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[Folder 2]: Human Cloning - Legal Protection for Bio-technological Inventions

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Section:

2

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3

Legal Protection of Biotechnological Inventions in Europe

Biotechnology investment and research in Europe have been impeded by disparities in the content and interpretation of national patent laws. A proposed EC directive, which would have established a uniform patent system for biological inventions throughout Europe, was rejected by the European Parliament in 1995, even after many changes had been made to accommodate Parliament's concerns. The European Commission has drafted a new directive that addresses Parliament's other objections to the earlier proposal.

The U.S. government is urged to endorse the adoption of the Commission's proposed Directive and to encourage European Union officials, in particular Members of Parliament, of the desirability for the EU to have a Directive which will standardize protection for biotechnology throughout Europe.

Three European institutions are involved in this legislative process. The Economic and Social Committee, an advisory body representing unions, employers and professionals, has issued a strongly positive opinion. The Council of Ministers, which has the final say, is expected to support the draft almost unanimously. The Parliament, which has amending and vetoing rights, will again be the toughest hurdle to take. There are clear signs, though, that the European Socialists, who were instrumental in the negative vote two years ago, are now largely supporting the new draft.

The Legal Affairs Committee of the European Parliament is to conclude the article-by-article discussion by the end of May. As expected, the debate has concentrated on article 3 ("the human body and its elements") and 9 ("inventions considered unpatentable"). Both are likely to be rewritten by the rapporteur in consensus language which would remain consistent with the spirit of the Commission draft and have the support of all Committee members except the Greens and a few sympathizers in other political groups. Together with an amendment calling for an Ethics Committee, but without specifying its terms of reference, this would allow for the withdrawal of the vast majority of the 204 amendments presently tabled and for a simplified vote.

Despite efforts to the contrary by the Greens and their allies, the Committee appears resolved to have this vote before July 2, which could still allow for a plenary vote before the summer recess if the same resolve prevails at the level of the presidency and the chairs of the political groups. In this way, Council and Commission could still agree on a "Common Position"* during the British presidency (first half of 1998), which is strongly supportive of the directive. The Austrian presidency (second half of 1998), under heavy pressure from a national anti-biotech campaign, would at best be non-committal and at worst shelve the draft until 1999.

TRIPS 1999 Review

Article 27.3 of the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) provides an outline for the standards of protection of biotechnology. It specifies what WTO members may exclude from patentability and also provides for a review of the provisions of this paragraph in 1999, four years after the entry into force of the Agreement establishing the WTO.

The research-based pharmaceutical industry believes Article 27.3 should be strengthened. Certain anti-patent forces including India will seek to use the opportunity of these renegotiations to weaken the provisions of TRIPS, including Article 27.3. We strongly urge the U.S. government to anticipate and counter such effort by preparing now to seek enhanced and stronger intellectual property protection under the TRIPS.

During the Summit the President should avail himself of any opportunity during side conversations to urge the strengthening of TRIPS and its accelerated implementation to promote innovation.