#### COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 14.1.2002 SEC(2002) 50

#### **COMMISSION STAFF WORKING PAPER**

## **Examples of the Questionnaires QRES and QPAT**

### ANNEX TO THE

# 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

{COM(2002)2 final}

## 1. Questionnaire QRES



#### **EUROPEAN COMMISSION**

RESEARCH DIRECTORATE-GENERAL

Directorate E - Life Sciences: biotechnology, agricultural and food research

Directorate F - Life Sciences: health research

The Directors

Dear colleague:

## Patentability of results of basic genetic engineering research and implications for publications of these results

The implementation of Directive 98/44 on the "Legal protection of biotechnological inventions" will allow patenting of subjects of basic genetic engineering research thereby encouraging researchers to seek patent protection in cases where they previously wouldn't have done so. This may possibly lead to a delay in publication of the research results, in part also to the lack of a "grace period".

When adopting the directive in 1998, the European Parliament has requested the Commission to assess the implications of this directive on the failure to publish, or the late publication of, papers on subjects in basic genetic engineering that could be patentable. As the directive came into effect just 6 months ago, it may be difficult to fully assess the impact of the directive in this area.

That is why our directorate, together with DG MARKT, which is responsible for implementation of the directive, has initiated this survey among European researchers in basic genetic engineering. The aim of the attached questionnaire is that you, as a potential user of the patent system, will provide us with some information on the actual experience you may have already encountered with the patent system and/or how you will potentially make use of this system. We have kept the questionnaire very short and hope that you will be ready to devote time to help the Commission in this important issue. Completed questionnaires will be kept strictly confidential and only used in aggregate form.

Thanking you in advance for your co-operation.

Yours sincerely

**BRUNO HANSEN** 

PETER KIND

Directors Life Sciences Programme, DG RESEARCH, European Commission

If you have any questions, please fell free to contact: Waldemar Kütt, DG RTD Life Sciences, TEL: +32-2-299-4145.

PLEASE RETURN THIS FORM VIA FAX/E-MAIL TO:

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BEFORE FEBRUARY 14, 2001

1. Research org	ganisation and type	of research				
A. What organisation do you currently work with? (Tick appropriate box)  large industry small or medium sized company start-up company public research organisation university hospital/health institute other, please specify:						
B. What is your foc	us of research? (Tic	k one box for area a	nd one for activity, res	spectively)		
	AREA:			ACTIVIT`	Y	
plant biology animal biology			genetic engineer genome mapping			
human biology			functional genor	nics (including p	proteomics)	
microbial biology	1 ( 11 6	1	other, please spe	cify:		
other, please specif	ology (cell factory, f	ood, etc)				
other, pieuse speen	. ,					
C. Research collaboration  Did you perform this research  mainly in-house in collaboration with other partners from academia industry  both academia and industry						
2. Number of pu	iblications and paten	t applications				
*	*	_	_			
(Please indicate wheth	er the numbers given	apply to  approx  appr	nal level	institute/compa	any level)	
A. How many publications in refereed journals have you (your institution) authored or co-authored in recent years in the areas ticked under 1.B above?						
	1996	1997	1998	1999	2000	
No. of publ.					<u> </u>	
If you do not know the approximate numbers, please indicate whether the numbers of publications have stayed constant over the years decreased continuously grown steeply increased went up and down						
<b>B.</b> How many paten YEAR		you (your institution 1997		ignee have bee	n filed?	
No. of filings	1990	1997	1998	1999	2000	
Of which national	1					
filings						
Filings at EPO Filings in US						
Timigs in OS	Fillings III US					
If you do not know the approximate numbers, please indicate whether the numbers of patent applications have stayed constant over the years decreased continuously grown steeply increased went up and down						
and whether they were filed predominantly in   US   JP   EPO   National Patent Office.						
If these patents have been filed in collaboration with other organisations, which were the main partners?  academic institutions industry both academic institutions/industry						
C. Do you intend to file patent applications in the near future?  ☐No ☐Yes If yes, will you file in ☐ US ☐ JP ☐ EPO ☐ National Patent Office						
	If yes, will you	file in US	JP EPO 1	National Patent (	Jiffice	

 $<sup>^{1}</sup>$  An SME is defined as having less than 250 employees, a turnover of less than 40 mio. € or a balance sheet income of less than 27 mio € and is considered to be independent (not owned more than 25% by a large company).

3. Effect of patenting on publication behaviour	
A. If you have applied for patents, did patent filing actually delay scientific publication?  Yes, considerably Yes, marginally No	
B. If you have not applied for patents yet, but intent to do so in the future, do you think that p actually delay scientific publication?	atent filing would
Yes, considerably Yes, marginally No	
C. If there was a (potential) delay in publication, what would be possible measures to avoid the	is? Rank importance of
the possible measures (start with 1 = highest, 2,)  Measure	Importance
Revise corporate/university intellectual property strategy/policy	importance
Introduce a grace period, allowing authors of scientific papers to file for a patent within a defined period (6-12 months) after initial publication	
Provide support and assistance in patent filing (e.g. university licensing offices, etc.)	
Allow "provisional patent application" <sup>2</sup>	
Initiate awareness measures	
Others:	
4. Patent law	
7. I atcht law	
A. Are you aware of the recent adaptations in patent law, which allow (or clarify) patenting of were not (or not clearly) patentable before?	f certain subjects that
☐ Yes ☐ No	
<ul> <li>If YES, which of the following legislative changes concerning patenting of biotechnological inv</li> <li>□ Directive 98/44, adopted on July 6, 1998 and currently being implemented by the Member S protection of biotechnological inventions"</li> <li>□ New implementation rules of the European Patent Convention of June 16, 1999, inserting a "Biotechnological inventions", closely following the 98/44 directive</li> <li>□ Other recent changes in national laws, please specify:</li> </ul>	tates, on the "Legal
B. Has the change in the legal framework allowed you to publicise scientific results (through s and/or patent applications), that would have been kept secret without patent protection?	cientific publications
☐ Yes ☐ No	
5. General comments to this issue, if any	

<sup>&</sup>lt;sup>2</sup> In principle, it would allow to provisionally file for a patent application under reduced formal requirements, e.g. by depositing a scientific paper.

## 2. Questionnaire QPAT



#### **EUROPEAN COMMISSION**

Internal Market DG

SERVICES, ELECTRONIC COMMERCE, INTELLECTUAL AND INDUSTRIAL PROPERTY AND THE MEDIA Industrial property

Brussels, MARKT/E/2 D(2001)

Dear colleague:

Subject: Patentability of results of basic genetic engineering research and implications for publications of these results

The implementation of Directive 98/44 on the "Legal protection of biotechnological inventions" will allow patenting of subjects of basic genetic engineering research thereby encouraging researchers to seek patent protection in cases where they previously wouldn't have done so. This may possibly lead to a delay in publication of the research results, in part also to the lack of a "grace period".

When adopting the directive in 1998, the European Parliament has requested the Commission to assess the implications of this directive on the failure to publish, or the late publication of, papers on subjects in basic genetic engineering that could be patentable. As the directive came into effect just 6 months ago, it may be difficult to fully assess the impact of the directive in this area.

Our directorate, which is responsible for implementation of the directive, together with DG RESEARCH has initiated this survey among researchers, companies, government agencies and organisations who are working in the field of basic genetic engineering in Europe. The aim of the attached questionnaire is that you, as a potential or actual user of the patent system, will provide us with some information on the experience you, or those you represent, may have already encountered with the patent system and/or how you will potentially make use of this system. We have kept the questionnaire very short and hope that you will be ready to devote time to help the Commission in this important issue. Completed questionnaires will be kept strictly confidential and only used in aggregate form. Thanking you in advance for your co-operation. Yours sincerely,

Erik Nooteboom

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BEFORE March 19, 2001

1. Research organisation and type of research						
D. What type of organisation are you or do you mainly work with? (Tick appropriate box)						
large industry	small	or medium sized	co	$mpany^3$ $\square$ s	tart-up company	
public research organ					ospital/health ins	stitute
individual/private in		, please specify:		_	•	
E. What is your involvement with biotechnological inventions? (Tick one box for area and one for activity, respectively)						
	AREA:				ACTIVITY	
independent patent a				advice on paten		
private company				granting of pate		
academic institution				applying for pa		
research organisation	1			other, please sp	ecify:	
patent office						
other, please specify						
F. Performance of Work  Where do you perform this work  ☐ mainly in-house ☐ in government department/agency/ministry ☐ use of outside agency/advice ☐ in collaboration with other partners from ☐ academia ☐ industry ☐ both academia and industry						
2. Effect of patent	applications on p	ublication				
<ul> <li>D. Have you had to delay or advise the delay of scientific publications because of the need to apply for a patent?</li> <li>Yes</li> <li>No</li> <li>Not Relevant</li> </ul>						
F Di	. t. 1 1	1 C	4•	10079		
E. Please indicate if the					1000	2000
YEAR Mara Fraguent	1996	1997	J	1998	1999	2000
More Frequent						
Less Frequent No Effect						
Not Applicable						_
F. If patents were filed, where were they predominantly filed  US JP EPO National Patent Office Not Relevant  G. If you have applied for patents, did patent filing actually delay scientific publication?  Yes, considerably Yes, marginally No Not Relevant  H. If you have not applied for patents yet, but intend to do so in the future, do you think that patent filing would actually delay scientific publication?						
Yes, considerably	∐ Yes, ı	marginally		☐ No	Not Relev	ant

 $<sup>^3</sup>$  An SME is defined as having less than 250 employees, a turnover of less than 40 million € or a balance sheet income of less than 27 million € and is considered to be independent (not more than 25% owned by a large company).

<sup>&</sup>lt;sup>4</sup> This refers to all legally qualified persons providing assistance for persons applying for patents

I.	If there was a (potential) delay in publication, what would be possible measures to avoid this? Rank
	importance of the possible measures (start with 1 = highest, 2,)

M	T
Measure  Pavisa corporate/university intellectual property strategy/policy	Importance
Revise corporate/university intellectual property strategy/policy  Introduce a grace period, allowing authors of scientific papers to file for a patent within a	
defined period (6-12 months) after initial publication	
Provide support and assistance in patent filing (e.g. university licensing offices, etc.)	
Allow "provisional patent application" Allow "provisional patent application" 5	
Initiate awareness measures	
Others:	
Others:	
3. Patent law	
C. Are you aware of the recent adaptations in patent law, which allow (or clarify) patent	ting of certain
subjects that were not (or not clearly) patentable before?	
☐ Yes ☐ No	
If YES, which of the following legislative changes concerning patenting of biotechnologic	cal inventions are you
aware of:	1 0 1
Directive 98/44, adopted on July 6, 1998 and currently being implemented by the Men	iber States, on the
"Legal protection of biotechnological inventions"  New implementation rules of the European Potent Convention of June 16, 1000 inserts.	ina a narri ahantan an
New implementation rules of the European Patent Convention of June 16, 1999, inserts "Biotechnological inventions", closely following the 98/44 directive	ing a new chapter on
Other recent changes in national laws, please specify:	
Unter recent changes in national laws, please specify.	
D. Has the change in the legal framework allowed you to publicise scientific results (through publications and/or patent applications), that would have been kept secret without pa	
passions and si passion approved and would have soon represented the	procession.
☐ Yes ☐ No	
4. General comments on the effects of patent applications on scientific publications, if	any

<sup>&</sup>lt;sup>5</sup> In principle, it would allow one to file provisionally for a patent application under reduced formal requirements, e.g. by depositing a scientific paper.