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Office: Civil Appeals Court, 2nd District

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Montevideo, 10 March 2010

VIEWS:
In the definitive disposition of the appeal of the case entitled "Marquez Velazquez Antonio Gerardo vs. Ministry of Public Health and others—writ of amparo" File No. 2-53705/2009, which was brought to the attention of the Court on merit of a request for appeal by the appellant against judgment No. 11, dated 15 December 2009, decided by the Judge of the 4th Admnistrative District, Dr. Adolfo Fernández de la Vega Méndez.

RESULTING:
(I) The decision under appeal to which background the Court refers dismissed the process of amparo without special costs orders made in this instance (folios 348-363)

(II) The appellant filed the appeal on the grounds that the evidence proved that the treatment with SORAFENIB failed and that SUNITINIB is in her opinion the only drug able to increase patient survival and improve quality of life. In medicine, one can never be completely sure nor entirely dismiss that a medication or treatment will work. It is always about chances and never assured results. It is logical that due to intolerance to SORAFENIB one resorts to SUNITINIB. It is not a valid excuse that there are no studies showing evidence of its benefits so as to deny coverage; the right to life of the patient must be prioritized. The defendant has taken no action to protect the appellant, which is manifestly illegal. Ultimately, it was requested a reversal of the appeal and that the Amparo remedy be sustained so as to ensure the appellant could obtain the drug until the final disposition of the case by the TAC of the 6th district, or, according to the evidence, until a failure in treatment is detected (folios 364-368).

(III) The grievances were answered by the National Resource Foundation (Fondo Nacional de Recursos, hereinafter FNR) (folios 371-374) and by the Ministry of Public Health (hereinafter MSP) (folios 376-379). On 8 February, the appeal was allowed with suspensive effect as usual (folio 380).

(IV) On 4 March 2009, the Court received the process, the case was analyzed and the following was decided.

CONSIDERING:

(I) With the vote of its natural members, the appeal is partially allowed, dismissing part of the [lower court] decision, whose background the Court refers to, for the following reasons.

(II) The decision on appeal, to which background the Court refers to, rejected the amparo remedy after analyzing the evidence produced and to understand that there was no unlawful omissions of the defendants in their actions

(III) The rationale for dismissing the amparo claim in relation to the MSP was the understanding that there did not exist any express accusation of unlawful omission one hand and on the other hand, regarding the drug required by the appellant (SUNITINIB), it was said that the MSP performed the necessary technical and political studies which ended with the drug inclusion in the Therapeutic Drug Form (Formulario Terapéutico de Medicamentos, hereinafter FTM) Annex III by decree. Accordingly, to the extent that the FNR takes charge of the drug coverage, it was understood that the MSP acted according to the law and as such, responsibility cannot be attributed to the MSP.

The appeal will be dismissed regarding the MSP, as the Department has done, what it should have within its reach, to add the drug that is claimed to the FTM, so as to receive coverage; for that reason it was included in the FTM. Thus, it was allowed to be supplied and sold; it is the responsibility of the FNR as part of the State in a broad sense, to supply or not such drugs within the health system, such is their jurisdiction. It is therefore not appropriate for it to be provided by the MSP when, as is in the case, there exists a public entity whose specific mandate is to cover the treatment of the disease the appellant suffers.

The basis for the dismissal of the amparo in relation to the FNR was that illegitimate conduct or manifestly illegitimate conduct in refusing to provide the appellant coverage of the drug SUBITINIB was not found to exist. It was understood that there are no studies that show with the necessary degree of certainty the real benefit to the patient using it after the failure of SORAFENIB, and that this was consistent with law (folios 361-362).

For the purpose of the resolution of the present case, it should be analyzed whether all the elements of the action of amparo are met; in particular, the actual or imminent threat to a fundamental right by means of an illegitimate action or omission (art. 1 of Law No. 16.011). Also, it is important to remember that the amparo proceeds even in the case of a State Department or a government entity such as this.

The Court understands that the injury/damages sustained regarding the dismissal of the amparo initiated against the FNR are acceptable and therefore the appeal shall be revoked and the action sustained in the terms requested by the appellant.

At the time of assessing whether the FNR actions were manifestly illegitimate, it cannot be forgotten what is at clearly stake and what are the fundamental rights to be protected.

The rights claimed are related to the preservation of the right to, and the protection of, life and health that are of constitutional standing (arts. 44 and 72 of the Constitution of the Republic). They are also enshrined in the International Covenant on Economic, Social, and

Cultural Rights, as ratified by Law No. 13.751, and in the San Salvador Protocol which extends the American Convention on Human Rights, ratified by art. 10 of Law No. 16.519, and finally at the legislative level in art. 10 of Law No. 18.335.

Regarding the right to health, it has been said that, "…it is indisputable to start from the recognition of the existence of the fundamental right to protection of people's health; that this right should be implemented by the State through all available means and for the benefit of all the people; that equal access of every person to the necessary care according to their health condition and, particularly, access to the necessary medicines are an essential part of the right to health.
These rights are part of the broad meaning of legality in a constitutional State governed by the rule of law as substantive rules; and like the principle of equality and other fundamental rights, they limit and bind the executive power in different ways, excluding or imposing specific content to their regulatory activities " (Dissenting Judgment 101 of 17 July 2007 of TAC . LJU 15510 and recent decisions of this Court).

Therefore, Administrative actions in these cases are controllable; if they were not one might wonder what would be the purpose of having judges if we could not review administrative actions affecting citizens' fundamental rights.

As noted by Larenz (Civil Law, General part, pg. 254 et seq, Jaen, 1978), subjective rights are necessarily associated to other people's (or everybody's) duties, limitations, or legal relationships; the subjective right is balanced with the possibility of its imposition through action, concluding that if the person has a subjective right to that legal interest/asset, that means that she/he is entitled to this right according to law.

The illegitimate dissatisfaction of a subjective right does not harm a legitimate interest but is rather a violation of a subjective right to which protection should be procured from the Judiciary through declarative actions or special orders (Cassinelli, The guaranteed legal status of the legitimate interest in the Uruguayan Constitution, Studies in homage to Prof. Sayagués Laso, pg. 283 and following).

The problem should be approached with criteria of logic and reasonability as well as without losing sight of the appellant's illness, the reason of this case of amparo.

This patient is undergoing treatment for metastatic kidney cancer. His treating physicians, and in particular Dr. Verónica Terzieff (Oncology) requested to the FNR—after a failed treatment with SORAFENIB—to begin supplying the drug SUNITINIB (covered by the FNR). The treating physician was clear in stating that this particular patient was under consideration for this treatment because it was the only one in this instance that would benefit the patient's health condition, which could improve his quality of life, and that it is not possible to wait until we have the absolute certainty as to whether the medication requested is effective or to develop the level 1 studies required by the FNR to receive the authorization. The professional treating oncologist said that the prescription of the drug mentioned is based on her experience and refers to the case of the appellant, whose previous treatment was ineffective. She indicated that she requested the change of

treatment (from SORAFENIB to SUNITINIB) because the presented a progression in the lesion under the first and studies had suggested that such cases could benefit from using the second (SUNITINIB). Finally, it was clear in stating that they could not continue treating with SORAFENIB and the only alternative for the patient was to wait for some efficacy with the drug SUNITINIB (folios 288-289).

That which was proposed by the treating physician—and subsequently denied by the FNR—cannot be understood as a use of a therapy lacking technical rigor. As relevant here, there is no evidence of a reckless or poorly understood therapeutic innovation.

The above considerations have their own support in the expert opinion provided by Dr. Mario Varangot (Professor of Clinical Oncology) that is presented in folios 324-326, analyzed in the relevant hearing (folios 327-332).

The medical acts should be in accordance with the recognized or accepted scientific knowledge at the time in question.

In fact, years ago, it was only required to proceed in accordance with experience, with previous experimental evidence sufficiently acquired over time, as surveyed by renowned authors. However today, we cannot settle for that. The law requires that on the face of a valid therapeutic option, the prescription must have sufficient and actual scientific support and the Court understands—along with the testimony by the treating physician and the expert—that in this case there is, since the drug Sunitinib is a modern drug, accepted in central countries and included in the FTM, as suitable for the patient's pathology.

This is not the case of a treatment lacking rigor; on the other hand there is no evidence that this is a reckless or poorly understood therapeutic innovation. The treatment option chosen by the treating physician is supported, not denied,-in the opinion of the Court—by the expert in the case who said that both Sorafenib and Sunitinib exert their therapeutic effects by inhibiting an enzyme involved in a significant step in the biological activity of tumors, with the result of inhibiting their growth and multiplication, with active drugs in patients with spread kidney cancer who have not yet received treatment, or who have received other drugs. Regarding the sequential use of these with the therapeutic failure of the molecules mentioned, there is a proven high level of scientific evidence supporting the use of Sorafenib or Sunitinib sequentially as tyrosine-kinase inhibitors.

Now, for the concrete settlement of this case, it should be remembered that the physician's obligation is an obligation to provide means and not one to produce results. And in this case, the Court finds that the FNR manifest illegitimacy lies in the fact that the drug in question was accepted and included in the FTM but the FNR denies its supply or coverage because its efficacy or outcome has not been sufficiently tested. Therefore, it is appropriate to ratify and endorse Dr. Tabaré Sosa's words in his judgment in the sense that the provision of the drug was denied as if it were an obligation to produce results; the provision of the drug was subjected to proof of a high probability of efficacy. In doing that, an obligation to produce results (in this case to prolong or improve survival) had been mistaken with what is legally understood as the content of the medical service, which is an

obligation to provide means, principle established by case law since Mercier's case in 1936 decided by the French Cassation and which dealt with judicial review based on "experience data" of medicine. (Gammarra, Medical Liability, Vol. I, pg. 9, that Court ruled that the physician must provide conscientious and thoughtful care which conform to the knowledge acquired through science). Nowadays, that concept has been improved in the sense that in order to establish the model of "bonus medicus", the leading doctrine and jurisprudence convened to the "actual knowledge" of medicine so that the technical and scientific progress which improve the quality of life reach the entire population, consumers of the services provided by medical personnel. This formula sanctions that it must take into account scientific progress (Lambert-Faivre, Le droit du dommage corporel, pg. 493), all in accordance with proper medical humanism.

The medical act must conform to the scientific knowledge recognized or accepted at the time in question.

As a result, the Court understands that the technical feasibility of the drug is undisputed according to expert evidence and more specifically, to the clinical situation of the appellant in using Sunitinib after Sorafenib. What it really matters is each particular case, because as the expert concluded, it is the choice of the patient (who will potentially benefit from the drug) what would determine, according to the empirical and non-transferable medical skill in each particular case, in the doctor's office and away from generalizations, the issues that will be considered for the purposes of each treatment.

As Judge John Pérez Brignani held in his judgment, the difference in existing technical criteria between the treating physician and FNR, medical staff cannot deprive the claimant of his constitutional and legal rights conferred by the law. If such a possibility were admittted we would not only be giving the authorities a power they clearly do not possess, but we will be also legitimizing the violation of constitutional rights guaranteed by the Constitution(arts. 7, 8, 19, 44 of the Constitution).

Again, the expert in the case held that both Sorafenib and Sunitinib exert their therapeutic effect by inhibiting an enzyme involved in a significant step in the biological activity of tumor cells, with the result of inhibiting their growth and multiplication, with active drugs in patients with spread kidney cancer who had not received treatment yet, or who have previously received other drugs. Regarding the sequential use of these with the therapeutic failure of the mentioned molecules, there is a proven high level of scientific evidence supporting the use of Sorafenib or Sunitinib sequentially as tyrosine-kinase inhibitors.

The technical viability of the drug is undisputed in the case according to the expert evidence, and all tested in accordance with the rules of sound judgment (art. 140 CGP); and in cases like this where the fundamental right to life is at stake, as was expressed in the hearing (folios 329, back), the only way to know whether the drug works is to give it to the patient. The Court would unfoundedly depart from expert evidence (art. 184 CGP) if it reasoned as the "a quo' did, in the sense that the drug's effectiveness does not count with the backing of necessary scientific evidence.

If the treating physician, as in this case, understands that the best treatment and medication for his patient is the one requested, it is a technical and scientific decision that should be respected especially when it relates to a drug that has been authorized by the MSP (included in the FTM) and that is covered by the FNR. The decision of physicians to prescribe treatment with certain drugs covered by the FNR cannot be considered a minor or capricious decision, let alone subject to change or conditions of any kind, based on regulations that are obviously unable to consider the individual and unique circumstances of each patient.

The refusal of the FNR to provide the drug coverage requested by the treating physician based on regulation and fundamentally on the fact that it has not been proven by Level 1 studies, is in the opinion of the Court, manifestly illegitimate , contrary to the lower court decision, because, again,, it would mean to consider the case as an obligation to produce results which is not lawful.

The Court reiterates that the endorsement of the FNR's position confuses the physician's obligation, an obligation to provide means, with one to produce results. The aim is recovery, proper treatment, acquiring the commitment to care with diligence and care. It is unknown that in the medical field, the principle of discretion, which manifests in the election accorded to the doctor to adapt known therapeutic systems to particular circumstances of each case and in that every consumer is entitled to the least dangerous and problematic treatment available according to the technical advances of medical science, must rule. If the logic of the a-quo were followed, we would be denying the treatment that the physician understood was the appropriate according to the disease; as another drug was tried but it did him wrong. Then, the alternative left to the patient is the drug subject to this appeal and which the lower court denied.

Ultimately, the position of both, the FNR and the a-quo denying the complainant the possibility to gain a precise and real hope, which our legal system clearly confers as positive law, is illegal. It is not about trying to prove that the drug will have a successful outcome (it is impossible to test), but that it is a suitable drug to treat the condition being suffered, that there is a need for the claimed treatment and that if the drug were not supplied it would remove any likelihood of improvement (or even halt the progression of the illness).

(IV) Ultimately, the appeal is partially allowed and the amparo is sustained, in the form this Court would determine, compelling the FNR to do whatever is the necessary so the requested medication is supplied to the appellant until the final disposition of the case by the Court of Civil Appeals, 6th District, (annulment action promoted) or—according to the evidence of the case—as requested by the appellant, until the failure of the treatment is identified (see folios 331 and 368), all in accordance with the provisions of art. 198 CGP.

(V) Consideration with general character:

In the future, precaution should be taken so in an Amparo process, in which fundamental rights are at stake, procedural matters are dealt with urgency. It is not convenient that after

the last court order effecting service of the appeal, the case had taken almost a month to reach the attention of this court.

(VI) The costs and expenses will be established by the proper judicial action of the parties (arts. 56 CGP and 688 CC).

For the reasons stated and applicable provisions set forth, the Court…

FINDS:
To partially allow the appeal and in that merit order the FNR to supply the requested medication to the appellant until the time of final disposition of the case by the Court of Civil Appeals, 6th district (annulment action promoted) or -according to the evidence of the case—as requested by the appellant, until the failure of the treatment is identified in the span of five calendar days since notification of this judgment, without special costs.

In due course, notify and return the form for the justices (fees for each party, notionally 5 BPC