

## Critical voices against the EU patents directive 98/44/EC by official government bodies

Update, November 2000

### EUROPE

In Europe the directive has come under increasing criticism not only from NGOs and professional interest groups (like farmer's and doctor's associations) but also from Governments.

#### **European Governments:**

##### *The Netherlands*

The Netherlands have challenged the directive before the European Court of Justice (ECJ) (Case C-377/89). The Dutch Parliament is unwilling to transpose the directive without major changes.

##### *Italy*

Italy has joined the Dutch challenge before the ECJ.

##### *Norway*

Norway, as part of the EEA (European Economic Area), has intervened at the ECJ in support of the Dutch/Italian challenge (15 March 1999, based on Article 37(3) of the Protocol on the Statute of the Court of Justice) and is not willing to implement the directive.

##### *France*

The French government had asked for an opinion from its advisory council on ethics (CCNE-Conseil consultatif national d'éthique) which published the opinion Nr 64 on 8 June 2000. Therein the Council advises the government to implement the directive only with substantial modifications. The government reacts by saying it will not transpose the directive until such substantial changes are being re-negotiated on European level. President Chirac writes a letter to European Commission President Prodi demanding such a re-negotiation.

##### *Belgium*

The Belgian government has difficulties implementing the directive as well. It put a draft implementation law onto their webpage inviting comments from the public. The draft law includes fundamental differences to the directive with regard to the basis of an invention.

##### *Germany*

On 18 October 2000 the government adopts a draft implementation law to be passed to the national parliament. The draft law includes some differences to the directive, notably a reference to the German law on human embryos.

More importantly, at the same time the government states that the directive itself is not adequate and decides to initiate a re-negotiation process on European level.

*"The groundbreaking advances made in decoding human genes and the genes of other forms of life, and the continuing discussion in a number of EU member countries, are however clear indications that European patent law has not at all points found definitive answers to the challenges of the new sphere of technology.*

*The German government is with this in mind initiating a process of change at the European level and advocating necessary improvements and greater clarification.*

*In particular, the range of the product patent in the biotechnological sphere must be examined. This means examining the pre-conditions for being able to patent genes, genetic sequences or part of them, where these stem from humans, animals, plants or micro-organisms.*

*Given the latest developments in bio-medical research, the necessary ethical limits to patent law must be protected against efforts to patent parts of the human body, and enforced worldwide.*

*The relationship between patent law and the protection of varieties must also be devised in an appropriate form. “ (unofficial translation)*

### *Denmark*

The Advisory Council on Ethical Questions of the Danish Government issued a statement in May 2000 (J.Nr.ER 1998-3.0-212dok.:45) strongly advising against transposition of the directive into national law. The Council considered the patenting of genes as highly unethical and also saw many negative effects for patients in the medical area.

Despite this clear statement the parliament voted narrowly in favour of transposition.

### **Council of Europe**

Recommendation 1425 (99), 23 September 1999, states: “The Assembly therefore believes that neither plant, animal nor human derived genes, cells, tissues or organs can be considered as invention and nor be subject to monopolies granted by patents.”

Recommendation 1468 (2000), 29 June 2000, adopted with unanimity, calls on EU-Member States:

- not to implement directive 98/44/EC
- to request the re-negotiation of the directive
- and to support the challenges before the ECJ

### **INTERNATIONAL BODIES**

The EU-Directive 98/44/EC fits into the trend amongst industrialised countries to fundamentally broaden patent protection so as to include living organisms, such as genes, plants, animals and parts of the human body, and has to be seen in context of the international WTO-regulations.

Within the WTO the chapter dealing with patents, the TRIPs-Agreement (Trade Related Intellectual Property Rights), is currently under review. Traditionally patents on plants, animals and living organisms were not possible. Through the TRIPs regime the industrialised countries are trying to force such patents onto the rest of the world. But developing countries increasingly object to these principle and argue that the industrialised world’s patent regime, and explicitly the EU Directive 98/44/EC, is a threat to their development.

There is mounting international criticism of the notion of patenting living organisms, as the EU directive does. Here are examples of what some international bodies have to say on this subject:

### **UN Subcommission on the Promotion and Protection of Human Rights Resolution 17 August 2000**

There is mounting concern in international human rights bodies about the patenting of living organisms. This extraordinary level of activity by international human rights bodies on this rather technical aspect on international economic law is founded on increasingly widespread understanding about the social impacts of the enhanced regime of patent protection under TRIPs.

On August 17, 2000, the UN Subcommission on the Promotion and Protection of Human Rights passed a landmark resolution (E/CN.4/Sub.2/RES/2000/7), identifying key human rights as being at threat under the WTO’s TRIPs regime:

“The implementation of the TRIPs Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination.”

„...there are apparent conflicts between the intellectual property rights regime embodied in the TRIPs Agreement, on the one hand, and international human rights law, on the other“.

In this resolution, the Sub-Commission also reminded all Governments of the primacy of human rights obligations over economic policies and agreements, and requested them to integrate into their legislation and policies, provisions, in accordance with international human rights obligations and principles, that protect the „social function of intellectual property“.

#### **UNDP – UN Development Programme,**

##### **“Report on the Human Development 2000: Human Rights and Human Development”**

Just like in last year’s report, the UNDP again attacks the global patent-regime as a threat to development and human rights:

"Global technology could have a huge impact on poverty eradication - by giving poor people access to seeds for high-yielding food crops or life-saving medicines. Yet the 1994 agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) tightens patent and copyright protection, favouring those who develop and market technology rather than society's interest in liberal diffusion of new technology. The agreement has raised concerns about the consequences for protecting the traditional and collective knowledge of indigenous peoples and for public health."

" 'Bioprospecting' has mushroomed - with scientists 're-inventing' and patenting products and processes using traditional knowledge that communities have held for centuries."

"There are also questions about the compatibility of the TRIPS agreement with human rights law and environmental agreements."

#### **OAU – Organisation of African Unity**

##### **Official position against Patents on Life**

The OAU adopted a position in August 1999 clearly calling for plants, animals and micro-organisms and parts thereof not to be considered patentable inventions, and that natural processes used to create plants, animals and other living organisms may also not be patented. To emphasise its position the OAU put forward a model-law on how to achieve this goal within the ongoing WTO-TRIPS negotiations. From the preamble: “All forms of life are the basis for human survival, and, therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental human right to life.”

#### **World Bank**

##### **“Annual report: Knowledge for Development”, 1998**

In its 21st report in the banks annual series on world development, the World Bank calls for a fairer deal on patents and knowledge. Of special concern is the current tendency for patents to cover not just products but broad areas of technology, in particular biotechnology. “So many industrial-country firms are acquiring strong IPR positions, often covering fundamental research tools (...) that it may prove hard for new firms and researchers to elbow into this new global industry.” Furthermore the report argues that patents are not an appropriate mechanism to stimulate research in many areas of health and medicine, such as AIDS or malaria. The report even advises developing countries to be assertive in defending the terms under which companies are given access to their natural resources.