second, the following: "… Following the argumentative line regarding the reserve herein discussed, it is needed to say that such reserve is the one established by the General Directorate of Health and Health Products, when the labs, owners of the medicinal product, requested the funding with charge to the Social Security, and the General Directorate authorized such funding under conditions related to the prescription, use and distribution within the scope of the National System of Health.

Effectively, the norm that establishes the responsibility of the Administration to impose restrictions is the one established in article 22 of the Law of Medicines, which provides: 'The Ministry of Health and Consumer Affairs, by objective reasons of health, may subject the authorization of medicinal products to special conditions, because of its nature or characteristics, as well as the general conditions for the prescription and distribution of such products or the specific ones of the National System of Health.' Section 3 of the same article, reads: 'The limitation may also consist in a restriction of the hospital use of the medicinal product, in requiring a hospital diagnosis or requiring a prescription by specialized doctors'."

Therefore, we see how the Administration, after a first identification of the medicinal product by an evaluation made by the National Agency of Medicinal products, and upon the request of Social Security funding, when making a global consideration of the product, takes into account not only the technical characteristics (as the Agency did) but also the implications from an economic perspective, of both the selling and the conditions of access to the product by the totality of the population.

The technical characteristics is taking into consideration in regard to the fact that this is a medicinal product that shall be prescribed in a hospital by a specialized doctor for the treatment of a chronic disease.

Regarding the economic reasons, it promotes a free distribution regime guaranteed to the patients by the National Health System because of the exclusive commercialization of the product by the hospital pharmacies. This way can assure that the Public Health patient that needs to acquire such product, may do so without paying the 40% that would be obliged to pay if he acquires it in a pharmacy, since the medicinal product is included in the therapeutic subgroup J 05 (systematic antivirals) in accordance with article 2 of the Royal Decree 1605/1980, in connection with the Royal Decree 83/1993. All this, without having a repercussion in respect of those patients that after getting the prescription for the medicinal product in a private health hospital, would try to acquire it in the pharmacy offices in which the distribution will be under the referred conditions.

Consequently this Chamber must frame its assessment to determine if the reasoning of the public administration to limit the conditions of distribution to patients of Public Health Services in the hospital pharmacies, that may be qualified as "objective reasons of health." In the first place, the reasoning given (treatment of the chronic disease that requires a prolonged prescription of the drug that has an elevated cost -167,963 pesetas 140 capsules and 201,557 pesetas, (sic) of which a 40%, 67,185 and 80,623 respectively, will be disbursed by the patient at the pharmacy offices) are objective reasons because it is based upon real data affecting the patient. Where we may find the discrepancy is in the consideration of such reasons as of "health". Appealing to semantics, there is no doubt that health is a term that evokes a determined field that is related to health, and within which are included the means for the reestablishment of such health, both human and material means. Health protection is a fundamental right recognized by article 43 of the Constitution to all the Spanish people, assigning its organization and protection to the public authorities, concreting in article 3 of the Law 14/1996, that the means and undertaking of the health system shall be destined, with priority to the promotion of health and prevention of diseases, the extension of health care to all the Spanish people, and that the access and health services shall be done in conditions of effective equality, among other things.

Therefore, all of those that include the provision of health assistance, globally deemed, shall be considered as health reasons, among which are the technical characteristics of the means provided to the patients (drugs, among others) and also the manner in which those are distributed in optimal conditions. This is, because evidently, the competence of the public administration to undertake the actions provided in article 22, gives us the threshold about the extension of the measures to be taken and to consider as of health, with all the amplitude allowed by the term referred above, this is, the provision and distribution of the material and human means to procure health to the population. What had to be contrasted with the pure medical reasons, of certain similarity to them, that after a diagnosis are used to obtain the healing of a patient, or the maintenance of a recommendable situation from a medical perspective, that therefore have a scope.

Then, there is no way to categorize medical reasons as health reasons, since neither from a competence to issue acts point of view, nor from the matter of the act, they can be confused.

The conclusion is, although the adoption of the conditions has been made in view of the pronouncement related to the covering of the drug by the social security, such measures do not have an economic and subjective measure from a covering perspective of the social security, but it considers other factors that affect more the conclusion that because of the nature of the drug, it is needed by a collective of persons, who's ailment must be controlled in a hospital regularly and that will consume the drug during long periods of time, avoiding then, that for its acquisition a disbursement like the abovementioned, that can be considered as burdensome for the average citizen.

So, this Chamber understands that an amplified definition of the word "health", and the fact that has to be related to objective facts or circumstances, determines that all the reasons given by both resolutions (the one of the General Direction of Pharmacy and of the Sub-secretariat of Health and Consumer Affairs) shall be considered in within the scope required to be held accordingly to the rule of law, as provided in article 22.1 of the Law of Medicines. In the other hand, we need to consider that the measure only reaches the covering of the drug in the sphere of the National Health System, so who may need to acquire it outside such sphere may do so in the pharmacy offices.

Finally the appellant adds a series of arguments regarding the manner in which it could have been hold the same guaranties in which the public administration sustains the adoption of the conditions. However, it is not of the competence of this chamber to assess the alternatives to the adopted measure, but the legality of it, that is upheld herein by the reasoning aforementioned. In any case the consequences for the pharmacy offices would be the same than those derived from some cases where they limit themselves to distribute without obtaining the correspondent amounts.

It also states, that article 103.1, ap.b) of the General Law of Health establishes the cases in which the custody, preservation and distribution of drugs shall be up to the pharmacy services of the health center hospitals, and to the centers of primary attention of the National Health Service, to the cases in which its application is undertaken within such institutions or for those that require a particular vigilance, supervision and control of the multidisciplinary team of health care.

With the herein referred measure, as we stated, the qualification made by the Drug Agency for the commercialization of the Rebetol in Spain has been restricted, binding the drug not only to the diagnosis but also to the prescription and distribution in the hospitals of the National Health System, implying a vigilance and absolute control of the doctors in the sphere of the hospital, in respect of such drug,

which is why we can locate this condition in the first of the cases established in the article abovementioned.
It is because all of this arguments that this Chamber considers that the appealed resolutions are in accordance to the Law, and consequently, proceeds to dismiss the appeal.

Second. – This Chamber in decision dated November 18 2005, deciding the appeal number 4221/2003, against the decision of the Superior Court of Justice of Madrid dated March 12 2003, that confirmed the resolution of the General Direction of Pharmacy and Health Products of the Health and Consumer Affairs Ministry, dated November 11, 1999, that authorized the covering by the National Health System of the drug denominated TEMODAL, under the following conditions, 1. The prescription and use was restricted t the assistance level of the specialized attention; 2. That the distribution would be done exclusively by the pharmacy services of the Hospitals, has upheld the appeal and reverse the appealed decision stating in it legal rationales scond and third, the following: "Second. – Against this decision the General Council of Colleges defeated in the trial appeals making two pleas, both under article 88.1 of the Law of Jurisdiction for an infraction of the legal order. As the appealed, appears before the court the State's Attorney. In the first plea, sections 1 and 3 of article 22 of the Law of Medicines 25/1990 are alleged to be infringed, and also, by wrongful application of article 59 of the aforementioned Law. The reasoning therein starts insisting on the veracity that, as in stated by the decision, the Spanish Drug Agency has restricted the prescription and use of the pharmaceutical drug TEMODAL to the hospital sphere, without interfering with the faculties of the General Direction of Pharmacy and other Health Products. It sustains that above all, this is a about appreciating which are those faculties and concretely those related to the setting up of conditions or limitations, as regulated by article 22 of the Law of Medicines. The plea basis its argument in a thesis is just a new version of the thesis held before the lower court. It goes over the fact that the referred article 22 of the Law of Medicines, in its section 1, requires the conditions and limitations to be established on objective reasons of health basis. This is why the debate has to be centered on the existence of such reasons so to exclude the distribution of the drug by the pharmacy offices, different from the prescription and use of the drug realized in the hospital's ambit. It is alleged that the existing reasons are not in any way of a health nature, since nothing impedes the drug to be freely used, distributed and prescribed while is not covered by the National Health System. Effectively, the conditioning or limitation in the impugned resolution only has the potentiality in this last case, this is, in the case that the expense is charged to the National System mentioned. Also, the decision in critiqued since it reasons on article 22 of the Law, about the health conditions of use and prescription, but then regarding the distribution it does not use this rule, but quotes article 94 of the Law of Medicines and the Royal Decree 9/1996, of January 15, referring to the economical reasons of the condition. In consideration that the allegation, by the way with an actual basis, that eh Royal Decree just quoted is not applicable to the drugs but only to the effects and accessories, coming to sustain that the health

administration can exclude or not the drugs from the Social Security and National Health System, but not to establish restriction to the distribution. It is sustained as well, that the health reasons and the economical reasons cannot be held together, because when the legislator wants the economical aspect to be taken into account it declares it expressly. Now then, before making a holding over the allegations of this motive, it is convenient to refer to the second plea, since both of them should be resolved jointly. The allegations in this other plea can be found in article 103.1 of the General Law of Health, sections a) and b), and establishes that the custody, conservation and distribution of the drugs correspond generally to the pharmacy offices, differently from the specific cases to be attended by the pharmaceutical hospital services. It is alleged also that nothing prevents the use and prescriptions to be in the hospital, and the distribution to be done by the pharmacy offices, especially in the case of patients that are no hospitalized that in any case should be require to go to the hospital just to get the drug. The argumentation is closed alleging that there are not objective reasons of health, is contradictory that they are no more assessed than when is about use and reception of pharmaceutical drugs subjected to the Social Security and the National Health System. From this contradiction we can clearly deduct, according to the General Council of Official Colleges of Pharmaceuticals, that the established restriction is not made by health reasons but because other reasons of a strictly economical character. Well then, that should be that the may adjust themselves to one or another plea will be up to the interpretation of the precepts of the Law of Medicine, starting at the fact of a jointly interpretation of article 22.1 and 94.1, of which article 22.1 of the Law of Medicine was modified by article 110 of the later Law 50/1998 of December 30, adding to the quoted section 1 of the article a sentence where it is mentioned the conditioning of the distribution. We need to consider then, that article 94.1 of the so much quoted Law 25/1990, December 20, the drug, authorizes and enforces with general character that the health authorities, in order to exclude benefits from the Social Security of pharmaceutical character by diverse reasons, among which was a limitation due to the public expenses. Until the Law 50/1998, December 30, modified article 22.1 of the Law of Medicine, was obliged by a joint interpretation according to which a drug could be excluded from the Social Security by diverse reasons, among which was the economical character. Instead, it could not establish special conditions or restrictions for anything else but for objective reasons of health, although it should have been understood that the conditions could affect the use and prescription of the pharmaceutical drug as well as the distribution. The introduction of the sentence aforementioned into article 22.1 by the Law 50/1998, has been interpreted by the Health and Consumer Affairs Ministry in the sense that if the drugs can be excluded from Social Security system (and in general from the National Health System) by economic reasons, they may also be established a condition for the same reasons, for both the use and the prescription as well as for the distribution. An interpretation that is the one challenged in the appeal, considering that is infringing not only not only the precepts abovementioned, but also article 103.1 of the General Law of Health, according to which the distribution of pharmaceutical drugs is up to the pharmacy offices. This Chamber believes that

the appealing General Council of Colleges is right when alleges that the conditioning to the distribution must be due to objective reasons of health, as is established by article 22.1 of the Law of Medicines. The final sentence introduced by the Law 50/1998, does not mean a modification of the first sentence of article 22.1 referred clearly to the reasons of conditioning only as objective reasons of health. In this case, without any doubt the condition established as a limitation of to distribution is not based in this reasons, but in other ones exclusively economic and related to the limitation of public expending. It must be considered that, since the distribution that is not under the National Health System, as well as the use and prescription, are not subjected to any conditioning, what must have been done in the reasons were of a health character. This is, that after the modification of article 22.1 of the Law of Medicines, the power of the administration to establish conditionings or restrictions in pharmaceutical drug matters still exist, even if when dealing with the distribution aforementioned expressly. This must be done based on objective reasons of health since the public authorities are still forced to do so by the initial sentence of the article. The Chamber estimates that effectively, as is argued by the appealing General Council of Colleges, an article of the Law that alludes unequivocally to the reapeated reasons of health cannot be applied in a valid manner with the purpose of limiting the expenses of the Social Security in pharmaceutical benefits, and to with the objective of protecting the population's health. In view of this, we must hold in favor of the reasoning of the appealing party, and uphold therefore both of its pleas.

Third. – Since we have upheld the pleas of the appeal, we must resolve with all our jurisdictional power, the appeal before the administrative courts filed before the Superior Court of Justice. Now then, of the statements made in the previous legal rationale we can deduce that this appeal must be upheld, and obviously only in what is referred to the distribution of the drug. Therefore we must annul the sentence of the appealed resolution located in the second part of the decision of such resolution, in which is expressed literally that 'its distribution (of the pharmaceutical drug TEMODAL) must be realized exclusively by the hospital's pharmacy services".

Third. – In view of all of the above, and taking into account also that in the present appeal, has as precedent the authorization of the drug REBETOL, in similar conditions to the abovementioned TEMODAL, and that the allegations of the parties, as well as the terms of the decisions of the lower courts are similar in their terms and particularly, that the pleas of the present appeal, are basically the same as the ones made in appeal number 4221/2003, this is, the first of the pleas made under article 88.1.d) of the Law of Jurisdiction, because of infringement of article 22 of the Law of Medicines; and the second of the pleas made under article 88.1.d) of the Law of Jurisdiction by infraction of article 103 of the General Law of Health, it must be upheld, by an application of the equality principle, that demands equal decisions for equal cases, to sustain herein the same doctrine already expressed by this Chamber, since there is no circumstance that would justify a different solution, neither a possibility to change our criterion. Consequently, it must also be upheld herein both

of the pleas of the appeal, for the reasons exposed in the decision aforementioned dated November 18 2005.

This, without disregarding the allegation of the State's Attorney related to the impossibility to consider in this sort of appeals an analysis of the facts of the case assessed in the lower court's decision, because even though when this is true and has been declared so repeatedly by this Chamber of the Supreme Court, we must not forget what the lower Court Chamber has assessed about whether the objective reasons of health concurred or not, and the determination of this concept considering that is a undetermined legal concept, that requires a legal appraisal, that this Chamber can and must analyze, without this being any alteration of the assessment of the fact done by the lower Court Chamber, since, as we have seen wer are not before a simple appreciation of the facts but before a legal appraisal directed to concrete the indeterminacy of the legal concept that is "objective reasons of health".

We must then reiterate, as this Chamber has already declared, that the analysis of article 22 of the Law of Medicine, clearly shows that the restriction, limitations and conditions that the quoted article authorizes, are done always and exclusively by objective reasons of health, and that therefore under it, it is given to establish restrictions and limitations but always because of objective reasons of health, without allowing an extension of the interpretation or application of the concept objective reasons of health to other reason, not even to economic reasons, as important and transcendent they might be, because the rule states exclusively objective reasons of health and any amplification would lead to a misapplication of the will of the legislator.

Fourth. – The upholding of the pleas of the appeal, forces this Chamber in accordance to article 95 of the Law of the Jurisdiction, to resolve the issue as it was settled in the debate before us.

On this respect, what is questioned in the litigation is the prohibition of the distribution of the drug in the pharmacy, being then in order to upheld the appeal before the Administrative Court and to annul the appealed resolution in that case, for the reasons already stated herein and because that was the solution this Chamber gave in a similar case as it was referred above.

On the other hand we must state, that if we analyze the content of the preceding resolution, we will observe that it establishes an exclusive distribution of the drug in the hospitals' pharmacies, because of purely economic reasons, and this sort of restriction based on economic reasons would not be authorized nor contemplated by the rule trying to by applied of article 22 of the Law of Medicines, Law 25/1990 of December 20, and this evidences furthermore, as the appellant states that the appealed resolution projects its limitation over the public health care, letting aside

the private care, since if the limitation was because of reasons of health should also affect the private sphere.

Fifth. – The previous assessments force us, in accordance to article 95 of the Law of Jurisdiction, to declare upheld the appeal, and to reverse and annul the appealed decision, annulling also in particular the appealed resolution that limits the distribution of the drug to the pharmacy services of the hospitals, which is what this Chamber already declared in relation to the drug TEMODAL.
Without being at place the condemnation for the costs, and being each party obliged to pay for the one caused by them in this appeal,

WE RULE

That we must declare and so we do, as upheld the appeal, filed by the General Council of the Official Colleges of Pharmaceutics, represented by court agent Ramiro Reynolds Martínez, against the decision of the Chamber of Administrative Law of the Superior Court of Justice of Madrid, which decided the administrative action number 532/2000, and in virtue of which: FIRST. – We reverse and annul the aforementioned decision. SECOND. – We upheld substantially the appeal before the administrative court number 532/2000, filed by the General Council of Official Colleges of Pharmaceutics, challenging the resolution dated March 8, 2000, issued by the Sub-secretariat of Health and Consumer Affairs, that declined the administrative appeal against the resolution dated November 25, 1999 issued by the General Directorate of Pharmacy and Health Products, an annul the aforementioned resolutions in their second section related to the "distribution to be done exclusively by the pharmacy services of the hospitals", since it is not adjusted to Law. Without being at place the condemnation for the costs, and being each party obliged to pay for the one caused by them in this appeal.

Therefore, by this, our decision, that shall by introduced in the Legislative Collection, we hold, order and sign PUBLICATION. – The previous decision was read and published by the Reporting Judge, his Excellency Mr. Antonio Martí García, , in public hearing, all of which, as Secretary I herein certify.