Protection of biotechnological inventions

1988/0159(COD) - 23/01/1995

In relation to the common position of 7 February 1994, the joint text incorporated the amendments proposed by the EP at second reading, with the exception of the amendment concerning Recital 10 (patentability of parts of the human

Body). The Conciliation Committee reached agreement on a new wording of this key recital: '…an invention based on elements that were susceptible of industrial

application and produced from the human body by means of a technical process in such a way that they are no longer directly linked to a specific individual shall not be excluded from patentability due to the human origin of the elements, even where the structure of those elements is identical to those of a natural element, on the understanding that the parts of the human body from which those elements are derived shall be excluded from patentability'. In other words, parts of the human body were not patentable in principle, but they could be patentable when they formed part of an industrial invention and had been modified in such a way as to no longer be directly linked to an individual. However, problems of interpretation could arise in relation to the phrase 'in such a way that they are no longer directly linked to a specific individual'. After noting that there was disagreement, it was decided that the Council and the EP would each make a statement on their interpretation of this phrase. The EP also pointed out that where there were different interpretations of legislative texts, it would be up to the Court of Justice to take a decision. The other main aspects of the Parliament/Council compromise related to: - modification of the genetic identity of animals. Provision was made to exclude from patentability 'processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes, insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued'; - germ gene therapy. The EP, the Council and the Commission agreed on a joint statement that referred to the recent opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European

Commission. In this opinion, the Group had stated that 'having regard to the importance and the controversial nature of germ gene therapy and in light of the scientific knowledge available, human gene therapy is not currently acceptable from an ethical point of view'. - farmers' rights. On this issue the Commission made the following statement: 'When a Community legal provision on the breeding of animals enables farmers to use protected livestock for reproduction purposes on his farm in order to renew his stock, the Commission shall give due consideration to this for the purposes of incorporating such a derogation within the framework of the Directive'.