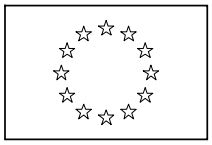

COMMISSION OF THE EUROPEAN COMMUNITIES

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Development and implications of patent law in the field of biotechnology and genetic engineering

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EXECUTIVE SUMMARY

This report is provided for by Article 16(c) of Directive 98/44/EC on the legal protection of biotechnological inventions, which lays down that the Commission must transmit each year to the European Parliament and the Council a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

Directive 98/44/EC was adopted after a long and constructive debate lasting about ten years in both the Council and the European Parliament. During those negotiations, it emerged as a fact that biotechnological inventions are a sector in full expansion: new techniques of great promise for cures and foodstuffs are becoming established very rapidly, and the European legislator considered it essential not to hamper their development. However, there was a need to establish a sound legal framework which allowed European businesses to develop and market the products and processes deriving from genetic engineering. The European legislator felt that this rapidly developing sector had to be watched very closely in order to monitor its development and prevent any malfunctions.

The Commission Communication of 23 January 2002 entitled "Life sciences and biotechnology" reiterates this objective clearly. It is against that background that the first annual report provided for under Directive 98/44/EC was drawn up for submission to the Council and the European Parliament. It is intended to highlight the key provisions of the Directive in the light of the judgment of the Court of Justice of the European Community of 9 October 2001.

It emerges from this analysis that the Articles relating to the patentability of plants and animals and the patentability of elements isolated from the human body or otherwise produced, take account of society's concerns and of the financing needed for research. They comply strictly with the ethical rules recognised in the European Community, while protecting inventions developed in that field. Since biotechnology and genetic engineering are not fixed and static sciences, it is incumbent on the Commission to identify and assess problems which have recently appeared or which have become more pressing.

In the light of the above, the Commission should, in particular, consider two questions identified in this first report, viz.:

- The scope to be conferred on patents relating to sequences or part-sequences of genes isolated from the human body;

- The patentability of human stem cells and of cell lines obtained from them.

INTRODUCTION

The biotechnology sector was identified by the Stockholm European Council as one of the most promising in terms of economic development and employment. However, positive measures need to be taken at Community level in order to derive maximum benefit from this resource.

The conclusions of the Presidency, for instance, state that: "The ability of EU businesses to embrace technologies will depend on factors such as research, entrepreneurship, a regulatory framework encouraging innovation and risk-taking, including community wide industrial property protection at globally competitive costs, and the availability of willing investors, particularly at an early stage"[1].

The European Council gave the Commission, in cooperation with the Council, of examining the measures required to utilise the full potential of biotechnology and to strengthen Europe's competitiveness in this sector in order to match its leading Japanese and American competitors[2][3].

On 23 January 2002, therefore, the Commission adopted a Communication entitled "Life sciences and biotechnology – A Strategy for Europe"[4]. This Communication, which is intended to summarise all the various aspects of biotechnology, including the patentability of inventions in this field, aims to provide an overview of the situation in the European Community. In addition, an action plan attached to the Communication sets out the priority guidelines for biotechnology, accompanied where appropriate with a timetable for the measures to be taken.

Action 5 - the most relevant for the purposes of this Report - states explicitly that the Member States must incorporate Directive 98/44/EC into national law without delay[5]. This Report can only emphasise this essential precondition. The Communication insists on the fact that "The full implementation of Directive 98/44/EC on the legal protection of biotechnological inventions will considerably improve legal certainty for industry. The clarification of the legislative environment within the EC will provide innovative firms in the various industries using biotechnology with an incentive to continue or even increase their investments in research."[6].

The Communication also points out that, in view of the rapid scientific progress to be observed in this field of technology, close attention must be paid to the legislation on

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1 Conclusions of the Presidency – Stockholm, 23 and 24 March 2001 –SN 100/01, point 43, p.11

2 Conclusions of the Presidency, op. cit., point 44, p.11

3 With a view to the Barcelona European Council, the Dutch and British Prime Ministers, Mr Kok and Mr Blair, addressed a letter to the Spanish Prime Minister, Mr Aznar, entitled 'Overcoming the European Paradox', in which they call upon the European Community to take the measures needed to achieve the objectives set out at the Lisbon European Council in March 2000, aimed at making the European Union the most competitive and dynamic economy in the world by 2010. To do so, the Commission should deliver, in the spring of 2003, an action plan for creating an integrated European research and innovation area.
For further details of this letter: http://www.pm.gov.uk/news.asp?newsID=3657.

4 COM(2002)27 final.

5 COM op.cit. Action 5 of the action plan p.25

6 COM op. cit. p.11.

intellectual property. Regular assessments, for instance, will be needed to determine whether the patent system is meeting the needs of researchers and companies[7].

This Report is fully in line with the foregoing.

When Directive 98/44/EC was adopted on 6 July 1998, the European legislator considered it useful to incorporate into it various reports to be submitted by the Commission to the Council and the European Parliament.

Article 16(a) provides for a five-yearly report on whether the Directive has raised any problems with regard to the international agreements on the protection of human rights to which the Member States have acceded. Under Article 16(b), the Commission must draw up a study assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable[8].

Finally, Article 16(c) of the Directive provides for an annual report on the development and implications of patent law in the field of biotechnology and genetic engineering[9].

This is the first such Report.

1. THE CURRENT SITUATION IN EUROPE

1.1. Implementation of the Directive in the Member States

It should be pointed out that it proved rather difficult to draw up this Report since, according to the information available to the Commission at the time of drafting it, only six Member States had transposed the Directive into their national legal systems: Denmark, Finland, Ireland, the united Kingdom, Greece and Spain[10].

The other Member States are currently at varying stages of progress. In some countries (Germany, Italy, Luxembourg, Netherlands, Austria, Portugal) the discussions are already taking place before the national parliaments. In Belgium, France and Sweden, a draft law transposing Directive 98/44/EC has been given the go-ahead by the various ministers involved, but it has not yet been possible to submit it to the national parliaments.

However, this transposal is essential in order to avoid any discrepancies between the legislations of the Member States. If such a situation were to continue, it would have the effect of considerably hampering the development of biotechnology in Europe.

It appears important to stress the fact that patent protection in the European Union is currently ensured by two systems, neither of which is based on a Community legal instrument: the European Patent System and the national patent systems.

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7 COM op. cit. p.15.

8 That Report was transmitted by the Commission on 14 January 2002, COM(2002)2 final.

9 Genetic engineering can be defined as a technique involving the introduction of changes to the DNA molecule of a living organism without the intervention of natural means of reproduction.

10 Progress in transposing Directive 98/44/EC in the Member States of the European Community is shown in a document attached to this Report (Annex 1).

It nevertheless remains desirable, particularly in the field of biotechnology, to be able to obtain a Community patent of a unitary nature valid in all the Member States of the European Community. It is with that in mind that the Commission has submitted a draft Regulation on the Community patent[11], which is currently being discussed in the Council[12]. The European Parliament delivered its opinion on 10 April 2002[13].

In the light of the recent ruling of the Court of Justice confirming the compatibility of the Directive with various legal principles and international obligations, the Commission will make every effort to consider what action is appropriate to help ensure a full and speedy transposal of the Directive into national law, where this has not already been achieved.

1.2. Incorporation of the Directive by the European Patent Organisation

It should also be pointed out that the main provisions of Directive 98/44/EC have been incorporated into the Implementing Regulations to the European Patent Convention (hereinafter "the EPC") by a Decision of the Administrative Council of the European Patent Organisation (hereinafter "the Organisation") of 16 June 1999[14]. The new rules 23b *et seq.* and Rule 28(6) take over the essential provisions of the Directive, and in particular its Articles 4, 5 and 6. Moreover, Rule 23b lays down that Directive 98/44/EC is a supplementary means of interpreting these rules, and hence the relevant provisions of the Convention. The Boards of Appeal, which are not bound by any instructions and must comply only with the provisions of the Convention and its Implementing Regulations, may profitably refer to the Articles of the Directive and the attached recitals to back up their decisions. Certain decisions reached by the quasi-judicial bodies of the Organisation refer explicitly to Directive 98/44/EC[15].

This incorporation of Community law by the Organisation is important. The European Patent Convention lays down a single procedure for examining applications for patents (carried out by the European Patent Office (hereinafter "the EPO")), which makes it possible to have a range of national patents governed by national and Community law. Patents for biotechnological inventions are thus granted in compliance with the provisions of the Directive.

Moreover, the provisions of the Directive taken over into the Implementing Regulations apply also to patents granted for Switzerland, Liechtenstein, Monaco, Cyprus, Turkey, the Czech Republic, Slovakia, Bulgaria and Estonia[16].

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11 COM(2000)412 final, 1.8.2000.

12 In point 5 of the action plan adopted in the Communication on Life sciences and biotechnology, the Commission enjoins the Council to adopt the Regulation on the Community patent.
COM, op.cit., p.25.

13 Not yet published in the OJ.

14 JO EPO 7/1999, p. 437.

15 Decision of an Opposition Division of the EPO of 20 June 2001, OJ EPO 6/2002, p.293; cf. footnote 52.

16 The last four countries listed joined the European Patent Organisation on 1 July 2002. In addition, following an agreement between the Organisation and Albania, Lithuania, Latvia, the Former Yugoslav Republic of Macedonia, Romania and Slovakia, the European Patent Office grants patents with effect in those countries.

1.3. Annulment proceedings by the Netherlands against Directive 98/44/EC - Decision of the Court of Justice of the European Communities of 9 October 2001

By application of 19 October 1998, the Kingdom of the Netherlands, with the support of Italy and Norway (by virtue of the Agreement on the European Economic Area) brought an action for annulment of Directive 98/44/EC.

The Council and the European Parliament were the defending parties, with the Commission intervening in support of the Directive.

The application by the Netherlands put forward six pleas, relating respectively to the incorrect legal basis for the Directive, breach of the principle of subsidiarity, breach of the principle of legal certainty, breach of obligations in international law, breach of the fundamental right to respect for human dignity and breach of procedural rules in the adoption of the Commission's proposal.

In addition, the Kingdom of the Netherlands submitted an interim application to the President of the Court of Justice of the European Community aimed at postponing the implementation of Directive 98/44/EC, on the grounds of the urgent need of the Member States not to be forced to implement Directive 98/44/EC after the expiry of the deadline for transposal. According to the Netherlands, transposal would have had serious and irreversible consequences which could not have been rectified in future. By an injunction of 25 July 2000, the President of the Court rejected that application.

The pleadings took place before the Court of Justice on 13 February 2001. The conclusions of Advocate-General Jacobs were delivered on 14 June 2001 and recommended that the action for annulment be dismissed[17].

The judgment of the Court of 9 October 2001[18] upheld the conclusions of the Advocate-General and dismissed the action.

This judgment is of particular importance in that it allowed the Court to reiterate *de jure* the essential principles of Directive 98/44/EC. In addition, the new light cast on the precise provisions[19] should facilitate and speed up the transposal of the Directive in certain Member States.

The reasoning behind this judgment is dealt with later in this Report[20].

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17 http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=fr&Submit=Rechercher&docrequire=alldocs&numaff=C-377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100

18 http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docrequire=alldocs&numaff=C-377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100

19 In particular, certain provisions examined in this Report (patentability of plants, of elements isolated from the human body or otherwise produced, exceptions to patentability for reasons of *ordre public* and morality).

20 This Report will deal only with the grounds relating to the essential provisions of the Directive, and more specifically the arguments in support of Article 4 (patentability of plants and animals), Article 5 (patentability of elements isolated from the human body), and Article 6 (exclusion from patentability for reasons of *ordre public* and morality).

1.4. Review of the key provisions of the Directive

The Commission's intention here is not necessarily to provide guidelines for interpreting Directive 98/44/EC, because the Directive contains provisions which are sufficiently clear to allow its implementation in the national law of the Member States.

The objective is rather to summarise the various elements emerging from the preparatory work on the Directive, the conclusions of the Advocate-General and the judgment of the Court. These should therefore be viewed in parallel with the relevant provisions of Directive 98/44/EC.

It must first of all be stressed that the Court of Justice reiterated the scope of the Directive: the Directive essentially restricts itself to laying down certain principles applicable to the patentability of biological material and the extent of the protection conferred by a patent for a biotechnological invention. The conditions relating to authorisation of the research (in particular research on human stem cells) or the exploitation of the patented products are governed by the applicable and relevant national, Community or international provisions[21].

As an example, the Directive may not therefore regulate the free and informed consent of the donor and recipient of biological material of human origin, which remains governed by the substantive law applicable in compliance with the fundamental principle of human integrity[22].

This Report will focus on the following four essential topics:

- The compatibility of the Directive with the relevant international agreements.
- The patentability of inventions relating to plants and animals.
- The patentability of inventions relating to elements isolated from the human body.
- The exclusions from patentability set out in Article 6 of the Directive.

These major principles will be discussed at length in this Report.

2. THE COMPATIBILITY OF THE DIRECTIVE WITH THE RELEVANT INTERNATIONAL AGREEMENTS

Many bodies at international level have looked into, or are currently looking into, the question of the protection of biotechnological inventions. The Council of TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights), when studying the provisions of Article 27(3)(b) of the Agreement, has frequently had occasion to look into this question. The discussions held in the FAO or under the CBD have also dealt with this problem.

[21] Point 79 of the judgment.
[22] Points 78 to 80 of the judgment.

It appears incontestable that the Directive is fully compatible with the existing treaties in the field of biotechnology.

2.1. The compatibility of the Directive with regard to certain international agreements

In connection with the action for annulment of Directive 98/44/EC, the Court examined whether it was competent to assess the validity of the Directive with regard to certain international agreements, such as the EPC, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the WTO, and the Convention on Biological Diversity (CBD).

To start with, it should be pointed out that the Directive does not set out to affect the obligations incumbent on the Member States under international agreements. Article 1(2) lays down, in particular, that the Directive is without prejudice to the provisions of the TRIPS Agreement and those of the Convention on Biological Diversity.

The Court does not consider itself competent to assess the validity of the Directive with regard to the European Patent Convention, in that the European Community is not a party to it. Likewise, the Court declines its competence with regard to the compatibility of the Directive with the TRIPS Agreement (to which the EC is a party for those aspects for which it is competent), in view of the fact that that Agreement is based on a principle of reciprocal and mutually advantageous arrangements[23].

On the other hand, the Court declares itself competent with regard to the legality of the Directive vis-à-vis the Convention on Biological Diversity[24]. However, it points out that there is no provision in the CBD which requires that the conditions for the grant of a patent for biotechnological inventions should include the consideration of the interests of the country from which the genetic resource originates or the existence of measures for transferring technology[25]. Moreover, the Court reiterates that, by virtue of Article 1(2) of Directive 98/44/EC, the Member States are required to apply the Directive in accordance with the obligations they have undertaken as regards biological diversity[26]. It is also stipulated, in recital 55 of the Directive, that the Member States, when implementing it, must give particular weight to Article 3 (ownership of genetic resources), Article 8(j) (traditional know-how) and Article 16 (access to and transfer of technology) of the CBD.

2.2. The Substantive Patent Law Treaty (negotiated in the framework of the WIPO)

Of the work being done at international level, that being done in WIPO (World Intellectual Property Organisation) on the SPLT (Substantive Patent Law Treaty) is particularly likely to have an impact on Directive 98/44/EC.

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23 Point 53 of the judgment.

24 Point 53 of the judgment.

25 Point 66 of the judgment.

26 Point 67 of the judgment.

It should be reiterated first that the European Community as such is not a member of WIPO[27]. Since, however, the Member States are all parties to that Organisation, they are obliged, by virtue of Article 10 of the EC Treaty, not to compromise existing policies and Community law. Moreover, with the advent of the future Community patent, the European Community is destined to become a party to that future treaty.

Work on the SPLT started after the adoption of the PLT (Patent Law Treaty) in June 2000[28], relating to the formal harmonisation of patent law. The governing bodies of WIPO have decided to relaunch the process of harmonising substantive patent law to include, in particular, inventions in the field of biotechnology[29].

This new draft treaty is intended to establish, at international level, binding provisions applicable to substantive patent law. The treaty aims to dovetail with the TRIPS Agreement, the PLT and the PCT (Patent Cooperation Treaty).

At the current stage in the negotiations, the provisions of the Directive which might be affected by the negotiations are those relating to industrial application and those relating to the deposit of a biological material with a recognised institution. The Commission intends to keep a close eye on developments in these international negotiations.

3. THE PATENTABILITY OF INVENTIONS RELATING TO PLANTS AND ANIMALS

The Directive distinguishes between plant and animals which are patentable and plant and animal varieties which are not. The reason for this differentiation lies in the means of achieving the product concerned: a plant or animal variety is generally obtained by essentially biological processes (sexual reproduction observable in nature), while transgenic plants and animals are obtained through non-biological processes forming part of genetic engineering.

By virtue of the leeway provided by Article 27(3)(b) of the TRIPS Agreement, the Directive did not make use of the possibility afforded to the Members to exclude plants and animals from protection through patents.

3.1. The patentability of inventions relating to plants

The Directive reiterates that, while plants are patentable, plant varieties are excluded from patentability and are protected by plant variety rights. This right complies with the *sui generis* protection provided for by the TRIPS Agreement[30].

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27 The work on the SPLT is taking place in the Standing Committee on the Law of Patents. The European Community has observer status only. However, it has delegation status in other committees, e.g. the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications.

28 http://www.wipo.org/treaties/ip/plt/index.html

29 It should be borne in mind that a similar exercise had already been embarked upon in the 1980s and had ended in failure at the Diplomatic Conference in The Hague in 1991.

30 The TRIPS Agreement offers its Members three possible ways of protecting plant varieties:
- protection by patents;
- protection by an effective *sui generis* system. In western countries, it is generally accepted that the system that should serve as a basis for this type of protection is that offered by the UPOV Convention, particularly as last amended in 1991. However, some Members of the WTO consider

Article 5(2) of Council Regulation (EC) 2100/94 of 27 July 1994 defines a plant variety as a plant grouping within a single botanical taxon of the lowest known rank[31].

3.1.1. The relevant provisions of the Directive

The relevant provisions of the Directive are to be found in Article 4 and recitals 29 to 32.

In the action for annulment of Directive 98/44/EC, the applicants considered that the provisions relating to the patentability of plants and animals were unclear and ambiguous, and hence a source of legal uncertainty which justified an annulment of the Directive.

The Court rejected those arguments. It referred to the substance of Article 4 of the Directive, which lays down that a patent cannot be granted for a plant variety, but may be for an invention if its technical feasibility is not confined to a particular plant variety[32].

On the basis of recitals 29 to 32 of the Directive, therefore, it reiterated that plant varieties are defined by their whole genome and are protected by plant variety rights. However, plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, may be protected by patent if the relevant invention incorporates only one gene and concerns a grouping wider than a single plant variety.

The Court concluded that a genetic modification of a specific plant variety is not patentable but a modification of wider scope, concerning, for example, a species, may be protected by a patent[33] [34].

It should be noted that this distinction does not apply in the United States. The Supreme Court, in a Decision of 10 December 2001, judged that a patent could be granted for an invention relating to a plant variety if it met the conditions required (novelty, non-

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that protection models organised within the framework of the Convention on Biological Diversity can also serve as the basis for the *sui generis* protection referred to in the TRIPS Agreement;
- a combination of those two means. This is particularly the case with the situation in the United States, where protection by patent or by plant variety right is possible for one and the same plant variety.

31 The taxon represents a group of organisms forming a clearly defined unit at each of the different hierarchical levels of classification.

32 Point 43 of the judgment.

33 Points 44 and 45 of the judgment.

34 The Enlarged Board of Appeal of the European Patent Organisation was seised of a dispute involving this very question. Its Decision of 20 December 1999 is based *mutatis mutandis* on the same considerations as contained in Directive 98/44/EC, viz.:
- A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.
- If the subject of a patent relates, for example, to a process for obtaining a plant variety, the rights conferred by that patent do not extend to the plant variety obtained directly by that process.
- The exception to patentability in Article 53(b), first half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability OJ EPO 3/2000, p.111.

obvious subject matter, utility, sufficient description and deposit of biological material accessible to the public)[35].

3.1.2. Community action needed on cross-licences

Article 12 of the Directive establishes a system of cross-licences between plant variety rights and patents where a breeder cannot obtain or exploit a plant variety right without infringing a prior patent, and vice versa.

Applicants for licences must demonstrate that they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence, and that the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

Paragraph 4 of that Article lays down that, where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

Member States cannot be expected not to transpose into national law a provision which would have to be amended by the Commission under the Regulation cited above.

Article 29 lays down that the Community Plant Variety Office shall grant such licences **only on grounds of public interest**.

Moreover, pursuant to Article 29(7) of Regulation (EC) 2100/94, only the Community Plant Variety Office is authorised to grant compulsory licences. However, under the applicable national law, that Office cannot be responsible for granting compulsory licences for national patents.

The Commission has examined the impact of Article 12 of the Directive on Article 29 of Regulation 2100/94. It has already taken the necessary steps to submit to the Council any suitable proposal for overcoming this difficulty.

3.2. The patentability of inventions relating to animals

This question was not broached in the judgment of the Court[36]. There is no legal definition of an animal variety. This can be defined as a taxonomical grouping ranking next below a sub-species (where present) or species, whose members differ from others of the same species[37] or sub-species in minor but permanent or heritable characters[38].

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35 JEM AG Supply, Inc./Pioneer Hi-Bred International, Inc., 10 December 2001, BNA's 14-12-01 (Vol. 63, No 1552), p.144. This Decision is based on the very broad field of protection established by the Diamond/Chakrabarty judgment, 447 US 303 (1980).
It is important to note that one judge did not take part in the vote and that two others expressed a dissenting opinion.

36 However, Advocate-General Jacobs touched on it in his conclusions.

37 A "species" is taken to mean a grouping of individuals with common morphological, anatomical, ecological, ethological, biochemical and physiological characteristics … the individuals in which resemble each other more than they resemble other equivalent groupings. To belong the same species, the individuals must together have fertile common descendants in natural conditions.

The relevant provisions of the Directive are essentially Articles 4 and 6(2)(d). It should also be noted that there is no protection of animal varieties in Community law.

3.2.1. Application of Article 4(2) of the Directive

Under Article 4(1)(a), animal varieties are not patentable. However, inventions relating to animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety[39]. If an animal can be obtained only through genetic engineering, to the exclusion of any natural breeding, the invention relating to such an animal may be protected by patent[40].

This question has been debated many times in the context of the patent for the Harvard oncomouse. This patent relates to a mammal modified by genetic transfer. Thanks to this manipulation, the animal may, under certain conditions, develop tumours which can be used for cancer research[41].

After more than 16 years of proceedings, the Opposition Division of the EPO responsible for this case decided on 7 November 2001 to limit this patent to transgenic rodents with the cancerous gene, and hence not to authorise its extension to all mammals with the introduced gene. In the United States, this patent was granted in its initial form, i.e. it covers any non-human transgenic mammal[42].

It should also be noted that, in a judgment of 3 August 2000, the Canadian Federal Court of Appeal accepted that this patent had the same scope as that granted by the American Patent Office (USPTO)[43].

3.2.2. Patent EP 0 578 653 B [Seabright Patent]

Since the adoption of Directive 98/44/EC in July 1998, amongst the many patents granted in the field of biotechnology and genetic engineering, some of the patents granted by the European Patent Office have raised public concern. One particular case is a patent granted to the Seabright company.

European Patent EP 0 578 653, granted on 18 July 2001, relates to the creation of a transgenic fish characterised by the incorporation of a chimeric gene[44] of non-human origin. This patent also covers the tests for determining transgenic fish.

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38 Definition taken from the Shorter Oxford English Dictionary, cf. the conclusions of Advocate-General Jacobs, point 131.

39 It should be noted that, under Article 4(3) of the Directive, it is also possible to obtain a patent for technical processes which make it possible to obtain a new animal, or for the animal obtained by such processes.

40 The reasoning put forward for plants applies *mutatis mutandis* to animals.

41 For further information, consult the EPO website: http://www.european-patent-office.org/news/pressrel/2001_11_05_e.htmm

42 US Patent 4.736.866.

43 President and Fellows of Harvard College/Canada, FCJ No 1213. For more information on this case, see Mark Perry and Priti Krishna 'Making Sense of Mouse Tales: Canada Lifeform Patents Topsy-Turvy', EIPR [2001] 4, p. 196

44 Chimera: organism having developed from an embryo formed of cells originating in two different individuals, and hence made up of cells possessing two different genotypes.

EMP Jaime Valdivielso de Cué submitted a written question to the Commission on the compatibility of granting such a patent with the exclusion from patentability of animal varieties. On behalf of the Commission, Mr Bolkestein replied to this question on 21 December 2001. He pointed out that Rule 23b of the Implementing Regulations to the European Patent Convention, which takes over the substance of Article 4 of Directive 98/44/EC, lays down that a patent for an invention relating to an animal may be obtained if the technical contribution involved in the claimed invention is not confined to a particular animal variety. This would appear to be the case here.

It should be noted that the chimeric gene behind the creation of this transgenic fish is not intended to produce a hybrid being formed from germ or totipotent human and animal cells. If that were the case, this invention would involve the cloning of a chimeric being (of partly human origin) and would hence be excluded from patentabiity.

3.2.3. Exclusion under Article 6(2)(d) of the Directive

Article 6(2)(d) lays down that processes for modifying the genetic identity of animals which are likely to cause them suffering, without any substantial medical benefit to man or animal, and also animals resulting from such processes, are excluded from patentability.

This exception is in line with the general exclusion concept laid down for invention whose commercial exploitation would be contrary to *ordre public* or morality.

Recital 45 states that the substantial medical benefit for man and animal referred to in Article 6(2)(d) must be present in the field of research, prevention, diagnosis and therapy.

The European Group on Ethics in Science and New Technologies delivered an Opinion on 21 May 1996[45] on the ethical aspects of the genetic modification of animals. According to that Opinion, such modifications are admissible and can be parented, but in view of the consequences which the techniques used might have for human and animal health, as well as for the environment and society, extreme care is called for. This care must apply to both the obtaining of genetically modified animals and to their use and welfare.

3.3. Exclusion of essentially biological processes - patentability of microorganisms

To be exhaustive on this question, it should be pointed out that essentially biological processes for obtaining animals and plants are not patentable. *A contrario*, an essentially non-biological process will be patentable. It is for the courts to assess this difference.

Article 27(1)of the TRIPS Agreement lays down a general principle of patentability in all fields of technology. However, under Article 27(3)(b), Members may exclude plants and animals from patentability even when the inventions relating to them meet the classic conditions for patentability. However, the same Article states that its Members must provide for patent protection of non-biological processes.

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[45] Opinion No 7 available at the following website: http://europa.eu.int/comm/european_group_ethics

The same applies to microbiological processes. Moreover, again according to the TRIPS Agreement, microorganisms must be patentable if the patentability conditions are met.

That is why Article 4(3) lays down that inventions which concern a microbiological or other technical process or a product obtained by means of such a process are not *per se* excluded from patentability.

4. THE PATENTABILITY OF INVENTIONS RELATING TO ELEMENTS ISOLATED FROM THE HUMAN BODY:

The human body, at the various stages of its formation and development, is not patentable, as it involves a simple discovery. The same applies to the simple decoding of one of its elements. This exclusion also covers the discovery of a sequence or partial sequence of a gene.

However, an element isolated from the human body, including a sequence or partial sequence of a gene, by techniques of identification, purification, characterisation and multiplication, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The same reasoning can obviously be applied to any element produced otherwise synthetically by a technical process.

This type of invention, which is eligible for patent protection, must nevertheless fulfil the classic conditions for patentability, i.e. novelty, inventive step and industrial application.

The Directive allows a degree of flexibility as to the extent of the protection to be conferred on inventions relating to elements isolated from the human body.

4.1. Distinction to be made between simple discoveries and patentable inventions - conditions for patentability

4.1.1. The relevant provisions of Directive 98/44/EC:

In the context of its scope, the Directive considers the conditions to be met for patent protection of inventions relating to biological material. For instance, the Directive reiterates the basic principles of patent law, i.e. that inventions which are **new**, which involve an **inventive step** and which are susceptible of **industrial application** are patentable.

In the case of the human body, elements isolated from it or otherwise produced by a technical process, the Directive provides guidelines in addition to the classic conditions for patentability.

Articles 5(1) and 5(2), in conjunction with recitals 16, 20 and 21, strive to make the distinction between non-patentable discoveries and patentable inventions. In the first place, they lay down that the human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

It also emerges from the explanatory memorandum to the common position adopted by the Council on 26 February with a view to the adoption of Directive 98/44/EC that the

terms "the human body, at the various stages of its formation and development" cover the embryo[46].

It follows that neither the human genome in its natural state nor the crude fundamental data relating to the human genome constitute patentable inventions. The Directive is thus in line with Article 4 of the UNESCO Declaration on the human genome, in that it does not provide for any financial gain relating to the human genome in its natural state[47]. The Directive in line with the Joint Declaration on the human genome made in 2000 by President Clinton and Prime Minister Blair[48].

Nevertheless, Article 5(2) of the Directive lays down 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 should be noted from the outset that, contrary to what is sometimes affirmed, the Directive is not intended to jeopardise respect for the integrity of the human body. A valid patent cannot be obtained for an invention aimed at isolating from its natural state an organ of the human body, for instance a kidney, in order to sell it. Such an invention would undoubtedly run counter to non-ownership of the human body, an essential principle of the European Community, and would have to be excluded from patentability on the basis of Article 6(2) of the Directive[49].

Some people nevertheless consider that this second paragraph amounts to a denial of the general principle of non-patentability set out in the first paragraph and thus makes a nonsense of the non-patentability of the human body. This is not so. As set out in recital 21, the reasoning is that, to qualify for patentability, an element from the human body, including a sequence or partial sequence of a gene, must, for instance, be the result of technical processes which have identified, purified, characterised and multiplied it outside of the human body. Such techniques cannot be found in nature. Taken out of their natural context, elements isolated from the human body cannot be exploited on an industrial basis. They would show only natural properties which man alone, through genetic engineering, is capable of exploiting and inserting into a technical process. The well-known distinction in patent law between a discovery and an invention thus applies fully in the field of biotechnology[50].

In the context of Directive 98/44/EC, Article 5(2) confines itself to laying down that an element isolated from the human body may constitute a patentable invention. That

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46 OJ C 110, 8 April 1998, p.28, point 20.

47 http://www.unesco.org/ibc/en/genome/projet/index.htm.

48 Joint Declaration made by videoconference from the White House. The relevant passages of the Declaration are as follows:
"As with the greatest scientific achievements, the ethical and the moral questions raised by the astonishing breakthrough are profound. We, all of us, share a duty to ensure that the common property of the human genome is used freely for the common good of the whole human race, to ensure that the powerful information now at our disposal is used to transform medicine, not abused to make man his own creator or invade individual privacy."

49 See the passages devoted to this question in Section 5 of this Report.

50 In the United States, the Supreme Court affirmed in its Diamond/Chakrabarty judgment (op.cit.) that the scope of patentability included absolutely everything produced by mankind. The exact implications of this judgment appear open to interpretation.

invention would still have to meet the standard criteria for patentability, with particular reference to its inventive nature and its industrial applicability. It should be noted that American law also requires compliance with similar criteria (novelty, non-obviousness, utility[51]).

It is sometimes countered that the process of isolating a particular gene by cloning has become so routine that it does not involve any inventive step. If that is the case, that particular gene might nevertheless represent an invention, although it would not be patentable as it did not meet the standard criterion of an inventive step. The Directive does not modify the well-established criterion allowing determination of whether an invention fulfils the requirement of an inventive step.

It is nowadays possible to deduce the function of a gene by making computer comparisons with other genes whose functions are already known. In such cases, the patentability of the gene can be refused on the grounds of the absence of an inventive step.

Whereas the Directive did not need to provide additional guidelines on the question of the inventive step, this did not appear to be the case with industrial applicability. Here, it was judged necessary to provide guidelines to help to determine whether a gene sequence meets the requirement of industrial applicability. Recital 23 lays down that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.

Recital 24 adds that, in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, it is necessary, in order to meet the requirement of industrial application, to specify which protein or part of a protein is produced or what function it performs: the level of description required as to the specific utility may vary from case to case, depend on the knowledge available, and vary as the use of genes for therapeutic and diagnostic purposes spreads.

In a very recent decision, an Opposition Division of the EPO laid down what was to be understood by industrial application in the context of a gene sequence. The potential utilisation of a sequence disclosed in an application must not be speculative, i.e. it must be specific, substantial and credible[52].

Finally, meeting the criterion of industrial applicability is only one of the obstacles on the road to obtaining a patent. The fact is that the general rules on assessing the patentability of an invention relating to a gene or partial gene sequence continue to apply. Recital 8 of the Directive reiterates this unambiguously. It is necessary, for instance, to meet in particular the requirement to describe the invention sufficiently clearly and fully for it to be possible for it to be reproduced by a person skilled in the art. The examiner assessing

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51 The concept of non-obviousness overlaps more or less with that of inventive step. On the other hand, the concept of utility may sometimes diverge from that of industrial application.

52 Decision of the Opposition Division of 20 June 2001, ICOS/SmithKline Beecham and Duphar International Research, OJ EPO 6/02, p.293. An appeal has been lodged against this Decision.
It should be pointed out that the guidelines published by the USPTO adopt more or less the same approach. For instance, an application relating to an invention involving an isolated and purified gene for which a specific, substantial and credible utility has been claimed, may lead to the granting of a patent.
Federal Register/Vol. 66, N°4/ Friday January 5, 2001/Notices, p. 1093

the patent application must be in a position theoretically to reproduce the invention on the basis of the elements provided to him in the application. According to Article 13 of the Directive, where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered adequate for the purposes of patent law only if the biological material has been deposited no later than the date on which the patent application was filed with a recognised depository institution[53]. This Article also lays down that the application as filed must contain such relevant information as is available to the applicant on the characteristics of the biological material to which the invention relates or which is used in the context of the invention.

In its Opinion No 8 of 25 September 1996[54], on "The ethical aspects of patenting inventions involving elements of human origin", the European Group on Ethics considered that:

– The traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular ethical dimension.

– The simple knowledge of the complete or partial structure of a gene cannot be patented.

– Concerning the inventions issued from the knowledge of a human gene or a partial human gene sequence, the granting of a patent is acceptable only if, on the one hand, the identification of the function attached to a human gene, or a partial human gene sequence allows new possibilities (for instance the production of new drugs), and, on the other hand, if the intended use of the patent is sufficiently specific and identified.

4.1.2. The relevant passages of the judgment of the Court:

The Court was called upon to rule on the grounds adduced for an annulment of the Directive in the framework of its adoption, and in particular on the failure to comply with the fundamental rights relating to the respect of human dignity and human integrity with regard to Article 5 of the Directive, and to call for the annulment of that Directive.

As regards human dignity, the Court points out that that principle is clearly taken into account in the Directive in so far as Article 5(1) of the Directive provides that the human body at the various stages of its formation and development cannot constitute a patentable invention[55].

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53 The same Article 13 lays down that: "At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty`, shall be recognised."

54 Opinion available at the following address: http://www.europa.eu.int/comm/european_group_ethics

55 Point 71 of the judgment.

The Court affirms that respect for individual integrity is also respected by the Directive. It points out that an element of the human body may not, in its natural environment, be appropriated. The mere fact of discovery does not confer any right[56].

On the other hand, only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent[57].

The Court goes on to affirm that the same applies to sequences or partial sequences of human genes. It states that the result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead. If these two conditions are not met, the patent could not be granted, as it would involve a mere discovery[58].

4.1.3. Patents EP 699 754 and EP 705 903 [Myriad Genetics patents on the detection of breast cancer]

These two patents granted to the company Myriad Genetics are based on an invention which allows screening for cancer of the breast and ovaries in women (these tests are based on the two genes BRCA1 and BRCA2). The patents granted to Myriad Genetics relate to methods and material used to isolate and screen for the mutation of certain alleles of the BRCA1 and BRCA2 genes which may cause breast or ovarian cancer. The tests planned by the company appear to be more comprehensive than those previously available. Moreover, unlike the tests previously available, these tests do not require samples taken from relatives who have themselves contracted breast or ovarian cancer.

Numerous questions on these patents have been put to the Commission, e.g. by the MEPs Raffaele Costa[59], Dorette Corbey and Ria Oomen-Ruijten[60], Astrid Thors[61], Nelly Maes[62] and Bart Staes[63]. These questions focused principally on the danger which granting the patents might pose for the freedom of research in the European Community, as well as on the high costs to European patients of access to the technology contained in the patents.

The Commission pointed out that Directive 98/44/EC is not intended to call into question the freedom of research in Europe[64]. Under that principle, acts undertaken done privately and for non-commercial purposes, as well as acts done for experimental purposes, do not constitute acts of infringement.

What is more, the Commission reiterated that, if research results are commercialised and these results use a technique which has already been patented, a sub-licence should be

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56 Points 72 and 73 of the judgment.
57 Point 72 of the judgment.
58 Point 74 of the judgment.
59 Written Question E-01/2676
60 Written Question E-3472/01
61 Oral Question H-0939/01
62 Written Question E-3399/01
63 Oral Question H-0061/02
64 See below, Section 4.2. Directive 98/44/EC on the legal protection of biotechnological inventions did not derogate from that principle. Likewise, the proposal for a Regulation on the Community patent reiterates unambiguously the concept of the freedom of research.

obtained from the holder of the patent. If the latter refuses to grant this licence on reasonable grounds, a compulsory licence could be granted against equitable remuneration in accordance with the applicable national provisions in the Member States' legislation[65].

Finally, the Commission reiterated that all national legislation in the Member States of the European Community contains the principle of exempting prior use, which allows anyone who had already used the invention in the European Community, or had made effective and serious preparations for such use, before the patent was filed[66], to continue such use or to use the invention as envisaged in the preparations. Here again, the proposal for a Regulation on the Community patent restates this principle unambiguously.

The European Parliament has adopted a Resolution[67] in which it calls upon the European Patent Office to give public account of the exercise of its duties of granting patents. It also asks for the European Patent Convention to be amended to allow the Office to revoke patents which it has granted at its own initiative.

The European Parliament calls upon the Council, the Commission and the Member States to take adequate measures to ensure that the human genetic code remains free of access and that the medical applications of certain human genes are not hampered by patents.

In a Declaration dates 17 October 2001, the EPO reiterates that it applies rules identical to those contained in Directive 98/44/EC when dealing with applications relating to biotechnological inventions. Furthermore, the Office is accountable for such acts to the Administrative Council of the European Patent Organisation. Finally, the Office draws attention to the existence of opposition procedures which can be invoked by any individual without his needing to prove a legitimate interest[68].

The problem raised by these patents appears to derive mainly from the field of patent law, in that it relates more to the extent of the protection to be conferred on these inventions.

4.2. The scope to be conferred on patents relating to elements isolated from the human body

Recital 8 of Directive 98/44/EC reiterates unambiguously that the general rules for assessing the patentability of an invention involving a gene or a partial gene sequence remain applicable.

Recital 28 reiterates that the Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a product already patented. If any new application of a sequence or partial sequence is patentable, the question arises as to what its status will be in relation to an initial patent

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65 In so far as the conditions laid down in the national legislation for the granting of compulsory licences (which are based on Article 31 of the TRIPS Agreement) are fulfilled.

66 Or, where priority is claimed, before the date of priority of the application on the basis of which the patent is granted.

67 B5-0633, 0641, 0651 and 0663/2001.

68 AC/145/01.

granted to that same sequence or partial sequence. Article 83 of the European Patent Convention lays down that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Further more, Article 84 adds that the claims must be clear and concise and be supported by the description[69].

On the basis of these Articles, the patent examiner will have the possibility of rejecting applications whose claims are too broad or, in discussions with the applicant, of obtaining a limitation of the claims to what is actually described in the patent.

The national offices can therefore grant patents relating only to the gene sequence which is essential for the function described, and excluding those that are not indispensable for that function.

Moreover, recital 13 of the Directive states that details must be provided of the extent of the protection conferred by a patent in the field of biotechnology.

Article 9 of the Directive lays down that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.

The explicit exclusion in Article 5(1) of the Directive clearly avoids any extension of the patent protection for an element isolated from the human body to the human body itself.

Moreover, recital 25 lays down that, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms.

A reading of Article 9 and the corresponding recital 25 would indicate that the Directive might provide some degree of flexibility as regards the scope of an invention involving a gene sequence. In fact, the use of the provisions contained in the Articles, in conjunction with certain recitals, gives a better picture of the scope to be conferred on patents for genes or partial gene sequences.

The judgment of the Court, for its part, indicates that the protection to be conferred on such inventions extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application[70].

In view of the rapid advances in the field of biotechnology, the extent of patent protection for genes or gene sequences could be a matter for review in the context of the reports provided for in Article 16(c) of the Directive, with a view to assessing whether various fields of patent protection involving elements isolated or otherwise produced from the human body could be accepted. If so, thought should be given to the measures required.

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69 It should be pointed out that national law on the granting of patents contains numerous provisions identical to those contained in the European Patent Convention.

70 Point 75 of the judgment.

In particular, consideration should be given to the scope to be conferred on patents involving DNA sequences and proteins deriving from those sequences, as well as those based on expressed sequence tags[71] (ESTs) and on single nucleotide polymorphisms[72] (SNPs).

5. EXCLUSION FROM PATENTABILITY OF INVENTIONS WHOSE COMMERCIAL EXPLOITATION WOULD BE CONTRARY TO *ORDRE PUBLIC* AND MORALITY:

The European legislator wished to exclude the patentability of inventions whose commercial exploitation would be contrary to *ordre public* and morality. To this end, processes for cloning human beings were recognised as being contrary to the principles of respect for human dignity. The legislator also wished to explicitly exclude processes for modifying the genetic identity of the human being and the use of human embryos for industrial or commercial purposes.

5.1. The general principle of exclusion under Article 6(1)

Article 6(1) of the Directive establishes a general principle of exclusion for inventions whose commercial exploitation would be contrary to *ordre public* or morality.

This Article is modelled on Article 27(2) of the TRIPS Agreement, which offers Members the possibility of including such an exclusion in their legislation. Under the TRIPS Agreement, this exclusion relates in particular to the protection of human life and health[73].

It was argued that the Directive was insufficiently precise and that there might therefore be wide differences of interpretation between Member States, leading to legal uncertainty. The judgment of the Court rejected that argument. It reiterated in this context that the mere prohibition by law or regulation does not make the commercial exploitation of an invention contrary to *ordre public* or morality[74].

It appeared necessary to leave the Member States with some margin of manoeuvre in assessing whether, on their territory, a biotechnological invention could be considered valid in the ethical, sociological or philosophical context of each country.

The Court therefore considered that the national legislative, administrative and court authorities are best placed to understand the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State[75].

Moreover, the Directive included four explicit exclusions from patentability, which was not the case in the body of law applicable to patents. This is thus in fact a clear source of legal certainty[76].

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71 ESTs are short fragments of DNA.

72 SNPs are genome sites at which there is a variation in the population of a particular base within a DNA sequence.

73 Under the TRIPS Agreement, other possible cases of exclusion are the protection of the life and health of animals, the preservation of plants and the need to avoid serious prejudice to the environment.

74 Point 39 of the judgment.

75 Point 38 of the judgment.

Similarly, the Court considers that the difference in wording between the exclusion provided for under Article 53 of the EPC and that provided for in Article 6 of the Directive is not such as to give rise to differences in assessing whether one and the same invention is contrary to *ordre public* or morality[77].

5.2. The specific list of exclusions in Article 6(2):

Article 6(2) of the Directive lays down an illustrative list of exclusions from patentability. Moreover, recital 38 states that this list is not exhaustive and that any process whose application offends against human dignity must also be excluded from patentability[78].

The aforementioned judgment of the Court thus reiterates that respect for human dignity, in particular as regards human embryos, is fully assured. Article 6(2) lays down that processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes are excluded from patentability.

5.2.1. Processes for cloning human beings

5.2.1.1. The text of the Directive

Processes for cloning human beings are defined in recital 41 as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another human being. The Common Position adopted by the Council with a view to the adoption of the Directive set out to exclude any form of cloning of human beings. In agreement with the Parliament, therefore, the Council preferred to replace the words "procedures for human reproductive cloning" with the words "procedure for cloning human beings" because it considered that the adjective "reproductive" could be too restrictive. In addition, it stated in the Explanatory Memorandum that the words "human beings" referred to the human being from the embryonic stage[79].

5.2.1.2. Patent EP 0 695 351 [so-called "Edinburgh Patent"]

A European patent was granted by the European Patent Office on 8 December 1999 for an invention entitled "isolation, selection and propagation of animal transgenic stem cells".

In scientific English, the term "animal" covers not just animals but also human beings, which might indicate that that the patent could cover the cloning of human beings. Oppositions were filed by various parties within the period allowed (nine months from the date of publication of the grant of the patent in the Official Bulletin).

By letter of 29 March 2000, the Commission enjoined the President of the European Patent Office to take all the necessary steps to amend the patent granted to ensure that

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76 Points 39 and 40 of the judgment.
77 Point 62 of the judgment.
78 Points 76 and 77 of the judgment.
79 OJ C 110, 8.4.1998, p.30, point 35.

was in compliance with the law in force in Europe. On 12 April 2000, the President of the Office pointed out that the Office was not in a position to amend *ex officio* the patent granted, but that an Opposition Division had already been entrusted with the case in order to assess the oppositions filed.

At the same time, the European Parliament expressed its unambiguous opposition to the grant of this patent in a Resolution adopted on 30 March 2000.

The Opposition Division of the European Patent Organisation handed down an initial preliminary judgment on 19 April 2000. Its opinion was based on the amendment of the set of claims by the proprietor of the patent, the University of Edinburgh, which added to claims 47 and 48 the adjective "non-human". The new set of claims now appeared to be in compliance with both the European Patent Convention and its Implementing Regulations and Directive 98/44/EC on the legal protection of biotechnological inventions.

The criticisms of this point expressed at the time of the grant of the patent were largely taken into account by the Opposition Division of the EPO. The opposition procedure is continuing on the basis of other grounds for annulment (in particular the concept of adequate description).

5.2.2. Patentability of human stem cells and cell lines obtained from them

It emerges clearly from the discussions when Directive 98/44/EC was being negotiated that the European legislator wished to avoid an instrumentalisation of humans and the creation of viable genetically modified human beings.

Furthermore, recent developments in the field of biotechnology and human stem cells show great promise for cures, particularly in the treatment of degenerative diseases, and European companies must be encouraged to work in these promising fields. Granting patents could, in particular, play this role.

The prospect of being able to devise cells created by the technique known as parthenogenesis[80] appears to open up new and as yet unknown paths which may well cut short the controversy about "therapeutic cloning".

The status of the cell lines obtained from multipotent cells which were or were not themselves created by "therapeutic cloning"[81] appears controversial. However, these cell lines are therapeutically promising, and European companies should be encouraged to develop them. As things stand, it would appear that Article 5(2) of the Directive on the patentability of elements isolated from the human body could be applied.

Discussions should therefore continue on this question and on measures which might be taken to encourage this type of research.

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80 Parthenogenesis is defined as the development of an ovule without there having been any fertilisation by a spermatozoid. Parthenogenesis is a uniparental sexual reproduction.

81 This involves transferring the nucleus of a somatic cell to the interior of asexual cell. This technique is known by its English abbreviation: SCNT (Somatic Cell Nuclear Transfer). It should be noted that this technique may be used in the context of both reproductive cloning and therapeutic cloning. Only the objective of the two types of cloning differs.

At the same time, the European Group on Ethics was asked by the President of the Commission to look into the ethical aspects of the patentability of inventions involving human stem cells. The Group issued its Opinion No 16 on 7 May 2002[82].

In this Opinion, the Group recognises the importance of patents as a means of encouraging innovation by granting monetary compensation to the inventor in return for the transparency and publication of his results.

The Group insists on the importance of ensuring an equitable balance between the interests of the inventor and those of society, and hence of defining the conditions and limits for the patentability of stem cells. The Group underlines the need to avoid excessively broad patents on cell lines of stem cells. The protection conferred by a patent should relate to precisely described industrial applications, and not to a wide range of potential applications which cannot be described.

Human stem cells may be cells of adult, foetal or embryonic origin. The ethical issues vary according to the source of the cells, which is why the Group is of the view that any application for a patent involving human stem cells should specify their origin.

5.2.3. Processes for modifying the germ line genetic identity of human beings

This prohibition unambiguously prevents the patentability of processes for gene therapy on human germ cells[83], in particular in order to respect the physical integrity of descendants. On the other hand, this prohibition cannot by itself prevent techniques for gene therapy on somatic cells[84], such techniques being very valuable for the treatment of genetic diseases. In his conclusions, Advocate-General Jacobs queried the status of recital 38, and particularly whether the exclusion of processes to produce chimeras from germ cells or totipotent cells of humans and animals, as set out in that recital, could be covered by the exclusion provided for in Article 6(2)(b)[85]. He pointed out that a chimera is an organism or recombinant DNA molecule created by joining DNA fragments from two or more different organisms. According to the Advocate-General, the production of chimeras from germ cells or from totipotent cells of humans and animals would inevitably modify the germ line genetic identity of human beings. In conclusion, he considered that, at all events, if the exclusion provided for in recital 38 could not be covered by this explicit exclusion, it could be covered by the general conclusion provided for in Article 6(1). The Commission cannot but share this view.

5.2.4. The use of human embryos for industrial or commercial purposes

In the Common Position adopted by the Council, the latter stated that the exclusion from patentability of the use of human embryos applied only when such use was for industrial or commercial purposes[86]. It can be seen from recital 42 that it was the wish of the Council, as well as of Parliament, that inventions for therapeutic or diagnostic purposes

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82 Opinion available at the following address: http://www.europa.eu.int/comm/european_group_ethics

83 Male and female reproductive cells (sperm and eggs).

84 Already differentiated non-germ cells from the human body.

85 Points 110 to 112 of the conclusions.

86 OJ C110, 8.4.1998, p.30, point 37.

which are applied to the human embryo and are useful to it should not be affected by this exclusion.

6. CONCLUSION

The information given in this Report allows one to conclude that the European legislator wished to lay down provisions which took account of the diverging interests of society in this field of technology. It should be noted that some of them leave the Member States with some room for manoeuvre in transposal.

The Directive appears to comply with the international agreements in force relating to biotechnological inventions. The Commission will follow with the greatest interest the treaties currently being negotiated which might have a bearing on this field (SPLT) and those to come.

As regards the actual provisions of the Directive, the European legislator has succeeded in creating a functional system which respects the major ethical principles recognised within the European Community. In this context, the European Group on Ethics is an important element in the ethical debate on these questions at Community level.

A clear distinction is drawn between animals and plants, on the one hand, which are patentable, and plant and animal varieties on the other, which are not. Similarly, while essentially biological processes cannot be covered by a patent, that is not the case with processes devised by genetic engineering which make it possible to obtain transgenic animals and plants.

In the highly sensitive field of the patentability of elements isolated from the human body, the Directive reiterates the distinction to be made between what is patentable and what is not. The principles of the dignity, integrity and non-ownership of the human body must be adhered to scrupulously, and the Directive reiterates this unambiguously. On the other hand, elements isolated from the human body or otherwise obtained by genetic engineering must be eligible for patent protection if the conditions for patentability are met.

The Directive lays down a general principle of exclusion for inventions whose commercial exploitation would be contrary to *ordre public* or morality. The illustrative list of what is to be understood by this concept indicates unambiguously certain processes judged ethically unacceptable (cloning, modification of the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes). These exclusions allow society to protect itself against inventions which might have negative repercussions.

Certain provisions of the Directive appear to give the Member States some leeway in its transposal into national law. In the light of the developments set out in this Report, it appears that the scope to be conferred on sequences or partial sequences of genes remains a topical subject which may give rise to differing interpretations.

Similarly, the recent and irresistible advances in the culture of stem cells of human origin has raised some questions as to the possibilities for obtaining patents on the inventions developed around them.

It is undoubtedly for the Commission to monitor and assess the scientific and legal developments visible in this field of technology and to report on them to the interested parties within the European Community. In this respect, the Commission will stimulate an exchange between scientists, lawyers and patent administrators to analyse and discuss the interplay between scientific advances and legal developments, in particular by setting up a group of experts.

These assessments comply fully with the line set out by the Commission in its Communication of 23 January 2002 entitled "Life sciences and biotechnology", which stresses that the interpretation of key concepts in the field of patents must not be left exclusively to courts and national patent offices[87].

In view of the above, the Commission will therefore have to investigate the following:

- The scope to be conferred to patents on sequences or partial sequences of genes isolated from the human body.

- The patentability of human stem cells and of cell lines obtained from them.

The results of these deliberations will be communicated to the public in the next reports provided for under Article 16(c) of the Directive.

[87] COM, op. cit., p.17.

ANNEX 1: IMPLEMENTATION OF DIRECTIVE 98/44/EC ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

COUNTRY		STATE OF PLAY OF THE IMPLEMENTATION 16/07/2002	IMPLEMENTATION DATE
AT	AUSTRIA	Bill of law submitted to the Parliament	Not clear
BE	BELGIUM	1st Bill of law submitted to inter-ministerial discussion during autumn 2000	Not clear
DE	GERMANY	18-10-2000 : Bill of law adopted by the Government and submitted to the Parliament Debates ongoing at the Parliament	Not clear
DK	*DENMARK*	/	***May 2000***
ES	SPAIN		**30 April 2002**
FIN	*FINLAND*	/	***30 June 2000***
FR	FRANCE	Bill of law adopted by the Government on 31-10-2001	Delayed
GR	*GREECE*	Decree on 15-10-2001	***22 October 2001*** *: Communication to the Commission*
IRL	*IRELAND*	/	***30 July 2000*** *: Regulations* *Notification to the Commission done*
IT	ITALY	19-10-1999 : Bill of law submitted to the Parliament Committee created in the Senate	Not clear
LU	LUXEMBOURG	Bill of law submitted to the Parliament in June 2000 Parliamentary Committee on Ethics in charge of the file (last meeting on 23 January with experts from EPO)	Not clear

NL	NETHERLANDS	Report of the 2nd Chamber (7-6-2000) providing for several amendments to draft law submitted on 28-05-1999 Debate in Plenary on 02-10-2000	Not clear
PT	PORTUGAL	Bill of law submitted to the Parliament	Expected during the first semester 2002
SE	SWEDEN	A bill of a law should be adopted during Spring (debates at the Parliament during Spring session)	July 2002 (date indicated in the memorandum of the bill of law)
UK	*UNITED KINGDOM*	• Implementation of Art 12. Entered into force on 1 march 2002 • Implementation of Art. 13 and 14 on July 6th 2001	***28 July 2000**: Implementation on time for articles 1-11* ***6 July 2001**: Implementation of Articles 13 and 14* ***1 March 2002:** implementation of Article 12*

ANNEX 2: COHERENT STRATEGY FOR BIOTECHNOLOGY AND LIFE SCIENCES IN EUROPE

Life sciences and biotechnology are widely recognised as one of the most promising frontier technologies in the new knowledge-based economy. As explained above, this has been recognised by the Stockholm European Council[88] in March 2001.

Regulatory principles, such as those set down in intellectual property law, are an important part of the Commission's communication. In particular biotechnology inventions typically require high capital investments and it is generally recognised that effective patent protection is a crucial incentive to R&D and innovation. For this reason and in view of rapid scientific progress, the strategy paper recognises that the intellectual property system needs to be closely monitored.

1°) Investments in the biotechnology sector

The total world market potential for applications of the life sciences and biotechnology, excluding agriculture, is estimated to surpass €2 000 billion in 2010. About one quarter of this is attributed to the pharma sector and three-quarters to the sustainable industrial and environmental technology sector. A major part of these technologies would come from biotechnology companies, which are a crucial success factor for industrial competitiveness in biotechnology, in addition to a sound knowledge base and availability of private capital, in particular venture capital investment.

The knowledge base in biotechnology and life sciences has seen an explosion in recent years. The number of scientific publications of OECD countries in biotechnology and applied microbiology journals increased from 1574 in 1986 to 3261 in 1998, of which EU Member States hold 34% while the US holds 23.9%[89].

As regards the status of biotechnology companies, the EU has overtaken the US in the total number of companies (EU: 1570 compared to US: 1273). Although EU figures related to average size, revenues and RTD expenses of the total sector are on average a factor of 2.5 smaller than the corresponding US figures, the EU figures per employee are comparable or even better than US figures. This is an encouraging demonstration of entrepreneurial potential in Europe.

Venture capital investment in the EU biotechnology sector has steadily increased in the second half of the last decade and reached a value of more than €1 billion in the year 2000. However, total public funding (including buy-outs and IPOs) is still a factor of 5 higher in the US (€30 billion) than in the EU (€6 billion).

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88 Stockholm European Council - 23 and 24 March 2001; Presidency conclusions available at http://ue.eu.int/en/Info/eurocouncil/index.htm

89 Source: OECD DSTI/EAS/STP/NESTI (2001)2

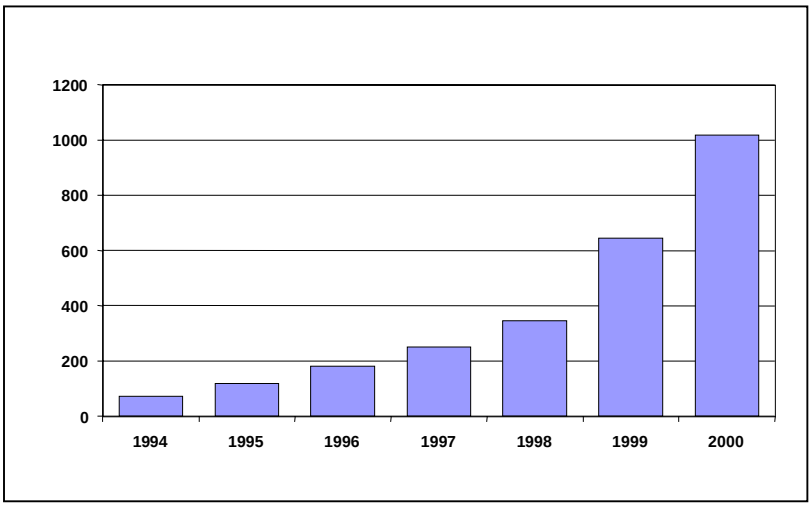

Fig. 1: Venture capital investments in the EU biotechnology sector

2°) Patenting activity in the biotechnology sector

Patenting activity of EU Member States, Japan and the US in the biotechnology and genetic engineering sectors at the European Patent Office has increased drastically in the last decade[90]. Table 1, which displays the total filing figures for the periods 1996-2000 and 1986-1990 in both the biotechnology and genetic engineering sectors, shows an overall increase of 226% and 287%, respectively, for the two sectors.

Germany is the largest applicant within the EU Member States, followed by the UK. France and Netherlands are close together on third place, as are the followers Belgium and Denmark. Statistically significant above average increases of filing activities between the two periods are observed for DK, UK, NL in both technology sectors, while Italy shows below average figures. The figures for Germany are close to the total average figure in both sectors, while France is close to average in the biotechnology sector and above average in the genetic engineering sector.

Total US filing figures are above the total EU Member States periods in all sectors, and US filing figures between the two periods have increased more strongly than EU average figures. For Japan, the increase in filing figures is very low at 52% and 90% respectively.

Table 2 shows the shares between the EU, Japan, the US and other countries for patent filings at the EPO for the classes C12N (biotechnology) and C12N15 (genetic engineering) for two time periods. The share of US patents for these countries in the genetic engineering sector is given for comparison.

In the 1996-2000 period US filed the largest number of patents at the EPO in the biotechnology sector (around 45.4% of total), followed by the EU Member States (around 38.8%). Japan filed only around 9% of patents in this period, down from around 19.6% in the 1986-1990 period. Both EU Member States and the US increased their patent shares from the 1986-1990 period to the 1996-2000 period, with somewhat larger increases by the US.

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90 Sources: OECD, USPTO, EPO

	EPO applications					
	Biotechnology (C12N)			Genetic Engineering (C12N15)		
	1986 to 1990	1996 to 2000	% increase	1986 to 1990	1996 to 2000	% increase
DE	326	970	198%	189	762	303%
UK	161	713	343%	107	593	454%
NL	140	549	292%	92	422	359%
FR	170	547	222%	107	457	327%
DK	46	235	411%	20	88	340%
BE	73	220	201%	57	141	147%
IT	44	80	82%	32	53	66%
SE	35	73	109%	22	50	127%
AT	15	42	180%	9	33	267%
FI	8	30	275%	7	17	143%
ES	7	22	214%	5	17	240%
IE	5	11	120%	3	7	133%
GR	1	5	400%	1	5	400%
EU	**1031**	**3497**	**239%**	**651**	**2645**	**306%**
US	**1058**	**4129**	**290%**	**732**	**3251**	**344%**
JP	**539**	**817**	**52%**	**312**	**594**	**90%**
Total	**2881**	**9398**	**226%**	**1872**	**7249**	**287%**

Table 1: Patent applications of EU Member States, Japan and the US at the EPO in the biotechnology/genetic engineering sectors in the period 1986 to 1990 compared to 1996-2000

	EPO applications				US grants	
	Biotechnology (C12N)		Genetic Engineering (C12N15)		Genetic Engineering (USPTO definition)	
	1996-2000	1986-1990	1996-2000	1986-1990	1994-1997	1984-1987
EU	38.8%	37.4%	38.3%	36.6%	14.5%	11.0%
Japan	9.0%	19.6%	8.5%	17.5%	7.5%	10.8%
US	45.4%	38.4%	46.3%	41.1%	72.5%	75.4%
Others	6.8%	4.6%	7.0%	4.7%	5.4%	2.8%

Table 2: Country shares of patent applications in the biotechnology/genetic engineering sectors at the EPO compared to patent grants at the USPTO

At the US Patent and Trademark Office, the large majority of patents granted in the genetic engineering sector between 1994-1997 went to US inventors (72.5%). EU Member States reached a 14.5% share and Japan a 7.5% share. While the US and JP shares both dropped by about 3 percentage points from the 1984-1987 period, the EU Member States increased their share by 3.5 percentage points.

The growth rate in patent applications at the EPO and patent grants at the USPTO in the genetic engineering sector is depicted in Table 3 for different time periods. USPTO growth rates in the 1993-1997 period have been 31%, almost double the EPO growth rate of 17.7% for the period 1996-2000.

EPO applications		US grants	
1996-2000	1990-1995	1993-1997	1988-1982
17.7%	15.8%	31%	21.4%

Table 3: Average growth rates of patent applications in the genetic engineering sector[91] *at the EPO compared to granting figures at the USPTO*

The previous data show that EU Member States clearly lag behind the US in patenting activity. Not only are EU Member States behind the US in protecting their European markets, but they also have a comparatively small share of patents in the more dynamic US technology market. The significant increase of the EU shares of granted patents at the USPTO from 11% in the 1984-1987 period to 14.5% in the 1994-1997 period may indicate an increased RTD activity of EU actors in the US and/or an increase in collaborative activity between EU and US actors.

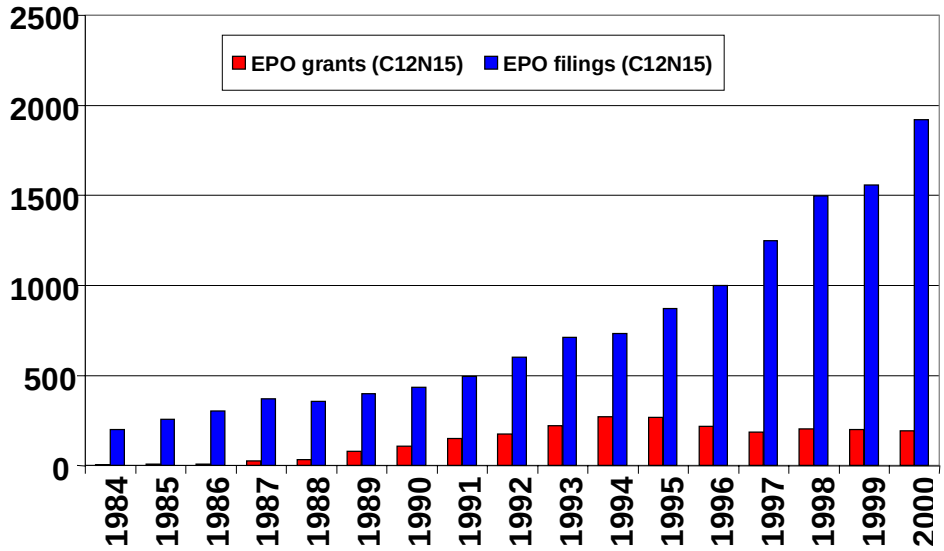

Fig. 2: Number of patent applications and number of granted patents at the EPO in the genetic engineering sector

Patent protection in the EU Member States is also hampered by the long delay in granting procedures at the EPO. Fig. 2 compares the number of patent applications at the EPO in the genetic engineering sector to the number of granted patents in this sector for the 1984 to 2000 period. It shows that the number of granted patents per year is stagnating and even slightly decreasing since 1995. The major reason for this is the large amount of searches that has to be handled by the EPO in the framework of PCT applications. Under the terms of the Patent Co-operation Treaty (PCT), the more than 100 countries that have adhered to this treaty can choose one out of nine international patent offices to perform

[91] Definitions of "genetic engineering" differ between the USPTO and EPO due to different classification systems

the search and/or preliminary examination. Currently, the EPO is handling about 60% of all international applications, 50% of those coming from the US. To ease the situation, the EPO has decided not to accept from US residents under the PCT treaty any application directed to biotechnology, business methods and telecommunication as from 1 March 2002.

As we will see in the next paragraph, a specific characteristic of research and innovation in biotechnology is the strong collaboration and technology transfer between large industry, biotech companies and the public research sector. The strategic use of intellectual property rights by all these actors plays a vital role for the development of a functioning technology market. This fact is demonstrated by data for USPTO biotechnology patents[92] granted to UK, German and French assignees for 2001. It shows that 30% of the assignees came from the public research sector, 22% from biotech companies and 48% from large industry.

3°) Industrial competitiveness in biotechnology

A report issued by Directorate General Enterprise on the competitiveness of European biotechnology has identified some crucial factors that contribute to industrial competitiveness in this sector[93]:

- A strong knowledge base offering potential for new developments and applications in health care, agriculture and food production, environmental protection as well as new scientific discoveries.

- The transformation of fundamental knowledge created in universities and public research organisations into commercially useful techniques and products through collaboration between scientists and professional managers in start-ups, backed by venture capital.

- An effective division of labour between smaller and larger companies having different comparative advantages in technology/product development and product marketing.

- Clearly defined and effective property rights, which have a crucial role in the functioning of markets for technologies, i.e. technology transfer and collaboration between different players (universities, small and large companies). Strong intellectual property rights are also necessary for securing venture capital for start-up companies.

The contribution of the intellectual property regime to competitiveness of the biotech sector in the US as compared to the EU cannot be quantified exactly. However, some facts indicate that the US has a number of comparative advantages:

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92 Data obtained from the USPTO database http://www.uspto.gov/patft/index.html for section C12N15/00 and the period 1.1.2001 to 31.12.2001

93 See chapter 5 of the "**European competitiveness report 2001"** on "The competitiveness of European Biotechnology: a case study of innovation". This chapter can be downloaded from http://europa.eu.int/comm/enterprise/enterprise_policy/competitiveness/doc/competitiveness_report_2001/chapter_5.pdf

- Patenting activity in the biotechnology sector in the US has been slightly more dynamic in recent years than in the EU (16% increase in US compared to 13% increase in the EU) and much more dynamic in the genetic engineering sector.

- The recent USPTO guidelines have provided legal certainty by giving a clear definition of what can be considered a biotechnological invention and what is eligible for patent protection, albeit not having touched upon "ordre public" issues, in contrast to most other patent legislation in the developed countries.

- The development of technology markets between technology producers and users is clearly supported by low transaction costs, e.g. a cost-effective patent system.

The Commission communication on "Life sciences and biotechnology: A strategy for Europe" has pointed out that the competitive position depends on the availability of an effective, harmonised and affordable European IP (intellectual property) system, providing an incentive for R&D and innovation. In order to close the competitive gap between the US and the EU the following actions, among others, are proposed in the communication:

- implementation of the directive on the Legal Protection of Biotechnological Inventions EC/98/44/EC by the Member States;

- Council adopting the Community patent regulation[94];

- clarification of rules of ownership of IP stemming from public research;

- training academics in the strategic use of the IP system and raising awareness for the commercial potential of the research, encouraging entrepreneurship and movement between academia and companies;

- taking steps to harmonise patent protection in industrialised countries to ensure a level playing field.

[94] Op. cit., Introduction.

ANNEX 3: ACCOUNT OF NEGOTIATIONS ON DIRECTIVE 98/44/EC

Subsequent to the intensification of scientific research and the major discoveries made over the last 40 years in the field of molecular biology, biotechnology emerged as one of the most important and promising technologies. The impact of the processes, techniques and biotechnological material is felt in many sectors: health, agriculture, foodstuffs and industry.

In the mid-1980s, however, the diversity, or rather the absence, of national legislation in the field was proving harmful for research and development and for the competitiveness of European undertakings compared with the Japanese or American companies active in this sector.

It therefore seemed essential for the European Community to take measures in this field to harmonise national legislation within the Internal Market.

As early as 1985, the Commission's White Paper on completing the Internal Market had noted this situation.

There was a need for clarification with a view to establishing clear and legally sound rules allowing for the harmonious development of this type of industry.

To that end, the Commission presented an initial proposal for a Directive on 21 October 1988[95].

That proposal was rejected on 1 March 1995[96] by the European Parliament after a conciliation procedure, in particular because of the lack of distinction, in the field of DNA sequences, between discoveries which are not eligible for patent protection and genuine inventions which can be covered by an intellectual property right.

A new and amended proposal was presented at the end of 1996[97].

The Opinion of the European Group on Ethics, which had been requested by the President of the Commission, was issued on 25 September 1996[98]: it recognised that, in the field of biotechnology, the traditional distinction between discoveries and inventions had an important ethical dimension. However, the Opinion stresses that the Directive establishes adequate guarantees in this field.

The Directive was finally adopted on 6 July 1998[99]. The Netherlands Government voted against the Directive, while Italy and Belgium abstained. The Directive was published in the Official Journal on 30 July 1998[100].

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95 COM(88)496 final/SYN 159 of 21 October 1988, OJ C 10 of 13.1.1989.

96 C4-0042/95 – 94/0159(COD), Doc. PE-CONS 3606/1/95 of 21.2.95, OJ C 68 of 20.3.95, p26.

97 OJ C 296 of 8.10.1996, p. 4, OJ C 311 of 11.10.1997, p. 12.

98 http://www.europa.eu.int/comm/european_group_ethics/gaieb/en/avis8.pdf

99 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

100 OJ L 213 of 30 July 1998, p. 13.

Article 15 lays down that the Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000.

ANNEX 4 : WORK UNDERTAKEN SINCE THE ADOPTION OF THE DIRECTIVE:

1°) In the context of exchanges between the Commission and the Member States:

1-1) Meeting organised by the Commission with the experts from the Member States in January 1999:

An initial meeting with the Member States was organised even before the expiry of the period for transposal of Directive 98/44/EC with a view to helping the latter to implement the Directive. On that occasion, a dialogue was established between the various participants on the provisions of the Directive whose transposal was most sensitive (Articles 5 and 6). Moreover, the difficulties encountered in the specific implementation of Article 12 of the Directive concerning cross-licences between patents and plant variety rights were raised by various delegations.

1-2) Meeting organised by the Commission with the experts from the Member States on 23 January 2001:

The purpose of the meeting organised by the Commission was to review the situation after the expiry of period for transposal of Directive 98/44/EC and progress in implementing in the national law of the Member States.

The proceedings were divided into two parts: the first was devoted to a *tour de table* on progress in transposing the Directive in the Member States. The second was devoted to an exchange of views on the provisions of the Directive which are facing difficulties in their implementation.

By the day of the meeting, only four countries had formally notified the Commission of the implementation of the Directive: Denmark, Finland, Ireland and the United Kingdom.

During the meeting, the Member States were asked whether any of them wished a renegotiation of the Directive. No Member State expressed such an intention.

Some delegations wished the Commission to publish guidelines for implementing the Directive. The Commission does not favour this approach, since all the information needed to implement the Directive is already contained in it. The Commission considered that the publication of this Report would make it possible to review the measures which needed to be taken.

Finally, the Commission indicated that it intended to monitor the implementation of the Directive closely and proposed its assistance to any Member State which wished it.

1-3) Letter of formal notice from the Commission to the Member States which had not transposed Directive 98/44/EC.

By letter of 30 November 2000, the Commission enjoined the Member States to transpose Directive 98/44/EC as soon as possible. It also called upon them to communicate to it their observations within 30 working days.

1-4°) Dialogue with the Member States:

The Commission has embarked on a dialogue with those Member States which asked for its intervention, essentially on the basis of an exchange of correspondence (France, Germany, Italy, Belgium and the Netherlands).

In addition, other Member States informed the Commission of the situation as regards transposing the Directive in their countries (Luxembourg, Greece, Austria).

The gist of the correspondence could be divided into two main topics:

- requests for clarification concerning the distinction made in Article 5 of the Directive between discoveries and inventions eligible for protection by a patent on elements isolated from the human body.

- questions about the scope to be conferred on inventions involving elements isolated from the human body.

The Commission replied to each of these letters point by point.

It should be noted that closer collaboration between the Commission and the Member States was widely desired. This Report should make it possible to embark on a fruitful dialogue between the Member States and the Commission and to provide further information in reply to the questions raised.

Alongside this correspondence, working meetings were held with delegations from the Member States in order to facilitate the transposal of the Directive in their legislation.

2) Activities within the European Parliament:

By Decision of 13 September 2000, the European Parliament set up a temporary committee on human genetics and other new technologies of modern medicine.

Its mandate was to examine the latest developments in the field of human genetics and the possibilities opened up by this progress. In the context of that examination, particular attention was devoted to the patentability of elements isolated from the human body, and in particular patent protection for DNA sequences.

For the purpose of drawing up its report, the temporary committee heard a series of experts in the field in question.

A report was drafted and adopted by the temporary Committee on Human Genetics on 8 November 2001[101]. However, the report was rejected by the vote in plenary session. Discussions on D 98/44/EC should nevertheless continue in a restricted committee.

3) The work done by the European Group on Ethics in Science and New Technologies of the European Commission.

The European Group on Ethics in Science and New Technologies is an independent, pluralist and multidisciplinary body set up in 1992 by the Commission to advise it on

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[101] Draft report by the Temporary Committee on Human Genetics and Other New Technologies of Modern Medicine on the ethical, legal, economic and social implications of human genetics. PR\445704EN.Doc. PE 300.127.

ethical aspects of new technologies raised in connection with the establishment of Community policies or the drafting of legislation.

The Group has submitted 16 Opinions, including Opinion No 3 of 30 September 1993 on ethical questions arising from the Commission proposal for a Council directive for legal protection of biotechnological inventions, and Opinion No 8 of 25 September 1996 on the ethical aspects of patenting inventions involving elements of human origin.

This Group, which is attached to the President of the European Commission, is entrusted by Article 7 of Directive 98/44/EC with evaluating all ethical aspects of biotechnology. By virtue of recital 44 to the Directive, consultation of this Group, including consultation concerning patent law, is confined to assessing the basic principles of biotechnology.

It is against this background, and at the request of President Prodi, that the Group was asked to deliver an Opinion on the "ethical aspects of human stem cell research and use" (Opinion No 15 published on 14 November 2000), and an Opinion on the "ethical aspects of patenting inventions involving human stem cells" (Opinion No 16 published on 7 May 2002).

4°) The activities of the high-level Group on Life Sciences.

The European Group on Life Sciences (EGLS), composed of 11 European biologists recognised for their scientific excellence and their commitment to communicate with the public on the stakes of research in genetics, has been set up on April 26 2000 to inform the European Commissioner responsible for Research on the prospects of Life Sciences Research. Having recognised the important role of intellectual property for research and development, some members of the group, together with experts from research, industry, law and the European Patent Office discussed the issues related to “Patenting of Genes” in a workshop on July 5th 2001. Among other issues, the meeting addressed:

- the use and management of intellectual property rights related to biotechnological inventions in academia and industry;

- the legal environment regarding patenting of biotechnological inventions in the EU, in particular directive 98/44/EC, and a comparison to the US system; and

- the challenges introduced by the impact of patent law on research and, vice versa, the interplay between advances in science and the interpretation and development of patent law.

As a result of extensive and constructive discussion at the workshop and subsequent consultation of all EGLS members, the EGLS formulated a statement that identified important research policy issues related to the patenting of genes and proposed possible policy measures. The major conclusions of the statement are:

- The EGLS highlighted the important role of patenting of biotechnological inventions to support research and innovation.

- The group pointed out that genes as such are not patentable, but only in connection with a particular inventive step and a proven industrial application.

- There is a need for a broader communication of the objectives of patent law and its potential socio-economic benefits to scientist and the general public.

- Overly broad patents may lead to potential dependency problems. This issue should be closely monitored in the framework of the reporting requirements, e.g. article 16 of the directive.

- The group recommends the establishment of an expert group involving legal expert, scientist and patent administrators (EPO) to discuss the interplay between scientific progress and the development and implication of patent law in the area of biotechnology and genetic engineering.

5°) OECD activity on "Genetic inventions, intellectual property rights and licensing practices"

In February 2001 the OECD Working Party on Biotechnology (WPB) agreed on a proposal from the German Ministry of Research and Education (BMBF) to start a project on "Genetic inventions, Intellectual Property Rights and Licensing Practices". A workshop was held in Berlin on 24-25 January 2002, with over 100 experts from the public and private sector. Participants reviewed empirical evidence demonstrating the impact of patenting and licensing of genetic inventions on access to technology by researchers, companies and within healthcare systems.

A large study funded by the US National Academy of Science revealed that patents in biotechnology generally stimulate research and the entry of new technology into markets[102]. The growth in number and complexity of biotechnology patents did not cause a breakdown of the patent system, in contrast to some expectations and fears. The study shows that users and providers of technology were able to develop "working solutions", such as taking licenses, inventing around patents, using the research exemptions in a flexible way and developing public databases (SNIPs consortium)[103].

In the US, rapid advances in science and technology were accounted for through changes in the institutional environment, such as the new USPTO guidelines or the courts' view towards research tool patents. The authors of the study do not rule out future problems that may arise from patents currently under review or new scientific developments and court decisions. However, they remain optimistic that a system can be found that provides strong incentives to conduct research as well as to maintain a free space for research and discovery.

The workshop also identified difficulties that sometimes occur around patents related to genetic tests and discussed ways to improve access and market penetration without undermining the patent system and respecting limited public health budgets. In this respect, improved international harmonisation of patent and licensing practises would seem necessary as well as clarifying the scope and function of research exemptions in different countries.

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102 A preliminary draft report can be downloaded from http://www4.nationalacademies.org/PD/step.nsf/files/walsh2.pdf/$file/walsh2.pdf

103 Similar results were obtained by the Max-Planck-Institute for Foreign Patent Law in a limited survey among German research institutions and small and large companies.

ANNEX 5: STATISTICS

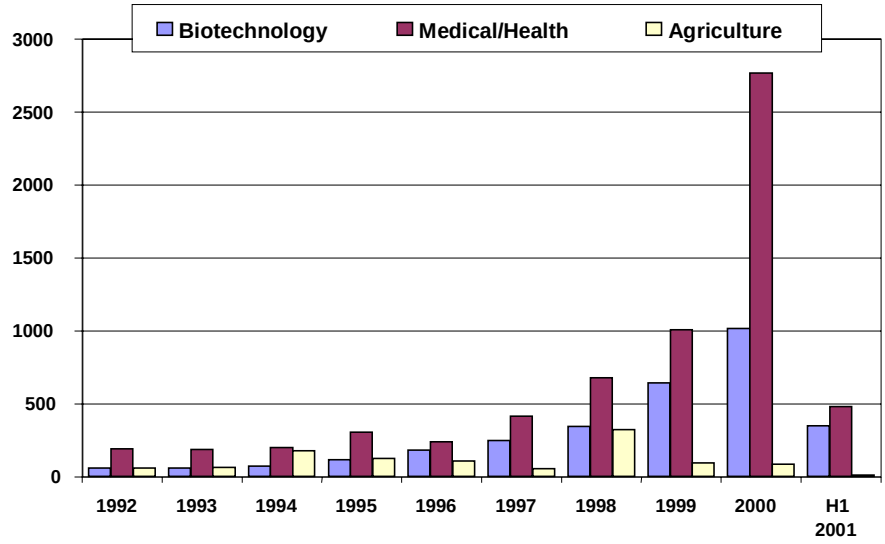

Fig. 1 : EU VC investments in the Life Sciences sectors in millions of Euros (Source: EVCA)

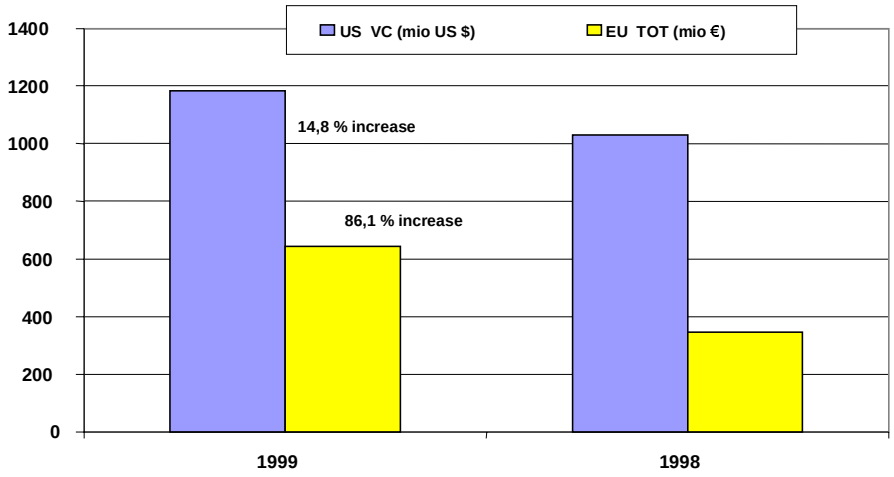

Fig. 2: VC investments in Biotechnology - US vs EU

EU data includes replacement and buy-out investments, for which no separate information is available. It is likely that for the biotechnology sector, these investments are much lower than the average of 58% over all sectors.

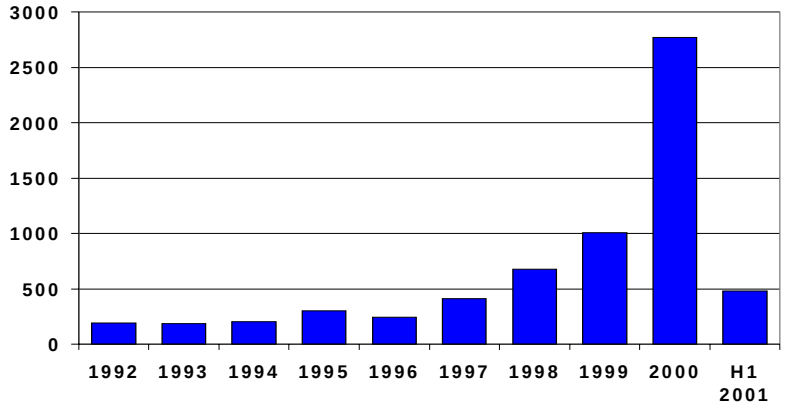

Fig. 3 : EU VC investments in the Medical/Health sector in millions of Euros (Source: EVCA)

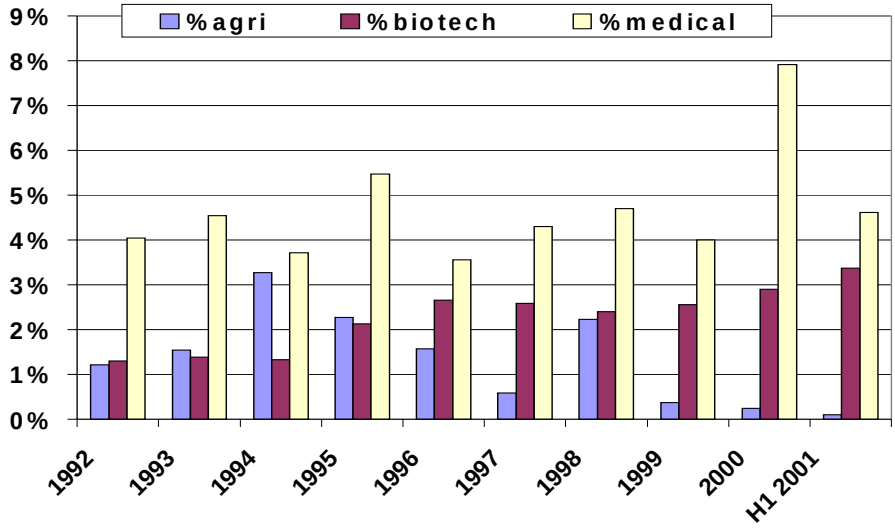

Fig. 4 : Investments in Life Sciences sectors as % of total VC investments in EU (Source: EVCA)

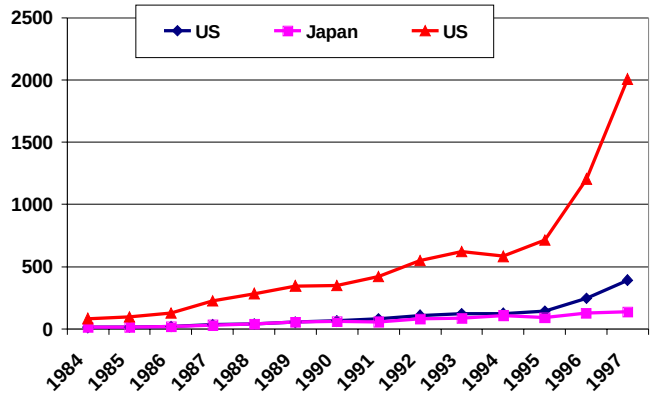

Fig. 5 : USPTO patents granted in the genetic engineering sector per country – 1984-1997

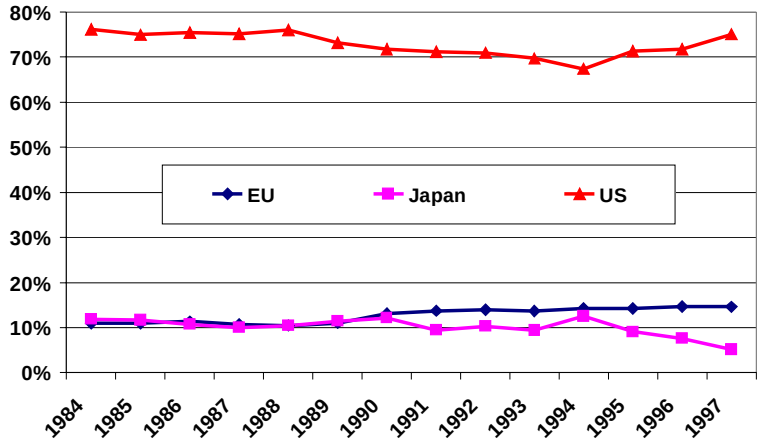

Fig. 6 : Genetic engineering - % of granted USPTO patents per country

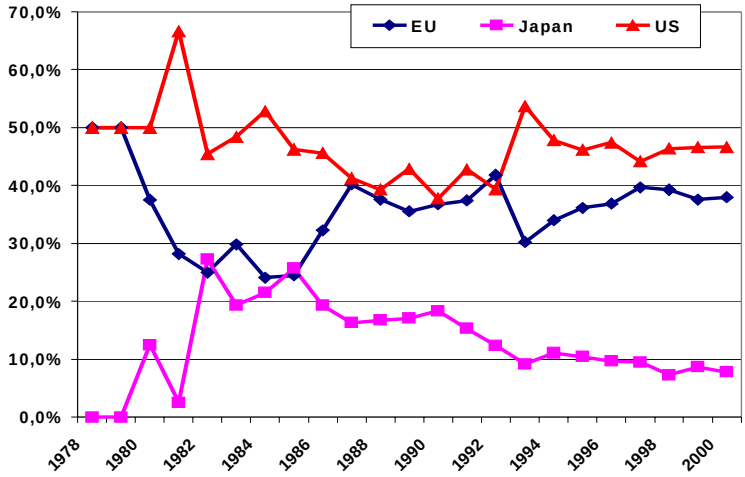

Fig. 7 : EPO filings in genetic engineering - percentage per country

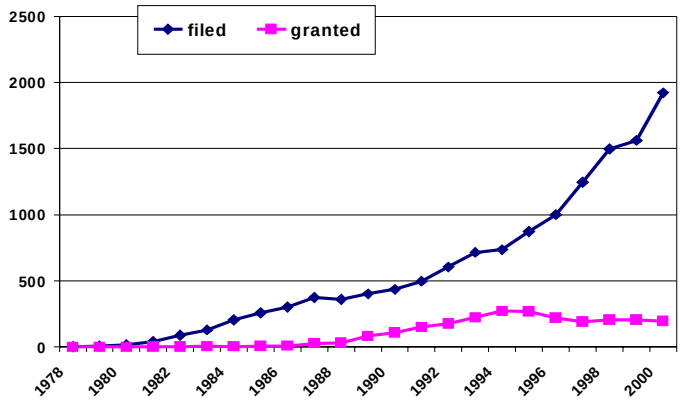

Fig. 8 : EPO patent applications and grants in genetic engineering

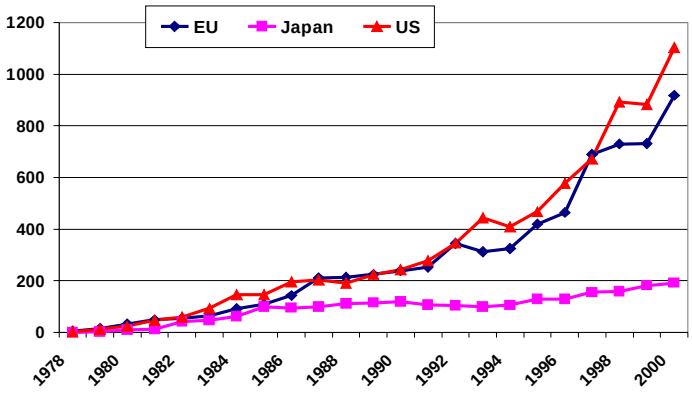

Fig. 9 : EPO filings in the biotechnology sector

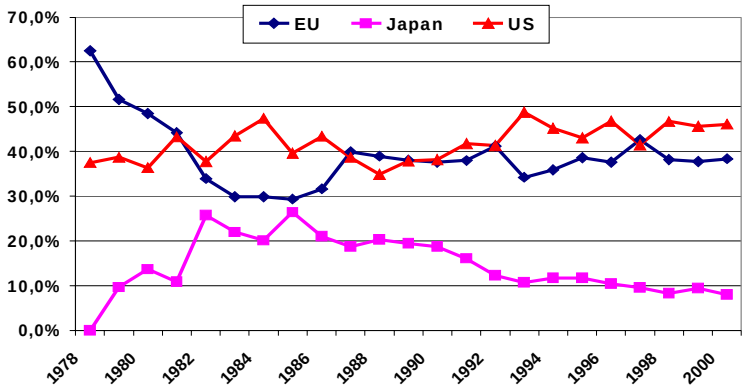

Fig. 10 : EPO filings in biotechnology

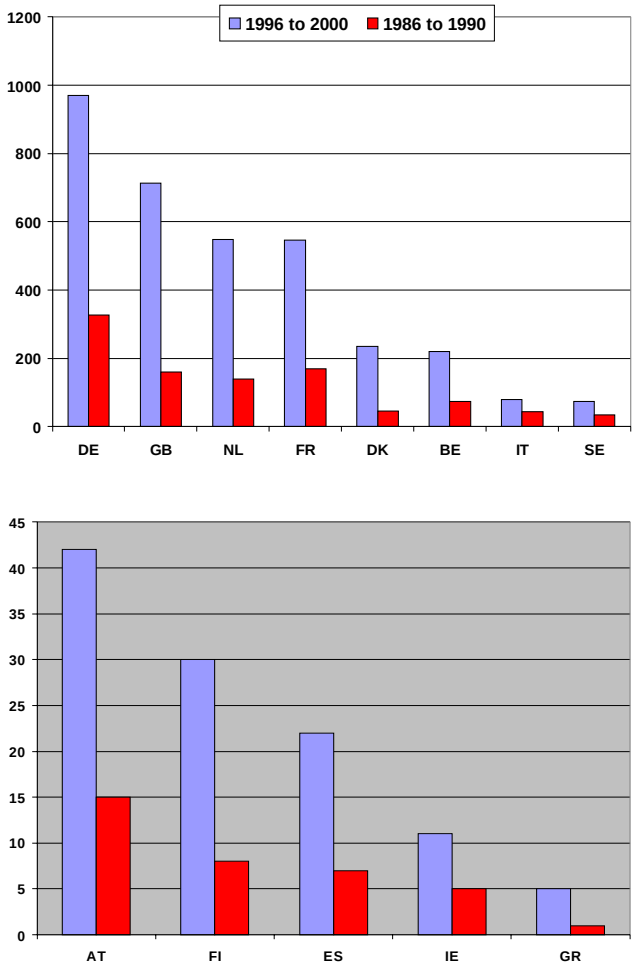

Fig. 11 and 12 : EU Member States application at the EPO in genetic engineering