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No.: 393/2011

Office: 2nd Chamber of the Court of Civil Appeals

DECISION NO. 393/2011

SECOND CHAMBER OF THE COURT OF CIVIL APPEALS WRITING FOR THE COURT: Dr. John Pérez Brignani

SIGNING JUDGES: Dr. Tabaré Sosa Aguirre, Dr. John Pérez Brignani, Dr. Álvaro José FrançaNebot.

Montevideo, December 21, 2011

DECISION NO. 393

WHEREAS, the case to be decided in the second and final instance is entitled "HERNANDEZ EDWARD V. FONDO NACIONAL DE RECURSOS (*NATIONAL MONETARY FUND*). PROTECTION ACTION IUE: 2-103147/2011." Case referred to this Court by the Honorable Lilian Morales of the 10th Chamber of the Civil Court, in respect of the appeal of lower court decision No. 67.

WHEREAS:

- I) The facts of the case as presented by the lower court are considered repeated herein, in respect of their relationship to the present ruling.
- II) Ruling No. 67, in respect of the claim for authorization of coverage for the drug "NEXAVAR-DROGA SORAFENIB", found for the claimant, determining that the aforementioned drug should be covered for the patient until a decision was reached in respect of its inclusion on the Therapeutic Drug Roster for the his case...".
- III) The respondent presented an appeal, arguing essentially that its decision was not manifestly unlawful, given that although the medication was included in the FTM (the Therapeutic Drug Roster), it was not included for the purposes for which the patient had requested it. Therefore there had been no unlawful action or omission by the FNR, which followed procedure. The appeal also states that the FNR [the National Monetary Fund] cannot serve as a substitute for the MSP [the Ministry of Public Health]. The patient's claim that the drug is covered for "actual" cancer (see page 245 of the record) is erroneous, as this was the result of a typographic error in the policy, which omitted the letter "n" from the word "renal", resulting in the policy's reading [in Spanish] "actual cancer", instead of "renal cancer", as intended. The patient's case is against a "quasi-State" agency and therefore involves no right that must be respected by the FNR. The FNR is required to follow the FTM, which only covered renal cancer in 2007.
- IV) The Court issued order No. 3161, ordering that the claimant be notified of the appeal, with the claimant's confirmation thereof appearing at page 251 of the record of the proceedings.
- V) The Court admitted the appeal through order No. 3443.

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VI) Having received the case file, the Court ordered that the respective Ministries be notified in order to provide their opinions.

VII) Having received said opinions and the corresponding agreement, the Court has decided to issue an advance ruling in the case in respect of Art. 200 of CGP [acronym is not defined in the original text], with Judge John Perez Brignani writing for the Court.

THEREFORE:

I) The Court unanimously votes to confirm the lower court's decision, finding the arguments presented in the appeal without merit.

II) In this respect, the Court confirms the lower court's ruling that: "For purposes of the resolution of the present case, it must be determined if the elements required for the protection action are met—essentially, if there exists an action or omission that is manifestly unlawful and that actually or imminently harms a fundamental right" (article 1 of Law 16011). The Court also notes that the protection action can be brought against the State or a quasi-state agency, as in the case at hand.

It should also be noted in respect of the decision as to whether the interpretation of the FNR was manifestly unlawful, it must be clear what is at stake, and what fundamental rights the claimant is seeking to protect.

The rights in question in the case at hand are related to the safeguarding of the right to and protection of life and health, which are protected by the Constitution (Articles 44 and 72 of the Constitution of the Republic). These rights are also protected by the International Covenant on Economic, Social and Political Rights, and ratified by Law No. 13.751, and by the San Salvador Protocol, which broadened the American Convention on Human Rights, and was ratified by Article 10 of Law No. 16.519, and finally, by domestic legislation, as per Article 10 of Law No. 18.335.

In respect of the right to health, it has been said that, "...It is indisputable that we must begin from a place of recognition of the fundamental right to the protection of human health; this protection must be put in place by the State, making use of all methods at its disposition and to the benefit of all persons; equal access for all persons to the necessary care in accordance with the health of each person, and particularly, the right to have access to necessary medicines, which form an essential part of the right to health.

These rights are broadly recognized under the framework of a constitutional rule of law State as substantive norms equal to the principle of equality and other fundamental rights, and administrative authorities are broadly limited and barred from excluding or imposing certain content

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within their regulatory actions." (Dissenting opinion in Decision 101, August 17, 2007, of the 5th TAC (Court of Administrative Litigation) (LJU [acronym not defined in text] 15510 and recent jurisprudence of the Court of Administrative Litigation).

Therefore, administrative authorities' actions can be regulated in these cases. If this were not the case, we would have to ask ourselves what is the judiciary's role, if we are unable to regulate administrative actions that affect the fundamental rights of citizens.

"As LARENZ points out (*Derecho Civil, Parte General* (Civil Law, General Section), p. 254 et seq., Jaen, 1978), the subjective rights of other persons or of the general population are necessarily linked to certain duties, limitations or bonds under the law; subjective law equates to the possibility of its imposition through action, with the conclusion that if a person has a subjective right to a certain thing, this means that such thing belongs to that person under the law.

The unlawful failure to satisfy a subjective right is not manifest through an injury to a legitimate interest, but instead through a violation a subjective right. The person whose right has been violated has the right to demand its protection before the Judicial Branch, through declarative actions or sanctions (CASSINELLI, *El interes legitimo como situacion juridical garantida en la ConstitucionUruguaya* (Legitimate interests as a judicial guarantee under the Uruguayan Constitution), *Estudios en Homenaje al Prof. Sayagues Laso* (Studies in Honor of Prof. Sayagues Laso), p. 283 et seq.).

The issue must take into account logic and reasonability, without losing sight of the violation of the claimant's right that is underlying the present protection action." (Cfm decision 39/2010 of this Court).

In this case at hand, the respondent timely rejected the claimant's petition, despite the fact that the drug in question was listed in the FTM, because the drug was not specifically included as a treatment for liver cancer.

In fact, Sorafenib is included in the list as an oncological medication, but as a treatment for renal cancer.

Therefore, there is no argument whatsoever, as the respondent would have, that there is no manifest illegality, given that we are dealing with a medication that is covered by the FNR for the treatment of cancer, and which was rejected for a technicality.

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In this respect, we must keep in mind that the medical profession must be governed by the principle of discretion, which manifests itself in the physician's choice of drug for a patient's treatment, with his or her knowledge of the particularities of the case and the fact that all consumers have the right to a treatment that causes the least problems or dangers to them, in light of all scientific advantages that medicine can put at the patient's disposal.

Another important issue is the fact that: "prescriptions and therapies chosen by the physician cannot be dictated by politicians and administrative authorities. An independent and individual position in respect of all types of State control is therefore legitimate. If administrative authorities are permitted to tell doctors what to do, this would be putting patients in the hands of political powers. This is why certain medical reference practices based on recognized and current medical opinion arrived at through notable scientific advances, although they may result in concerns about health costs from the administering authorities, cannot be put at risk, and even more so when we take into account respect from freedom to choose one's treatment. The medical profession may refer to the treatment indications established by administrative policies for serious technical uses, but it is, in practice and under the law, possible for a doctor to deviate from instructions, when his or her patient's care so requires. Freedom of treatment overrides documents regarding the right to health insurance."

"It would be frightening indeed if practices of a strictly regulatory and financial nature were to lose sight of the fundamental right to choose."

"Freedom of medical treatment is not ordered exclusively in the interest of the doctor, but is primarily an issue of patients' rights. Its exercise involves liability for the doctor in the case of abuse, whether for having taken an inappropriate risk with the patient's care, or for having failed to act in the interest of curing the patient." (Cfm Memeteau Gerard Trate de la responsabilite medicale, Les Etudes Hospitalieres 1996, p. 80 et seq.)

These principles are clearly applicable to the case at hand. In fact, Article 10 of Law 18355 provides that: "the State shall guarantee in all cases access to medicines included in the therapeutic drug roster."

In addition, the patient has the right to comprehensive care, in respect of which, "All patients have the right to have access to quality medication duly authorized by the Ministry of Public Health, and included by the Ministry of Health in the therapeutic drug roster, as well as to be informed of possible side effects associated with the use thereof." Art. 7, paragraph 2, of the aforementioned law.

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In the case at hand, the rights herein described have clearly been irrefutably violated, given that the doctor and the patient agreed to a course of treatment within the treatments prescribed by the relevant health authority. However, the FNR denied treatment for a medication that it itself had agreed to cover. This clearly violates the principle of equality under the law, given that the Court has established that it was unjustly and senselessly discriminatory to deprive the claimant of the rights due to him.

As Bidart Campos has written, the obligation to refrain from taking any action that would have a harmful effect on the health of a rights holder binds all actors, including the State and private persons, "specifically, this is an obligation that is classically referred to as universal liability." Cfm Bidart Campos German, National study on the Constitution and the right to health (*Estudionacional sobre la constitucion y el derecho a la salud*). E AAVV the right to health in the Americas (*el derecho a la salud en las Americas*), Comparative Constitutional Study (*Estudio constitucional comparado*), Pan-American Health Organization (*Organizacion Panamericana de la Salud*), Washington, 1989, pp. 33 and 34.

The physician's action must conform to scientific knowledge that is recognized or accepted at the time of the treatment. The difference in medical opinions between the treating physician and the FNR's physicians cannot serve to deprive the patient of constitutional and legal rights that the national legal framework grants to him or her. If this were the case, we would not only be granting the aforementioned authorities with a power that they clearly do not possess, but also legitimizing a violation of rights guaranteed by the Constitution (Articles 7, 8, 10 and 44 of the Constitution).

When the treating physician, as in the case at hand, is of the opinion that the medicine that he or she prescribes is the best treatment and medicine for the patient, we are dealing with a technical and scientific decision that must be respected, and particularly in the case of a prescription for a medication authorized by the MSP (and included in the FTM), and which is also covered by the FNR.

The decision of a doctor or doctors to prescribe a certain medication, which is included under the FNR's coverage, for treatment of a patient cannot be considered a minor or capricious decision, particularly when such prescription is subject to change or any conditions that are based on rules that obviously do not take into account and the unique and individual situation of each patient.

In sum: The FNR's denial of coverage of the medication prescribed by the treating physician, based on its regulation in force at the time, and on the fact that the drug was only indicated for another type of cancer, has no logical or scientific basis whatsoever, and therefore, in the Court's opinion, the decision was manifestly unlawful, particularly given the fact that the expert testimony indicated

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that the medication that is the subject of the present action is appropriate for the claimant's condition.

This, then, means that the appellee's claim is without merit, and the appeal is therefore denied.

III) Separately, the Court finds sufficient reason to opine on the proceedings presided over by the Honorable Judge Martinez de las Heras in the first instance of the proceedings before the 2nd Chamber of the Court of Administrative Litigation (Arts. 90, 109 and 116 of Law 15750).

In fact, in the first, the lower court's actions with respect to procedures for giving notice were completely divorced from applicable law.

At pages 12 and 56 of the record, the claimant and the respondent, respectively, provided or requested to change their email addresses. However, the lower court, through a direct order of the aforementioned Honorable Judge, in resolutions appearing at pages 19, 207 and 209 of the record, ordered that notifications would be made by the court bailiff (see the acts appearing at pages 20, 210 and 211 of the record, at physical addresses, also changed but not indicated as addresses for notifications for purposes of the proceedings, as demonstrated, in the respondent's case, at pages 56 and 210 of the record).

Proceeding as such, besides contradicting the applicable law regarding notifications. Law 18237 and Agreements 7637 and 7648, and particularly Article 1 of the latter, provide that once local courts are able to use electronic mail systems, the only obligatory and valid domicile for judicial notifications is the electronic mail address, and judges are required to take the necessary measures so that parties to an action comply with this law. The judge's actions in this case led to a failure to optimize the Institution's (that is, the Judiciary's) procedural resources, which the applicable law put at his disposal, thereby compromising procedural speed and economy.

In addition, keeping in mind that the Honorable 2nd Chamber of the Court of Administrative Litigation has had access to the new electronic procedural system (SGT, for its initials in Spanish) since 5/9/2011, it is clear that the judge's actions in these proceedings did not comply with the new system, given that the notifications that appear at pages 66 v, 207 and 209 of the record are all handwritten, as per the previous system. (See Agreement 7731, where the Procedural Registration Office clearly states that, "All registrations and/or documents belonging to the legal record of any proceeding must be generated under the SGT." "Notifications given at the bench, acceptance of appointments, and similar actions, shall be prepared using the SGT, and shall be printed and signed by the interested party.")

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The Honorable 2nd Chamber of the Court of Administrative Litigation is to be notified, by copy of this resolution, of these observations in respect of the aforementioned court's failure to apply the correct procedures for notifications in the case at hand.

The parties' conduct in the proceedings does not merit any special procedural sanctions.

Based on the foregoing considerations, and in accordance with Article 688 of the CC [acronym not defined in the text] and Law 16011, the COURT HOLDS THAT:

The lower court's decision is hereby confirmed, with no special sanction on the lower court.

The orders set forth in the final part of whereas clause III are hereby to be carried out.

JUDGE TABARA SOSA AGUIRRE MINISTER

JUDGE JOHN PEREZ BRGINANI MINISTER

JUDGE ALVARO JOSE FRANCA NEBOT MINISTER