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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND COUNCIL

An assessment of the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions

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(Text with EEA relevance)

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EXECUTIVE SUMMARY

This report is requested in accordance with Article 16b of Directive 98/44/EC on "The legal protection of biotechnological inventions", which requires the Commission to produce "within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable".

The Stockholm Council has identified biotechnology, and in particular genetic engineering, as a new frontier technology. In the last decade, the number of publications in the biotechnology sector in the OECD countries has more than doubled. In the same period, the number of patents filed in the biotechnology sector at the United States Patent and Trademark Office and the European Patent Office on average increased by 13-15% p.a., compared to overall annual growth rates of only 5%.

Research institutes, universities and small biotech companies, which are major contributors to innovation in the life sciences, may wish to file patent applications but at the same time they will want to disclose as quickly as possible the results of their research to the scientific community and/or investors. The conflict between these "protection" and "publication" strategies may lead to a delay in publication of scientific results and hinder the rapid dissemination of scientific knowledge, thereby slowing down scientific progress. On the other hand, the patent system ensures the publication of results that might otherwise have been kept secret.

A survey has been performed among public and private researchers and institutions in industry and public research, as well as those involved in intellectual property rights issues (e.g., patent agents) to investigate the issue of publication delay. The major results of this survey are:

- Only a very small fraction of researchers and organisations actually experience a considerable delay in publication of research results that are the subject of a patent application, and this fraction is lowest for the most experienced users (10%) and highest for the less experienced users of the patent system (40%).

- The public research sector strongly favours the introduction of a grace period and large industry strongly opposes it, with both positions being present in small and medium sized enterprises. There is no clear position among patent agents, which reflects the varied nature of their customers.

- The possibility of filing a provisional patent application also ranks high in importance, both with industry and academia, while understandably it is of low priority for patent agents. Researchers from academia consider support for patent filing as an important issue, while industry and patent agents consider awareness activities to be of some importance.

The survey confirms the positions of academia and industry towards the possible introduction of a grace period which were brought forward at the hearing on the grace period organised by the European Commission in October 1998 and the expert opinions recently published on the web-site of the European Patent Office (EPO).

Despite a number of studies, no precise figures are available which quantify the economic effects for industry or which assess the value in practical terms for academia of the

introduction of a grace period. Throughout the member states of WIPO, different concepts of a "grace period" have been developed (e.g., in US, JP), which should be investigated in detail concerning the balance they provide between the interests of the academic sector and of industry. The US concept of a "grace period" together with the "first-to-invent" system is considered to provide the highest level of "legal uncertainty" and should not serve as "best practice" example. In view of the increasing internationalisation of research both of the public and private sector and their importance for innovation, and the fact that the public research sector has become a more experienced and major user of the patent system, efforts to define and harmonise the concept of the 'grace period' should be considered. However, this concept will only work at a global level if it provides 'legal certainty', which is the major concern of the industrial users of the patent system. This should be taken into account by the Standing Committee on Patent Law (SCP) of WIPO during the current discussions taking place on the possible introduction of a grace period.

Framework conditions should be further optimised to ease the use of the patent system by academics and small and medium sized enterprises. These should include, among others:

- The introduction of a provisional patent application in all member states in line with Article 5 of the Patent Law Treaty, adopted in Geneva on June 2, 2000.

- Support and advice for academic and SMEs in the proper use of the patent system and the strategic use of intellectual property rights as well as teaching and training on these issues.

- A simple and cost-effective patent system, as will be provided through the proposed Community Patent.

INTRODUCTION

Directive 98/44/EC on "The legal protection of biotechnological inventions"[1] has been adopted by the European Parliament and the Council on 6 July 1998. Article 16b of this directive requires the Commission to produce "*within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable*".

This report has been prepared jointly by the Internal Market Directorate General (DG Internal Market) and the Research Directorate General (DG Research) of the European Commission in full consultation with other relevant Commission services.

The objective of this report is to investigate:

- Is there any delay in scientific publication in the area of genetic engineering research on subjects that could be patentable?
- What are the possible implications of this delay, if significant, for basic genetic engineering research?
- What are the possible measures to remedy negative implications, if significant, in particular policy initiatives at Community or Member State level?

Biotechnology, and in particular genomics, is considered to be a frontier technology of the knowledge-based society, with a huge potential for health, food and environment. Section 1 provides data on the increasing number of patent applications and publications in the EU, and compares it to US figures. Section 2 reviews the general role of patenting and scientific publications for research and innovation. Section 3 provides results of a questionnaire survey on the question of patenting and publication delay carried out among EU scientists and organisations from industry and academia working in basic genetic engineering research and amongst a number of industrial, private and academic organisations involved in patenting the results of such research. Section 4 summarises the current discussions on the possible benefits and drawbacks of a grace period and discusses other alternatives and possible policy measures to avoid and/or minimise any delays in the publication of scientific papers which contain research results that could be the subject of patent applications.

1. BIOTECHNOLOGY AND GENOMICS

1.1. Biotechnology and genomics – a frontier technology of the third millennium

Recent decades have seen fundamental advances in the human understanding of the biology, molecular structure, genetic basis and ecology of all living entities. The new life sciences knowledge has stimulated a series of technical innovations, broadly described as biotechnology, which includes such techniques as genetic engineering, cloning, bio-catalysis, genetic testing, gene therapy and monoclonal antibodies. These techniques may be applied to many of the challenges faced by the health, food and environmental sectors. Examples

[1] OJ L213 of 30.7.98

include new drugs for the treatment of formerly incurable diseases and renewable sources of energy based on biomass fermentation ("bio-fuel").

The Stockholm European Council[2] has identified biotechnology as a frontier technology. Research, entrepreneurship and a regulatory framework that encourages innovation have been identified as the most important factors that enable EU businesses to embrace these new technologies and utilise their full potential.

1.2. Advancing the knowledge base and competitiveness of industry

The knowledge base in biotechnology is characterised by intense scientific rivalry and strong industrial competition on a worldwide level and being built at a rapid pace. The speed of genome sequencing has typically doubled each year while the costs have dropped markedly. Scientific and technological progress in genetic engineering is largely dependent on the rapid dissemination of and easy access to scientific data, in particular raw genome data. This has, among others, been pointed out in the statement of March 14, 2000 by UK Prime Minister Blair and (then) US President Clinton:

> "To realise the full promise of (human genome) research, raw fundamental data on the human genome, …., should be made freely available to scientists everywhere. Unencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health around the world and enhance the quality of life for all mankind."

The Blair-Clinton statement also recognises that "Intellectual property protection for gene based inventions will also play an important role in stimulating the development of important new health care products". Handling the rapid spread of new knowledge through scientific publications while at the same time ensuring strong and effective protection of intellectual property for the development of new technologies and products is thus a major issue.

1.3. The development of basic genetic engineering research: Patenting and scientific publication statistics

The increased importance of the biotechnological sciences, and in particular genetic engineering, is evident from the patenting and publication activity in this sector. Patenting activity[3] in the biotechnology sector in the 1990-1999 period has seen yearly growth rates of around 15% at the United States Patent and Trademark Office (USPTO) and 13% at the European Patent Office (EPO), compared to overall growth rate in total patent number of only 5% in both the USPTO and the EPO. In the genetic engineering sector, USPTO statistics[4] has shown that the average growth rate between 1985 and 1997 has been around 30% p.a., with average figures of around 60% in recent years.

However, the EU lags behind the US in the patenting of biotechnological inventions. As shown in Table 1, the share of biotechnology patents, both in terms of patents granted in 2000 at the USPTO and patents applied for in 1997 at the EPO, is lower for applicants from EU member states than those from US applicants. Government organisations and public research organisations are among the top patentees in the genetic engineering sector in the US. In the

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

3 Sources: OECD, USPTO, EPO

4 "Technology Profiling Report: Genetic Engineering 1977-1997", USPTO, August 1998

period 1977 to 1997, the US Department of Health and Human Services and the University of California led the ranking list for biotechnology based patents granted in the US, followed by the California-based company Genentech.

	% of biotechnology patents granted at USPTO in 2000	% of biotechnology patents applied for at the EPO in 1997
US	65.5	48
EU	18.7	33
JP	7.5	10

Table 1: Share of biotechnology patents of applicants from US, EU and JP at the USPTO and EPO

From 1986 to 1997, scientific publications from the biotechnology sector more than doubled, from 1574 to 3261 papers. EU member states together accounted for the largest share, 34%, while the US accounted for 23.9%, although US papers on average were cited more often than papers originating from the EU[5].

The above statistics show that Europe on average has a high quality science base (measured through the rate of publication) but that it is weak in its technological and economic exploitation (as measured through patenting activity). This "European paradox", which is typical also in other sectors and seems to indicate a weakness of the EU innovation system, has been analysed and discussed in detail elsewhere[6].

2. THE ROLE OF SCIENTIFIC PUBLICATIONS AND PATENTS

2.1. Different strategies to manage intellectual property: publish – patent - keep secret

The way intellectual property generated through public and private research is managed may have a strong impact on scientific progress and the competitiveness of industry. There are basically three different strategies:

- To publish the results and thereby obtain "copyright" or other "authors' rights" on the published subject matter, while in most cases leaving the inventions themselves unprotected (public domain approach). Public research organisations and the scientific community largely pursue this strategy of rapid publication and the "publication" list usually determines the reputation of a researcher, the quality of his/her work and the career development.

- To patent the results or obtain another form of industrial property right. In return for a limited period of exclusive protection in the country or countries concerned, the inventor agrees to the publication of the details of his invention, usually after a period of 18 months. This allows third parties to improve the patented invention or invent alternative solutions,

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5 Source: OECD, based on data from NUTEK, the Swedish Business Development Agency

6 European Commission, "2nd European Report on Science and Technology Indicators", Dec. 1997

thereby advancing the state of the art. This strategy is largely used by commercial entities in order to protect investments in further research and development or the commercialisation of the patented invention. It is also increasingly used by public research institutions for the exploitation of research results through licensing or spin-off generation.

- The "secrecy" strategy, i.e., to keep the results secret thus strongly restricting the use and dissemination of these results. It is often used for results that cannot be protected, or sufficiently protected, through the use of intellectual property rights. This strategy is used mainly by commercial entities in order to obtain and maintain a competitive advantage.

2.2. Protection of creative inventions and dissemination of knowledge – the two objectives of the patent system

The patent system thus provides protection for inventions that have a strong commercial potential for industry and at the same time are valuable for scientific and technological progress. The mandatory publication of the patent application (after 18 months in EU member states) ensures dissemination of information on important technological inventions, in particular those from the industrial sector, which might have been kept secret otherwise. The publication delay is considered acceptable in view of the implications of the alternative "secrecy" strategy, which would result in a complete failure of publication to occur. Thus while patenting may lead to a delay in publication, it does avoid the complete failure to publish the results of scientific research.

2.3. The role of patents for commercialisation of publicly funded research

Since the 1970's, the public research sector has been using the "patent strategy" to support commercialisation of the results of their research through contract research, licensing and the creation of spin-off companies. Public policies, in particular in the US and, recently, also in European member states, have supported commercialisation of publicly funded research results by creating a favourable regulatory environment and suitable infrastructure. For example, partners in research and development (RTD) projects funded through the multi-annual Framework Programmes of the European Communities, may, in exceptional circumstances, acquire exclusive exploitation rights to the results of their research in view of the high market risk and large investment necessary to achieve (successful) commercialisation. Research partners in these publicly funded programmes also have the obligation to protect and/or to make use of the results of their research. Similar rules apply for national RTD programmes in most EU Member States.

In the US, policy measures in the early 80's led to the creation of technology licensing offices at all major US universities, hospitals and large research organisations. These are organised under a national umbrella organisation, the Association of University Technology Managers (AUTM). The enormous success of these US policy measures can be shown from the data in the latest annual report of the AUTM[7], which discloses licensing fee income and details of spin-off companies generated at US public research organisations for the year 1999:

- 5545 U.S. patent applications were filed and 3914 new licenses and options were granted in 1999.

- 344 new companies were formed based on university inventions.

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[7] *AUTM Licensing Survey, FY 1999 Survey Summary* at http://www.autm.net/surveys/99/survey99A.pdf

- Life sciences contributed 86% to the total licensing income of US$ 862 million, comparable to the proportion of the 5th EU RTD Framework Programme that is dedicated to life sciences.

The exploitation of patented inventions generated through publicly funded research can thus have a major effect on competitiveness and economic development. This effect may increase further in the future as a consequence of the important role academic research and university-industry collaboration play in advancing the "knowledge based society" and new technologies. This applies, in particular, to the areas of biotechnology and genetic engineering.

2.4. Possible conflicts between "publishing" and "patenting" strategies

Industrial strategies for intellectual property management focus more strongly on effective protection and less on the rapid publication of research results, which may or may not occur before the "built-in" 18-month period foreseen in the patent system in Europe. Early disclosure of research and development results may be important for some young biotech companies in order to attract investors.

In particular for researchers from the public research sector, who are obliged to rapidly disclose their results to the scientific community, a conflict may arise between the "rapid publication" strategy and the "patent protection" strategy. In most national patent systems, which have strict novelty requirements and are based on the "first-to-file" system without a grace period, this conflict may result in a delay of scientific publication. This conflict may arise for a number of reasons, such as:

- Publication may not occur before the patent application has been filed;

- The patent application procedure may be delayed because of delays in securing the financing of the application;

- Lack of know-how of the inventor about the patent system and/or missing support infrastructures that advise and support public researchers in obtaining patent protection may delay the patent application and therefore the scientific publication.

A public research policy that supports both rapid dissemination to foster scientific progress **and** patenting to support exploitation of results of publicly funded research has to establish framework conditions that helps researchers to avoid a conflict of interest, e.g. ensures rapid publication while allowing to protect results.

2.5. Does patenting delay scientific publication?

Patenting of biotechnological inventions was possible in Europe prior to the adoption of Directive 98/44. However, the main effect of the directive was to confer greater legal certainty on patents related to biotechnological inventions. Therefore, it may be assumed that Directive 98/44 had no major impact on the protection or publication strategies of industry. However, protection of scientific results from basic genetic engineering research by the public research sector and its exploitation through contract research, licensing to industry, or generation of spin-off companies, is set to become an important factor for the competitiveness of EU industries. The publication strategies of public researchers may thus come into conflict with the commercial interest of their industrial research partners or licensees. The delay in publication of the results of scientific research, which may be the subject of a patent

application under the terms of Directive 98/44, could hinder the rapid dissemination of scientific knowledge and hence may slow down further advances in science and technology.

3. PATENTING AND DELAY OF SCIENTIFIC PUBLICATIONS – RESULTS OF A SURVEY

In order to determine whether the patenting of results from basic genetic engineering research actually delays the scientific publication of these results, the Commission services have performed a survey among scientists and organisations involved in basic genetic engineering research. The main objective of this survey was to identify whether a delay exists and if so, whether it is marginal or considerable and how it could be minimised.

3.1. Questionnaire survey – target audience and response

The survey was carried out using a questionnaire, which was mailed to two target groups: the first (and largest group), concerning those working in the area of genetic research, were contacted by DG Research while the second group, concerning those with responsibility for the filing and maintenance of patents, were contacted by DG Internal Market. This necessitated that the questions for both groups be framed in a slightly different manner. Examples of the questionnaire distributed by DG Research, denoted as QRES, and that distributed by DG Internal Market, denoted as QPAT, are included in Annex I of this report. Both groups were asked the same questions regarding the delays, if any, experienced with the publication of scientific results which were also the subject of patent applications and the frequency of such delays. They were also asked the same question regarding possible measures to avoid such delays

QRES was sent to some 1500 scientists from academia and industry working in the area of genetic engineering. The contact data were extracted from the EU RTD projects database of its 4th and 5th Multiannual Framework Programmes for Research and Technological Development by selecting specific calls for proposals dealing with genetic engineering and/or by identifying, through keyword searches in the title, appropriate projects in this field. Around 240 answers were received which represents a response rate of approximately 16%. Of these answers 191 were from individual persons or private or public institutions that were using the patent system at present and/or intended to use it in the future. The data of these 191 responses and data of 11 responses from large industry taken from the QPAT questionnaire response were used for a statistical analysis. In total, 48 (24%) of these responses were from industry (large industry, SMEs and start-ups) and the remaining 154 (76%) from academia (public research organisations, universities, and hospitals). One half of the questionnaires used for the statistical analysis were answered on a personal level and the other half on an institutional level.

QPAT was sent to approx. 150 individuals, companies and organisations identified from a database of entities involved with obtaining Intellectual Property Rights (IPRs). A total of 34 answers were received, of which 30 were from entities that have actually used the patent system and were suitable for inclusion in the analysis. This corresponds to a response rate of 20%. Of these replies, 13 (43%) were from the Patent or IP departments of Large Companies; 11 (37%) were from independent patent agencies, individual patent practitioners or their representative organisation; 4 (13%) were from entities involved in providing IP services to academia (public research organisations, universities, hospital or health institutions) and 1 each (7%) were received from an inventors organisation and a public organisation concerned with the ethics of biotechnological patents. The vast majority of the replies were answered at the institutional level, with only 2 being answered on a personal level.

3.2. Statistical analysis of survey responses

3.2.1. Delay of publication on subjects that could be patentable

The respondents were asked whether a delay in scientific publication had occurred (could occur) on results that had been (could be) the subject of a patent application (Questions 3a and 3b of questionnaire QRES and questions 2d and 2e of QPAT). The possible answers ranged from "no delay", "marginal delay", "considerable delay" to "Not relevant/no opinion". Figure 1 shows the distribution of answers (in percentage of total) for three groups: "Industry", "academics with patenting experience" and "academics without patenting experience".

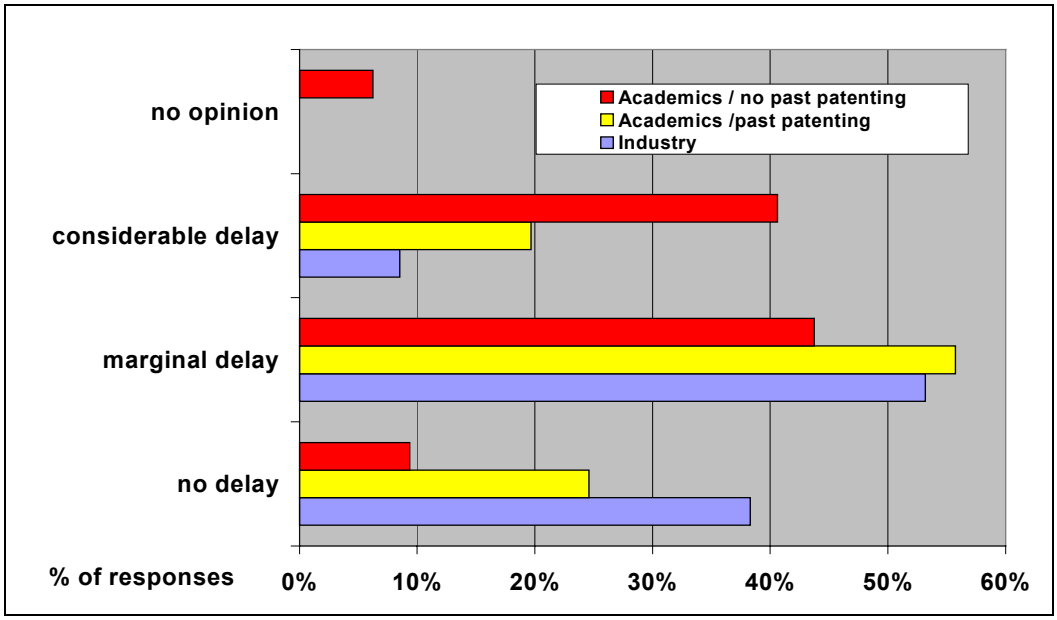


FIG. 1: Actual (and perceived) delay of publication

The results presented in Fig. 1 clearly show that those scientists and organisations in industry and academia that have previously made use of the patent system experience no, or a marginal delay, in around 80-90% of all cases. The perceived delay of publication by academics that had not previously made use of the patent system is much higher (40%) than by academics or industry that had experience with the patent system (20% and 8% respectively).

3.2.2. Measures to avoid delays

The respondents that did experience (or perceived) delays were asked to comment on the importance of measures to avoid or minimise the delay (Question 3c of Questionnaire QRES and question 2f of Questionnaire QPAT). Possible answers offered were

1. revise corporate/university IP strategy/policy,
2. introduce a grace period,
3. provide support and assistance in patent filing,
4. allow a "provisional patent application" (see section 4.2),
5. initiate awareness measures or

6. others.

The respondents were asked to rank these measures in order of importance. The responses varied strongly for the different groups (industry, academia) and were therefore analysed separately for each group.

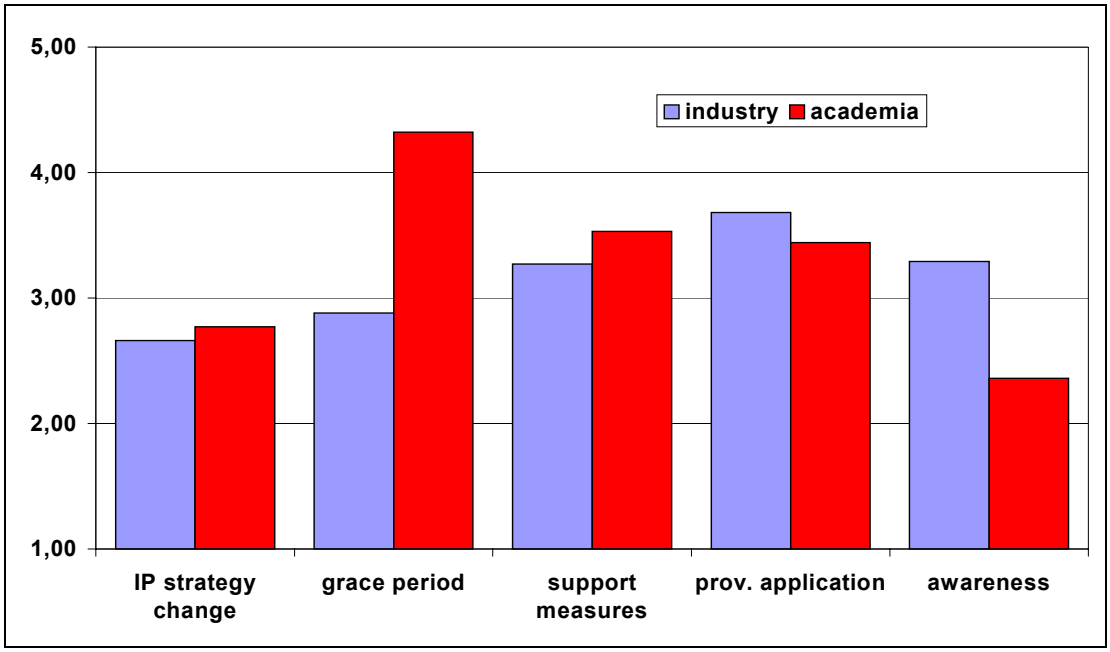


Figure 2: Importance of measures to avoid publication delay: industry response vs. academia

Figure 2 shows the average level of importance for each measure (on a scale from 1 lowest to 5 highest) for respondents from industry and from academia. In addition, an analysis of specific groups and the variation of responses among different groups have been analysed. The results can be summarised as follows:

Industry response:

- Industry of all sizes, whether on a company level or from researchers or patent agents within industry, favour the provisional patent application (PPA) as the most important measure to avoid delay in scientific publications of results that are the subject of a patent application. However, the level of importance only reaches a figure of 3.68 on a scale of 1 to 5.

- Large industry is strictly against a "grace period" (level of 1.7) and strongly favours the provisional patent application (level of 4.3) together with awareness measures (3.9 of 5).

- The consensus among industry on the PPA is much stronger than on the grace period, with some SMEs and start-ups being in favour of a grace period.

Response from public researchers and research organisations:

- Academia clearly favours the grace period as the most important measure to minimise delays in scientific publication.

- Support and advice for patent filing is ranked second as a measure to avoid publication delay directly followed by the "provisional patent application" measure. (The level of importance for the PPA is comparable to that of the industry!)

- Scientists in academia rank "awareness measures" lowest on their importance scale of measures to take to avoid publication delay. Industry, who ranks it No. 2, believes scientists are not sufficiently aware of this issue.

Views of independent patent agents reflect the diverse nature of their customers:

Although only a small number of replies were received from independent patent agents and therefore they are not included in the statistical analysis, it is useful to consider these responses. As most large companies have their own patent and IP departments, it is usually SMEs, academia (including hospital/health institutes, public research organisations (PROs), universities), start-up companies and individuals who use the services of independent patent agents. However, the replies received from the independent patent agents do not show any consistent opinion on the merits of a grace period or the provisional patent application. Increasing awareness of IP, support and assistance for filing of patents and revising IP strategy/policy were all considered to be of higher importance than the grace period or the provisional patent application by those who provide advice on patents to all classes of applicants.

3.2.3. Additional results

Patent filing by academia and industry

The 49 academic institutions that had given data on the numbers of patent filings in the 1996-2000 period had on average filed 57 patents (in total 2779) in this period, 50% of these institutions having filled less than 10 patents. This compares with the figure of 5320 patent filings given by one single large company alone, although one large public research organisation (PRO) had also filed about 900 patents in this period.

The data collected through the questionnaire is in line with the fact that large industry files the majority of patent applications in the biotechnology sector. USPTO statistics covering genetic engineering patents in the 1984 to 1997 period indicate that around 91% of all patents with US ownership are granted to US corporations, while the remaining 9% go to US government and individuals. However, large public research organisations are among the top patentees, as shown in section 1.3.

Patent system promotes publication of results:

About 25% of industry responses and 8% of academia responded positively to the question on whether "… the change in the legal framework allowed you to publicise scientific results (through scientific publications and/or patent applications), that would have been kept secret without patent protection?" The majority of cases occurred in large industry and with large public research organisations. This gives some evidence that, in some cases, the patent system actually facilitated publication of research results.

Partnerships in patent filing:

Patentees were asked whether patents were filed in collaboration with other partners, and if so, whether the main partners were academia, industry or both. The results show that around ¾ of large industry (76.5%) file patents in collaboration with academia and/or industry. The

percentage of academic institutions collaborating with third parties is only slightly lower (73.4%). SME and start-ups file patents both on their own (50%) and in collaboration with academia (40%). Inventions in SMEs and start-ups thus seem to be generated within the company or through collaboration with academia but to a much lesser extent in collaboration with large industry. This demonstrates the importance of the academic sector for SMEs and start-ups, in particular regarding transfer and/or generation of new knowledge.

3.2.4. Summary of comments provided by the respondents

Numerous written comments have been received; the majority of them highlighting the issues addressed in the above analysis, but additional issues of importance were raised. Among those that were mentioned repeatedly are:

- the need for a cost-effective European patent system,
- international harmonisation of patent law,
- the need for advice and support infrastructures at universities, including improvements in teaching patent law to academics.

Other important issues were brought forward, such as:

- The need for information dissemination on European regulations and law, for instance via a central European web site;
- Provisional patent filing is not required in Europe, as low-cost or free application processes already exist in countries such as UK and Sweden.

Finally, it was mentioned in some responses that the solution to the problem of the publication delay could be addressed as one gained more experience with the patent system because the level of detail required in a patent application, i.e., to demonstrate the 'proof of concept' is less than that required for a successful scientific publication. Thus scientists with experience of both processes should in general prepare the patent application at an earlier stage than the submission of the scientific paper for publication in order to eliminate publication delays arising from an application for a patent.

4. MEASURES TO AVOID PUBLICATION DELAYS

4.1. The grace period

4.1.1. Possible benefits and drawbacks of the grace period – Results of an EC hearing

The grace period has been identified by the academic sector as the most important measure to avoid publication delay. Large industry however, is strongly opposed to the introduction of a grace period into the national or EU patent systems.

Similar positions were presented in a hearing on the grace period organised by the European Commission in October 1998, to which 150 persons have participated. The arguments brought forward by the different parties are documented in a summary of this meeting[8]. The

[8] http://europa.eu.int/comm/internal_market/fr/intprop/430.htm

proponents of the grace period point out that under the present system, any inadvertent disclosure leads to the total loss of intellectual property rights. However, academic researchers and small companies may need to disclose the invention to potential future partners (industry, financiers, etc.) in order to develop the invention further. Large industry argues that a grace period will lead to legal uncertainty that may cause a disincentive for industry to invest in areas where it is uncertain whether intellectual property rights are/will be filed. The discussion also identified possible alternative solutions, in particular, the option of filing a provisional patent application or broadening the exemptions that apply to the principle of complete novelty, which currently only apply in the case of "evident abuse" and "disclosure at international exhibitions". The need for international harmonisation was also expressed.

4.1.2. Expert opinions for and against a grace period

The Intergovernmental Conference of the member states of the European Patent Organisation on the reform of the patent system in Europe (Paris, 24 to 25 June 1999) mandated the EPO to "examine, under what conditions the effects of disclosure prior to filing could be taken into account in European Patent Law". This was done considering the facts that:

- Public research organisations, universities and certain firms may wish to be able to file patent applications while at the same time being obliged to practice certain forms of disclosure.

- In addition, certain forms of communication, for example the Internet, increase the risk that the results of research might be disclosed involuntarily.

- In Europe and in other countries, such disclosures prevent inventors from obtaining patent protection for their inventions.

The EPO requested opinions from two experts, Mr Jan Galama and Professor Dr Joseph Straus[9] on the case for and against a so-called "grace period", protecting an inventor from being harmed by a disclosure of his invention prior to the filing of a patent application. These opinions are brought to the attention of the interested public via the EPO website[9] in order to stimulate the ongoing debate on this controversial issue and to provide a basis for a broad public consultation at European and national level. A summary of their arguments has been reproduced in Box 1 and 2 respectively.

[9] see details of opinions at http://www.european-patent-office.org/news/headlns/2000_07_25_e.htm

Box 1: The case against a grace period – summary of Mr. Galama's opinion

The thrust of Mr Galama's opinion is that the introduction of a grace period into European patent law would be detrimental and should not be supported because it would reduce legal certainty for third parties and may confuse individual inventors giving them a false sense of security. Global high-speed communication through the Internet, the growing economic significance of patents and world-wide competition require a clear-cut patent system on which every one can and must rely. Personal inventors would be most at risk from a grace period in that third parties may derive intervening rights from an early disclosure. This would effectively diminish the inventor's rights especially in highly competitive fields such as information technology and biotechnology. If academics wish to compete in the economic world they should be prepared to relinquish old habits, such as early publication.

The introduction of a general grace period by revision of the EPC would put European inventors in a disadvantageous position because there would be no guarantee of reciprocity from other countries.

The introduction of a grace period within the context of an international treaty without substantive patent law harmonisation would still leave the problem, encountered during the negotiations on the "old" Patent Law Treaty in the early 1990's that, due to the peculiarities of the US "first-to-invent" system, the US understanding of the notion of grace period is not the same as in Europe. In particular the issue of prior user rights and European insistence that disclosures during the grace period should not be understood as creating a priority date may prove "impossible" to reconcile with the US position.

The introduction of a grace period as part of broad international harmonisation of patent law remains somewhat hypothetical given that the US show no willingness to abandon the first-to-invent system, and even if it did, it is likely that in any negotiations elements of the first-to-invent system would be retained, threatening to "compromise" the integrity of the clear and well functioning first-to-file system.

Mr Galama concludes that even if the US were willing to move on first-to-invent, this would not be sufficient reason to adopt a grace period due to the uncertainties and likely misconceptions involved.

Jan E. Galama, Corporate Intellectual Property, Philips International B.V., Eindhoven

Box 2: The case in favour of a grace period – summary of Professor Straus's opinion

Professor Straus argues that the introduction of a general grace period into European patent law is desirable since some form of grace period is currently provided for in the patent laws of thirty eight countries world-wide including three countries, Estonia, Romania and Slovenia which may join the EPO in 2002. The absence of such provision in Europe could have negative economic consequences including the shifting of investment and technological development out of Europe to countries where pre-filing disclosures are not necessarily prejudicial to patent filing.

- Both the United Kingdom and Germany previously recognised a grace period in their patent laws and this did not give rise to any difficulty. Neither does experience in jurisdictions such as Canada and Japan suggest that such a provision gives rise to problems and it is primarily used as a "safety net".

- Even existing European patent law cannot guarantee absolute legal certainty. In patent grant proceedings account has to be taken of oral disclosures and public use in determining the state of the art. The situation will become more difficult with the increased use of the Internet. Legal certainty is therefore a relative concept and does not depend upon the existence or otherwise of a grace period.

- Furthermore, third parties already have to cope with some degree of uncertainty. Patent applications are not published until eighteen months from the priority date and even then it is not clear until the grant procedure has finished what exactly the nature of the exclusive rights claimed will be.

- Account has to be taken of the growing significance of academic and research institutes as patent applicants and generators of innovation relevant knowledge. There is a need to facilitate early publication of research results. Disclosure in parallel to or only after filing a patent application does not entirely meet this need since it is not always feasible to file a patent application at an early stage and in any event the absolute bar on filing for previously disclosed inventions is disproportionate to any inadvertence on the part of the inventor. It is not only inventors who suffer whenever a useful invention is excluded from patent protection but society at large. Statistics from Japan, US and Germany make clear that early disclosure is of particular importance for academic/research institutions and independent inventors and the needs of this sector should be given more recognition in Europe. However, statistics from Japan, where the grace period has to be invoked, also clearly reveal its importance for large industry: 47% of applications invoking grace period in 1999 were filed by large companies.

- Provisional applications do not offer a satisfactory remedy because they do not address inadvertent disclosures at all and even in other cases they pose a risk that the original disclosure will prove inadequate as a basis for any subsequent application.

Prof. Dr. Joseph Straus, Max-Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich

4.1.3. The work undertaken under the auspices of WIPO (World Intellectual Property Organisation)

Within the framework of the Standing Committee on Patent Law (SCP) of WIPO, discussions have been undertaken in order to harmonise substantial patent law worldwide. This on-going work covers important issues such as novelty, inventive step or non-obviousness and industrial application or utility. A draft article dedicated to the introduction of a grace period into the national legislation has also been discussed. It should be noted that a decision on the adoption of a grace period has not yet been reached. The provisions contained in this article are very close to those that were proposed in 1991 (first draft Treaty on the harmonisation of patent law, which failed).

The main principles are as follows:

- Introduction of a grace period for any disclosure of the invention (by the inventor, by a third party or by a National Patent Office – NPO) within 12 months before the filing date of the request or 12 months before the priority date;

- The inventor may always invoke this grace period;

- The inventor has to prove that the disclosure took place less than 12 months before the filing date (or where priority is claimed, the priority date of the application).

The discussions both on the principle of the introduction of such a grace period and on its content will continue during the coming meetings of the SCP.

4.2. The provisional patent application

The PLT (Patent Law Treaty)[10] was adopted in Geneva on June 2nd 2000 aiming at harmonising the formal requirements of patent law. One of the most important provisions deals with the possibility for the applicant to obtain a filing date without fulfilling the formal requirements generally requested to examine the application, in particular the obligation for the applicant to provide a description and some claims and to file it in one of the languages accepted by the Office.

New article 5 of the PLT allows any applicant to obtain a filing date provided that the application was transmitted to the Office on paper or by any other means (including electronic)[11]:

- an express or implicit indication to the effect that the elements are intended to be an application;

- indications allowing the identity of the applicant to be established or allowing the applicant to be contacted by the Office;

- a part which on the face appears to be a description (any Contracting Party might allow the filing of drawing instead of the aforementioned part). Moreover, it is not necessary that the communicated part is written in one of the official languages of the Office

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[10] http://www.wipo.int/treaties/ip/plt/treaty.html

[11] The European Community, after the introduction of an effective Community patent system, could become a party to the Patent law Treaty

The interest of such provision is to confer on the applicant a filing date. As from this date, he is allowed to disclose his invention without prejudice to the patentability.

These provisions are new in the European legislation. However, these rules are already in force in the USA. The European Patent Convention has been amended to take into consideration these new conditions for obtaining a filing date (Diplomatic Conference, Munich, 20-29 November 2000)[12].

4.3. Support and awareness activities, in particular for public researchers

A large number of small enterprises and public research organisations have neither the personnel nor the financial resources to manage their intellectual property.

For public researchers, the complexity of regulations concerning employee inventions, (such as ownership, "professor privilege", regulations concerning ownership of and access rights to IP in publicly funded, collaborative research, etc.) by itself is a hurdle to application for intellectual property protection of their research results. While large research organisations may have the necessary resources to define an IP policy and provide a support infrastructure to scientists, similar infrastructures and IP policies are largely missing at universities. Ideally, these support infrastructures should provide, among others:

- advice and expertise on the valuation of the intellectual property and the best protection strategy,
- legal advice on employee invention law, IP law and regulations concerning IP,
- help with and financial support for patent filing, and
- support for exploiting the intellectual property (licensing, start-ups).

The European Commission and member states are supporting or initiating a number of activities that are geared to raise awareness for patenting issues or provide direct support to researchers for preparing, filing and financing patent applications and exploitation of patent rights. Among those are the IPR-Helpdesk financed by DG Enterprise of the European Commission[13] and the new "Patent academia" initiative to be launched by the same directorate-general. The latter will provide a network of technology licensing offices of European research organisations in order to exchange best practice and experience in protection and exploitation of publicly funded research. The European Commission is also supporting national Patent Offices to develop patenting support initiatives and services in particular for academia and small and medium sized enterprises.

4.4. Legal framework, regulations and other policies related to intellectual property rights

A number of other factors may contribute to the delay of publication of subjects that may be patentable:

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[12] These provision shall enter into force two years after the fifteenth Contracting State has deposited its instrument of ratification.

[13] http://www.ipr-helpdesk.org

- The lack of a cost-effective and simple Community Patent may cause delays because of the difficulty of finding the finance for patent applications. Some inventions may not be filed due to the high costs associated with patent protection and may be kept secret instead, in particular with SMEs.

- Regulations concerning ownership and use of inventions, such as employees law, and the lack of knowledge of this legal framework in particular in SMEs and universities may complicate and delay the decision process related to patent filing and therefore delay publication.

- Inventions generated in research collaborations between university and industry may be delayed because no clear agreements have been made beforehand on how best to manage the intellectual property generated within such consortia while taking into account the different interests and strategies of the partners. Academic partners sometimes lack a clear understanding and/or policy on IP matters as well as the necessary negotiating skills to achieve their goals when such collaboration agreements are being drawn up. Industrial partners do not always take into account the importance of rapid publication of scientific results to their academic partners .

While some of these policy issues are currently under consideration at European Union or member state level (i.e., Community Patent[14]; employee invention law in Germany[15], etc.), other issues need to be considered in more detail and possible policy measures on these issues need to be identified.

5. SUMMARY AND CONCLUSIONS

- Providing patent protection for results of genetic engineering research usually facilitates publication and avoids secrecy strategies. Papers are published after filing of the patent application(s), at the latest, through the publication of the patent application (up to 18 months after the application date).

- The public research sector has become a major user of the patent system. The conflict between the scientific "publication and dissemination" strategy and the "protection and exploitation" strategy may cause delays in publication of scientific results that might be the subject of patent applications.

- A survey among EU researchers and research organisations from both industry and academia has shown that publication delays do occur, but less so with more experienced users of the patent system. With experienced users significant delays occur in less than 20% of all cases (20% for academic institutions and 8% in industry).

- Almost half of the surveyed researchers from academia that have no previous experience with the patent system but intend to use it in the future are of the opinion that considerable

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14 "Proposal for a Council Regulation on the Community patent", COM/2000/0412 final, OJ C 337 E, 28/11/2000, p278

15 A draft law (14/5975 of 09.052001: http://dip.bundestag.de/btd/14/059/1405975.pdf) has been introduced by members of the German Parliament to drop the "professors' privilege", which gave professors full ownership and rights to inventions made in the course of their work, and assign rights to the university, in order to stimulate the setting up of university licensing and technology transfer infrastructures

delays will occur. There is a need for awareness actions and support activities to counteract these (inaccurate) perceptions and to help researchers to become more familiar with the patent system itself. This should be done on all levels - regional, national and European.

- The survey showed a clear preference of the academic sector for a grace period in order to avoid and/or minimise any delays of publication of research results that may be the subject of a patent application. In contrast, large industry is strongly against a grace period and favours rather the introduction of a provisional patent application (PPA) into European legislation. The replies received from medium sized industry and from independent patent agents did not show any consistent opinion on the merits of a grace period. In particular patent agents stressed the needs for awareness activities, assistance and support measures. A comparably high level of importance was attributed to the PPA by both industry and academia.

- Experience has shown that the level of detail required in a patent application, i.e., to demonstrate the 'proof of concept' is less than that required for a successful scientific publication. Thus scientists with experience of both processes should learn to make the patent application at an earlier stage than the submission of the scientific paper for publication and thus avoid any delay in publication of the scientific paper.

- Despite a number of studies, no precise figures are available which quantify the economic effects for industry, or which assess the value in practical terms for academia, of the introduction of a grace period. Throughout the member states of WIPO, different concepts of a "grace period" have developed (e.g., in US, JP), all of which should be investigated in detail concerning the balance they provide between the interests of the academic sector and those of industry. The US structure involving a "grace period" coupled with the "first-to-invent" system provides the highest level of "legal uncertainty" and should not serve as the "best practice" example.

- In view of the increasing internationalisation of research, in particular in the genetic engineering sector (both public and private sector funded research), and also given the fact that the public research sector has become a more experienced and major user of the patent system, efforts to define and harmonise the concept of the 'grace period' should be considered. However, this concept will only work at a global level and will only be effective if it provides 'legal certainty', which is the major concern of industry. This should be taken into account during the current discussions by the Standing Committee on Patent Law (SCP) of WIPO on the possible introduction of a grace period.

- In 1991 WIPO discussed the inclusion of an article into the first draft of a "Treaty on Harmonisation of Patent Law" concerning the introduction of a grace period into national laws. This was rejected based on the grounds that a grace period would be counter to education and awareness campaigns among academic researchers concerning the proper use of the patent system. These arguments clearly no longer hold good today.

- The legal framework conditions should be further optimised to ease the use of the patent system by academics and small and medium sized enterprises. These should include, among others:

    – the introduction of a provisional patent application in all member states in line with Article 5 of the Patent Law Treaty, adopted in Geneva on June 2, 2000.

– support and advice for academic bodies and SMEs in the proper use of the patent system and the strategic use of intellectual property rights as well as teaching and training on these issues.

– a simple and cost-effective patent system, as will be provided through the proposed Community Patent.