

Anonymised version

Translation

C-96/20 – 1

Case C-96/20

Request for a preliminary ruling

Date lodged:

24 February 2020

Referring court:

Corte suprema di cassazione (Italy)

Date of the decision to refer:

7 November 2019

Appellants:

Ordine Nazionale dei Biologi

MX

NY

OZ

Respondent:

Presidenza del Consiglio dei Ministri

ITALIAN REPUBLIC

**THE CORTE SUPREMA DI CASSAZIONE (SUPREME COURT OF
CASSATION)**

FIRST CIVIL DIVISION

... [procedure]

INTERLOCUTORYY ORDER

in the proceedings ... brought by:

EN

Ordine Nazionale dei Biologi ...

– appellant –

v

Presidenza del Consiglio dei Ministri ...

[Or.2]

– cross-appellant –

...

against Judgment No 3817/2015 of the CORTE D'APPELLO di ROMA (Court of Appeal, Rome, Italy), lodged on 19 June 2015;

... [procedure]

FACTS

By summons dated 10 June 2008, the Ordine Nazionale dei Biologi (National Association of Biologists, Italy) and the medical biologists MX, NY, ... and OZ brought an action before the Tribunale di Roma (District Court, Rome, Italy) against the Presidenza del Consiglio dei Ministri (Presidency of the Council of Ministers, Italy) ... [as well as certain other public authorities], alleging infringement of the right to be appointed as the responsible person of an establishment providing blood transfusion services, which is granted – where the applicant meets specific requirements regarding experience – to individuals holding a degree in biological sciences and individuals holding a degree in medicine and surgery by Article 9(2) of Directive 2002/98/EC, which sets standards [Or.3] of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

The applicants complained that Legislative Decree No 261 of 2007, which implements that directive, instead specified, in Article 6(2) thereof, that only individuals holding a degree in medicine and surgery may be appointed as the responsible person of such an establishment, thus excluding biologists from appointment as responsible persons, under rules which conflict with European Union legislation and which should be disapplied.

The court seised ... dismissed the application ...; the court held ... that the directive was not self-implementing, inasmuch as it was intended to lay down general rules on the institution of blood transfusion establishments, for the creation and operation of which national legislation was necessary. In so far as the application related to State liability for incorrect transposition of the directive, the court found that it had to be dismissed on the ground that the EU rules left the

Member State free to choose between doctors and biologists, or to choose both, and that that discretion was unfettered.

That judgment was upheld by the Corte d'Appello di Roma (Court of Appeal, Rome) ... by Judgment No 3817 of 19 June 2015 ... **[Or.4]** ... [repetition of the grounds of the judgment at first instance].

An appeal on a point of law against that judgment ... [procedure] was brought by the Ordine Nazionale dei Biologi, MX, NY and OZ, which put forward two grounds of appeal. That appeal is challenged by the Presidenza del Consiglio, as cross-appellant ... [procedure].

POINTS OF LAW

1. By their first ground of appeal, the appellants allege infringement of Article 2909 of the Civil Code and Article 112 of the Code of Civil Procedure. They submit that the appeal court erred in its construction of the application, by which they sought a finding establishing the right, conferred by Article 9(2) of the directive but not implemented by the Italian State, of biologists to be appointed as the 'responsible person' of a blood establishment.
2. By their second ground of appeal, they allege infringement of Articles 10 and 117 of the Italian Constitution, of Article 288 TFEU, of Article 9 of Directive 2002/98/EC and of 12 general provisions of law. They assert that, in its judgment, the court wrongly held that the directive was not self-implementing: Article 9(2) draws no distinction between individuals holding a degree in medicine and surgery and individuals holding a degree in biology. Individuals in both groups, where they have the same practical experience, are identified as being eligible for appointment as responsible persons of blood establishments.

[Or.5]

3. In its [cross-appeal] ..., the Presidenza del Consiglio alleges infringement of Articles 112 and 276(2) of the Code of Civil Procedure, in that the court of first instance examined the issue of the lawfulness of Article 6(2) of Legislative Decree No 261 of 2007 with regard to its alleged incompatibility with European Union law, without any such request having been made by the applicants, which had merely sought a finding establishing a right which they regarded as derived directly from the directive.
4. The issue of the construction of the application, on which the appellants and the cross-appellant take opposing views, and which must be considered first, should be resolved in favour of the appellants. It is clear from a direct examination of the legal texts, which, given the procedural nature of the issue, is quite permissible, that the Ordine Nazionale dei Biologi and the individual biologists, while seeking the disapplication of the provision of national law, at the same time argue that the content of the directive was not reflected when it was transposed into national law. That placed a category of professionals as well as individual biologists at a

disadvantage, inasmuch as rules were introduced that discriminated against them. It is therefore apparent that it is alleged (1) that the rule of EU law infringed (Article 9(2)) was designed to confer rights on individuals, (2) that the infringement was a sufficiently serious one, and (3) that there is a causal nexus between the breach of the obligation imposed on the Member State and the harm suffered by the injured party (see, in this connection, the judgments of the Court of Justice of 10 November 1991, *Francovich*, C-6/90 and C-9/90, on the obligation upon Member States to make good loss and damage suffered as a result of failure to implement Community directives, [Or.6] and of 5 March 1996, *Brasserie du pecheur and Factortame*, C-46/93 and C-48/93, on the obligation upon Member States to make good damage caused to individuals as a result of breaches of Community law).

It should be added that, in accordance with the principles of effectiveness and non-discrimination, rules of European Union law must be applied in their entirety, even by courts acting of their own motion, and that no procedural bars can prevent that ... [procedure].

5. Recitals 13 to 15 of Directive 2002/98/EC state as follows:

– Member States should ensure that an appropriate mechanism for designating, authorising, accrediting or licensing exists to ensure that the activities of blood establishments are performed in accordance with the requirements of this directive;

– Member States should organise inspection and control measures, to be carried out by officials representing the competent authority, to ensure the compliance of the blood establishment with the provisions of this directive;

– Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be [Or.7] appropriately qualified and provided with timely and relevant training, without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers;

– Article 1 of the directive states the objectives thereof as follows: ‘This directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection’;

– Article 4 of the directive provides, inter alia, as follows: ‘1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this directive. 2. This directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty. ...’;

– Article 5(1) provides as follows: ‘Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution

when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose’;

– Article 9(1) sets out the responsibilities of the ‘responsible person’ designated by the blood establishment. Article 9(2) provides that ‘The responsible person shall fulfil the following minimum conditions of qualification: (a) he/she shall possess a **[Or.8]** diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned; (b) he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution’.

6. Legislative Decree No 261 of 20 December 2007, entitled ‘Revision of Legislative Decree No 191 of 19 August 2005 implementing Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components’:

– Article 2(1)(e) defines ‘blood establishments’ as the structures and related organisational units, including collection units, provided for by the legislation in force and in accordance with regional organisational models, which are responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, distribution and allocation, when intended for transfusion;

– Article 4 provides that activities relating to the collection and testing of human blood and blood components, including the performance of tests for biological evaluation provided for by the legislation in force, whatever their intended purpose, and to their preparation, storage, distribution and allocation, when intended for transfusion, are to be undertaken only in designated **[Or.9]** establishments that have been authorised and accredited;

– Article 6(1) provides that bodies which have a transfusion service must designate a responsible person and it lists the duties of such persons. Article 6(2) provides that ‘The responsible person referred to in paragraph 1 shall possess a university degree in medicine and surgery and shall meet the requirements laid down by the legislation in force for eligibility to hold a position within the management of a complex structure in the field of transfusion medicine.’

7. Under Italian law, graduates in biologists are therefore precluded from taking up the duties of responsible person within a blood establishment, even though, as mentioned above, the directive includes among the relevant qualifications for that purpose academic qualifications obtained ‘*in the field of medical or biological sciences*’.

It is ... true, however, that the directive lays down minimum requirements and allows the Member States to maintain and introduce more stringent protective measures in the area. Consequently, this court is in doubt about the structure of the provision and is uncertain whether, by means of Article 9(2), the directive directly grants individuals having a degree in biological sciences as well as those having a degree in medical sciences (when in possession of the requisite experience, of course) the right to be appointed as responsible person of a blood establishment or whether, on the contrary, it allows the Member States the option of choosing between the two groups — those being the positions argued by the appellants and the government authority respectively.

If it is the former, then the transposition of the EU rules **[Or.10]** into national law was incorrect, as is alleged by the biologists, who emphasise the discriminatory aspect — medical doctors being treated as better trained and more expert — and point out that their application is not merely directed at the recognition of qualifications, but addresses a real failure on the part of the State which, in a manner incompatible with EU law, denies them access to this top position.

If it is the latter, the issue would then be the discretionary power of the State to select the individuals which it regards as best suited to carrying out the duty in question, which is not a matter open to review by the courts.

8. Since it is not immediately clear which of those two interpretations is correct, even having regard to the systematic criterion applied within the rules of which the provision forms a part, this court considers that it must refer this issue of interpretation to the Court of Justice of the European Union, to which, pursuant to Article 267 TFEU, it therefore refers the following questions for a preliminary ruling:

‘Is Article 9(2) of Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components to be interpreted as meaning that, by identifying as minimum conditions of qualification for appointment to the position of responsible person of a blood establishment the possession of an academic qualification ‘in the field of medical or biological sciences’, it confers directly on individuals having a degree in either discipline the right to carry out the duties of responsible person within a **[Or.11]** blood establishment?’

Does European Union law accordingly permit national law to exclude individuals having a degree in biological sciences from carrying out the duties of responsible person within a blood establishment or preclude it from doing so?’

... [procedure]

... Rome, 7 November 2019.

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