

## OXFAM SOLIDARITY

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### Biopiracy above the law ?

(translation from the French version by Sophie Borel)

#### European Directive 98/44 Violates Eight International Instruments !

#### FROM BIODIVERSITY TO BIOPIRACY

On the 22 October 1988, the European Commission put a proposal entitled '*Directive of the European Parliament and Council on the legal protection of biotechnological inventions*' to the European Parliament. In accordance with the consistent respect of European countries with regards to living matter and humanity's common heritage, this text was rejected by the European Parliament on the 1 March 1995.

On the 13 December 1995, the Commission adopted a new directive proposal, almost identical in its content to the proposal rejected by the European Parliament. Under pressures of unprecedented intensity from trans-national pharmaceutical and biotechnological companies, the European Parliament adopted, upon first reading, an amended directive proposal on the 16 July 1997. With but very few exceptions, the amendments do not modify the extent of the original text.

On the 29 August 1997, the European Commission adopted a text integrating a very large number of amendments accepted by the European Parliament. Nevertheless, it rejected or modified the most significant of them. On the 27 November 1997, the Council of Ministers adopted the text of the Commission. Denmark voted against. Belgium and Italy abstained.

On the 28 January 1998 in Rome, the Italian House of Representatives rejected the Directive. It was followed by the Senate on the 10 March 1998.

On the 12 May 1998, the European Parliament, upon second reading, approved the text adopted by the Council of Ministers on the 27 November 1997. On the 30 July 1998, Directive 98/44 dated 6 July 1998 was published in the Official Journal of the European Communities.

On the 16 October 1998, the Netherlands' government submitted an action of annulment for Directive 98/44 to the European Court of Justice. The Italian government joined this action on the 22 February 1999 and the Norwegian government (as a Member State of the European Economical Space) followed on the 19 March. The written procedures have now been concluded. An oral procedure will start soon.

In accordance with article 15 of the Directive, Member States must integrate the provisions contained therein within their national legislation no later than 30 July 2000.

#### A LEGAL MONSTER

This Directive is a legal monster :

- Because it legalises biopiracy. Article 3, § 2 establishes that "*biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature*". A text which confuses a discovery (the isolation of a previously occurring material in a natural state) and an invention (the creation stemming from a technical process) is being used as a legal base for the patenting of plant, animal or human life. In the case of subject matter originating from the human body, the Directive constitutes, from the perspective of humanity's entire history, one of the most advanced forms of legal aggression against the human species, namely, the biopiracy of the human person. Indeed, article 5, § 2 states that "*an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element*". It is therefore possible, today in Europe, to patent a gene from the body of a person who is not duly informed and who is not categorically asked to give permission to the patenting process ! Even the texts of the World Trade Organisation relating to the patenting of life are not as far reached.
- Because it conceals internal contradictions authorising the most divergent of interpretations. The points of the preamble – there is a total of 56! – give, in most cases, a presentation of the articles. This presentation is almost systematically in contradiction with the actual text of the articles themselves (ex. no. 16: "*patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person*"). In nearly all of the other cases, the points of the preamble express categorical affirmations (ex. no. 34: "*the Directive shall be without prejudice to the concepts of invention and discovery*") that are in no way supported by the articles. Contradictions between the points of the preamble (which, even if they are the primary source for the interpretation of the articles, do not have any legal effect as was shown

by the European Patent Office Administrative Council decision of the 16 June 1999 – see below: 5. The Directive Violates the European Patent Convention) and the articles, but also contradictions between the articles themselves and, at times, between the paragraphs of a same article! Thus, article 3, § 2 already quoted above stands in opposition to article 4, § 1 which states that plant varieties and animal species are not patentable. Yet, within this very same article 4, § 2 and 3 present exceptions to § 1 which greatly reduce its significance. In the same way, § 1 of article 5 prohibits the patenting of all or part of the human body whereas, as has been shown above, § 2 authorises it. Any jurist is aware of the fact that a text must translate the manifestation of conforming will to have a legal consequence. This is far from being the case with a directive that seems to say everything and its opposite.

- Because it violates 8 international instruments:

- the European Union treaty,
- the international instruments protecting the fundamental human rights,
- the International Covenant on Economic, Social and Cultural Rights,
- the Convention on Biological Diversity,
- the European Patent Convention,
- the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine,
- the Universal Declaration on the human genome,
- the Vienna Convention on the Law of Treaties.

## **1. Directive 98/44 Violates the European Union Treaty**

### 1.1 Violation of the rules of adoption of a directive:

Either the Directive harmonises national law. If this is the case, in virtue of article 95 (ex article 100 A) of the EC Treaty, only a qualified majority is required for the adoption of the Directive. Member States must then automatically ensure that their national laws conform with the provisions of the Directive.

Or, the Directive takes a step further and creates a new norm. In this case, it is the procedure provided by article 308 (ex article 235) of the EC Treaty which comes into play. This procedure requires the unanimous agreement of the Member States.

Yet, contrary to what has been asserted by point 8 of the Directive's preamble, its objectives surpass, and this by far, the Member State legislations. The Directive

- establishes the patentability of biological matter
- accordingly, it creates a patent,
- it imposes this patent to the Member States.

By doing so, it contradicts the legislations and even, in certain cases, the provisions of national constitutions. We are confronted not to an exercise of harmonisation but, rather, to a formal review of the legal practices concerning patents.

In a desire to overcome the foreseeable opposition of certain Member States and to ignore the legal and constitutional provisions in force in a number of cases, the Commission based itself on article 95 (ex article 100 A) of the EC Treaty to pass a text which, in all evidence, should come under article 235. There is, therefore, an abuse of power of the European Commission and a violation of the EC Treaty.

### 1.2 Violation of the principle of subsidiarity (articles 3 B and 190 of the EC Treaty):

Had the real objective of the Commission been the harmonisation of national legislations, the signatory States to the European Patent Convention of 1973 (see below) would have been asked to review this very Convention.

This adaptation could only have been carried out by the signatory States to the Convention since it also associates States other than the Members of the European Union. Once again, the Commission has assumed the right to exercise a power which belongs to the States alone. There is thus, on this second issue, violation of the EC Treaty too.

### 1.3 Violation of article 228/7 of the EC Treaty (contradictions with international treaties):

Directive 98/44 stands in contradiction to the International Covenant on Economic, Social and Cultural Rights, the European Convention for the Protection of Human Rights and Fundamental Freedoms, the Convention on Biological Diversity and the European Patent Convention. This contradiction is a violation *per se* of article 228, § 7 of the EC Treaty which imposes the compatibility of European legislation with international treaties in force.

## **2. Directive 98/44 Violates the International Instruments Protecting the Fundamental Human Rights**

The Universal Declaration of Human Rights, adopted on the 10 December 1948, states in its first article that "*all human beings are born free and equal in dignity and rights*", in article 3 that "*everyone has the right to life, liberty and security of person*", in article 5 that "*no one shall be subjected to torture or cruel, inhuman or degrading treatment or punishment*" and in article 6 that "*everyone has the right to recognition everywhere as a person before the law*".

The European Convention for the Protection of Human Rights refers explicitly to the Universal Declaration on Human Rights in its preamble. As indicated in this very same preamble, it constitutes the expression of the will of European States to *"take the first steps for the collective enforcement of certain of the rights stated in the Universal Declaration"*.

Directive 98/44 created a norm which is in violation the respect of human dignity. Doctrine establishes that the human body is the vehicle of human dignity. Yet, article 5, § 2 already cited above authorises the patenting of elements isolated from the human body. The use of the human body in this manner violates the principle of respect of human dignity stated in both, the Universal Declaration of Human Rights and the European Convention for the Protection of Human Rights and Fundamental Freedoms.

Furthermore, according to Directive 98/44, human body material can be patented without the knowledge or even consent of the person from whom the material has been taken, even if point 26 of the preamble, which has no legal value, indicates that *"the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto"*. None of the articles of the Directive create this obligation.

From an international perspective, this article violates a well established rule, that is that no intervention can, in principle, be imposed upon anyone without that person's consent. The autonomy of will is a fundamental right of international law according to which the obligations of States to respect the fundamental rights of human persons are *erga omnes* obligations that can in no circumstances be limited.

Lastly, Directive 98/44 creates a relationship of dependence between the patients and the private companies holding the patents. Private corporations hold the monopoly of medicine, *ie* the monopoly of the treatment of diseases. Corporations are free to market or not a treatment resulting from works on biological material removed from patients who, for economical reasons, could be deprived of a treatment created from themselves.

And yet, the European Commission's intention is precise: after the text's adoption, upon first reading by the European Parliament, the European Commission, before the second reading, deliberately set aside an amendment introduced within the text which required the agreement of the person from whose body the material is taken. This amendment had been adopted by a large majority of parliamentarians upon first reading on the 16 July 1997 (Amendment 76/rev, new article 8 bis § 2).

### **3. Directive 98/44 Violates the International Covenant on Economic, Social and Cultural Rights**

The International Covenant on Economic, Social and Cultural Rights, adopted on the 16 December 1966 and in force since the 3 January 1976, specifies, in the first two paragraphs of the first article:

1. *"All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development."*
2. *"All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence."*

Directive 98/44 violates these principles. It allows the appropriation for private interests, without the consent of the concerned States, of the natural resources of a country in an international economic context that is evidently not founded on mutual interest, but that, on the contrary, strengthens the dependence links in the relationship between peoples and trans-national corporations. In deliberately casting aside an amendment obligating the respect of the principles stated in the International Covenant on Economic, Social and Cultural Rights, the European Commission's intention has been made clear. This amendment was adopted upon first reading by a large majority of parliamentarians on the 16 July 1997 (Amendment 76/rev, new article 8 § 1).

### **4. Directive 98/44 Violates the Convention on Biological Diversity**

The Convention is unaware of several of the provisions of the Convention on Biological Diversity (CBD) of the 5 June 1992 even if the European Union is one of the contracting parties.

The Convention's objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources (article 1). It contains several provisions aiming to preserve biological diversity and protect the sovereignty of States:

- The right of sovereign States to exploit their own resources is recognised and the access to genetic resources is subject to national legislation (article 3 and article 15.1).
- Prior informed consent of the country providing genetic resources is required for access their access (article 15.5).

The access to technology and its transfer towards countries producing genetic resources are considered as *"essential elements in the realisation of the Convention's objectives"*. They are guaranteed by the following provisions:

- The scientific research based on the genetic resources of a country must be carried out with the full and effective participation of this country (articles 15.6 and articles 19.1).

- The contracting parties must integrate within their national legislation the mechanisms enabling the fair and equitable sharing of the results of research (article 15.7) and the biotechnology developed from genetic material must be made available to the country of origin where the material comes from (articles 16.1, 16.3, 18.2, 19.1 and 19.2).
- The information obtained from all genetic resource must be communicated to the country of origin (articles 15.6, 16.3, 17, 19.3, 19.4).

Directive 98/44 totally contradicts the objectives of the CBD. It violates articles 3, 15, 16, 17, 19 and 20.

- It flouts the sovereign right of States to their biological resources. In not enforcing the obligation to indicate the country of origin of the patented material in the patent's specification and to bring proof that the material has been used according to the legislation of the country of origin governing legal access and export, Directive 98/44 stands in opposition with several of the major provisions of the CBD. Point 27 of the Directive's preamble gives but a feeble indication expressing the optional wish ("*where appropriate*") to see this information on the request for a patent.
- It ignores the obligation made to those States utilising genetic resources to organise access to the biotechnology of States from where these resources originate and the transfer of the ensuing technologies.
- It defies the obligation made by the CBD to the States to protect their biological resources and the obligation made to other States, not only to avoid all action that could hinder the enforcement of this obligation, but also to collaborate to this enforcement by an exchange of information, technical and scientific co-operation and the transfer of financial resources.

The silence or ambiguity of Directive 98/44 cannot be used as a pretext. The text, as it was when it came into force, clearly translates the evident will of the Commission to provide a legal framework to biopiracy. Once again, the European Commission leaves no doubts as to its intentions: after the adoption of the text upon first reading by the European Parliament, the European Commission, prior to the second reading, deliberately set aside an amendment introduced by the Parliament within the text. This amendment would have enabled to satisfy the requirements of the CBD. It had been adopted by a large majority of parliamentarians upon first reading on the 16 July 1997 (Amendment 76/rev, new article 8 bis §1).

The preparatory work provides multiple examples of the will of the European Commission to favour the privatisation of humanity's common heritage and, to do so, to deprive countries of their natural resources. There is an undeniably repeated evidence of a will that stands in complete opposition to the objectives of the Convention on Biological Diversity.

## 5. Directive 98/44 Violates the European Patent Convention

A European Patent Convention (EPC), adopted on the 5 October 1973, was in force at the time of adoption of Directive 98/44. Directive 98/44 violates articles 1, 52, 53, 54, 56 and 172 of this Convention.

Article 1 states that the EPC establishes "*a system of law, common to the Contracting States*". Directive 98/44 violates this article in that it unilaterally modifies this system of law on essential points. It does so when there are no grounds upon which the European Union can base itself to modify the EPC.

Article 52 of the EPC establishes that only "*new inventions*" can be patented. It does not include in the scope of these inventions "*discoveries*" and "*methods for treatment of the human or animal body by surgery or therapy*". This article is violated by articles 3, 4 and 5 of Directive 98/44.

Article 53, b. of the EPC states that "*European patents shall not be granted in respect of plant or animal varieties or essential biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof*". It is violated by articles 3 § 2 and 4 § 2 of Directive 98/44.

Articles 54 and 56 of the EPC define the terms *new invention* and an *inventive step* as that which does not form part of the state of the art and which has not been made available to the public. There is a necessary human contribution. These articles are violated by articles 3 § 2 and 5 § 2 of Directive 98/44.

Article 172 organises the procedures of revision of the EPC which should have been respected by those European States wishing to reform patent practices, particularly in the area of biotechnologies. In refusing to use such procedure, the European Union violates the EPC.

These violations of the EPC were so evident that the Administrative Council of the European Patent Office chose to include a new chapter devoted to "*biotechnological inventions*" in the regulation concerning the enforcement of the Convention instead of referring to a legal contradiction. In fact, the new chapter integrates the most sensitive provisions of Directive 98/44 on the patenting of life. This decision, taken on the 16 June 1999, was countered by several of the Contracting States to the EPC for reasons of content as well as of law.

It is now up to the States, of which the governments want to prevent the violation of the EPC by Directive 98/44 and annul the *coup de force* which the decision of Administrative Council of the European Patent Office dated 16 June 1999 represents, to present the case, following the modalities provided by article 173, § 2 of the EPC, to the International Court of Justice.

## 6. Directive 98/44 Violates the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine

Under the aegis of the Council of Europe, a "Convention on the Unification of Certain Points of Substantive Law on Patents for Invention" came into force on the 1 August 1980. It clarifies very precisely the notion of invention. Its first article aims to consolidate and define the notion of invention. It states that "*patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. An invention which does not comply with these conditions shall not be the subject of a valid patent.*". Article 2 indicates that the contracting States are not bound to provide for the grant of patents in respect of "*b. plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes or the products thereof.*"

In 1993, through its Recommendation 1213 relating to developments in biotechnology and the consequences for agriculture, the Council of Europe had invited Member States and the European Commission to "*take the appropriate means for the protection of biodiversity and of ecosystems from all harmful influences susceptible of being caused by biotechnological inventions and to use biotechnology for the safeguard of biodiversity*" and to "*adopt a policy of caution with regard to the grant of patents in respect of inventions and applications in biotechnology*".

In 1994, through its Recommendation 1240 on the protection and patentability of material of human origin, the Council of Europe considered that the approach taken for the elaboration of the Directive of the European Union on the legal protection of biotechnological inventions (which would become Directive 98/44) is "limiting" (point 10) and that "*ethical issues relating to live matter should be considered at the forefront, prior to the problems of marketing*" (point 11).

Finally, the Council of Europe adopted, on the 4 April 1997, a Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. It came into force on the 1 December 1999.

Article 5, § 2 (quoted above) of Directive 98/44 violates 7 articles of this Convention:

- Article 1: "*Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.*"
- Article 2: "*The interests and welfare of the human being shall prevail over the sole interest of society or science.*"
- Article 5: "*An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. ( . . . )*"
- Article 10: "*( . . . ) Everyone is entitled to know any information collected about his or her health. ( . . . )*"
- article 16: "*Research on a person may only be undertaken if all the following conditions are met: ( . . . )*
  - iv. *the persons undergoing research have been informed on their right and the safeguards prescribed by law for their protection,*
  - v. *the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.*"
- Article 21: "*The human being and its parts shall not, as such, give rise to financial gain.*"
- Article 22: "*When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.*"

It must be noted that, through Recommendation 1425 (1999) adopted on the 23 September 1999, the Parliamentary Assembly of the Council of Europe, conscious of the "*deep reserves opposing the patentability of live organisms*" and after having taken into consideration the challenge of Directive 98/44 by the governments of the Netherlands and Italy, considered that:

- "*the monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of the traditional knowledge of those countries that provide access to these resources.*"
- "*the aim of sharing the benefits from the utilisation of genetic resources within this broader view does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the "common heritage of mankind"*"
- "*neither plant-, animal-, nor human-derived genes, cells, tissues or organs can be considered as inventions, nor be the subject to monopolies granted by patents*".

As has been stated previously, the European Commission cast aside an amendment which went along with the respect of human dignity and which had been approved, on the 16 July 1997, by a significant majority of the European Parliament (Amendment 76/rev, new article 8 bis § 2).

## **7. Directive 98/44 Violates the Universal Declaration on the Human Genome**

This text was adopted by UNESCO's General Assembly on the 11 November 1997. The delegations of 15 States members of the European Union voted it in.

This Declaration has no constraining value. And yet, where is the coherence when governments vote in texts that stand in complete contradiction according to whether they are in Paris or in Strasbourg-Brussels ?

At least 3 articles of this Declaration are defied by article 5 § 2 (quoted above) of Directive 98/44.

- Article 1: *"The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their integrity and diversity. In a symbolic sense, it is the heritage of humanity."*
- Article 2: *"(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics. (b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."*
- Article 5: *"(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment pertaining thereto and in accordance with any other requirement of national law; (b) in all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent and authorisation shall be obtained in the manner prescribed by law, guided by the person's best interest (. . .)."*

On the 8 December 1998, on the occasion of the 50<sup>th</sup> anniversary of the Universal Declaration of Human Rights, the United Nations General Assembly took in UNESCO's text. The 15 delegations of the European Union adopted it. . .

## **8. Directive 98/44 Violated the Vienna Convention on the Law of Treaties**

In consequence of what has been stated above, Directive 98/44 infringes upon 3 provisions of the Vienna Convention on the Law of Treaties.

- Article 26 of this Convention specifies that:  
*"Every treaty in force is binding upon the parties to it and must be performed by them in good faith."*
- Article 31 stipulates that:  
*"A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty and in their context and in light of its objectives and purpose."*
- Article 53, since then become a key principle of international law, establishes that:  
*"A treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law. For the purpose of the present convention, a peremptory norm of general international law is a norm accepted and recognised by the international community of states as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character."*

In violating several international instruments to which itself and/or the members States are parties and in deterring their subject, through Directive 98/44, several international instruments to which its members and even itself are bound to; the European Union has not fulfilled the demands of these articles.

None of the international instruments reviewed in the present paper have been interpreted *in good faith* by Directive 98/44.

International organisations cannot participate to a contentious authority in front of the International Court of Justice. Nevertheless, by referring to the above mentioned articles of the Vienna Convention, those States wishing to question the Directive can refer the case to the International Court of Justice to request and 'advisory note' on the basis of articles 92 to 94 of the United Nations Charter and articles 65 and 66 of the Statute of the Court.

## **CONCLUSION : LEGALLY NOT TRANSFERABLE**

The Directive requires Member States to adopt the provisions contained therein in their national law before the 30 July 2000. Within the next couple of months, the Legislative branch of each of the Member States will have to debate on the provisions that it can but accept in virtue of a misused European law.

Because, in brutal contradiction with the ethics relating to living matter, ethics which have been constantly addressed and protected, particularly by the Council of Europe, Directive 98/44 legalises the biopiracy of plant, animal and human life,

Because it concerns a text blurred by legal irregularities,  
Because it concerns a text which violates several international instruments of which a certain number are restrictive,  
Because no State can be forced to integrate within its national legislation provisions smeared with legal dirt,  
Because no State can be forced to violate international instruments which it supports,

**Directive 98/44 is not, in its current state, transferable in the national law of the Member States of the European Union.**