E U R O P E A N E C O N O M I C A R E A

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O F T H E E F T A S T A T E S

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WORKING GROUP ON INTELLECTUAL PROPERTY

POSITION OF THE EFTA/EEA STATES ON THE PROPOSAL FOR A EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

1. Of the EFTA/EEA States, **Iceland and Norway** may be more directly affected by the new proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions. Liechtenstein's policy and legislation is generally not incompatible with the new proposal. However, special solutions might have to be found for Liechtenstein in view of its Patent Union with Switzerland. The following position therefore reflects the views of Iceland and Norway only.

2. In the view of **Iceland and Norway**, the new proposal represents an improvement as compared to the initial proposal of 23 January 1995. However, it is suggested that some further amendments should be made. The relevant points are spelled out below.

3. At the meeting of the EEA Joint Committee on 26 January 1996, **Norway** presented its principle view on the protection of biotechnological inventions. **Norway** favours a restrictive practice when drawing the dividing line between what is to be considered as a discovery and as an invention. Thus, patents should not be granted on naturally occurring biological material, including isolated and characterized genes. Neither should patents be granted on plants and animals, nor on methods for producing plants and animals.

4. **Norway** would seize the opportunity to point out that the proposal has not addressed the fact that patents on living organisms imply interpretations which distinguish them from traditional patents, e.g. as to what is to be considered as the same product in Article 17. Clarification through a court decision might be difficult due to the reversal of the burden of proof. The negative consequences mentioned above may be fortified due to the tendency in patent practice to grant "broad" patents (e.g. on a "non-human mammal" in the oncomouse case) and patents on material not yet known to solve a technical problem (e.g. characterized gene sequences with no known industrial application).

5. Re. **Articles 2 and 4**: Unlike the term "plant varieties", the term "animal varieties" has (yet) no internationally recognised definition. A definition should be included in the directive, e.g. in Article 2.

6. Re. **Articles 4 and 6**: In the view of **Norway**, patents should neither be granted for plants and animals, nor for processes for producing plants and animals, regardless of whether those processes are biological or microbiological. **Iceland** agrees that there should be a prohibition against patents on animals, not only on varieties thereof as such. With regard to processes for producing animals and plants, **Iceland** finds a prohibition against patents for essentially biological processes sufficient.

7. Re. **Article 8**: **Iceland and Norway** appreciate the effort made to draw a clear dividing line between patentable inventions and non-patentable discoveries. **Norway** believes, however, that the dividing line should be drawn so as to exclude all naturally occurring material from patentability.

8. Re. **Article 9.1**: **Iceland and Norway** emphasize that biotechnological inventions may more often than other inventions be considered to be contrary to public policy and morality. As stated by the European Court of Justice, it is for each Member State to determine, in accordance with its own scale of values and in the form selected by it, the requirements of public morality on its territory (Case 34/79 Henn & Derby).

9. Re. **Article 9.2**: **Iceland and Norway** appreciate the more restrictive drafting as compared to the initial proposal. The present drafting of subparagraph (a) may, however, through an antithetic interpretation cast doubt on the validity of the general principle that methods for treatment of the human (or animal) body by therapy are not to be regarded as inventions which are susceptible of industrial application within the meaning of patent law, cf. EPC Article 52 (4) and the corresponding provisions in national patent acts in Europe. Furthermore, the present drafting may be read so as to allow patenting of all methods for genetic modification of human germ cells, provided that the aim of the method is not to be regarded as therapeutic. Such an interpretation might infer that e.g. eugenic methods may be patented.

Besides these remarks, **Iceland** agrees with Article 9.2 of the proposal.

In the view of **Norway**, all processes for modifying the genetic identity of humans should be excluded from patentability. The same should apply to all processes for modifying the genetic identity of animals.

10. Re. **Article 13.2**: The scope of the expression "livestock" should be clarified. In the Danish version of the proposal, an expression ("avlskvæg") is used which has a more restricted meaning than what appears to be intended. In the view of **Norway**, primary producers should be given a high degree of freedom to replenish their stock by breeding on their own farms.

11. Re. **Article 17: Iceland and Norway** agree that identical rules should regulate the question of burden of proof for patents in all fields of technology, of CPA Article 35 and Section 62a of the Danish Patents Act. In the view of **Norway**, the rules generally applicable before the courts of law should apply also for patent infringement cases. **Norway** would therefore prefer the alternative offered in subparagraph (b) of TRIPS Article 34 paragraph 1.

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