

## **DIRECT INCONSTITUCIONALITY**

### **ACCUMULATED CASE FILES Nos. 355-92 AND 359-92**

**THE CONSTITUTIONAL COURT, WITH PRESIDING JUDGE EPAMINONDAS GONZÁLEZ DUBÓN, AND SITTING JUDGES ADOLFO GONZÁLEZ RODAS, JORGE MARIO GARCÍA LAGUARDIA, GABRIEL LARIOS OCHAITA, JOSEFINA CHACÓN DE MACHADO, JOSÉ ANTONIO MONZÓN JUÁREZ AND RAMIRO LÓPEZ NIMATUJ.** Guatemala, the twelfth of May of the year nineteen ninety-three.

The cases before the Court for its resolution are the accumulated unconstitutionality actions brought against Decree 28-92 issued by the Congress of the Republic, the Law of Liberation of the Importation of Medicines, brought by attorney Ricardo Alfonso Umaña Aragón and the Guatemalan Association of Pharmacists and Chemists. The first claimant appeared in representation of himself, along with his attorneys Juan Carlos Lobo Sandoval and María Claudia Toledo Sarti; the second claimant is represented by attorneys Gabriel Orellana Rojas, Norma Ondina Gudiel Aldana de López and Alfonso Rafael Orellana Stormont.

### **BACKGROUND OF THE CASE**

#### **I. LEGAL BASES FOR THE CHALLENGE**

**A) Ricardo Alfonso Umaña Aragón** stated that: **1)** Decree 28-92 of the Congress of the Republic was intended to provide consumers with economic and practical options for the acquisition of medicines, but, by so doing, it eliminated basic formalities such as that medicines have an expiration date, come with instructions in Spanish, and that government laboratories test them, which result in the unconstitutionality of the decree. **2)** The challenged decree violates the following provisions of the Constitution: **a)** Article 4, which guarantees the right to equality. The liberalization of the importation of medicines, and the requirement of only a health certificate and a certificate of free sale issued by the country of origin, and the overturning of any regulation or law that restricts the marketing of such medicines, result in discriminatory treatment between the requirements for the production and marketing of national medicines as compared to those for foreign medicines, given that national products are subject to a series of requirements established by the Health Code and by tax, intellectual property and professional practice laws, among others, while the challenged law eliminates all obstacles and formal procedures in respect of both health and tax regulations for medicines produced abroad. In addition, unlike national products, foreign products are not subject to any labeling requirements, or requirements regarding instructions for their preparation or dosage. **b)** The challenged law violates Articles 39 and 42, which guarantee rights to private, intellectual and industrial property, by allowing foreign medicines to enter the country and deregulating the marketing of such medicines. In addition, the cited Decree eliminates the exclusivity conferred on registered trademarks and patents, by preventing their owners from bringing claims in respect of conduct that would normally constitute an infraction of such owners' rights. **c)** Article 46 of the Constitution establishes the preeminence of international human rights treaties over domestic law, which means that if a law violates one such treaty, such law automatically is also in violation of this constitutional provision. This is the case here, because the challenged Decree ignores the exclusivity of registration that is conferred upon trademarks registered with the Intellectual Property Registry, thereby violating Articles 23 and 26 of the Central American Convention for the Protection of Industrial Property, Article 30 of the Law on Patents, Utility Models, Drawings and Industrial Designs, Article 17.1 of the Universal Declaration of Human Rights, and Article 21 of the American Convention on Human Rights, all of which protect individual and collective intellectual property. The Decree also violates Articles 12 and 26 of the International Covenant on Civil and Political Rights, which provide for equality of rights and non-discriminatory treatment, by imposing requirements on Guatemalan manufacturers that do not apply to foreign

manufacturers, thereby resulting in unequal treatment. **d)** The challenged Decree also violates Articles 93, 94, 95 and 96 of the Constitution, which guarantee and protect the health of the inhabitants of the Republic and order the State to control the quality of pharmaceutical products, as the Decree does away with existing quality control measures, imposing, as its sole requirement, the presentation of a health certificate and a certificate of free sale issued by the country of origin, and establishing that the Ministry of Public Health and Social Assistance will exercise control only in the case of drugs that may result in addiction. **e)** Article 119, paragraph i), provides for the defense of consumers and users in respect of quality control of products for both domestic consumption and for export, in order to protect health, safety and legitimate economic interests. In this respect, the challenged Decree orders the free importation of medicines, allowing any person to import medicines, including those not registered with health offices. The Decree also eliminates the control of the Ministry of Public Health and Social Assistance. Both of these provisions of the Decree are completely contrary to the aforementioned constitutional provision. **f)** Article 154 of the Political Constitution of the Republic establishes that public powers cannot be delegated, which Decree 28-92 passed by the Congress of the Republic contravenes, as it delegates to foreign powers the power and responsibility of the State to control medicines, given that for the importation of drugs it imposes the sole requirement of a certificate of free sale and a health certificate, both issued by the country of origin. In addition, the Article 5 of the challenged Decree overturns any law that restricts or prohibits the commercialization of medicines, accepting the aforementioned foreign control as the only oversight. **B) The Guatemalan Association of Pharmacists and Chemists** stated that: **1)** The Law of Liberation of the Importation of Medicines violates the principle of reasonability of the law, which requires "that a law and its components be consistent with the spirit of the Constitution," for the following reasons: **a)** the legislature has sought to deprive the State of one of its fundamental obligations, which is the constitutional power to control the quality of consumer products; **b)** the Law undermines the constitutional mandate that requires the State of Guatemala to orient its economic policies toward the defense of consumers and users by ensuring the quality of consumer products; **c)** the Law limits the State's control solely to drugs that may result in addiction; the legislature forgets the danger posed by the use of medicines, given that medicines may be toxic and have side effects. **2)** By providing that any natural or legal person may import medicines, with the sole requirement of the presentation of a health certificate and a certificate of free sale issued by the country of origin of the product, and by overturning any regulation or law that prohibits or restricts the commercialization of medicines, the Law violates Article 87 of the Constitution, which provides that, "Legal dispositions may not be promulgated that authorize privileges to the detriment of those who hold a degree that entitles them to exercise their profession or of those who have been legally authorized to exercise such profession." **3)** The Law also violates Article 96 of the Constitution, by removing the State's power to control the quality of alimentary, pharmaceutical and chemical products, as well as all products that may affect the health and well being of the nation's inhabitants. In addition, the Law violates Article 4 of the Constitution, as well as Article 24 of the American Convention on Human Rights, which uphold the principle of equality, given that only imported medicines are exempt from the requirements of state controls, while domestically produced products are subject to control and oversight requirements. **4)** The challenged Decree is unconstitutional because it affects the rights previously acquired by the titleholders of the registrations and authorizations for the commercialization and consumption of certain products in our country. This results in a retroactive application of the law, by affecting legitimately acquired rights. **5)** By overturning any provision that contradicts, restricts or prohibits the commercialization of medicines, the Law completely overturns the Health Code, as well as Articles 304, 307, 309, 310 and 336 of the Penal Code, in contravention of Articles 93, 94, 95 and 96 of the Political Constitution of the Republic.

## **II. UNCONSTITUTIONALITY PROCEDURES**

No injunction was ordered. Audiences were held within the legally prescribed period with the Public Ministry, the Congress of the Republic, the Ministry of Public Health and Social Assistance, the Ministry of Economics, the Ministry of Public Finance, the Guatemalan Chamber of Commerce, the Guatemalan Chamber of Industry and the Guatemalan Association of Physicians and Surgeons. The date and time were duly published for each of the audiences that were open to the public.

### **III. SUMMARY OF THE PARTIES' ARGUMENTS**

**A)** During the audience: **1)** The Chambers of Commerce and Industry stated that: **a)** The State's highest purpose is to protect the common good, and part of the State's responsibilities in order to achieve this purpose is to protect all people, by guaranteeing them health, social security and social assistance. In order to achieve these ends, Article 96 of the Political Constitution of the Republic sets forth that the State will control the quality of alimentary, pharmaceutical, chemical and all other products that may affect the health and well-being of its inhabitants. In light of this, Article 1 of the challenged Law is unconstitutional, given that it seeks to remove the State's power to control the quality of pharmaceutical, chemical and other products that may affect the health and well-being of its inhabitants; **b)** Article 2 of the Law of the Liberation of Importation of Medicines contradicts the principle of equality in accordance with the fourth article of the Constitution, by establishing discriminatory treatment in respect of the requirements for pharmaceutical products to enter into the country, given that all health requirements are eliminated for products produced in foreign countries, while products produced domestically by local industries remain subject to the health laws, such as the health certificates issued by the Department of Registration and control of Medicines of the General Office of Health Services of the Ministry of Public Health and Social Assistance; **c)** Article 1 of the challenged Decree, by allowing importers to be responsible for the quality of pharmaceutical products, violates Article 154 of the Constitution, which provides that public powers cannot be delegated, as it eliminates the requirement that such products must have health certificates, through which a product is certified to comply with the specifications and chemical and pharmacological characteristics for human use, and this power is delegated to the State, acting through the Ministry of Public Health and Social Assistance; **d)** Article 3 of Decree 28-92, passed by the Congress of the Republic, violates Articles 39 and 42 of the Constitution by doing away with the previously acquired rights of the titleholders of the registries and authorizations for the commercialization and consumption of certain products in our country; **e)** Article 4 of the aforementioned Decree also contradicts the principle of equality, as it establishes a discriminatory treatment in respect of the requirements for pharmaceutical products to enter the country, given that in respect of such products, all obstacles for importation are eliminated, including the requirement of the health certificate, while domestic products remain subject to a large number of difficulties, formalities and requirements. This principle is also violated by Article 5 of the aforementioned Decree, which establishes a discriminatory treatment between imported medicines, which are exempt from any payments or fees in respect of their registration or analysis, while products produced by domestic industries are required to pay all tariffs imposed for these purposes. In addition, the aforementioned article is so broadly drafted as to result in the total revocation of the Health Code, of those articles of the Penal Code that refer to the subject matter of the violation, as well as to Articles 93, 94, 95 and 96 of the Political Constitution of the Republic.

**2)** The Ministry of Public Health and Social Assistance stated that: **a)** Decree 28-92, passed by the Congress of the Republic, may result in the commercialization of medicines that pose a risk to public health, by allowing the importation and commercialization of foreign pharmaceutical products without the corresponding health records and controls, through which quality control of consumer products is achieved, and which control is the obligation of said Ministry, acting through its distinct branches. The Decree thereby violates and undermines the constitutional mandates that require the safeguarding of the lives and health of the nation's inhabitants; **b)** Article 1 of the challenged Decree is unconstitutional because it provides that the importer will be responsible for the quality of the products he or she imports, in violation of Article 96 of the Constitution, by releasing product manufacturers from liability and eliminating the State's public power to control

the quality of consumer products; **c)** Article 2 of the challenged Decree is also unconstitutional, as it violates the fourth article of the Political Constitution of the Republic, by providing for discriminatory treatment between domestic pharmaceutical products, requiring that such products be subject to registration through a health certificate with its respective controls, while foreign products are only required to provide a health certificate and a certificate of free sale issued in the country of origin for importation, which do not demonstrate fully and credibly that these products are safe, effective, and of good quality. In addition, the law violates Article 96, by delegating to other countries, and to authorities other than the Guatemalan authorities, a public power that belongs to the State of Guatemala, to exercise through its own institutions; **d)** Articles 4 and 5 of the aforementioned Decree tacitly overturn all underlying provisions contained in the Health Code and its regulations in respect of medicines and their commercialization. **3)** The Public Ministry stated that the challenged Decree is not unconstitutional, for the following reasons: **a)** it does not violate the fourth article of the Constitution, because there is no unequal treatment within the same class of products; that is, domestic manufacturers may import medicines if they consider it convenient. There would be unequal treatment if domestic manufacturers did not have this right; **b)** Article 39 of the Constitution is not violated, given that intellectual and industrial property remains protected. The only thing that is occurring under the Decree is that any person may import medicines and sell them in the country through a simple purchase and sale process, without any impact on industrial or intellectual property. Author's and inventor's rights are not violated, given that free importation does not result in a violation of such rights, and protection of trademarks and patents remains in place, given that if the sale of a product is legal in foreign countries, it is also legal in any other country; **d)** Articles 94, 95 and 96 of the Constitution are not violated, given that permitting the free importation of medicines does not mean that the Ministry of Public Health and Social Assistance cannot impose certain controls, inspections or oversight over imported medicines; **e)** with respect to the argument that public powers are not delegable, Article 154 of the Constitution provides that such power is delegable in those cases established by the law, and Decree 28-92, passed by Congress, is a law, and has determined to accept foreign controls of certain products. Therefore there is no unconstitutionality. **4)** The Ministry of Public Finance stated that: **a)** Decree 28-92, passed by the Congress of the Republic, intends to provide the Guatemalan public with access to medicines, and the sole requirement for the importation of such medicines is the provision of a health certificate and a certificate of free sale issued by the country of origin. These requirements will ensure the health, hygiene, and essential requirements for the consumption of such products, given that health requirements in all countries are similar. The majority of medicines are produced by international laboratories health, hygiene and quality standards similar to those of Guatemala, making it unnecessary to impose new internal control mechanisms for these products in our country; **b)** the principle of equality means that the same treatment must be provided for the same things, and different treatment for different things. It is not the same thing to be a producer as to be an importer, and therefore, producers and importers are not required to receive the same treatment under the law, and therefore, in the present case, the principle of equality is not violated; **c)** Articles 39 and 42 of the Constitution are not violated, because the challenged law is of a general character and benefits the common good, and therefore promotes the public interest over individual interests, thereby benefiting the population as a whole, and particularly those with limited economic means; **d)** one of the claimants states that the challenged Decree is unconstitutional because it violates Article 30 of the Law of Patents, Utility Models, Drawings and Industrial Designs, which is not the case, given that if an unauthorized use of a registered trademark or patent is identified and proven, this will result in a tort or crime punishable under the laws of the country; **e)** Articles 93, 94, 95 and 96 of the Constitution are not violated, given that the purpose for which the challenged Decree was issued is to guarantee the health of the country's inhabitants, by providing them with easy and direct access to necessary medicines. **5)** The Association of Guatemalan Physicians and Surgeons stated that: **a)** Decree 28-92, passed by the Congress, is unconstitutional, as it violates various constitutional provisions, and

violates the human rights of Guatemalan citizens; **b)** in accordance with Article 96 of the Constitution, the State will control the quality of alimentary, pharmaceutical, chemical and all other products that may affect the health and well-being of the nation's inhabitants, and therefore no authority may issue any regulation that releases the State from its responsibility to provide control of medicines, and to delegate such responsibility to private parties; **c)** it is of the same opinion as the Guatemalan Association of Pharmacists and Chemists, in respect of the fact that if the challenged Decree remains in effect, public health could be put at serious risk due to the poor quality of products that could enter the market, with consequences ranging from medicines that provide ineffective treatment, to mass outbreaks of public illness, as has occurred in other countries. **B)** On the day of the hearing: **1)** the claimant Ricardo Alfonso Umaña Aragón responded to the arguments of the Ministry of Public Finance and the Public Ministry, during the course of the hearing that was granted to such Ministries, stating that: **a)** the Ministry of Public Finance, whose function is to collect funds for the State, stated that the challenged regulation would not modify, alter or reduce any of the legal provisions inherent to the control of medicines for human consumption, contrary to what was argued by the Ministry of Public Health and Social Assistance, whose specific function is to protect the health of the country's inhabitants; **b)** the aforementioned Ministry stated that there is no discrimination, given that like is treated as like and unlike is treated as unlike; the claimant disagrees with this argument, given that in the case at hand the conflict is not as between manufacturers and importers, but between foreign manufacturers and domestic manufacturers, with the former receiving favorable treatment at the latter's expense; **c)** in respect of the violation of intellectual and industrial property, the Public Ministry stated that, given the fact that the challenged Decree is of a general character and provides a benefit that runs to the public good, the public interest prevails over private interests, thereby justifying the violation of industrial property rights and international instruments; **d)** in respect of the argument that the challenged regulation does not violate Decree-Law 153-85 (the Law of Patents, Utility Models, Drawings and Industrial Designs), this argument is unacceptable, given that Decree 28-92 allows for the free importation of medicines, even when such importation would violate intellectual property rights, and, as a result, it would be difficult to the titleholder of such rights to argue that an action permitted by the law should also be considered as a crime and punished as such; **e)** the Ministries argue that the challenge Decree seeks to comply with the State's obligation to protect the health of the nation's inhabitants, by guaranteeing easy access to medicines, but such access is not sufficient, as medicines must be of a certain minimum quality, and the State must confirm this quality for its own account, and not rely on other states to make such a judgment; **f)** there is here a violation in respect of the fact that public powers cannot be delegated, because the authorizations that the challenged law allows infringe upon the national sovereignty, by allowing a sovereign power to be delegated; **g)** in respect of the argument that the that the challenged regulation does not violate industrial property rights, because free importation does not imply a violation of the rights of the inventor, it should be noted that, in accordance with international instruments and domestic law, the inventor has the right to limit the market in which products deriving from his or her invention are produced and commercialized, and the challenged decree prevents the inventor from making use of such right; **h)** the Public Ministry insists that the challenged regulation does not infringe on trademark rights, but by removing the exclusivity conferred upon registered trademarks and eliminating all provisions that restrict the commercialization of imported products, any person may bring into the country products bearing a trademark that have neither the same formula nor the same characteristics as the products protected under the original mark; **i)** the Public Ministry states that Articles 93 to 96 of the Constitution are not violated, given that by requiring the health certificate and certificate of free sale for a given product issued by the country of origin, the Decree is in compliance with the cited articles. However, it is necessary to take in account the fact that all countries change quality controls for their medicines; **j)** the Constitution is violated by the acceptance of the health certificate and certificate of free sale issued by the country of origin of a product as the only

documents required for its importation, because the Legislative Branch has exceeded its authority by delegating the control functions that below to the Ministry of Public Health and Social Assistance to other governments. **2)** The Guatemalan Association of Pharmacists and Chemists reiterated the arguments that were raised in its initial brief. **3)** The Public Ministry stated that: **a)** the unconstitutionality action should be declared inadmissible, given that the provisions of the challenged Decree establish that the State's primary responsibility is to protect the public health, and therefore, it should facilitate, by all means possible, the acquisition of medicines necessary for this purpose; **b)** it has been argued that Articles 93, 94, 95 and 96 of the Constitution are violated by the challenged Decree, but it is obvious that the State seeks to promote the common welfare, by providing all inhabitants of the country with the ability to procure medicines at a low price, through the direct importation of such medicines, without requiring additional quality controls for such products, which controls can be undertaken by the respective authorities, given that no internal health controls are waived, because once medicines are imported, the State is always responsible for their inspection and control, through the appropriate channels, given that Article 2 of the challenged Decree establishes requirements, but waives no obligation of the State.

#### **WHEREAS**

##### **-I-**

Article 268 of the Political Constitution of the Republic sets forth that the Constitutional Court is a permanent tribunal with exclusive jurisdiction, whose essential purpose is the defense of the constitutional order; the Court acts as a professional tribunal independent from other State entities and exercises specific powers designated to it by the Constitution and the relevant law. In addition, Article 267 of the same legal instrument establishes that actions brought against laws, regulations or dispositions of a general character that are alleged to be partially or totally unconstitutional shall be heard directly by the Constitutional Court. Therefore, it corresponds to this Court, as supreme tribunal on matters of constitutionality, to establish whether or not there is a divergence or contradiction between laws alleged to be unconstitutional and the fundamental provisions set forth in the Political Constitution of the Republic. If such dispositions violate, diminish or undermine constitutional precepts, the Court shall declare, as appropriate, their unconstitutionality.

##### **-II-**

The Constitution of the Republic includes, in its Title II on Human Rights, Chapter II, which deals with Social Rights, and included among these, in the Seventh Section, are those rights relating to health, social security and social assistance. Article 93 of the Constitution expressly recognizes that enjoyment of health is a fundamental right of all persons, without discrimination. Article 95 of the Constitution states that the health of the nation's inhabitants is a public asset, and that all persons and entities are obligated to protect its preservation and restoration. In addition, Article 94 of the Constitution obliges the State to protect the health and provide social assistance to all of the nation's inhabitants, in order to ensure their most complete physical, mental and social well-being. And, specifically, Article 96 attributes to the State the power to control the quality of alimentary, pharmaceutical, chemical and all other products that could affect the public's health and well-being. The Constitution broadly recognizes the right to health and to the protection of health, so that all persons may enjoy a biological and social balance that constitutes a state of well-being in relation to their surrounding environments; this implies that all persons have access to those services that allow for the maintenance or the restoration of physical, mental and social well-being. This right, along with others recognized by the text of the Constitution, belongs to all inhabitants of the nation, to whom equality of basic conditions in order to exercise such rights is guaranteed. It is the prerogative of all persons to take advantage of the opportunities and facilities that allow them to enjoy states of physical, mental and social well-being, and it is the State's responsibility to guarantee the full exercise of such rights, using the respective means of each country, which implies that the State must take adequate measures in order to protect individual and collective health, and to make the necessary services in order to satisfy basic needs accessible

to all persons. It also implies that adequate legislation be adopted so that the nation's inhabitants are able to exercise this right, and the State's collaboration in finding solutions to problems that affect the public health. In respect of regulations for the authorization to commercialize pharmaceutical products, taking into account the market, the free circulation of products and the effect on the health of the nation's inhabitants that such products may have, such commercialization must be regulated in accordance with constitutional provisions. The recognition of this right correlates to a conception of the State as a provider of those services established by the Constitution, which implies seeking a better quality of life for the State's inhabitants, and the chance for such inhabitants to take advantage of those social services that improve and humanize their lives. In order for this right to be effective, it is necessary to provide the means to make it so, and the State has the power and the responsibility to provide a system of regulations with the objective of protecting the public health, a power that it is traditional for the State to wield and exercise through State institutions established by law. In this respect, the State is empowered to regulate relevant activities and to enforce the corresponding controls, an oversight power which the State may not waive. The State's activities in respect of the public health should be understood as a public service that is exercised in response to the constitutional provisions that establish the bounds of public power to regulate and protect the public health through preventative measures and through the provision of necessary services. The constitutional objectives in recognizing the right to health are: to achieve the physical and mental well-being of the State's inhabitants; to improve and prolong the quality of life of all social sectors, especially those "more vulnerable populations" (Article 96 of the Constitution); to provide for the enjoyment of health services and social assistance that adequately satisfy the needs of the population; and to exercise strict controls of the quality of products that may affect the health and well-being of the public. And in this respect, the Constitution is controlling, in attributing to the State the power to control the quality of all alimentary, pharmaceutical, chemical and other products that may affect the health and well-being of the nation's inhabitants (Article 96) and the defense of consumers and users, in respect of the safeguarding of the quality of products for domestic consumption, among these being, of course, medicines, in order to protect the public's health and security (Article 119, paragraph i).

### **-III-**

For reasons of methodology, this Court will proceed to analyze the challenged Decree in its entirety, as a law that, essentially: a) seeks to liberalize the importation of medicines, in order to obtain better prices for such medicines for the inhabitants of the country; b) makes importers responsible for the quality of the products that they import; c) requires that sale of such medicines be through pharmacies or other authorized establishments; d) in order to import medicines, the only requirement is the presentation of a copy of the health certificate and the certificate of free sale issued by the country of origin of the product; e) the importation and commercialization of drugs that may result in addiction must be authorized and controlled by the Ministry of Public Health and Social Assistance; f) the owner or titleholder of the registry of medicines does not have the exclusive right over their importation, distribution and sale; g) establishes a single location for procedures related to the law; h) overturns those regulations or laws that contradict the provisions of the Decree, as well as those that prohibit or restrict the commercialization of medicines, or that impose fees for the registration or analysis of medications.

This Court notes that through the challenged Decree, the State seeks to lower the cost of medicines, through the liberalization of their importation. The socioeconomic objectives of the challenged law are therefore clear; however, the purposes or objectives of a law, although important, are not sufficient in and of themselves in order for the law to be considered constitutional, because, in addition to the objectives of the law, however noble they may be, the provisions contained within a law must be in harmony with the Constitution.

With this background, this Court, in exercise of the power conferred upon it to defend the constitutional order, will proceed to analyze the alleged unconstitutionality of the law.

It is argued that Decree 28-92, passed by the Congress of the Republic, violates Articles 93, 94, 95, 96, 119, paragraph i), and 154 of the Political Constitution of the Republic, the first three of which refer to the health of the inhabitants of the nation; the fourth, to the State's responsibility to control to the quality of products that may affect public health; the fifth, to the State's obligation, in economic terms, to safeguard products in order to protect public health; and the last, to the prohibition on the delegation of public powers. Due to the importance of the matter under regulation, and the diverse interpretations that the aforementioned provisions have resulted in within the unconstitutionality action at hand, this Court considers it necessary to proceed to interpret the aforementioned constitutional provisions, in order to determine if they were or were not infringed by the Decree alleged to be unconstitutional. As has been affirmed in prior decisions, in order to interpret constitutional standards, it is necessary to put them into the context of the institution to which they belong, in accordance with the purposes and the principles that govern them, and taking into account the values and the reality from which they arose.

In this regard, it should be taken into account that the constitutional legislature established by the 1<sup>st</sup> article of the Constitution that the State will seek to protect persons and families, and that its highest purpose is the common good; in accordance with this disposition, the 2<sup>nd</sup> article imposes upon the State the obligation to comply with specific duties intended to protect all persons; one of these duties is to protect the public health, for which the State must undertake, acting through its institutions, those activities that may be necessary in order to safeguard, promote, recover, rehabilitate and administer all areas in relation to the physical, mental and social well-being of individuals, in accordance with the provisions set forth in Articles 93, 94 and 95 of the Constitution. And, in accordance with these articles, Article 96 orders the State to control the quality of all pharmaceutical, chemical and any other products that may affect the health and well-being of individuals. Paragraph i) of Article 119 of the same instrument requires the State to develop its economic policies in order to provide for the defense of consumers and users in respect of the safeguarding of the quality of such products, in order to protect the health, security and legitimate economic interests of the nation's inhabitants. In addition, it is necessary to consider that, according to Article 154 of the Political Constitution, public powers cannot be delegated, and this same article refers to all powers of the State, both administrative, as well as legislative and judicial, that are exercised under the State's jurisdiction, and in accordance with the rules that limit the scope thereof. The State, in order to comply with its public functions, has been vested with a series of powers, which are the legal means that are recognized and authorized to it in order that it may carry out its objectives for the public good, which are inherent to it. These powers share several characteristics, among them: a) they have their origin and foundation in the legal system; b) they are inalienable and nontransferable; and c) they cannot be renounced and are imprescriptible. These powers do not only constitute the possible power to act, but are better described as "duties"; that is, they should be understood as a prerogative that must be necessarily exercised in the case that the circumstances for which they were conferred present themselves.

From the text and the context of the aforementioned constitutional provisions, it can be concluded that the protection of the public health is meant to be undertaken through the direct and decisive intervention of the State, given that it is the State's non-delegable and essential obligation to take action in the different spheres of the protection and promotion thereof, as the supreme value underlying the social order. As a result, the constitutional framework confers to the State the ineludible power to control those alimentary, pharmaceutical, chemical and, in general, all other products that may affect the public health.

In accordance with the interpretation of the constitutional provisions that are alleged to have been violated, and the analysis of the provisions contained in the challenged Decree, this Court finds that the law in question violates the Constitution because: 1) it relieves the State of its constitutional obligation, as set forth in Article 96, to control those products that may affect the public health, which power the State has exercised through health certificates and through the application of, among others, the provisions of the Health Code; 2) it ignores the mandate



contained in Article 119, paragraph i), which orders the State to direct its economic policies toward the defense of consumers and users, in respect of the safeguarding of the quality of consumer products, in order to guarantee, as the State's highest priority, the health of the nation's inhabitants; 3) by limiting the control that can be exercised by the Ministry of Public Health and Social Assistance only to those medicines that may result in addiction, the Decree also violates the aforementioned articles of the Political Constitution of the Republic, because it is the State's ineludible obligation to control not only the aforementioned medicines, but all products that may affect the public health; 4) by accepting as the sole requirement for the importation of medicinal products the health certificate and certificate of free sale issued by the country of origin, the Decree undermines the constitutional mandate to control such products, which the aforementioned provisions, and specifically Article 96, impose upon the State; 5) when, in Article 5, in very broad terms, the challenged Decree overturns all regulations that oppose it, this violate Articles 171, paragraph a), and the 2<sup>nd</sup> article of the Political Constitution, which establish, respectively, the power of Congress to decree, amend and overturn laws, and the duty of the State to guarantee, among other things, the security of the nation's inhabitants, because when this entity overturns laws in the abstract, as in the case at hand, without specifying the provision or provisions to be overturned, this contradicts the principles of legal certainty and security, which are basic pillars of the Guatemalan constitutional framework.

In conclusion, based on the foregoing considerations, this Court finds that Decree 28-92, passed by the Congress of the Republic, violates Articles 93, 94, 95, 96, 119, paragraph i), and 154 of the Political Constitution of the Republic, and therefore the Court proceeds to declare the unconstitutionality of the Decree in its entirety, for which reason it is unnecessary to treat herein the other challenges raised thereto.

#### **CITED LAWS**

The cited articles, and Articles 93, 94, 95, 96, 119, paragraph i), 267, 268 and 272, paragraph a), of the Political Constitution of the Republic; the 1st, 2nd, 3rd, 4th, 5th, 6th and 7th articles, and Articles 114, 115, 134, 137, 139, 140, 142, 145 and 146 of the Law of the Protection Action, Personal Liberties and Constitutionality; and Articles 31 and 32 of Agreement 4-89 of the Constitutional Court.

#### **THEREFORE**

The Constitutional Court, based on the considerations expressed herein and the laws herein cited, resolves: **I. To hold** that Decree 28-92, passed by the Congress of the Republic, is unconstitutional in its entirety. **II.** The cited Decree is therefore left without effect and shall have no effect as of the day following the date of publication of this decision in the Official Register. **III.** This decision to be published in the Official Register within three days of its signature. **IV.** So notified.

**EPAMINONDAS GONZÁLEZ DUBÓN, PRESIDENT. ADOLFO GONZÁLEZ RODAS, JUDGE. JORGE MARIO GARCÍA LAGUARDIA, JUDGE. GABRIEL LARIOS OCHAITA, JUDGE. JOSEFINA CHACÓN DE MACHADO, JUDGE. JOSÉ ANTONIO MONZÓN JUÁREZ, JUDGE. RAMIRO LÓPEZ NIMATUJ, JUDGE. RODRIGO HERRERA MOYA, CLERK OF THE COURT.**