

Role number :3284

Decision n°169/2005 Of 23 November 2005
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DECISION

At issue : the preliminary question regarding article 191, 14°, 15°, 15° *quarter* and 15° *quinquies* of the Law of 14 July 1994 regarding the obligatory health care and compensation insurance, asked by the Brussels Labour Court.

The Court of Arbitration,

Composed of the presidents A. Arts and M. Melchior, and the judges P. Martens, R. Henneuse, M. Bossuyt, E. De Groot et L. Lavrysen, assisted by the clerk P.-Y. Dutilleux, chaired by the president A. Arts,

After deliberation, delivers the following judgment:

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I. Purpose of the preliminary question and procedure

By judgment of 27 December 2004 opposing the Central Fractionation Unit of the Belgian Red Cross against the National Institute for Health and Disability Insurance, which was shipped to the Court of Arbitration on the 5 January 2005, the Brussels Labour Court asked the following question:

“Do the provisions of article 191, 14°, 15°, 15° *quarter* and 15° *quinquies* of the Law of 14 July 1994 regarding the obligatory health care and compensation insurance, as they were in force during the years of 2003 and 2004, violate articles 10 and 11 of the Constitution because they treat equally the pharmaceutical companies producing drugs of human origin (specifically drugs prepared from human blood or human plasma collected exclusively from voluntary Belgian donors, therefore available in limited quantity) and pharmaceutical companies producing drugs chemically prepared or by recombination?”.

Reports have been filed by the Central Fractionation Unit of the Belgian Red Cross, which has its head office at 1120 Brussels, avenue de Tyras 109, and by the Council of Ministers.

The Council of Ministers also filed a report as an answer.

To the 20 October 2005 public hearing:

- Appeared:

. Me D. Caestecker, lawyer of the Brussels Bar, for the Central Fractionation Unit of the Belgian Red Cross;

. Me P. Slegers, lawyer of the Brussels Bar, for the Council of Ministers;

- the aforementioned lawyers have been heard;

- the case was deliberated.

The dispositions of the special law of the 6 January 1989 about the procedure and the use of languages were applied.

II. The facts and the earlier procedure

The Central Fractionation Unit of the Belgian Red Cross introduced, before the Brussels Labour Court, a legal proceeding aimed, principally, to hear that it cannot be considered as a pharmaceutical company within the meaning of article 191, 14°, 15°, 15° *quarter* and 15° *quinquies*, of the Law of 14 July 1994, so that it is not liable, for the years 2003 and 2004, for the charges of conditioning and for the contributions on the sales generated in the Belgian drugs market that these provisions impose.

In the alternative, the claimant before the Court argues that the aforementioned provisions of the Law of 14 July 1994 violate articles 10 and 11 of the Constitution, in that, regarding the charges and contributions targeted, they establish without a reasonable justification an equal treatment between, on the one hand, the claimant which produce drugs of human origin and, on the other hand, companies producing pharmaceutical products chemically prepared or by recombination.

The Brussels Labour Court finds that the claimant shall be considered as a pharmaceutical company within the meaning of the contentious provisions of the Law of 14 July 1994. The Labour Court then decides to grant the request of the claimant aiming at asking a preliminary question to the Court concerning the possible violation of the constitutional principle of equality and non-discrimination.

III. The Law

- A -

A.1.1. The objections of the claimant before the judge *a quo*, the Central Fractionation Unit of the Belgian Red Cross, are brought against article 191, 14°, 15°, 15° *quarter* and 15° *quinquies* of the Law of 14 July 1994 regarding the obligatory health care and compensation insurance, as they are modified by articles 108, 109 and 110 of the law-program of 22 December 2003.

Article 191, 14° requires that the pharmaceutical companies that obtained the approval for the reimbursement of the health care insurance pay annual charges by conditioning. The other provisions require that a contribution of the sales generated on the Belgian drugs market be borne by the pharmaceutical companies.

A.1.2. The aforementioned provisions would violate articles 10 and 11 of the Constitution, in that the two different categories of drugs producers are treated in the same way, which are, on the one hand, the companies producing pharmaceutical products chemically prepared or by recombination, and on the other hand, the Central Fractionation Unit of the Belgian Red Cross producing drugs of human origin for which the production and marketing conditions are very specific. This equality of treatment cannot be objectively and reasonably justified. Unlike the

first of these two categories of producers, the Central Fractionation Unit of the Belgian Red Cross not only produces economically profitable drugs, but also drugs only intended for small groups of patients and for which it depends on the limited availability of the human material of voluntary donors. Therefore the objective of the measure, which is to curb the increase of drugs consumption, is not relevant for the Central Fractionation Unit of the Belgian Red Cross as an organization with no profitable motive.

A.2. The Council of Ministers finds that it is justified that the pharmaceutical companies whose drugs are reimbursed, which gives them a growth of their revenues, participate to the “alternative financing” of the health and disability insurance. Since the claimant is also a producer of drugs qualifying for reimbursement and is therefore subject to the same conditions and criteria as other reimbursable drugs producers, there is no difference justifying a separate treatment.

- B -

B.1. The preliminary question regards article 191, 14°, 15°, 15° *quarter* and 15° *quinquies*, of the Law of 14 July 1994 regarding the obligatory health care and compensation insurance, as they were in force during the years of 2003 and 2004.

Article 191, 14°, imposes on the pharmaceutical companies a requirement that they get an approval for reimbursement of health care insurance to pay an annual charge by conditioning. The other provisions impose, on the pharmaceutical companies, a contribution of the sales generated on the Belgian drugs market.

B.2.1. The judge *a quo* asks the Court if the contentious provisions violate articles 10 and 11 of the Constitution in that, regarding the charging of the fees and the contributions aimed at by the aforementioned provisions, two different categories of drug producers are treated equally. Those categories are, on the one hand, the pharmaceutical companies producing drugs chemically prepared or obtained by recombination and, on the other hand, those producing drugs of human origin, specifically drugs prepared from human blood or human plasma collected exclusively from voluntary Belgian donors, therefore available in limited quantity.

The ruling and the facts of this litigation reveal that, regarding the second category of drug producers, only the situation of the Central Fractionation Unit of the Belgian Red Cross is targeted.

B.2.2. The charges or contributions imposed by the provisions at issue fall within the “alternative financing” of the health and disability insurance and are a continuation of an existing scheme of many years. The contributions are due by the pharmaceutical companies that generate sales on the Belgian market for drugs which are on the list of the pharmaceutical reimbursable products.

B.2.3. The Central Fractionation Unit of the Belgian Red Cross, which is a company aiming at making a profit, provides pharmaceutical products which are on the list of the reimbursable products, targeted in article 35bis of the Law of 14 July 1994. This justifies the equal treatment with the other producers corresponding to the aforementioned conditions.

B.2.4. The fact that the Central Fractionation Unit of the Belgian Red Cross also produces drugs of human origin, prepared by a specific process and intended to a small segment of the market, does not imply that the non-exemption of the charges or the contributions imposed by the provisions at issue as a measure that would not be objectively and reasonably justified.

B.3. The preliminary question is answered by the negative.

For these reasons,

The Court

Rules that:

The article 191, 14°, 15°, 15° *quarter* and 15° *quinquies* of the Law of 14 July 1994 regarding the obligatory health care and compensation insurance, as it was in force during the years of 2003 and 2004, does not violate articles 10 and 11 of the Constitution.

Delivered in Dutch and in French, in accordance with article 65 of the special law of 6 January 1989, to the public hearing of 23 November 2005.

The clerk,

The president,

P.-Y. Dutilleux

A. Arts