

## APPEAL OF SENTENCE IN PROTECTION ACTION

### FILE 332-2010

**CONSTITUTIONAL COURT:** Guatemala, March 10, 2010.

On appeal and considering the prior procedural instances of the case, the Court will examine the sentence handed down on October 12, 2009, by the First Chamber of the Court of Appeals for Labor and Social Security, acting as a Protection Tribunal, in the constitutional action brought by the Public Defender for Human Rights on behalf of Maynor Wilfredo Cardenas Morales, against the Board of Directors of the Institute of Social Security of Guatemala. The claimant is represented by attorney José Guillermo Rodríguez Arévalo.

### PROCEDURAL HISTORY

#### I. THE PROTECTION ACTION

**A) Presentation and jurisdiction:** The case was filed before the Center for Auxiliary Services of Judicial Administration on September 30, 2008, and later remitted to the First Chamber of the Court of Appeals for Labor and Social Security. **B) Act giving rise to the protection action:** The claimant brings the action in respect of the respondent's decision not to provide him with the drugs Rapamune and Cellcep, which the claimant requires due to a kidney transplant, which he underwent due to chronic kidney failure. The claimant argues that the medications in question are only provided to those patients who receive a positive ruling from a competent protection tribunal. **C) Violation alleged:** the aforementioned patient's rights to life, health, social security and physical integrity. **D) Facts underlying the protection action:** The claimant's argument is summarized as follows: **D.1) Occurrence of the act complained of:** a) Maynor Wilfredo Cardenas Morales suffered from chronic kidney failure, and therefore received a kidney transplant; b) the medicines that he currently takes do not prevent his levels of creatine from rising, which could result in the loss of the transplanted kidney. For this reason, he requested that the Guatemalan Institute of Social Security provide him with coverage for the drugs Rapamune and Cellcep, which request the Institute denied, based on the fact that the drugs are not covered on the Institute's basic lists; this is the act giving rise to the claim. **D.2) Damages caused as a result of the act complained of:** the claimant complains that the respondent authority failed to provide him with the drugs Rapamune and Cellcep, which are appropriate for his condition, specifically, chronic kidney failure, which puts him at risk of his body rejecting the transplanted organ. The respondent authority denied coverage of the drugs despite the fact that they have been proven to be more effective, given that they provide a higher probability of success with the transplanted organ. The Court should therefore order that the respondent authority include the medications in question in its basic list, as the failure to include them would result in a violation of the claimant's rights to life, health and social security as guaranteed by the Political Constitution of the Republic of Guatemala, and other laws that protect life as the most fundamental of rights, and around which all other rights revolve. **D.3) Petition:** the claimant requests that the protection action be accepted by the Court, and, as a result, that the respondent authority be ordered to provide coverage of the medicines Rapamune and Cellcep, in the quantity and of the quality

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necessary for the healthy functioning of the claimant's transplanted organ. **E) Use of resources:** none. **F) Applicable law:** The claimant cites to paragraphs a) and b) of Article 10 of the Law of the Protection Action, Personal Liberties and Constitutionality. **G) Laws violated:** The claimant cites to Articles 3, 93, 94, 95 and 100 of the Political Constitution of the Republic of Guatemala.

## II. PROCEDURE OF THE PROTECTION ACTION

**A) Interim protective measures:** Granted. **B) Interested third parties:** The Office of the Attorney General. **C) Respondent's brief:** The respondent authority gave a detailed account of its beneficiary Maynor Wilfredo Cardenas Morales' clinical history, including a list of the medications that the patient receives for his illness, and which does not include the drugs Rapamune and Cellcep. **D) Evidence:** **a)** a certified copy of the Guatemalan Institute of Social Security's report; **b)** the complaint presented by Maynor Wilfredo Cardenas Morales before the Office of the Public Defender for Human Rights; **c)** memorandum REF.USSS—five hundred and three—sixteen—seven—two thousand eight (Ref.USSS-503-16-sept-2008) presented by Kattyna Elizabeth Acuna, with approval of Dr. Silvia Navarette Arias, Coordinator of the Division of Supervision of Health Services of the Office of the Public Defender for Human Rights; **d)** other legal and human rights arguments; **E) Decision of the lower court:** The Third Chamber of the Court of Appeals for Labor and Social Security, acting as a Protection Tribunal, **found that:** *"(...) The right to health guarantees equality of treatment in order to allow all persons to enjoy such opportunities and facilities as guarantee their physical, mental and social well-being. It is the State's duty to guarantee the full and free exercise [of such right] through the entities created by the Constitution and the legislature, as well as to take appropriate measures to ensure the protection of the public health and individuals' health, and to make available to all persons those services that are necessary to satisfy their basic needs. The right to social security has been instituted as a mechanism for the protection of life, which has as its fundamental purpose the provision of medical and hospital services that tend to preserve, protect or recover the health of the inhabitants of the country through medical treatment that necessarily must include coverage from the time of the patient's diagnosis until he or she has recovered his or her health. Such rights are guaranteed by Article 100 of the Political Constitution of the Republic of Guatemala, which guarantees the right to social security for the benefit of the nation's inhabitants, through an obligatory public service system. This right is to be enjoyed by all persons who are affiliated with the social security system configured by the Guatemalan Institute of Social Security, which establishes its own internal rules and regulations in respect of the system of authorizations of the provision of the Institute's medical and hospital services, in accordance with Articles 28, paragraph d, and 31 of the Organic Law of the Guatemalan Institute of Social Security. In the case at hand, this Court finds that Mr. MAYNOR WILFREDO CARDENAS MORALES is affiliated with the Guatemalan Institute of Social Security, and was diagnosed 14 years ago with chronic kidney failure, for which condition he has received treatment from the Guatemalan Institute of Social Security. However, the medications that currently serve his needs, RAPAMUNE and CELLCEP,*

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*which the claimant indicates are essential for the kidney transplant he received, are not covered by the Guatemalan Institute of Social Security's list of basic medicines. This is a serious situation, given that while the respondent authority considers the provision of the medicine and its inclusion in the basic list, MAYNOR WILFREDO CARDENAS MORALES' health, and life, are at risk. This situation constitutes a violation of Articles 3, 93, 95 and 10 of the Political Constitution of Guatemala, Article 4, numeral 1, of the International Covenant on Civil and Political Rights, and Article 12 of the International Covenant on Economic, Social and Cultural Rights (these international instruments are applicable in accordance with Article 46 of the Constitution). This Court, acting as a Protection Tribunal, concludes that the protection requested by MAYNOR WILFREDO CARDENAS MORALES should hereby be granted, in order to protect his rights to life, health and social security. The decision not to grant this preventative protection action would affect his fundamental rights, and clearly would result in serious and irreparable harm. In accordance with Article 45 of the Law of the Protection Action, Personal Liberties and Constitutionality, payment of costs is obligatory in the event that a protection action is granted. However the Tribunal may exonerate the responsible party from such payment when in the opinion of the Court, such party has acted in good faith. Given that the actions of the respondent authority fall within this latter category, the Court exonerates it from payment of costs (...).” **The Court therefore ordered:**“...I) The protection action brought by the Public Defender for Human Rights in respect of the direct and imminent threat to the health and life of MAYNOR WILFREDO CARDENAS MORALES caused by the failure of the Guatemalan Institute of Social Security to take appropriate measures in his case, by providing him with the medicines RAPAMUNE and CELLCEP, in such quantity and of such quality as required, in accordance with the lex artis, is hereby granted. II. The Guatemalan Institute of Social Security is hereby ordered to take the necessary actions to ensure that MAYNOR WILFREDO CARDENAS MORALES is able to fully enjoy his constitutional rights, and, as a result, to guarantee to him appropriate medical treatment in respect of his kidney transplant, which he received due to chronic kidney failure. III) For the reasons set forth herein, the respondent authority is not ordered to pay costs. So notified. (...)”*

### **III. APPEAL**

The respondent authority appealed the decision.

### **IV. ARGUMENTS BEFORE THE COURT.**

**A) The claimant** stated that the lower court's decision on the protection action in question is in keeping with the law and the appropriate procedural instances, and requests that the lower court's decision be upheld. **B) The respondent authority** argued that the action was not admissible, given that patients are provided with the appropriate medication in accordance with their respective diagnoses, and if any change is made to that system, such change must be made in accordance with the specific case in question. As the medication that the Office of the Public Defender for Human Rights requests be provided to the patient is not included in the Institute's basic registry of drugs, the drug cannot be provided to the patient. The respondent also indicated that

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the lower court's decision was detrimental to its interests, as the lower court exceeded its jurisdiction in resolving the claimant's petition, and sought to order the Institute to include the medications Rapamune and Cellcep in its basic registry of drugs, without taking into account that the patient was being provided with other drugs that were appropriate for his condition, and which have had satisfactory results in other patients. The lower court's decision, by ordering the respondent to provide the aforementioned drugs, was therefore affecting the Institute's autonomy. The respondent requested that the appeal be dismissed, the lower court's decision be overturned, and the protection action denied. **C) The Office of the Attorney General, as an interested third party**, did not appear at the hearing. **D) The Public Ombudsman** stated that it agreed with the lower court's decision, given that it is the State's responsibility to protect and safeguard human life and health, and if Maynor Wilfredo Cardenas Morales is not provided with the drugs Rapamune and Cellcep, which are indispensable for the treatment of the condition from which he suffers, his rights to life and health would be violated. The Ombudsman requested that the lower court's decision be upheld, and as a result, that the protection action be definitely granted.

#### WHEREAS

- I -

This Court has held on numerous occasions that it is an inalienable principle that the State's highest purpose is to protect the public interest. This Court has also confirmed that the State, among other functions that it exercises for this purpose, provides social security to its citizens. By legal mandate, this duty is assigned to the Guatemalan Institute of Social Security. This is a public, national, unified and obligatory responsibility.

The protection action will proceed in respect of any act or omission of a public authority or a private citizen that actually or imminently harms, restricts, alters or threatens those rights recognized by the Political Constitution of the Republic of Guatemala, treaties and the law, in a manifestly arbitrary or unlawful manner.

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The Public Defender for Human Rights brings this protection action against the Guatemalan Institute of Social Security, indicating that the act complained of is Institute's denial of coverage of the drugs Rapamune and Cellcep to Maynor Wilfredo Cardenas Morales, in order to improve his chances of a successful kidney transplant.

The claimant argues that the respondent authority failed to provide him with the drugs Rapamune and Cellcep, which are appropriate for his medical condition, specifically as a patient who has suffered from chronic kidney failure, and could be at risk of losing a transplanted kidney, despite the fact that it is has been proven that the aforementioned medicines are the most effective in these cases, as they offer the greatest probability that the patient's body will not reject the transplanted organ. The respondent authority should therefore be ordered to include the drugs in question in its basic registry of drugs, as the failure to do so would result in a violation of the claimant's rights to life, health and social security as guaranteed by the Political Constitution of the

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Republic of Guatemala and other applicable laws that protect the right to life as the most fundamental human right, around which all other human rights revolve.

- III -

From its analysis of the facts of the case, the Court observes that the claimant suffers from chronic kidney failure, and as such received a kidney transplant, in respect of which procedure the respondent authority has provided him with various medications, but not Rapamune and Cellcep, which, according to the Guatemalan Institute of Social Security, cannot be provided to the patient, as they are not included in the Institute's basic registry of drugs.

In this respect, the Constitutional Court considers that it would be improper to attempt to determine the appropriate medication for the patient's health problems without specific information relating to the patient who is requesting constitutional protection, and without the corresponding professional recommendation and prescriptions, as such a determination exceeds the technical and legal scope of this Court's expertise. Therefore, it must be taken into account that the Guatemalan Institute of Social Security is responsible for the quality of the medications it provides coverage for, in accordance with relevant clinical criteria that are sufficiently proven and verified by scientific testing, according to the condition of the individual patient and in accordance with his or her corresponding medical prescription, as well as for refraining from providing coverage for medications that may put the patient's health at risk, in accordance with each patient's specific course of treatment. Nevertheless, this Court considers that it must grant the protection action in the case at hand, but within the reasonable scope of the constitutional protections to which the claimant has a right, and respecting, in accordance with the dispositive principle, the patient's preference and his own acceptance of the risk of taking the drugs in question, and without limiting the respondent authority's right, always at its own risk and liability, to provide coverage for other drugs that, according to the proven and determined scientific criteria as described above, it considers appropriate for the medical conditions of its patients.

As a result, the Guatemalan Institute of Social Security must: **a)** undertake a complete and specific medical evaluation of the claimant, in order to provide him with the appropriate medications, according to his particular condition, and with the objective of preserving his life and health. This necessarily implies maintaining his medical assistance (out-patient and hospitalization services, as required), the appropriate medical treatment (including those drugs that the medical evaluation determines to be the most appropriate for his condition), and any other medical services that tend to preserve his life and health, with the timeliness that the case deserves and taking into account the individual circumstances of the patient; and **b)** keeping in mind the same considerations, the aforementioned Institute shall also confirm, through observation of the patient, after having undertaken the respective studies, and any other necessary clinical procedures, the appropriateness and effectiveness of the drugs prescribed to him. In addition, the protection granted under this action shall require the respondent authority to attend to any negative effects that may result from the medicines in question, as well as from any other medications

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prescribed under the patient's course of treatment, in order that, in accordance with the respondent authority's obligations, such information may be provided to the Ministry of Public Health and Social Assistance, so that in turn, in accordance with the applicable law, the appropriate measures may be taken in the case at hand, including, as appropriate, that any medical approvals be suspended or revoked for medications that are shown to be neither safe nor effective.

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As a result of the foregoing, the protection action requested is hereby granted, in the terms under which the petition was formulated, for the reasons set forth herein. Given that the lower court also determined that the protection action should be granted, the sentence under appeal is hereby upheld.

#### **APPLICABLE LAW**

Articles 265, 268, and 272, paragraph c), of the Political Constitution of the Republic of Guatemala, Articles 1, 5, 6, 8, 27, 42, 44, 49, 50, 52, 53, 55,58, 60, 61, 67, 149, 163, paragraph c), and 185, of the Law of the Protection Action, Personal Liberties and Constitutionality; and Article 17 of Agreement 4-89 of the Constitutional Court.

#### **THEREFORE**

The Constitutional Court, in base of the foregoing and the cited legal provisions, orders that: **1)** The decision of the lower court in the protection action brought by the Public Defender for Human Rights in favor of Maynor Wilfredo Cardenas Morales is hereby **confirmed**, with the following modification, in order that the respondent authority undertake the following actions in accordance with the granting of the protection action: **a)** the respondent authority shall immediately refrain from providing the patient with any pharmaceutical products that have not been previously classified as appropriate for his particular health condition, in order to preserve his life and an appropriate health condition, and that have not been prescribed to him by a medical professional. The respondent authority must notify the lower court, by official letter, within three days regarding its compliance with this order. As a result, the respondent authority shall, with the claimant to assume any risk associated therewith, continue to provide the claimant with coverage for the medications that are the subject of this protection action, referred to as "RAPAMUNE and CELLCEP", in the quality, quantity, and in all other aspects as appropriately prescribed to the patient by a medical professional; **b)** in the event that any complaint or information is received in respect of any negative effects as a result of the administration of the pharmaceutical products prescribed to patients that suffer from the same condition as the claimant, the respondent authority shall take the appropriate measures in order to verify the circumstances, and communicate this information to the Ministry of Public Health and Social Assistance, through the Department for the Regulation and Control of Pharmaceutical and Related Products, of the General Office for Regulation, Monitoring and Control of Public Health, the entity responsible for monitoring pharmaceuticals; and **c)** the respondent authority is hereby ordered to comply with the letter of this decision,

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under penalty of a fine in the amount of four thousand quetzals, without prejudice to any other attendant civil or criminal penalties. III) So notified, case files to be returned to the lower court, with certification of the present decision.

**JUAN FRANCISCO FLORES JUÁREZ**  
**CHIEF JUSTICE**

**ROBERTO MOLINA BARRETO**  
**JUSTICE**

**ALEJANDRO MALDONADO AGUIRRE**  
**JUSTICE**

**MARIO PÉREZ GUERRA**  
**JUSTICE**

**GLADYS CHACÓN CORADO**  
**JUSTICE**

**AYLIN ORDOÑEZ REYNA**  
**CLERK OF THE COURT**

#### **CLARIFICATION AND EXTENSION**

##### **FILE 332-2010**

**CONSTITUTIONAL COURT:** Guatemala, April 16, 2010.

The Court will consider the petition for clarification and extension presented by the Guatemalan Institute for Social Security, against the decision handed down by this Court on March 10, 2010, on appeal in the constitutional protection action brought by the Public Defender for Human Rights on behalf of Maynor Wilfredo Cardenas Morales, against the Board of Directors of the Institute of Social Security of Guatemala.

#### **PROCEDURAL HISTORY**

##### **I) REGARDING THE FACTS UNDERLYING THE PROTECTION ACTION AND THE LOWER COURT'S RULING:**

In the constitutional proceedings in respect of which the appeal now to be resolved was brought before the Court, the claimant, Maynor Wilfredo Cardenas Morales, indicated that the respondent authority violated his rights by denying him coverage for the drugs Rapamune and Cellcep, which are essential for his medical condition, as a person who had received a kidney transplant in order to treat his condition of chronic kidney failure.

In requesting the protection action, the claimant indicated that the respondent authority had denied him coverage of adequate medications for his health condition, despite the fact that, due to his medical condition of chronic kidney failure, he had received a kidney transplant, and as such, without the appropriate medication, his life was at risk. This denial of coverage violated his rights to life, health, and social security, as guaranteed by the Political Constitution of the Republic of Guatemala, and other applicable laws that protect the right to health, a fundamental human right around which all other rights revolve.

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The lower court, acting as a Protection Tribunal, granted the constitutional protection action, and as a result, ordered the respondent authority to take action in order to guarantee Maynor Wilfredo Cardenas Morales's full enjoyment of his constitutional rights, in the quantities and qualities as required in accordance with the *lex artis*.

## **II) REGARDING THE APPEAL AND THE COURT'S DECISION IN THE SECOND INSTANCE:**

The Guatemalan Institute of Social Security appealed the decision. In making its decision, this Court, among other issues, considered that although the Guatemalan Institute of Social Security could obtain other pharmaceuticals for its affiliates that it considered medically adequate to an appropriate scientific degree of certainty, it could not vary the coverage for the drugs referred to by the Public Defender for Human Rights in its complaint in the case of Maynor Wilfredo Cardenas Morales, as the patient does not have a medical diagnosis that indicates that the provision of the drugs in question should be suspended or changed, and that the other available drugs were not in any way superior to the drugs prescribed for him. In sum, the Court ordered the respondent authority to act in accordance with the needs of the patient's progressive health status, which it should analyze, evaluate and make a decision regarding, under its own strict liability.

As a result, the Guatemalan Institute of Social Security must: **a)** undertake a complete and specific medical evaluation of the claimant, in order to provide him with the appropriate medications, according to his particular condition, and with the objective of preserving his life and health. This necessarily implies maintaining his medical assistance (out-patient and hospitalization services, as required), the appropriate medical treatment (including those drugs that the medical evaluation determines to be the most appropriate for his condition), and any other medical services that tend to preserve his life and health, with the timeliness that the case deserves and taking into account the individual circumstances of the patient; and **b)** keeping in mind the same considerations, the aforementioned Institute shall also confirm, through observation of the patient, after having undertaken the respective studies, and any other necessary clinical procedures, the appropriateness and effectiveness of the drugs prescribed to him. In addition, the protection granted under this action shall require the respondent authority to attend to any negative effects that may result from the medicines in question, as well as from any other medications prescribed under the patient's course of treatment, in order that, in accordance with the respondent authority's obligations, such information may be provided to the Ministry of Public Health and Social Assistance, so that in turn, in accordance with the applicable law, the appropriate measures may be taken in the case at hand. The foregoing was also given in response to the argument referring to the fact that the products in question did not appear in the preferred drug registries. The constitutional protection was granted, in order to protect the fundamental rights of Maynor Wilfredo Cardenas Morales, which the respondent authority's decision had violated.



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The constitutional protection requested was confirmed on appeal, through the Court's sentence issued on March 10, 2010, and the respondent authority was ordered to *"notify the lower court, by official letter, within three days regarding its compliance with this order."*

### **III) THE ARGUMENTS FOR THE PETITION TO CLARIFY AND EXTEND:**

In the case at hand, the petitioner makes reference to the section of the decision on appeal that states that, *"The respondent authority must notify the lower court, by official letter, within three days regarding its compliance with this order."* The petitioner indicates that the Court did not specify at what point the three-day period in which to inform the lower court would begin to run, and therefore the petitioner considers that the Court's decision must be clarified and extended, in order to indicate the precise instance from which the period in which to comply with the Court's order would begin to run.

#### **WHEREAS**

- I -

Article 70 of the Law of the Protection Action, Personal Liberties and Constitutionality establishes that, *"when the provisions of a resolution or decision are unclear, ambiguous or contradictory, a clarification thereof may be requested. If any aspect of the matters over which the protection action was decided were not resolved, an extension of the decision may be requested."*

- II -

In its review of the petitioner's arguments, the Court notes the decision that is the subject of the petition clearly does not fall under any of the provisions of Article 70 of the relevant law that would require its extension, as no point of the decision in the protection action was left without a resolution. However, it is true that the Court did not specify at what point the period for effective compliance with its order would begin to run, which does require the Court's clarification. In this respect, the Court hereby specifies that the aforementioned three-day period will begin to run from the moment that notification of this decision is published, in light of the nature of the right in question.

In light of the foregoing, the petition for extension is dismissed, and the petition for clarification is granted, in accordance with the terms set forth in the previous paragraph.

#### **APPLICABLE LAW**

Articles 265, 268, and 272, paragraph i), of the Political Constitution of the Republic of Guatemala, Articles 71, 149, 163, paragraph i), and 185, of the Law of the Protection Action, Personal Liberties and Constitutionality; and Article 1 of Agreement 1-2009 of the Constitutional Court.

#### **THEREFORE**

The Constitutional Court, in base of the foregoing and the cited legal provisions, orders that: **I)** As of the present date, attorney Edgar Augusto Sec Quexel is participating in these proceedings. **II)** The petition for extension presented by the Guatemalan Institute

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of Social Security is hereby dismissed. **III)** The petition for clarification presented by the Guatemalan Institute of Social Security is hereby granted, and as a result, the Court clarifies that the three-day period referred to in its decision on appeal is to run as of the time that notification of this decision is published, in light of the nature of the right in question. **IV)** So notified.

**ROBERTO MOLINA BARRETO**  
**CHIEF JUSTICE**

**JUAN FRANCISCO FLORES JUÁREZ**  
**JUSTICE**

**ALEJANDRO MALDONADO AGUIRRE**  
**JUSTICE**

**MARIO PÉREZ GUERRA**  
**JUSTICE**

**GLADYS CHACÓN CORADO**  
**JUSTICE**

**MARTIN RAMON GUZMAN HERNANDEZ**  
**CLERK OF THE COURT**