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Office: Civil Appeals Court, 4th District

Redactor: Dr. Juan P. Tobía Fernández
Signatories: Dr. Eduardo J. Turell
Dr. Ana M. Maggi

Case: "Rodriguez, Allison vs. Executive Power and others- writ of amparo and appeal against refusal of leave to appeal"
Case No: 2-13.991/2011

Montevideo, 26 May 2011

(I) The object of this appeal is circumscribed by the contents of the appeal filed by the codefendant against judgment No. 40, dated 8 April 2011, issued by the First Instance judge of the Administrative Tribunal of the 2nd District, Dr. Loreley Pera Rodriguez, which partially allowed the promoted action, and compelled the State—Ministry of Public Health—to deliver the drug "Cetuximab" to the plaintiff within three working days, until the time in which the abovementioned Ministry decides whether it includes it or not in the Therapeutic Drug Form, without a special award as to costs (fs. 680-694).

(II) The appellant held, concretely and concisely that the decision questioned cannot be agreed with, as the conditions required by the law to allow leave to proceed with the amparo requested have not been fulfilled.

In particular, it cannot be completely visualized what is the manifestly wrongful act by the Ministry of Public Health (hereinafter MSP), which justifies the amparo action.

In the light of all the legal dispositions that were invoked, it should be expressed that in no way was there manifest illegitimacy or omission or delay. Therefore, and considering that there is illegitimacy every time that there is an act or event contrary to law, we find that this admissibility requirement of the action pursued by the plaintiff has not been met.

The considerations expressed by the ruling judge in the decision under appeal violate the principle of separation of powers and ignore the purpose and functions that the Constitution imposed to the MSP. The Constitution and other regulations cited make the duty of the MSP to ensure proper hygiene and public health, but have never placed upon the MSP the duty as a legal obligation so as to being compelled to supply medication directly to the public. It is clear and evident that our legal system does not place the MSP as a drug dispensing body, but rather confers it the exclusive role to adopt whatever necessary means to preserve the collective health. The goals that the Constitution and the law attribute to the MSP constitute rules of immediate and unquestionable compliance, especially updating the Therapeutic Drug Form (Formulario Terapéutico de Medicamentos, thereafter FTM).

The ruling judge starts from a wrong premise in her assessment of what seems to be a manifestly illegal lack of service, as it is the fact that a drug has been approved for commercialization by the Ministry, with the fact that a drug has been included in the FTM, two entirely different procedures.

Regarding the registration of drugs for commercialization, the MSP demands certain requirements at the time of registering a drug for sale and the criteria that are taken to allow that, as determined by Decree 324/99.

This should not be confused with the technical criteria that are taken into account to decide the inclusion of a drug in the FTM and, in turdeciding to which annex it should be added.

The fact that the FDA, EMEA, Argentina, and Brazil have approved this drug does not mean that these countries supply the drugs free of charge to the public.

Contrary to what it is being articulated, the acting solicitor for the MSP expressed that the drug in question has not been included in the aforementioned form because the Secretariat has not received any formal request to proceed in that direction.

Also it is worth noting that the last FTM update was made in December 2009, according to Ministerial bylaw No. 716 in 2009, therefore the activity of reviewing the mentioned Form is being fulfilled, in order that the incorporation of the drug be analyzed should it have been suggested.

There is no illegitimate action on the part of the MSP since in fulfilling its aim to safeguard public health, it evaluates in the benefit of the population with the greatest rationality the inclusion or not of a drug in the FTM.

On the other hand, it has not been demonstrated in this case that the medication required by the plaintiff is indeed effective or that his tumor counts have been lowered. .

There is no doubt that the right to health, and within it the plaintiff's right to access the medication is not violated by the refusal to supply the drug.

It is ultimately and concretely requested that the decision appealed be reversed with the consequences inherent to that effect (fs. 696-706).

(III) From the appeal, notice was served and the summoned opposing party appeared to defended the claim rejecting in the written submissions the wrongs pleaded by the appellant, the appeal was allowed and the matter was bound over to this Court, which was prepared to issue the pending decision in legal form (fs. 708, 712-713, 715-724, 726, 739, etc.; arts. 10 and conc. Law No 16.011).
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(IV) Firstly, it must be specified that in order for the amparo to proceed, the objective elements outlined in arts. 1 and 2 of Law No. 16.011 must be satisfied, ,

In this type of summary and exceptional action, it is necessary that all objective and subjective elements provided fundamentally in arts. 1 and 2 of Law No. 16.011,be cumulatively established, since they complement each other in such a way that, "they must all concur in a conceptual structure in which one cannot be understood without the other" (Viera, The law of amparo, pg. 21).

It is a solid criterion of the Court that the substantial elements of amparo be assessed under a rigorous view, as due to its essence, and its nature as extraordinary remedy of exceptional and restrictive character, the amparo is proper only in cases in which it can be established in a clear, precise and manifest way the unlawful restriction to Constitutional individual rights, or an imminent threat that the above could reasonably occur, and only in the absence of other means of protection within the ordinary administrative or judicial procedings which would allow to secure the same result sought through the process of amparo (Viera et al, The law of amparo, pg. 14, 21, etc.; LJU, c. 10482, from Court Judgment Nos. 18/89; 13, 116/98; 123/99; 175/01; 201, 281/02; 240/04, etc.).

That art. 4, inc 2, of the law establishes a limitation or extinction period barring the right to initiate action upon expiration, because as noted, the action must be filed "…within thirty days from the date on which the act, event or omission characterized by art. 1 occurred…",

It is also the Court's opinion that the amparo does not rule out administrative proceedings that the affected party must mobilize to prevent an act from becoming final; because through an amparo it cannot be requested the inefficacy of an administrative final decision; and at the same time, to avoid any damages resulting from the time required to litigate, nothing prevents activating the amparo action to procure ,a prompt procedure that will safeguard the right or freedom allegedly wronged (widely under Court Judgment Nos. 86, 151/98; 87/02; 94/05; 66/06; etc.).

Another important note is the need to warn against the misuse of the amparo, because it neither has, nor can have, the virtue of being a generic, universal or total means, capable of substituting all actions and appeals established by law (Rippe, in ADC No. 4, pg. 2930296, from Court Judgment. cit., etc.).

With these understandings, it is considered that the wrongs raised by the appellant do not entitle to a reviewable decision of the appealed judgment , as we will try to explain next.

Initially, because it must be seen that there was not personal presentation of the plaintiff before the National Resources Fund (Fondo Nacional de Recursos, hereinafter FNR) according to the documentation tendered (see note of 22 March 2011 in fs. 67), for that reason we cannot agree with the initial statement of the appellant (fs. 626-634) about following the necessary administrative remedies (applicable provisions of Law No. 16.343 and Decree No. 358/1993), with the consequence that the legal action cannot be understood as formally disadvantaged.

Equally, in the face of the refusal to supply the medication by the FNY before this proceeding (see fs. 67), it cannot be complained that the proceedings prescribed by Law No.

16.343 and art. 10 of Decree no. 265/2006 were necessary as a gateway of the amparo proceeding tried, as the appellant has also stated .

In essence, the appellants consider, as noted by the sixth district Court (Sentence No. 36/2001 in fs. 131-141), "..that the health is a legally-protected right intimately linked to life, to the physical, moral and psychological integrity of a subject, to her/his quality of life, and to the development of his/her individuality. Before all, the right to health implies that a human being has a right to an adequate professional care, to care for it, to prevent illnesses, to find a place to be treated and to receive the necessary treatment for their recovery (cf. Bidart Campos, The socioeconomic order in the Constitution, p. 306). The right to health is, therefore, a human right and, as such, it is internationally and constitutionally protected, which enables the writ of amparo."

With these understandings, Minister Dr. Maggi finds that the appellant's argument –based on the fact that because the drug "Cetuximab" was not included in the FTM, the appellant should not be compelled to supply it through an amparo and that there was not actually unlawful action on the appellant's part– should be dismissed..

In the first place, because it was proved extensively in the proceedings that "Cetuximab" is the only medicine that the plaintiff needed to mitigate and contain her disease, as resulting from the testimony of her treating physician, Adjunct Professor, Department of Oncology, Faculty of Medicine, who is conclusive in considering that this drug combined with chemotherapy can provide a greater progression-free survival rate (see fs. 65, 653vto.-657vto.).

That is also corroborated with expert evidence annexed (fs. 660-661) which was not observed or challenged by either of the interested parties (arts. 183 and conc. CGP; Véscovi et al, General Code Process, T. 5, pg. 344 et seq.), and in relation to which there are no elements available that could enable to set it aside based on criteria about the evaluation of the evidence (arts. 140, 184, and conc. CGP; Véscovi et al., op. cit. pg. 352 et seq., from Court Judgment Nos. 80/04, 304/05; 87/07, 20/08, 286/10 and others cited therein).

In the second place,] because this is a drug endorsed both internationally (see fs. 77-85, 660-661) and nationally (see fs. 89-100, 169-443) according to the guidelines developed by the Service of Clinical Oncology (Faculty of Medicine-UDELAR) and elevated to the National Cancer Program, dated 2 February 2010.

Besides, because it was corroborated that the MSP approved its commercialization on 5 March 2009 and it entered the market on 20 March 2009 (fs. 87).

Based upon such antecedents, Minister Dra. Maggi concludes that the MSP should provide the medication to the claimant, even if it is not included in the FTM, at least during the long and complex bureaucratic application process until the drug be included, and that for the simple reason that the Ministry is responsible for preserving the health of the inhabitants, a fundamental good that cannot be subject to the contingencies of a

bureaucratic application process of this nature, that can well last months or even years; so it must be inferred that by meeting the formal requirements on which the appellant claims to base its refusal to supply the drug (inclusion in the FTM, as well as the need to comply with the technical and scientific procedures for its inclusion), the fundamental rights recognized in the Constitution are, strictly speaking, being ignored .

It is worth noting, in particular, and with relation to welfare rights, that Article 44 inc. 2 of the Constitution is clear in saying that the State shall provide without charge means of prevention and care to “people with insufficient resources,” which is the case in this case according to the income of the plaintiff (fs. 104) and the high costs of the recommended medication (see fs. 101, 653vto.-657vto.).

And furthermore, even if it has not been proven in the administrative proceeding before the MSP that any formal request for the inclusion of the drug in the FTM (by the patient or relevant health institutions) (see especially fs 653vto.-657vto., etc.) had been put forward, it is also certain that the issue here is that the plaintiff not be deprived of a medicine essential to her health during the time this whole application procedure last, measure that would be indispensable if we consider that what it is at stake is the patient possibility to stay alive.

In turn, Ministers Dr. Turell and the redactor, even when they believe that manifest illegitimacy cannot be determined in the actions of the MSP for not including the drug in the FTM, as argued in similar cases to which we remit so as to avoid repetition (TAC 5th in Judgment Nos. 108/09 and others cited therein, etc.), according to the particular details of the scientific and technical procedures for the FTM inclusion and current update system (Decree Nos. 265/2006 and 4/2010 and other applicable provisions); and that, in principle, the obligation to supply the medication to the plaintiff enabled in the judgment questioned goes well beyond the functions of the MSP related to health policy, as well it has also been determined in decisions in similar cases, to which we remit to for the sake of brevity (widely TAC 5th, in Judgment Nos. 107/09, etc.; TAC 6th, Judgment Nos. 209/09, etc.), that the confirmatory decision foretold is in the case, correct.

It must be admitted that the solution of admission (arts. 130.2, 340.3, and conc. CGP), only reaches the facts, the factual principles raised, excluding the legal arguments that could have been invoked by the appellants , understanding those as not only the specific rule that was expected to be asserted, but also the assessment of the facts in the light of legal propositions and consequences of the alleged facts, which are subject to the judge’s tasks in possibilities of intervention “iura novit curia” (from Court Judgment Nos. 224/01; 306/06; 27, 320/07; 208/08, etc.).

For this matter, according to the contents of the application filed (fs. 1420156 especially lit. D. in fs. 144vto.-145) and of the responses made by the appellant (fs. 626-637), it must be necessarily agreed that it is an admitted fact that the MSP has been found to be supplying the same drug to other patients who suffer from the same disease as the plaintiff, as appears precisely proven in the proceedings (treating physician in fs. 654vto.-657vto.; expert testimony in fs. 660-661 especially in num. 8; acord. File No. 2- 25.211/2010 in fs. 76-77,

147, 148-157, 178-183; acord. File No. 2-9750/2010 in fs. 394-419, 469- 482; acord. File No. 2-55.702/2010 in fs. 232-246, etc.).

Due to the emergency, the Court concludes that the refusal of the MSP to provide the medicine is a flagrant violation of the principle of equality laid down in Articles 8 and 72 of the Constitution, derived from the basic principle of respect for human dignity, which imposes equal treatment to every person and does not assume absolute equality as a concept of perfect equivalence, but rather to treat equals equally and different, differently in proportion to their inequality; which is to say, that while the principle of equality does not prevent the establishment of differences in treatment inasmuch as there exist significant differences, the existence and relevance of these differences must be duly justified, noting points of fact and according to reasonable criteria (cf. TAC 6th, in Judgment No. 36/11 in fs 131-141; TAC 1st in Judgment No 93/10, TAC 3rd Judgment No. 3/11; of the Court Judgment Nos. 38/11, etc.).

Indeed, the conduct of the MSP in delivering the drug to other patients and refusing to provide it to the plaintiff who suffers the same disease and who is credited with the urgent need to count with it for an adequate treatment of her sufferings, amounts to a manifest illegitimacy, because there are no differences according to the factual aspects and reasonable criteria which justify unequal treatment.

What comprehensively weakens the defense based on the fact that the MSP primary obligation is to serve the public interest and it is not its role to provide drugs in particular situations, since it cannot not exempt itself from supplying the drug in this case, is that in parallel with its own behavior, it exceeds and surpasses what it defines as its own essential aim (arts. 160, 168 No. 4, 181 inc. 8 and conc. of the Charter; Laws Nos. 9.202, 15.181, 17.930, 18.211, 18.355, and other applicable clauses) in simple performance of the so-called “estoppel doctrine” (Judgment cit. etc); which is shared by the other member of the Court

(V) There are no merits to impose special procedural penalties (arts. 688 CC; 56, 261 CGP).

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

FINDS:
To confirm the appealed judgment in the precise extent of the wrongs committed, without any special procedural penalties.
In due course, be returned