National Judicial System

No.:3/2011

Court: Third Civil Appellate Court

DECISION NO. 3/2011
THIRD CIVIL APPELLATE COURT
Writing for the Court: Judge Mary Alonso Flumini
CONCURRING JUDGES: Dr. Fernando Cardinal, Dr. Tabare Sosa, Dr. Mary Alonso.
Montevideo, February 8, 2011.

CITATION:

The case before the Court for final resolution on appeal is entitled: "Fontes Braida, Oscar v. State – Executive Branch – Ministry of Public Health. Protection action." IUE 2-55702/2010, before this Court on appeal brought by the respondent, and including the claimant's partial appeal, against Decision No. 98, handed down on December 15, 2010, by the Honorable Dr. Pablo Eguren, of the Third Court of Civil Litigation.

WHEREAS:

I. The aforementioned decision ordered the Ministry of Public Health to provide Mr. Oscar Fontes Braida with the medicine Cetuximab, within a fixed time period of three business days, as prescribed by his treating physician or until the drug is included in the Therapeutic Drug Roster [FTM, for its initials in Spanish]. The Court ordered that non-compliance would be sanctioned with a monetary fine of 100 UR (Uruguayan pesos) daily, in accordance with the final paragraph of Art. 9 of Law 16.011. The decision also ordered payment of court-appointed expert Dr. Hugo Rodriguez in the deposited sum of $18,000. Without costs.

II. The representative of the Ministry of Public Health appealed the decision, in the terms presented in the respondent's brief appearing at pages 168 *et seq.* of the record, requesting that the lower court's decision be overturned.

III.The claimant acknowledged notification of the respondent's appeal, and brought its own appeal in respect of the Court's decision not to order the respondent to pay all costs of the proceedings.

The respondent acknowledged the claimant's adhesion to the appeal, arguing that such adhesion should be dismissed, or, in the alternative, the lower court's decision should be overturned and the protection action dismissed.

IV. The Court of Appeals, having received the action, assigned the case to this Chamber. As Magistrate Dr. Julio Chalar is on medical leave, Magistrate Dr. Tabare Sosa will sit as part of the tribunal in these proceedings (as per the assignation hearing on 3/2/2011), in accordance herewith.

WHEREAS:

I. The lower court's decision must be confirmed, for the reasons set forth as follows.

II. In the case at hand, the claimant, Mr. Oscar Fontes Braida, age 60, suffers from colon cancer, with side effects of the liver and lungs, and is treated with the drug CETUXIMAB, which has a monthly cost of over $200,000 (two hundred thousand Uruguayan pesos). Upon the refusal of COMECA [the Canelones Medical Cooperative] to cover Mr. Fontes' treatment with the drug in question, he assumed the cost of the first three doses, with excellent results, as he experienced significant

reduction in the growth of the cancerous tumors. When his family was no longer able to afford the drug on its own, Mr. Fontes applied to the National Health Fund [a State institution that covers specialized medical treatments and high cost medicines for social security beneficiaries, the FNR for its initials in Spanish]. When the FNR denied his request, as the drug he needs is not included on the Therapeutic Drug Roster (response received by mail on 17.11.2010), Mr. Fontes filed a petition dated 19.11.2010 with the Ministry of Public Health, requesting coverage. No response to the petition has been received as of the date of this action.

Given the FNR's denial of his request and the lack of a response from the MSP [the Ministry of Public Health, for its initials in Spanish] regarding coverage for this drug prescribed by Mr. Fontes' treating physicians (Dr. Carlos Brayer, treating physician, and Dr. Mario Varangot, consulting physician, and a professor of the School of Medicine and Director of the National Cancer Institute), Mr. Fontes brought the present Protection Action, alleging violations of his rights to life, health, equality and human dignity (in accordance with Arts. 7, 8, 44 and 72 of the Constitution).

The objective of the action—in the claimant's own words—is that "the Court order the Ministry of Public Health to provide the claimant, within a period of 24 hours, with the drug Cetuximab, in accordance with the respective medical prescription, and to assume the cost of the drug and the patient's future treatment therewith" (Numeral II of the claimant's introductory brief).

In his introductory brief the claimant highlighted that the Ministry of Public Health does voluntarily provide the cancer treatment requested to patients with the same illness, and therefore its decision to deny the drug in the case at hand is discriminatory. The claimant refers to a recent case with circumstances identical to his own (same illness, same drug, same discrimination) (Decision No. 93, dated 16 August 2010, attached).

II. In respect of the admissibility of the action, the Court does not find the claimant's adhesion to the appeal to be admissible in a summary protection action, for the following three reasons:

In the first place, as this is an exceptional resource, in which the speed of the proceedings and the need to concentrate those activities to be undertaken must be prioritized, any ruling or inclusion into the proceedings must be considered in strict observance of the need to avoid any delaying actions.

In the second place, in the context of the aforementioned interpretative principle, Law 16.011 does not specifically provide for adhesion to the proceedings, and as this would result in a necessary prolongation of the action, it should be understood that such adhesion thus may not be included within the general order to the proceedings.

In the third place, Art. 12 of Law 16.011 prohibits motions and counterclaims, and this petition for adhesion, by constituting an accumulation to the proceedings as an addition thereto through a petition for review in the second degree, has the same characteristics as a motion or counterclaim, and therefore should be understood to be excluded from the proceedings of a protection action.

As a result, the claimant's pretension in his petition for adhesion to the appeal must be dealt with through a direct appeal, and therefore this Court rejects the petition for adhesion to the appeal as formulated. The Fourth Court of Appeals has held to the same effect in various cases (decisions

179/2002, 65/2003, 234/2008, 238/2009 and 68/2010), as has the Fifth (*see generally*, decisions 135/2009 and 136/2009).

IV. Coming to the subject of the Ministry of Public Health's appeal, in the first place, the respondent states that, "the claimant at no point plead in his claim that CETUXIMAB be included in the FTM, nor was this petition included in the note sent to the MSP. Mr. Fontes only requests that the MSP provide him with the medication." The respondent therefore argues that the decision was *ultra petita*. There would therefore be no allegation of manifest illegality (pages 170 of the record of the proceedings).

The Court will not accept the appeal as formulated.

The Court understands that, giving the claim a reading in its context, and in virtue of the *pro actione* principle—a fundamental tool of a rule of law state and an essential instrument for the defense of human rights, which is especially relevant in protection action proceedings—it can be concluded that the direct cause of action against the MSP is, precisely, the MSP's failure to include the drug in the FTM—or at least to duly consider its inclusion. This is so given that the petition was made after the claimant requested that the National Health Fund provide the drug, which request was denied, based on the fact that the drug is not included in the FTM. The claimant seems to have accepted that this decision was appropriate, as he did not bring any action or claim to appeal it. Therefore, if the claimant requested that the National Health Fund provide him with the drug, and the National Health Fund denied the request for the aforementioned reason, there is no other way to understand the petition and claim against the Ministry of Public Health, except as a result of its failure to include the drug in the FTM. The reference to and inclusion of Resolution No. 93/2010 of the First Chamber of the TCA [NB: probably referring to the *Tribunal Contencioso Administrativo*, or the Administrative Litigation Court] in the claim indicates that this is the case.

In addition, the MSP itself seems to have understood that this was the case, by providing a clear defense to this allegation in its own response brief, giving its reasons as to why the drug was not included and offering evidence to support its position, through the presentation of the corresponding Commission regulation, and in turn allowing, with no objection, evidence to be presented regarding the inclusion procedures, and choosing its witnesses who would testify on the matter.

It must be concluded, then, that the claimant not only plead the issue in question with particularity, but the respondent also presented an effective defense thereto. Therefore, the Court will dismiss this argument.

In the second place, the appellant states that, "the MSP is not the institution that provides medicines, for the simple reason that neither the Constitution nor the Legislature has so determined," and that, "our legal framework does not designate (and certainly not with the diversification of ASSE [the State Health Services Administration]) the Ministry of Public Health as an institution that provides drugs, as the claimant erroneously believes, but instead is mandated exclusively to adopt those measures that it should find necessary in order to maintain the public health, and to execute such measures through the issuance of regulations and orders necessary for this important purpose."

The appellant argues that the MSP is not in a legal position to be able to directly provide a patient with his or her medication, but is only able to adopt measures necessary to protect the public health, with its specific obligation being to prepare and update the FTM (pages 171 of the record of the proceedings).

The Court will also not accept this argument. As noted in our analysis of the foregoing argument, the underlying claim in requesting a drug directly from the Ministry of Public Health is based on that entity's failure to comply with its duty to prepare and update the Therapeutic Drug Roster, and with another duty that is clearly manifest in the claim in relation to the specific facts of the case—the duty of non-discrimination, in that the MSP provided the drug to another patient in a similar situation. The MSP has not contradicted this fact.

Therefore it is necessary to dismiss this argument, keeping in mind that the claim does not lie in a duty to provide assistance, as the appellant would have it, but instead in a duty that arises from the right to equality that the State guarantees to all citizens. State institutions must therefore provide the same treatment to individuals in similar circumstances.

In the *sub causae* it has been shown that the MSP did not duly consider the inclusion of the drug—as we will see—and, in another case, the MSP voluntarily dispensed the same drug to another person in a similar situation. This fact was dispositive for the First Chamber of the TCA in upholding the decision to hear the protection action brought by Ms. Roxana Gonzalez against the MSP (Decision No. 93/2010, attached to the claim). This fact was expressly included in the claimant's brief, and was not contradicted by the respondent in its response brief, so there is no controversy in respect thereof. No more did the MSP give any explanation of this situation, given that the court disclaimed any order toprovide the drug.

This gives rise to the duty that the appellant puts into question, from the sum total of its omission—the due and timely evaluation of the drug's inclusion on the roster—with more than one action that tended to cure this omission in a previous, similar case, which raises the issue of the principle of non-discrimination as set forth in the Constitution. The violation of such principle deserves our attention.

The appellant thirdly raises the subjective "opinion" of the lower court, regarding the legal and regulatory procedure for updating the FTM, stating that the court's "opinion lacks technical support to back it up and in fact is not coherent with the reality of the formulation of the FTM," and argues that the administration's actions in respect of its consideration of the inclusion of the drug in question in the FTM were proper (pages 171 *et seq.* of the record).

In this regard, it is indisputable that we must begin from a point of acknowledging the existence of the fundamental right to health of all persons, and that such right must be protected by the State using all available means and in order to benefit all persons, and that the State must guarantee all persons equal access to the necessary treatment in accordance with each individual's state of health, and, particularly, the right to access to necessary medication. These elements form an essential part of the right to health.

These rights are substantive principles that broadly define the legal framework of a rule of law state, and, like the principle of non-discrimination and other fundamental rights, broadly limit and bind the executive power by excluding or imposing certain content from or on its regulatory actions.

National Judicial System

No.:3/2011

Court: Third Civil Appellate Court

In interpreting and applying the decree (Executive Decree No. 265, of 2006), which approved the "Therapeutic Drug Roster", the administration was obliged to apply the aforementioned fundamental principles and standards.

As such, in respect of the revision and updating of the FTM, which is supposed to take place "annually" (as per Art. 7 of the aforementioned decree), and taking into account the fact that rapid scientific advances can be a destabilizing element in respect of any legal standard that fails to keep in mind its objective and the nature of the issue that it is regulating—these imbalances arise from the fact that this "annual" adjustment has been lost in translation. This, undoubtedly, is and will continue to be an impediment to the correct application of the law in practice.

As a result, this time period, although it may be reasonable for control or review of the components of the FTM over time, should never be interpreted as a limiting factor for the inclusion of a new drug on the roster, given that this would be tantamount to ruling that patients in need during such time period would be subject to flagrant discrimination in terms of their access to preventative health care and necessary medical treatments, in violation of their fundamental rights, as discussed above.

It is necessary to state that legally, the regulation is an administrative act that is subject to hierarchically superior laws, and any violation of such laws, or the principles that inform them, would invalidate the regulation, which should then cease to be applied.

The issue or problem of the "due" time in this case is a given in accordance with the Administration's (the MSP's) response, which should be constant—that is, the MSP should deal with the diverse problems associated with the inclusion of new medicines in the FTM as they arise, without self-imposed periods of inactivity, so that any delays would only be the simple and natural result of the type of problems that the inclusion of new drugs gives rise to. We would not be talking about "undue delay" if the delay were only the result of the careful consideration that is necessary to properly evaluate a complex case.

Now. In the case at hand, there is nothing left for the Court to do but to share the lower court's analysis in its eleventh whereas clause, given that the drug Cetuximab is part of a study by the corresponding Commission, and in light of the depositions given by two doctors who form part of the organizations with jurisdiction to consider drugs for consideration in the FTM—Dr. Alejandra Croci (pages 92 *et seq*. of the record of the proceedings) and Dr. Ana Perez (pages 155 *et seq*. of the record of the proceedings)—from which a clear indifference emerges on the part of the Assessment Committee, given that the first witness to be deposed clearly declares that the technical working group "is still working on it" (page 92 of the record of the proceedings), although months had passed, and that, neither before or as of the date of her testimony, the Assessment Committee had not issued any reports regarding the drug in question, whether in respect of its cost, effectiveness, ideal subjects or benefits. The other witness, Dr. Ana Perez, acknowledged that, "We have prioritized [the drug Cetuximab] due to its social impact, because many patients are requesting it." (Page 155 of the record of the proceedings). When asked about the existence of any written report, she vaguely responded that, "I know there is a report that still does not include the evidence, which I understand is not relevant. I haven't seen it…" (Page 156 of the record of the proceedings). When asked which officials are charged with evaluating pharmaceuticals, she answered: "The MSP has a young, inexperienced technical team that deals with these issues. We are in the process of training them… We were supposed to have the drug included in the FTM in February … due to the urgency of the

cost-benefit study. The techs are working on provisional reports. Everything will be resolved when the Assessment Committee meets." (Page 156 of the record of the proceedings).

This Court cannot see how the MSP can insist that there is no omission while, without making any objection whatsoever—on the contrary, all evidence indicates that the drug should be covered in the case at hand—trying to defer its duties in respect of the protection of the claimant's right to health for more than a year.

The freedom to choose one's course of treatment is a fundamental principle of progressive medicine (the physician is free to prescribe the treatment that he or she considers most appropriate under the given circumstances), which also presupposes an important role for the State in ensuring the effectiveness of the efforts of our health system (public health institutions and services, collective assistance institutions and private medical centers).

The foregoing leads us to the conclusion that the respondent Administration must respond to petitions that new drugs be included in the FTM without delay, in a period that may vary according to the circumstances, but always in accordance with the governing principle of reasonability, which should be in line with the seriousness of the case at hand. In the claimant's case, the evidence set forth in the case file demonstrates an inertia that rises to the level of noncompliance—by omission—with the duty in question, for unjustified and undue delay in dealing with the issue. Therefore, this Court confirms that the Administration's actions were manifestly unlawful, due to the existence of a delay without any appropriate justification.

In addition, and as a fourth argument, the appellant states that the decision indicates that the MSP failed to invoke valid reasons in making its case for its decision not to include the drug Cetuximab in the FTM, when in fact the respondent, "…did not receive any formal request to proceed in such a manner, neither from the patient, nor from any of the national medical organizations (faculty and/or services at the School of Medicine, scientific associations, or others). Only a laboratory pamphlet commercializing the drug has been received, but this does not present any scientific, clinical or cost-benefit evidence that would support the need for its inclusion in the FTM…" (Page 172 of the record of the proceedings).

This argument fails in light of the testimonial declarations of Dr. Perez and Dr. Croci referred to *ut supra*, from which it is clear that the Assessment Committee is currently considering whether or not to include the drug in the FTM. In addition, the respondent expressly admitted to the same in its appeal brief, at the third paragraph of page 173 of the record of the proceedings, stating that, "As stated by Dr. Perez, the MSP considers the decision as to whether or not to include the drug as a priority, due to the concerns that have been raised by its own patients at the judicial level."

Similarly, the appellant's argument, underlined in its appellate brief (appearing beginning at page 174 of the record of the proceedings, at No. 21), which argues that, "…in consideration of the evaluation of this pharmaceutical for inclusion in the FTM, it should be highlighted that, according to the testimony of Dr. Perez, Director of the Department of Medicines of this Ministry, in respect of the process of consideration of the inclusion of this drug on the roster in question, the drug has not been put under evaluation, given that the aforementioned department has not received any formal petition to evaluate the drug for inclusion on the roster from any national medical organization (faculties and/or services at the School of Medicine, scientific associations, or others)", is defeated

by Dr. Perez's own declaration (at page 155 *in fine*, where she stated that a request to include the drug was received, and the pharmaceutical is a high priority for the Assessment Committee (see the first line of Dr. Perez's testimony at page 155 of the record of the proceedings)).

Finally, the appellant's fifth argument is that, "the scientific community in our country has not called on us, nor suggested to or advised us, as a State agency, to include the drug among those covered by the FTM. Therefore, it cannot be considered that this Ministry failed to take any action…" (Page 175 of the record of the proceedings).

However, the expert medical practice of (pages 145 *et seq*., and the clarification during a hearing, at pages 152 *et seq*. of the record of the proceedings)—to which no objection was raised—and the witness testimony of the treating physician, Dr. Carlos Brayer (pages 90 *et seq*. of the record of the proceedings), which was validated by consulting physician Dr. Mario Varangot, Director of the National Cancer Institute and medical school professor, show that in this case the medication has given results that can be classified as positive. Therefore, this argument is also unsustainable.

V. In accordance with the foregoing, this Court will uphold the lower court's decision, for the reasons—distinct from those raised by the respondent on appeal—proposed by the claimant in his action, and reiterated in his response to the appeal.

As such, even if it were the case that the respondent were to agree that there existed a direct duty on the Administration's part to provide medications, the Court understands that although there is no doubt regarding the Administration's duty to evaluate and decide whether—or not—to include drugs in the FTM, this evaluation, even as regulated, must be applied in line with the principle of reasonability, and must take place within an appropriate time period, which always requires an individual analysis.

In the case at hand, even though the evaluation of the drug in question was the Assessment Committee's first priority, as Dr. Perez put it (page 155 of the record of the proceedings), "We put together a list of priorities in respect of drugs to be included…this pharmaceutical was first on the list…", nothing was done regarding the study thereof, which shows a clear omission on the Administration's part. As stated, unlawfulness in the case at hand is manifest through the existence of a delay without due justification.

In addition, the Administration itself (the MSP) directly provided the medication, although it was not included in the FTM, in a similar case, upon a direct request that it be included. The MSP provided the drug voluntarily, which leads us to conclude that the alleged omission in fact occurred, in accordance with the theory of consistency in a party's own actions. The First Chamber of the TCA has ruled in the same vein, in Decision No. 93/2010.

This fact places the MSP in a legal situation of having to treat like cases as like, in accordance with the principle of equality set forth in Art. 8 of the Constitution.

The equality of circumstances—the factual supposition for the application of this standard—was not appropriately contested at the opportune moment—the reply to the claim—and therefore, *quaestio facti*, the claim must be admitted, in accordance with general principles.

The First Chamber of the TCA's conclusion in Decision 93/2010, which this Court has cited to multiple times already, is therefore pertinent, in that it states that, "The decision to authorize [a

drug] in one case and deny it in another—under similar circumstances—indicates that the respondent's conduct has violated the constitutional principle of equality. This results in discrimination, given that the Ministry of Public Health has given no reasons that justify its contradictory actions, which are therefore unjustified and manifestly unlawful…"

VI. The conduct of the parties in the proceedings before the lower court does not merit any particular sanction (Art. 688 of the Civil Code and Art. 56 of the Code of General Procedure).

FOR THE REASONS SET FORTH HEREIN,THE COURT

ORDERS THAT:

The petition for adhesion to the appeal is inadmissible.

The appeal is dismissed, and, as such, the lower court's decision is hereby confirmed, although on distinct reasoning.

Without particular sanction to the parties regarding the proceedings before the lower court. So notified.