

# **e****pi** **Information**

Institut der beim Europäischen Patentamt  
zugelassenen Vertreter

Institute of Professional Representatives  
before the European Patent Office

Institut des mandataires agréés près  
l'Office européen des brevets

Heft · Part · Fascicule 1 März · March · Mars 2006



Carl Heymanns Verlag

ISSN 1434-8853

2006 **1**



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l'Office européen des brevets

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*Verlag · Publishing House · Maison d'édition*

Carl Heymanns Verlag KG  
Luxemburger Straße 449  
D-50939 Köln  
Tel. (0221) 94 373-0  
Fax (0221) 94 373-901  
e-mail: [service@heymanns.com](mailto:service@heymanns.com)  
<http://www.heymanns.com>

*Anzeigen · Advertisements · Publicité*

*Druck Printing Imprimeur*

ISBN 3-452-26251-0  
ISSN 1434-8853

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*Carl Heymanns Verlag KG*

*grafik + druck, München*

*Vierteljahreszeitschrift*

Abonnement im Mitgliedsbeitrag enthalten,  
für Nichtmitglieder € 40,00 p. a. zzgl. Ver-  
sandkosten (€ 9,90 Inland / € 14,00 Aus-  
land), Einzelheft € 11,60 zzgl. Versandkosten  
(ca. € 2,27 Inland / ca. € 3,20 Ausland)  
je nach Heftumfang. Preise inkl. MwSt. Auf-  
kündigung des Bezuges 6 Wochen vor Jah-  
resende.

*Quarterly Publication*

Subscription fee included in membership fee,  
for non-members € 40,00 p. a. plus postage  
(national € 9,90 / abroad € 14,00), indivi-  
dual copy € 11,60 plus postage (national  
about € 2,27 / abroad about € 3,20) de-  
pending on the size of the issue, VAT inclu-  
ded. Cancellation of subscription is requi-  
red 6 weeks before any year's end.

*Publication trimestrielle*

Prix d'abonnement inclus dans la cotisation,  
pour non-membres € 40,00 p. a., frais d'en-  
voi en sus (national € 9,90 / étranger  
€ 14,00), prix à l'unité € 11,60, frais d'en-  
voi en sus (national environ € 2,27, étran-  
ger environ € 3,20) selon le volume du nu-  
méro, TVA incluse. Résiliation de l'abonne-  
ment 6 semaines avant la fin de l'année.

## Table of Contents

<b>Editorial</b> . . . . .	2
----------------------------	---

### **I – Information concerning epi**

#### **European Qualifying Examination**

New <i>epi</i> Tutorial . . . . .	3
<i>epi</i> Tutors wanted . . . . .	6

#### **Information from the Secretariat**

Deadline 2/2006 . . . . .	2
<i>epi</i> Artists Exhibition 2006 . . . . .	7
<i>epi</i> Membership chart as of 06.03.2006. . . . .	8
<i>epi</i> Seminar in Eindhoven . . . . .	9
VESPA/VIPS Prüfungstraining für die Europäische Eignungsprüfung 2007 . . . . .	33
<i>epi</i> Disciplinary bodies and Committees . . . . .	34
<i>epi</i> Board . . . . .	U3

### **II – Contributions from epi Members and other contributions**

#### **Articles**

The European Patent Academy – An Approach for EQE candidates, by W. Torlot. . . . .	10
Bachelor and Industrial Property Studies in Prague, by L. Jakl . . . . .	12
Opinion on Patent Profession rendered by CNIPA, by E. Lyndon-Stanford . . . . .	15
Of incomplete complete inventions: T1329/04-3.3.8, by F. Stolzenburg, B.A. Ruskin and H.-R. Jaenichen . . . . .	15
Reform of European Pharmaceutical Law and Patent Protection, by M. Krekora . . . . .	27
Begründung der Definitionsmethode zur Prüfung erfinderischer Tätigkeit, S. V. Kulhavy . . . . .	28

## Editorial

T. Johnson

The EPO is undoubtedly successful. It is probably true that the Founding Fathers would never have dreamed of the size of the Office as it exists to-day, nor would they have contemplated the number of applications being handled to-day. Perhaps the Office is a victim of its own success? There is a high level of demand for its services, and in certain areas it struggles to cope. On the other hand, users seem to like what they get, otherwise why do they keep filing? There are no doubt many reasons, one of which for some applicants being that they actually like the fact that there is a long pendency for their applications – only one renewal fee, no prosecution charges, or very few, uncertainty for competitors, Regulatory Authorities to convince in certain fields. Despite the demand for its services, no organisation is beyond criticism of its performance on, for example, timeliness (or lack of it), variable quality of examination, etc., etc. The EPO may think itself unfairly criticised and it may be addressing these issues internally. But the world is a different place than the one the Founding Fathers knew. For example, at the recent Davos meeting of the Great and the Good, one topic discussed was “a world without IP?” A big question. We think that most users do not trouble themselves to ask such questions. But there are “smaller” questions they do ask, in the context of the EPO, such as “why are my problems not understood, (by the Examining Division, Opposition Division etc).” A case in point is the appointment of Oral Proceedings. We

know of a recent case where an attorney was summoned to two completely separate Oral Proceedings, on two entirely separate cases, on the same day, at the same time. His perfectly reasonable request for one to be shifted fell on totally unsympathetic ears – as we understood it, he was told that another attorney should represent the client on one of the cases. This attitude does not serve the system, the Office or the users well at all.

A small shift in attitude by the Office to such issues, which matter to applicants, would go a long way to lessening criticism of the Office. Perhaps a way forward would be to set up a Users’ Group which could meet with the Office say annually to discuss aspects of procedure, changes to be implemented etc. We understand that such a system works well at the Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM), where meetings between the Office and the Users, represented in the main by NGOs meets in Alicante once a year. Such a body would not be to usurp the excellent work done by SACEPO. A “Users Group” would channel feelings of the Users to the EPO about such matters as Summons to Oral Proceedings, general handling of cases, actual and perceived frustrations felt by Users, etc. The Office in turn could present its views to the Users.

Perhaps the EPO could consider such an initiative? What do our readers think?

### Nächster Redaktions- schluss für epi Information

Informieren Sie bitte den Redaktionsausschuss so früh wie möglich über das Thema, das Sie veröffentlichen möchten. Redaktionsschluss für die nächste Ausgabe der epi Information ist der **12. Mai 2006**. Die Dokumente, die veröffentlicht werden sollen, müssen bis zu diesem Datum im Sekretariat eingegangen sein.

### Next deadline for epi Information

Please inform the Editorial Committee as soon as possible about the subject you want to publish. Deadline for the next issue of epi Information is **12 May 2006**. Documents for publication should have reached the Secretariat by this date.

### Prochaine date limite pour epi Information

Veuillez informer la Commission de rédaction le plus tôt possible du sujet que vous souhaitez publier. La date limite de remise des documents pour le prochain numéro de epi Information est le **12 mai 2006**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

## New *epi* Tutorial

PQC (Professional Qualification Committee of the *epi*) has developed a new approach for the *epi* Tutorials based on the known tutorials, on the experiences of tutors, and on discussions with members of the Examination Board. Every year members of the three Examination Committees meet with tutors to explain the papers and comment on the expected solutions. To spread out this knowledge a tutors' meeting is scheduled in the summer. Those tutors who have attended the 'Tutors' Meeting' will then pass on the information and explain how the papers are expected to be handled. The material used for the presentation is provided to all tutors.

The new *epi* Tutorial is a course comprising two modules – A/B and C/D – with a two days' seminar respectively. The seminars will be held Friday afternoon and Saturday morning. The groups will be small enough to allow intensive discussion, preferably 5 to 10 candidates per group. The papers can be booked independently.

### The schedule is as follows:

Candidates enrol for the tutorial as soon as possible, not later than 5 July for the summer tutorial, and by 5 September at the latest for the autumn tutorial. Candidates indicate the papers they want to discuss and the place they would favour for a meeting with their tutor. The enrolment is confirmed and candidates are informed about the assigned tutor.

In the first round candidates write the papers in real time; in this year's tutorials the 2004 and 2005 papers will be considered. The papers can be downloaded from the EPO website (<http://eqe.european-patent-office.org/site/archive/index.de.php>). They are also available on CD-ROM.

Candidates send their draft(s) to the tutor they have been assigned to by the *epi* secretariat. The tutor comments on the paper(s).

Candidates who do not get an answer to their papers from their tutor by the due date are asked to contact the *epi* Secretariat immediately.

In a second round meetings are scheduled for Papers A/B, and Papers C/D respectively. The papers in general, specific papers, and particular problems of the papers are discussed and questions answered. In order to provide enough time for intensive discussion the meetings will start on Friday early afternoon and will be continued on Saturday in the morning.

Seminars can take place at several places depending from the number of candidates. The candidates provide for their own travel expenses as well as for the travel expenses of their tutors.

The time schedule for the two modules for the preparation for the EQE 2007 will be published on the website of *epi*. Candidates will be informed by their tutors about the time and place of the meeting.

Summer tutorial	Sending drafts to tutors by 15 August
Autumn tutorial	Sending drafts to tutors by 15 October

### Fees for the tutorial:

150,00 € per paper for non-*epi* students  
75,00 € per paper for *epi* students

For candidates who do not need a copy of the papers from the *epi* Secretariat, the fees are:  
120,00 € per paper for non-*epi* students  
60,00 € per paper for *epi* students

Please visit our website for news !

[www.patentepi.com](http://www.patentepi.com)

# epi Summer Tutorial 2006

Please return by →  
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5 July 2006

Tel.: +49 89 24 20 52- 0  
Fax: +49 89 24 20 52-20

Name: .....

Address (business or private): .....

Telephone No.: ..... Fax No.: .....

e-mail: .....

Preferred language:      English ☐                      German ☐                      French ☐

Fields of interest:      Electricity/Mechanics ☐                      Chemistry ☐

I should like to enrol for:

## 2004

Module 1   Paper A ☐  
                 Paper B ☐

Module 2   Paper C ☐  
                 Paper D ☐

## 2005

Module 1   Paper A ☐  
                 Paper B ☐

Module 2   Paper C ☐  
                 Paper D ☐

I need a copy of the following papers: .....

I do not need any copy.                      ☐

I am a Student of the **epi**.                      ☐                      I am not a Student of the **epi**.                      ☐

## Fees

150,00 € per paper for non-**epi** students  
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If a candidate declares he/she does not need a copy from the *epi* Secretariat, the fees are:

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Previous courses attended on intellectual property (CEIPI, QMW, previous preparatory courses etc.):

.....  
.....

If you have already sat one or both of the following examinations, please indicate its date(s):

– National examination .....

– European Qualifying Examination: .....

Years of professional experience: .....

Would you be willing to travel to meet your tutor(s)? .....

If not, please be aware that the expenses of tutors, who travel to meet their candidates, will be borne by the candidates.

Date of fee payment into the following **epi** account, and its amount:

Postbank München  
Account No. 703-802  
BLZ (Bank Sorting Code) 700 100 80  
IBAN No. DE77700100800000703802  
BIC PBNKDEFF

.....

Please note that **epi** tutorial fees **cannot** be debited from accounts held with the European Patent Office and that payment by cheque is not possible.

Date: .....

Signature: .....

Name: .....





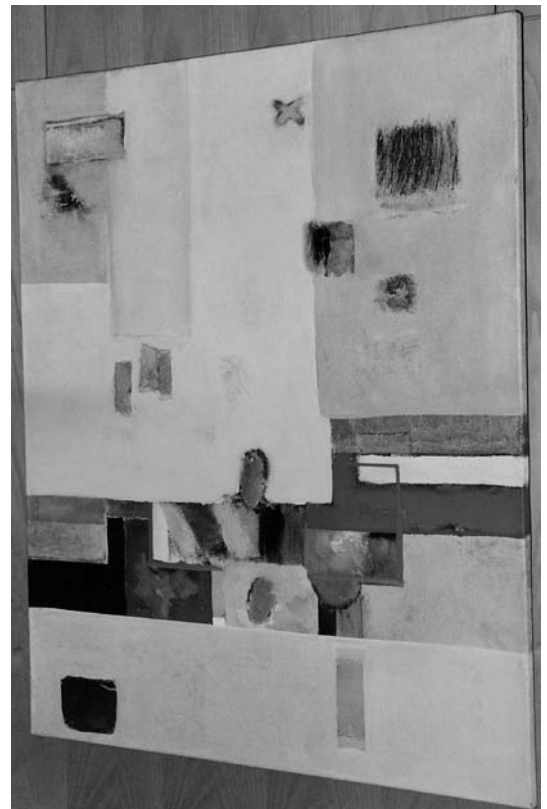
## Exhibition of *epi* Artists 2006

The 7th *epi* artists' exhibition took place from 16 February to 3 March 2006 in the EPO main building, in Munich. The exhibition, opened by the EPO President, Prof. Pompidou, and by the former *epi* President, Mr. W. Holzer, was, as usual, very successful. Dr. M. Berger from Liechtenstein, said a few words on behalf of the participants, F. Andréeff (FR), G. Antritter (DE), J. Antritter (DE), M. Berger (LI), M. Böckhorst (DE), L. Harley (NL), K. Hoffmann (DE), D. Monéger (FR), R. Pet (NL), J. Raß (DE) and R. Veith (DE). A large number of guests and visitors

showed considerable interest in the works displayed, mostly paintings in various techniques as well as two quilts, an interesting creation by R. Pet. We take this opportunity to thank those participants who could not be present on that evening but were kind enough to send their works of art and contributed to the success of the exhibition. We are looking forward to the next exhibition in 2009. Any comments and suggestions from our members are welcome!



Dr. M. Berger in front of his paintings



„Auf den Punkt gebracht“,  
Acrylic painting by M. Böckhorst



“Spring”, Acrylic painting by K. Hoffmann

(Photos: Denis Moisson)

# LIST OF PROFESSIONAL REPRESENTATIVES AS OF 06.03.2006

by their place of business or employment in the Contracting States and their entry according to A134 or A163

THIS TABLE AND THE CHARTS below ARE AS FROM 06.03.2006							
No.	Contr. State	A134	% A134	A163	% A163	Total Repr.	% of Tot/Repr.
1	AT	60	58,8	42	41,2	102	1,20
2	BE	91	66,4	46	33,6	137	1,62
3	BG		0,0	91	100,0	91	1,07
4	CH	228	62,0	140	38,0	368	4,35
5	CY		0,0	14	100,0	14	0,17
6	CZ		0,0	125	100,0	125	1,48
7	DE	1894	69,8	818	30,2	2712	32,02
8	DK	78	51,0	75	49,0	153	1,81
9	EE		0,0	32	100,0	32	0,38
10	ES	15	9,5	143	90,5	158	1,87
11	FI	14	9,3	136	90,7	150	1,77
12	FR	465	64,2	259	35,8	724	8,55
13	GB	1126	69,3	498	30,7	1624	19,18
14	GR	1	3,1	31	96,9	32	0,38
15	HU		0,0	127	100,0	127	1,50
16	IE	13	31,7	28	68,3	41	0,48
17	IS		0,0	26	100,0	26	0,31
18	IT	147	45,4	177	54,6	324	3,83
19	LI	7	70,0	3	30,0	10	0,12
20	LT		0,0	44	100,0	44	0,52
21	LU	9	60,0	6	40,0	15	0,18
22	LV		0,0	22	100,0	22	0,26
23	MC		0,0	2	100,0	2	0,02
24	NL	265	79,3	69	20,7	334	3,94
25	PL		0,0	471	100,0	471	5,56
26	PT		0,0	48	100,0	48	0,57
27	RO		0,0	99	100,0	99	1,17
28	SE	132	48,5	140	51,5	272	3,21
29	SI		0,0	34	100,0	34	0,40
30	SK		0,0	47	100,0	47	0,55
31	TR	1	0,8	130	99,2	131	1,55
	Total	4546	53,7	3923	46,3	8469	100,00

## *epi* Seminar in Eindhoven

On Friday, 24 February 2006 the *epi* organised at the High Tech Campus Eindhoven the Netherlands a seminar hosted by Philips, with the title „amendments to European patent applications during examination". This new seminar was developed and presented by Mr. Daniel Thomas, Director of DG2 of the EPO in Munich. This „pilot" seminar was opened by Mr. Chris Mercer, president of the *epi*.

About 160 *epi* members and students joined this day, the majority being Belgian and Dutch *epi* members and students, but we were happy to welcome participants

from other EPC member states as well. Besides the lecture by Mr. Thomas, in which he discussed the do's and don'ts during prosecution of a European patent application, two practical cases were presented by Mrs. Marie-José Luys and Mr. Claude Quintelier, Belgian *epi* members. As this seminar was a big success, similar seminars can be organised in the coming years in other EPC member states, upon request. Mr. Thomas is ready to adapt the content of his presentation to meet specific requests and needs of the envisaged target groups.



Mr. Daniel X. Thomas, Director DG2, EPO



Mr. Chris Mercer, epi President



The seminar was attended by many *epi* members and students

*The European Patent Academy is promoting and developing a co-ordinated approach to patent-related IP education and training in the present and future member states of the European Patent Organisation. One of the key target groups for the Academy, in close co-operation with the epi, is the training of future and present European professional representatives. In a series of three articles, William Torlot (Head of the Unit "Patent Professionals" in the Academy since Autumn 2005), explains the Academy's approach for the three distinct groups within this target group. This article looks at candidates preparing for the EQE. Future articles will then address the target groups of patent attorneys in the new EPC contracting states and further vocational training for current European patent attorneys. More information about the Academy and its activities can be found at: <http://academy.epo.org/>*

## The European Patent Academy – An approach for EQE candidates

W. Torlot (EPO)

Many courses exist throughout Europe for EQE candidates preparing them for their exams with some impressive results. We all know how the success rate varies enormously from country to country. There is also a sense of urgency in an increasing number of countries where more and more of the professional representatives under Article 163 are approaching retirement with insufficient replacements coming through the qualifying examination. There is general agreement of a need to raise the success rate without lowering the standards with resulting pressure on the Academy to provide more equal access to training opportunities throughout the member states. Feedback from tutors and from the Examination Committees suggests that there are a number of common reasons for candidates failing the EQE:

1. They have not understood what is expected by the examiners when answering the questions
2. They do not have a tried and tested method for resolving the complexity of the questions posed in the exam
3. They have not prepared sufficiently thoroughly before taking the examination

Other reasons such as language skills are given but are generally seen as secondary problems.

### Increasing the chances for success:

Based on this understanding of the problems, it is maintained that a successful candidate needs to have the following:

- I. Gained a reasonable understanding of the examinations and the factors which are seen as being important by the examiners
- II. For each of the exams, have a method which, when applied, allows them to come to terms with the information provided in the questions and process an answer in an efficient fashion using the information provided
- III. Have practised the methods sufficiently, with a broad enough range of examples, to be able to

use the methods automatically under examination conditions

- IV. Have received continued quality guidance accompanying their practice so as to enhance skills and learn from their own mistakes and successes during practice.



### An EQE training concept:

Nothing can replace the hard work and detailed preparation which a candidate must have put in to stand a chance of success with the EQE. However, a number of issues can be addressed to increase the likelihood that a candidate's practice and preparation is effective. Apart from the candidates themselves, another very important group affect the degree of preparation of candidates prior to taking the exam. These are the "mentors", "coaches", or "supervisors" in the patent attorney practices or patent departments who oversee the candidates during their 3-year internship prior to taking the exam. Clearly, structured practice and well formulated feedback to the candidate provides a very important part of the preparation of successful candidates. In order to support this, it is thought that some material for the candidates to practice on would be helpful, as well as assisting the mentors' understanding of the demands of the examination to ensure that appropriate guidance is given.



The Academy will address the different aspects of the problem in 3 ways:

### 1. EQE information events:

This course provides an insight into the exams and how to prepare for them. It is aimed at EQE candidates who are several years away from their exams, and the patent attorneys who are supervising their internships. Participants will learn the structure of the EQE and understand the critical factors being tested as well as gaining a clearer idea of how to structure their preparation. The first of these courses will be held in May in Stockholm, in co-operation with the Swedish Patent and Registration Office, PRV, with further courses being planned elsewhere.

### 2. Guided practice:

This aspect of EQE preparation is, to a great extent, in the hands of the candidates themselves together with their supervisors where they are carrying out their 3 year internship. In order to assist this process a number of possibilities are already in place such as the EQE compendium, the *epi* tutorials, and courses organised by universities and private schools around Europe.



In many patent firms, candidates get essential experience by working on real files under the guidance of their mentor or supervisor. The Academy has started a distance learning project aimed at candidates in countries where there are fewer European files to work on. The aim is to produce "dummy" EP files based on old EP applications and oppositions which have been systematically structured to provide a learning experience. Files will be provided in all three official languages and will focus on a number of different substantive and formal issues

giving the candidate the feel of working on a real EP file. The "tasks" will be set on a monthly basis with one or two exercises making up each instalment of the file, together with the part of the actual file which corresponded to the previous month's task. The first files are currently being prepared and tested and the project will be launched this summer. Dummy files are seen as being a foundation stone for a number of associated actions such as setting up study groups and providing tutors.

A project has also been started between CEIPI and the European Patent Academy to develop web-based exercises for EQE candidates. Currently, the most common exercises which candidates follow are past papers of the EQE. While this is clearly to be encouraged, there are only a limited number of papers available and their length and complexity make it difficult to practice the individual skills necessary for each paper. Shorter exercises are being developed which cover aspects of the papers. This project will not replace the courses already being given, rather it will provide exercises for candidates to practice the skills that they have learned during the more traditional courses.

Finally, in recognition of the vital role of the mentor or supervisor in training patent attorneys, the Academy is exploring ways to support this group by helping them understand their role and providing material for them. A longer term goal will be to provide specific courses aimed at supervisors and to develop regional networks of supervisors with an aim of raising standards, encouraging peer to peer support, and increasing efficiency.

### 3. Final preparation for the exams:

A number of possibilities already exist for candidates to polish their skills and maybe get those few extra marks which make the difference between passing and failing. These courses usually take the form of the candidates doing mock exams or past exam questions and getting detailed feedback on their answers. The opportunity of being away from home and work allows candidates to really concentrate on the examination preparation without distractions. Furthermore, the concentration of heterogeneous groups, with people from many different backgrounds and cultures, provides an excellent learning environment through an exchange of approaches and ideas. For these reasons, a centralised approach to the final preparation course is favoured and the Academy will continue to support CEIPI and its courses in Strasbourg.

As a trial project this year, the Academy together with the EQE Secretariat have provided EQE candidates for 2006 with an internet discussion forum and the service of online consultation with experts. Under the name of "EQE Online Academy", the candidates were able to post questions, answers and comments regarding the content of the 4 papers. In addition to this, experts on the EQE papers were available on-line once a week for half a day to answer questions on specific papers. At the time of going to press with this article, interest has been sufficiently high to justify repeating the service for EQE 2007 using this year's experience to improve and extend the concept.



European  
Patent Office

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## EQE Forum

EQE Forum and Expert Online is provided by the European Patent Academy in cooperation with the Examination Secretariat for the European Qualifying Examination

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Forum	Topics	Posts	Last Post
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Contact, Terms & Conditions Contact, Terms & Conditions. Moderator Moderatoren	2	2	03 Feb 2006 12:52 admin ➡
<b>Examination</b>			
Examination Paper A&B Chemistry Moderator Moderatoren	11	21	15 Feb 2006 19:51 gleci ➡
Examination Paper A&B Electricity/Mechanics Moderator Moderatoren	3	6	13 Feb 2006 09:55 xoeyle ➡
Examination Paper C Moderator Moderatoren	3	18	14 Feb 2006 16:24 yiasai ➡
Examination Paper D I Moderator Moderatoren	43	117	15 Feb 2006 17:31 repa ➡
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Examination Paper A&B Chemistry live session Live session with Experts on Monday 13th February and Wednesday 1st March 2006 between 13.00 and 17.00 CET Moderators Moderatoren, Live_tutors	13	25	13 Feb 2006 15:58 Tutor05 ➡
Examination Paper C live session Live session with Experts on Monday 27th February and Wednesday 1st March 2006 between 13.00 and 17.00 CET Moderators Moderatoren, Live_tutors	0	0	No Posts
Examination Paper D live session Live session with Experts on Friday 10th February and Wednesday 1st March 2006 between 13.00 and 17.00 CET Moderators Moderatoren, Live_tutors	55	73	10 Feb 2006 16:32 Tutor07 ➡

*The expertise within the patent attorney profession is vital to the success of the Academy in addressing this target group. Whether it is for training events or the development of projects, we need professional representatives to help us as tutors, expert speakers or consul-*

*ants. If you are interested in becoming a tutor or working on one of the projects listed above, please get in touch with William Torlot by e-mail at: [wtorlot@epo.org](mailto:wtorlot@epo.org) or by telephone: +49 89 2399 5023.*

## Bachelor and Master Industrial Property Studies in Prague

L. Jakl<sup>1</sup> (CZ)

In June 2002 the Ministry of Education, Youth and Sports of the Czech Republic granted to the University of Public Administration and International Relations of Prague (Vysoká škola veřejné správy a mezinárodních vztahů v Praze)<sup>2</sup> accreditation for a three-year Bachelor program specializing in the legal protection of industrial property. The program, titled "Legal Protection of Industrial Property", was launched as a part of law-oriented programs of this private university in the academic year 2002-2003.

Despite the relatively short time between the accreditation and the start of the said academic year twenty-seven students – some of them experienced specialists in legal protection of industrial property – enrolled in the program. The curriculum of the study program for the

first year of this Bachelor program was focused primarily to provide very good basic knowledge in legal, economic, and general subjects. In the subsequent two years the Bachelor program was concentrated on legal issues related to legal protection of industrial property.

The Bachelor study program in this specialization took six terms-semester, i. e. three years, in compliance with the accreditation decree. The first two terms were dedicated primarily to compulsory general subjects in law, economics, and international relations, such as history of the state and law, theory of the law and law philosophy, elementary economics, computer technology, civil law, constitutional law and elementary legislation, theory of international relations, history of international relations and development of European integration and institutions. Optional subjects in the first year included history of European thinking, history of culture, political science, and transformation of countries of Central and Eastern Europe, regional studies, personality psychology, history

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of the Czech state and law, and methods and techniques of sociological research.

During the following two years the compulsory courses were more focused on industrial and intellectual property and related rights, such as administrative law, business law, copyright protection, patent law, trademark law, marketing communication, international treaties, competitive law, antitrust law, European patent and trademark law, industrial law strategies and enforcement of industrial property rights. Furthermore, this Bachelor program included practical courses, such as drafting of patent and design applications, patent and design granting procedure, trademark application procedure, proceedings before the European Patent Office and Office for Harmonization in the Internal Market (Trademarks and Designs). Relatively considerable attention was paid to patent and trademark information, research and transfer of technology.

Optional subjects included courses in the Czech political system, social psychology, personnel psychology, labor and social policy in public administration, European educational systems, economic policy, global policy, informatics in public administration and international standards, marketing and advertising, business ethics, economic policy and comparative regional studies.

The Bachelor program also included language courses, mainly English, but also German and Russian. Although the accreditation requirements called for language courses in the first two terms only, language courses continued throughout the entire program, as language proficiency proved to be desirable in the following terms.

During the last term the curriculum included special subjects called "State Exam Seminar" and "Diploma Seminar". The latter covered elaboration and discussion of specific themes involving creation of dissertation theses, where the future authors of final dissertations could work on their respective themes. Themes were designated by the university and selected by students depending on their specialization. In these seminars each student had the opportunity to clarify all issues related to his/her thesis, in addition to being able to ask for consultations with his/her tutor. In the state exam seminar students actively learned ninety of the announced state exam questions that, in accordance with the accreditation requirements, covered basic information on general legal issues and subjects concerning legal protection and exercise of intellectual property rights. First state examinations held at the end of May and beginning of July 2005 proved that the inclusion of these two seminars in the program had been a very constructive decision.

As far as the results of the first state examinations and defenses of the bachelor theses on legal protection of industrial rights are concerned, it is to be noted that out of the 27 students originally enrolled in the program, 21 students passed and afterwards successfully graduated. It was accredited for granting the academic degree of a "Bachelor – Bc."

Their results were particularly good in specialized subjects, which were in part accountable to the fact

that many of them had practical experience in the industrial property sphere. This much could not be said about the final exams in languages. In fact, they were the main reason for the lower number of magna cum laude academic diplomas than anticipated, yet the number was still relatively high in comparison with graduates of other specialization majors.

Upon completing the first course of Bachelor study students evaluated the program and the results were analyzed. Since most of students did their studies in addition to full-time work, a combined distance form of study with four two-day lectures per each term was evaluated as an excellent solution. The fact that the majority of students were enrolled on this basis was reflected in their survey. As for the subjects proper, these were evaluated by students very positively, except for suggestions calling for a greater scope of themes to be included in the general legal and economic subjects. The curriculum was therefore broadened during the initial part of the Bachelor program, with additional topics such as the penal code, enforcement of industrial property rights and subjects dealing with social and economic topics. On the other hand, however, their suggestions led to concentration more on legal proceedings as a part of lectures on public administration. It was noted that students had a positive approach to case and theme studies that they had to elaborate as a part of individual subjects during the term. Students also positively commented on the opportunity to attend intensive language lectures with the day students. Some students, however, considered the study of languages as an extraordinary burden, although they did recognize knowledge of a foreign language as a necessity. On the whole, the program specializing in legal protection of industrial property rights at the University of Public Administration and International Relations in Prague was evaluated as one of the most important forms of university education. The fact that nearly 20% of the students originally enrolled in the three-year program graduated only testified to the academic sophistication of the program.

The first bachelors graduated in industrial property at the University of Public Administration and International Relations of Prague at the end of October 2005. The graduation ceremony was regarded as an extraordinarily positive event and a token of merit for the school. Another indication of appreciation for the school was the great number of parents and friends who came to share the special event with the bachelor graduates.

Perhaps the best validation of the university bachelor study program was the fact that most of those who had duly and successfully graduated showed interest in continuing their studies in the following two years Master program. The university therefore exerted extraordinary effort to acquire accreditation for the Master program specializing in legal protection of industrial and other intellectual property rights, in a context with other fields of science. In line with this objective the university drew up in the summer of 2005 a draft requisition for accreditation of its Master program that would not only tie in with the current Bachelor program in legal protection of

industrial property, but also with other bachelor programs or even with programs of other universities, whose graduates have prerequisites necessary for studying issues related to industrial property and well-rounded knowledge in other science fields, especially international relations.

Analysis of possibilities of Master accreditation to studies specializing in industrial property issues led to the conclusion that in view of the ever-expanding globalization of international trade, involving exchanges of intangible assets, it would serve a good purpose to make the program contingent on international territorial studies. The newly opened specialization for graduated students was therefore named "International and Regional Relations in Industrial Property". The regional aspect of the matter is that recently there have been tendencies towards gradual integration in the sphere of industrial property as a part of international relations among individual European as well as non-European regions, e.g. the European Patent Office, Office for Harmonization in the Internal Market, or various African integrated associations, such as ARIPO and OAPI.

The final version of the Master study program was accepted by the Accreditation Commission of the Ministry of Education, Youth and Sports of the Czech Republic at the end of November 2005 as a positive response to the university requisition for accreditation of the said graduate program, both in the form of a distance combined program and daily program. The Master program includes subjects both in general international and territorial studies as well as subjects focusing on legal protection of industrial and other intellectual property rights. This Master study program was accredited for granting the academic degree of a "Master – Mgr."

The first two terms of the Master program offer general educational and theoretical subjects, such as introduction to the study of international relations, theory of international relations, institutional framework of European integration and European economic integration. However, the first year of the program offers also legally oriented subjects, such as the European judicial system, antitrust law and relations between unfair competition and industrial property rights. These subjects are linked to specifically oriented subjects having a broader scientific base, such as national, regional and international protection of industrial property, international patent protection, the European and Eurasian patent systems and the Anglo-American and African intellectual property protection systems.

The second year of the graduate program is oriented predominantly towards subjects in the sphere of legal issues and relations arising from industrial property, such as resolutions of disputes involving intellectual property rights, international systems of legal information on industrial rights, specific aspects of the Czech Patent

and Trademark Law, evaluation of intellectual property rights, advertisement rights, Community trademark and Community design jurisdiction. In the second year, too, adequate attention is paid to general cross-sectional and theoretical subjects, such as international economic relations and obligatory relations in business.

In the Master program students have to elect at least two of the elective courses offered, which include courses dealing with issues concerning Central Europe, Eastern Europe and Russia or legal protection of intellectual rights in the Slovak Republic. Alternatively, students may choose professional English as their optional subject.

These studies are financed by tuition fees of the students. Tuition fee is 24 000,- cz crowns (800 EUR) per semester.

The University of public administration and international relations of Prague considers the accreditation of its two-years Master program an extraordinary success and recognition of its good results achieved in its history. The first students may enroll in this graduate Master program in October 2006. We anticipate considerable interest in this program, as this year about 30 of our Bachelor students specializing in legal protection of industrial property are going to graduate. Like every year thereafter, most of them are likely to be interested in continuing their studies to Master level. Presumably, students graduating from Bachelor programs of other private universities may show interest in this Master's program. Moreover, we expect interest in our Master industrial property program also on the part of bachelors from public and state universities and universities of various orientations, such as technical engineers or Master's of Science in other fields of specialization, wishing to upgrade their education by including knowledge in the sphere of legal protection of industrial property, as happens to be common elsewhere in the world.

The University of Public Administration and International Relations of Prague regards this occasion as a good opportunity to extend its gratitude, above all, to the Industrial Property Office that in its capacity of a central state administration authority has strongly supported our requisition for accreditation from the very beginning, both for the Bachelor and Master programs. Moreover, the Industrial Property Office has been significantly supportive of our programs and has in cooperation with the European Patent Office and European Patent Academy facilitated access to opportunities for our students in the sphere of international relations. Last but not least we must not to forget to mention the assistance we received from the World Intellectual Property Organization in the form of necessary English literature, thus significantly improving the quality of study on our University.



## Opinion on Patent Profession rendered by CNIPA<sup>\*</sup>

E. Lyndon-Stanford (GB)

### European countries in which the Patent Attorney Profession could be extinguished

In the course of the last CNIPA Meeting the President raised his concern that with the low pass rates of the European Qualifying Examination (EQE) in some member states of the EPC the patent attorney profession could be effectively extinguished. He asked whether CNIPA should take an initiative in this respect. He suggested that firms in countries with good pass rates should be paid to take trainees from countries with low pass rates, for an extended period of say four and a half years, with a view to them passing the EQE. The money (which would be considerable, say €100k) would have to be found from appropriate sources such as the EU and the EPO. It was commented that in some countries, there was little patent work and it was not worth spending the time and money to train European Patent Attorneys – there was also not enough local work to train candidates on the job. However it was also commented that industrial undertakings in at least one such country are sending patent work abroad. In some countries, recent adherents to the EPC, there were too many European Patent Attorneys. It was also commented that there was work for everyone with a competitive advantage and that the work was de-localised, so that one should not be pessimistic about having work and training candidates to pass the EQE. It was further commented that patents should be given their real value in company balance sheets, which would increase interest in patenting.

A view opposing that of the President's was expressed, namely that the level of the EQE should be

greatly reduced and then later possibly increased. Prof. Dreiss commented that the EQE is not too difficult but that it was overloaded with too much to do. One comment suggested that the EQE could be abandoned and qualification could be on the basis of entry onto a national list.

It was questioned whether it was an advantage to have professionals who had passed the EQE. The Vice-President stated that visibility was required, patent attorneys should be active, should be prepared to safeguard the profession regarding EU Commission directives, and should have the right to plead in court. Good training was essential.

The consensus was that CNIPA could create a platform to persuade European firms to provide training for countries with low EQE pass rates and that CNIPA should investigate the possibility of a seminar, Brussels parliamentary evening or conference to launch the platform, for instance comparing the training systems in DE, FR and GB with those in ES, PT and GR. The Vice-President proposed a questionnaire seeking to identify the problem and what solutions could be envisaged, involving the EPO, the European Commission and the Member Institutes. It was also suggested that the national training bodies could meet, to discuss how to train patent attorneys, with a European perspective. It was agreed that the Vice-President should contact Premier Cercle about the possibility of running a conference. An ad hoc group was formed to progress the conference.

## Of incomplete complete inventions: T 1329/04-3.3.8

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### Abstract

The present article deals with the question of when an invention should be considered as being complete. So far it appeared as if this issue had been settled to the effect that there is a complete invention if the technical teach-

ing provided in a patent application can be performed by the (average) person skilled in the art without inventive effort on the basis of the disclosure provided. Experimental data in the application as filed supporting the enablement of the technical teaching were not required, i.e. "performable" was sufficient while "performed" was unnecessary. Decision *T 1329/04* of Technical Board 3.3.8 has abandoned this established principle. Instead it took the position that a subjective test has to be applied according to which it is to be determined whether, in the

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absence of experimental data in the application as filed, it was plausible to the (average) person skilled in the art that the invention would really work as described. Consideration of later data confirming that the technical disclosure of the application as filed was entirely correct was refused. The decision is in the area of biotechnology but its principles would be equally applicable in all other areas of technology since, based on Article 52 (1) EPC, the requirement that there must be a complete invention is the common denominator for all patentability requirements. Thus: when is an invention complete?

### 1. Introduction

The first Technical Board to specifically focus on biotech inventions, Board 3.3.4, has been established by the European Patent Office (EPO) on April 1, 1994. It started with virtually nothing but guidance by principles coming from foundational jurisprudence in other areas of technology in the EPO and its contracting states, so that its work was necessarily as pioneering as the technology at issue. Thus, it had to establish a whole framework for the assessment of biotech inventions – and achieved a lot. There were only a few lonesome fixed stars for Board 3.3.4 in the patent universe, such as the pioneering interferon  $\alpha$ -case *T 301/87* decided as early as February 16, 1989 by Technical Board 3.3.2, the ancestor of Technical Board 3.3.4. Technical Board 3.3.2 already fully appreciated biotech's value in its decisions, for instance, in *T 292/85*, "Polypeptide expression/GENENTECH". It put the assessment of an invention's technical quality over formalism. Thus, it said in *T 301/87*:

The requirement for sufficiency is not a matter of satisfying the perfectionist but to enable the skilled person to handle the invention in normal practice.  
*T 301/87* at section 4.13

While stating in section 4.7 of *T 301/87*:

Unless claims with such functional connotations are allowable, no worthwhile protection is provided against a third party which faithfully repeats the process of the patent and obtains new but equally useful variants of the invention.

Based on this approach, (Bio) Technical Board 3.3.4's jurisprudence hinged on trying to find fair and meaningful protection for (bio)technical inventions. The Board's continuity of this attitude is evident from the much later decision *T 636/97*, "Erythropoietin III AMGEN" (March 26, 1998). There it stated:

For the board it is a fundamental principle of patent law that a claim can validly cover broad subject matter, even though the description of the relevant patent does not enable every method of arriving at that subject matter to be carried out. Otherwise no dominant patent could exist, and each developer of a new method of arriving at that subject matter would be free of earlier patents. In many cases in the field of biotechnology, patent protection would then become illusory.

In the entire jurisprudence developed by Technical Board 3.3.4, be it in the context of priority, enablement or novelty, it based its analysis of patentability on the

rationale that *an invention is complete if the application as filed or the priority document at stake discloses all essential elements for carrying out the invention*. The same rule was applied to the technical disclosure of prior art documents. In other words, if the technical disclosure was performable, it was complete, i.e. enabled. Hereinafter we will call this the "performable is sufficient" principle. The criterion for completeness was not that the invention or the technical teaching had to be performed at the relevant filing or disclosure date. This approach was in line with principles established by jurisprudence in the European Patent Convention's (EPC's) contracting state Germany and also appreciated the jurisprudence of other Technical Boards of the EPO. Details will be discussed below.

The mentioned network of patentability requirements and the requirements that a piece of prior art has to fulfil results from Article 52 (1) EPC. It is the common denominator for the assessment of these requirements since it states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. Only a complete technical teaching can be an invention in this sense and only a prior art that provides a complete technical teaching can be relevant in this sense for the assessment of the patentability of said invention; see also section 2, *infra*, for more details.

In 2003 Technical Board 3.3.4 underwent a division to allow the EPO to cope with the ever growing amount of work in the biotech area. Thus, the second "Biotech Board", Technical Board 3.3.8, was founded. Its jurisprudence differs noticeably. However, as said division has not been a strictly mitotic one in the genetic sense, this is not entirely surprising, since assessments in practicing patent law are normally influenced by the philosophy of those who form the practice – a rule that not only applies to Technical Board members but also to patent lawyers, such as the present authors.

Since the division, there have been about 3 years of independent jurisprudence by Technical Board 3.3.8. During this time, it has diligently produced a large number of written decisions, such as *T 1120/00*, "Soybean desaturase/DU PONT" of October 22, 2004, which provides very elaborate and useful guidance about what to consider when trying to properly disclaim the disclosure of a prior patent application. On the other hand, it appears as if Technical Board 3.3.8 tends to be more formalistic. This was noticeable from positions taken in several decisions with respect to what amendments can be allowed under Article 123 (2) EPC (the EPC's "no new matter clause") and from a couple of decisions dealing with the formal allowability of disclaimers. On June 28, 2005, there was decision *T 1329/04*, "Factor-9/JOHN HOPKINS". In this decision, Technical Board 3.3.8 wanted to see experimental data to acknowledge completeness of the invention that it related to, and thus we believe that it basically turned the "performable vs. performed" principle for the assessment of when an invention is complete upside down. This decision is thus not only relevant for the area of biotechnology but also

for all other areas of technologies. Therefore, there is a need to discuss it in detail.

*T 1329/04* bases its new approach to the (in)completeness of inventions (i) on a more technical than legal approach (rather relying on standards that would perhaps better apply to determine whether a scientific article has enough experimental data to deserve publication) and (ii) on differences between the first-to-file and the first-to-invent patent systems. Neither the former nor the latter grounds are justified, as we will demonstrate below. The consequences of this decision's principles for the relevance of prior art disclosures in terms of when are they now (in)complete – enabled (or not) – can be taken from the same Board's decision *T 179/01*, "*Herbicide resistant plants/MONSANTO*" (April 6, 2005); see section 7, *infra*. The latter is fully compatible with the former and with another case, *T 870/04*, "*BDP1 Phosphatase/MAX-PLANCK*" (May 11, 2005), denying industrial applicability pursuant to Article 57 EPC. This pattern of decisions by Technical Board 3.3.8 indicates to us that we are not confronted with a case of coincidence when reading *T 1329/04* but with a different philosophy. Where will we go from here? How is the evolution of patent law going to arrange itself with this new philosophy?

## 2. The completeness of inventions prior to *T 1329/04*

It has already been mentioned in the above introduction that the concept of having to disclose a complete invention in a patent application finds its basis in Article 52 (1) EPC, the common denominator of all patentability requirements. In his commentary on Article 52 EPC, Moufang says in Schulte, "*Patentgesetz mit EPÜ*", 7<sup>th</sup> edition, 2005, annotation 53 to §1 of the German Patent Act (GPA) and Article 52 EPC, that the term "invention" presupposes that a teaching is provided which leads to a concrete success. There is no invention if the teaching is not objectively realizable. In annotation 55 Moufang says that it results from the term "invention" as a technical teaching for a concrete success that in order to be an invention in the sense of the law it does not only have to be performable but that it also has to remain performable. It results from Moufang's annotation 57 a) that there is an invention in this sense if the disclosed teaching is objectively performable for the inventor and third parties. Moufang uses terms such as "objectively", "capable of being realized", "repeatability of an invention" or "performable" in the mentioned annotations as opposed to "subjectively", "has been realized" or "performed".

Naturally, the question of when an invention is complete has already been extensively discussed in connection with the requirement of enabling disclosure (Article 83 EPC). In this case law it has repeatedly been pointed out in line with the above that it is not necessary that the invention has actually been "performed" in order to meet the requirement of having to provide an enabling disclosure according to Article 83 EPC. It is only required that the invention is described in a manner sufficiently clear and complete for it to be "performable" by the

(average) person skilled in the art without undue burden. The relevant question discussed in this context was whether "all essential elements" were disclosed in the application as filed which allow the (average) person skilled in the art to perform the invention. Only if one or more essential elements were missing and there was a relevant gap of information would the invention be considered incomplete (and not enabled).

This concept has been applied, e.g., in *T 269/87*, "*Prochymosin/CELLTECH*", in *T 886/91*, "*Hepatitis B virus/BIOGEN*", and in *T 296/93*, "*HBV antigen production/BIOGEN*" when assessing whether a priority document provided an enabling disclosure for the claimed subject matter, a prerequisite to validly claim priority.

In *T 269/87* it had to be assessed whether a claimed process had already been enabled by the priority document. In section 7 of the Reasons for the Decision it was pointed out that

"... if any essential element of the invention for which protection is sought is missing, there is no right to priority."

*T 886/91* dealt with the appeal of several Opponents against the Opposition Division's finding that the opposed patent could be maintained in amended form. Claim 1 of the maintained patent read (see *T 886/91*, section III):

1. The use of a DNA sequence coding for a polypeptide displaying HBV antigenicity, said DNA sequence being selected from DNA sequences of the formulae:
  - (a) (first DNA sequence) and fragments thereof which encode polypeptides displaying HBV antigenicity;
  - (b) (second DNA sequence) and fragments thereof which encode polypeptides displaying HBV antigenicity; and
  - (c) DNA sequences which are degenerate as a result of the genetic code to any of the foregoing DNA sequences and which encode polypeptides displaying HBV antigenicity for the production of polypeptides displaying HBV antigenicity.

Claims 2, 3, 4, 5, 11 and 12 related to specific deposited recombinant DNA molecules, transformed hosts and corresponding processes for the recombinant production of the encoded HBV polypeptides; see *T 886/91*, section III.

In their attempt to have certain intermediate publications considered by the Technical Board in its analysis of novelty and inventive step, the opponents and the intervener tried to shift the relevant priority to a later date. Thus, they submitted that

... Claim 1 (b) was not entitled to the priority of BIII because in the latter document expression of the recited DNA sequence was not achieved. The mere identification of a sequence could not serve as a basis for a claim related to its actual expression in a transformed host cell. For the same reasons, Claims

6, 8 to 10 were not entitled to the said priority because the subject polypeptide was not produced.

Technical Board 3.3.4 agreed with Patentee that claims 1(b) [specific HBsAg DNA sequence], 6 [polypeptides and fragments thereof displaying HBsAg antigenicity] and 8 to 10 [compositions containing HBsAg] of the Main Request are entitled to the third priority:

The Board observes that the BIII priority document provides the complete DNA sequence of the cloned HBV DNA, identifies therein the actual portions which encode HBcAg and HBsAg and provides the corresponding amino acid sequences. Furthermore, BIII proposes some cleavages and construction schemes for expression vectors which are stated to result in the production of a polypeptide that exhibits antigen specificity in the radioimmunoassay for HBsAg (see page 7, line 17 to page 10, line 7). *Therefore, notwithstanding the absence of a worked example, it cannot be denied that the person skilled in the art has been given comprehensive information about how to carry out the invention, i. e. how to proceed in order to achieve expression ... Thus, in the absence of evidence to the contrary, there is no reason to believe that priority document BIII is deficient in respect of some relevant technical information necessary for reducing the claimed invention to practice by the person skilled in the art. If no essential elements (i. e. features) of the claimed invention can be said to have been recognized or added only later on in the sense that they are not part of the disclosure of the priority document, the claims in discussion and the priority document on which they are based must be regarded as relating to the **same invention** within the meaning of Article 87(1) EPC.* Consequently, the said claims are considered to be entitled to the BIII priority date.

(Emphasis by italics added)

This finding supported the established view that it is sufficient to provide in a patent application or patent a reproducible technical teaching and that it is not required to prove that the inventor has already successfully carried out the technical teaching that is provided.

T 296/93 dealt with matters similar to those of decision T 886/91. Claim 1 read:

1. A recombinant DNA molecule characterized by a DNA sequence coding for a polypeptide or a fragment thereof displaying HBV antigen specificity, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule and being expressed to produce a polypeptide displaying HBV antigen specificity when a suitable host cell transformed with said recombinant DNA molecule is cultured, *the transformed host cell not producing any human serum proteins and any primate serum proteins other than the polypeptide displaying HBV antigen specificity.* (Emphasis added; see respective remarks in section 5.1.6, supra).

Opponents again sought to shift priority of this claim in order to rely on intermediate documents. In their attempt to do so, they stated that claim 1 was not entitled to the first priority claimed because the first priority document did not specifically define any expression products having HBV antigen specificity, such as HBsAg or HBcAg, and did not enable the preparation of expression products other than those produced by the two deposited cell lines A and B.

The Board disagreed:

- 4.5 ... the lack of actual data on the production of a polypeptide with the antigen specificity and antigenicity of one or the other HBV antigen does not necessarily lead to the conclusion that essential elements of the claimed invention are missing in the disclosure of the BI priority document.

The worked examples in the BI priority document demonstrate that, by following the said experimental approach, expression in a recombinant DNA system of polypeptides displaying HBV antigen specificity can indeed be achieved.

None of the Respondents has succeeded in discharging the onus of proof by demonstrating that, by proceeding experimentally as indicated in the BI priority document, expression of proteins having the antigen specificity and antigenicity of either HBcAg or HBsAg cannot be achieved to some extent. *The Respondents have been unable to point to one or more essential elements recognized as essential only later which are missing in the BI priority document. Their objections derive mainly from the lack of actual data on the polypeptides which are or can be expressed, **not** from any proven inadequacy of the disclosed experimental approach.* The evidence on file rather indicates that, by proceeding experimentally as taught in the BI priority document, expression of proteins having the antigen specificity of either HBcAg or HBsAg was achieved to some extent. The European patent specification confirms the validity of the approach and demonstrates inter alia that deposits A and B express polypeptides with the antigen specificity of HBcAg.

- 4.6 ... *If no essential element (i. e. features) of the claimed invention can be said to have been recognized or added only later on in the sense that they are not part of the disclosure of the priority document, the claims under discussion and the priority document on which they are based must be regarded as relating to the **same invention** within the meaning of Article 87 (1) EPC.*

(Emphasis added)

Thus, the claim was entitled to the priority, because all essential elements were disclosed then.

The principle that the disclosure of all essential elements is sufficient to be in possession of a complete invention was also applied by Technical Board 3.3.4 in the later decision T 639/95, "Biopolymers/MIT" in connection with Article 83 EPC. This time, however, enablement was denied. The cloning of the essential element



"polyhydroxybutyrate (PHB) gene" was not described in a way which would have allowed to isolate the gene and practice the invention without undue burden. Inventive effort would have been required. This case demonstrates where the limits were. However, it did not establish as the limit that what is described has to have already been performed.

Technical Board 3.3.4 even pointed out explicitly in several other decisions that enabling disclosure *does not require that a working example is present* in the application as filed, a finding that clearly supported the "performable is sufficient" principle. For example, in *T 994/95, "Oligonucleotide therapeutic agent/MOLECULAR BIOSYSTEMS"*, Technical Board 3.3.4 stated:

"Pursuant to Article 83 EPC, adequate instructions should be given in the specification or on the basis of common knowledge for the skilled person to be able to prepare without undue effort such a therapeutic agent. This does not necessarily mean that it should be proven that the invention was actually carried out at the filing date. However, the written description of the invention should be such as to enable the person skilled in the art to make and use it without undue difficulties (cf eg *T 639/95* of 21 January 1998)."

(*T 994/95* at section 2)

In line with this, Technical Board 3.3.4 held in *T 984/00, "Ti-plasmid vectors/MAX-PLANCK-GESELLSCHAFT"*, that there was enablement of a claim directed to dicotyledonous plant cells comprising a chimeric gene even though the application as filed did not provide a working example in which a cell falling under the claim had actually been prepared. In section 14 of the Reasons for the Decision the following was pointed out by Board 3.3.4:

"The application does not describe a single example of the whole invention put into practice, but it does give precise instructions on what to do to cut down the T-region. During the examination procedure the appellant filed evidence that the method has subsequently been successfully put into practice. There is no evidence before the Board that successful integration depends on the particular promoter/coding sequence, though of course this might affect the degree of expression obtained."

Thus, Board 3.3.4 expressly accepted post-published evidence for proving "performability".

In *T 792/00, "Varied binding proteins/DYAX"*, Technical Board 3.3.4 denied enablement, because, although the teaching of the patent went against an established prejudice, there was no working example and no post-published evidence demonstrating that the invention could indeed be carried out according to the hypothetical example of the application as filed, i.e. as prescribed. After examining the facts, Board 3.3.4 concluded that it would have amounted to undue burden for a person skilled in the art to do research of its own to establish how the invention can be put into practice. Thus, compliance with the "performable is sufficient" principle had in fact never been proven.

The view that there is no need for a working example was shared previously by Technical Board 3.3.8 in *T 397/02, "Endogenous gene expression/APPLIED RESEARCH"*. Enablement was denied but Board 3.3.8 indicated that it would have been prepared to consider post-published documents as evidence demonstrating that the invention can indeed be carried out as taught by the application as filed – which did not provide an example.

In the further decision *T 1191/03, "Virus propagation/MEYER"*, Technical Board 3.3.8 again pointed out that neither the EPC itself nor the Implementing Regulations require that the invention be illustrated in the form of examples. The description, according to Article 83 and Rule 27 (1) e) EPC, only has to indicate at least one way to carry out the invention. Note that Rule 27 (1) e) EPC does not require the inventor to disclose "how" the invention has been carried out.

Thus, it is evident from the jurisprudence that the EPO's Technical Boards, including Technical Boards 3.3.4 and even 3.3.8, applied the following principles in the assessment of when an applicant is in possession of a complete invention:

- There is enablement, i.e. a complete invention, if no essential elements are missing.
- A working example is not required unless the technical facts lead to the conclusion that the information provided in the patent/application is not sufficient to allow the skilled person to put the invention into practice without undue burden.

In other words, it is clear from the jurisprudence before *T 1329/04* that there was disclosure of a complete invention if the disclosed technical teaching was performable. *There was no need for it to actually have been performed.*

### 3. The Requirements for completeness of an invention in Directive 98/44/EC

Directive 98/44/EC of July 6, 1998 („the Directive") attempted to harmonize the patenting of biotech inventions in the EU countries. In fact it basically codified the positions already taken by the EPO in its jurisprudence. Thus, it factually harmonized the EPO's practice with that forthcoming in its contracting states – if it only had been adopted 1:1 in all EU countries. But this is a different story.

The Directive stated in Recital (8):

"... Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability ..."

Thus, there was no intention to create a separate patent law for biotech inventions that is based on different legal principles (see also Recital (22), *infra*).

In the context of drafting the Directive, many discussions centered around the disclosure requirements for DNA sequence patent applications. The result of this discussion was that such inventions are complete if an industrial applicability and a function were disclosed for the DNA sequences concerned. Otherwise, the same criteria for patentability were to be applied as in other areas of technology; see Recitals (22) and (23):

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application of a sequence or partial sequence must be disclosed in the patent application as filed.

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. ...

These thoughts are reflected by Article 5 of the Directive:

#### Article 5

1. The human body, at the various stages of its formation and development, and the simply discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produce 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.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

In summary, the Directive did not intend to change foundational principles of patentability. Thus, the principle "performable is sufficient" remained untouched.

The EPO aligned its practice to the Directive by incorporating (effective as of September 1, 1999), among others, Article 5 of the Directive into its Implementing Regulations. Accordingly, Rule 23e EPC is literally identical with Article 5 of the Directive.

In summary, neither the Directive nor the amended Implementing Regulations provide any basis for abandoning the "performable is sufficient" principle.

#### 4. *The completeness of inventions in the jurisprudence of the EPC contracting state Germany*

A summary about when there is possession of a complete invention under the German Patent Act (GPA) can be found in Benkhard, Patentgesetz, 9<sup>th</sup> Edition, 1993, §1, Annotations 40, 43, 45 and 51. Accordingly, a complete invention is the reproducible teaching to use natural forces, compounds or energies to achieve a causal effect. With a view to inventive step, this defini-

tion has been supplemented by the phrase that achieving said effect must not have been expected by the average person skilled in the art. It is pointed out in Benkhard, §1, annotation 51, that an invention is complete if the average person skilled in the art is able to successfully carry it out based on the inventor's teaching. It is unnecessary that it has been reduced to practice already or that it is fit for marketing it. A teaching realized so clearly and defined according to its technical problem and solution that it can be carried out by the average person skilled in the art is complete. Benkhard specifically points out that the Federal Supreme Court abandoned a different view, as it took it in the 1950's. The inventor's certainty about the completeness is not required, only the objective performability is:

"As soon as, upon objective consideration, the disclosed invention discloses to the person of average skill in the art a concrete, practicable inventive teaching for technical performance, the protective purpose of the patent act demands that an invention disclosed in this manner be protected from endangerment by third parties. Thus, the creation of the right to the invention has to be set for this point in time."

Benkhard then goes on with pointing out that a scientific explanation about why the invention works is not required. In particular, no physical or chemical causes have to be provided. Even an error about why a desired effect can be achieved is irrelevant as long as it can be achieved. It is sufficient to disclose how the desired success can be achieved.

The German Patent Act has been amended, effective as of February 28, 2005, in order to "adapt" the German Patent Act to EU Directive 98/44/EC; see also section 3, *supra*. Thus, a new Section 1a was inserted. According to its subsection (4), only purpose-limited compound protection is now available if the subject matter of the invention is a sequence or partial sequence of a gene the structure of which is concordant to the structure of a natural sequence or partial sequence of a human gene.<sup>4</sup> While this amendment of the German Patent Act has significant consequences for the type of protection available for such inventions, the Legislator uses the same term for addressing these technical contributions as used in the still existing old § 1 of the German Patent Act: "invention". It is also evident from the German Legislator's comments on the draft for said amendment of October 15, 2003, that while there was an intention to restrict the scope of claims for the mentioned type of biotech inventions, there was no intention to create a new patent law for such inventions. Referring to Directive 98/44/EC the Legislator emphasized that as far as there are no specific stipulations, the existing rules of national patent law still have to be applied<sup>5</sup>.

In summary, when amending the German Patent Act in 2005, the German Legislator did not intend to abandon the "performable is sufficient" principle.

4 Kilger, Feldges, Jaenichen in The Journal of the Patent and Trademark Office Society, July 2005, 569, and Kilger, Jaenichen, in GRUR 12 (2005), 984

5 Deutscher Bundestag, Printed Matter 15/1709, page 8, right column

Thus, based on an evaluation of a plethora of German Federal Supreme Court decisions and in consideration of the recent amendment of the German Patent Act, there is possession of a complete invention under German law if a teaching in a patent application is performable. There is no need for it to have been carried out at the filing date. This is fully in line with the commentary on Article 52 (1) EPC discussed in section 2, *supra*.

#### 5. When is an invention complete in the United States' first-to-invent system?

As opposed to the EPO with its first-to-file system, the USPTO practices the first-to-invent system pursuant to the U.S. Patent Act (see, e.g., 35 U.S.C. Sections 101 and 102). According to early case law from the US Patent Appeals Court (CCPA), an invention is conceived by "the complete performance of the mental part of the inventive act" and "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice"; *Townsend v. Smith*, 36 F.2d 292, 295 (CCPA 1930). Conception has also been defined as a disclosure which enables one of ordinary skill in the art to reduce the invention to a practical form without "exercise of the inventive faculty"; *Gunter v. Stream*, 573 F.2d 77 (CCPA 1978). Accordingly, there is possession of a complete invention already at the date on which the inventor has conceived the invention if subsequently the inventor worked diligently to reduce the invention to practice and no inventive effort was required to do so.

On completeness of an enabling invention disclosure under US law where there are no working examples, the current Court of Appeals for the Federal Circuit (CAFC) stated in *Atlas Powder Company v. E.I. Du Pont De Nemours & Company*, 224 USPQ, 409, 414 (Fed. Cir. 1984):

"Use of prophetic examples ... does not automatically make a patent non-enabling. The burden is on one challenging validity to show by clear and convincing evidence that the prophetic examples together with other parts of the specification are not enabling."

In *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 32 USPQ2d, 1915 (Fed. Cir. 1994) the CAFC held:

1. "[T]he test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure .... The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity .... But an inventor need not know that his invention will work for conception to be complete. He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice." (*Id.* at 1919).
2. "The question is not whether [the inventors] reasonably believed that the inventions would work for their intended purpose ... but whether the inven-

tors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice. *For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea.*" (*Id.* at 1922-1923; emphasis added and citations omitted).

The above law on invention dates was confirmed by the US Supreme Court in *Pfaff v. Wells Electronics Inc.*, 525 U.S. 55, 48 USPQ2d, 1641 (1998):

1. "The primary meaning of the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented. Neither the statutory definition of the term in Section 100 nor the basic conditions for obtaining a patent set forth in Section 101 make any mention of 'reduction to practice.' ... [A]ssuming diligence on the part of the applicant [in an interference proceeding to determine who was first to invent], it is normally the first inventor to conceive, rather than the first to reduce to practice, who establishes the right to the patent. (48 USPQ2d, 1641, 1644)."
2. "It is well settled that an invention may be patented before it is reduced to practice. In 1888, this Court upheld a patent issued to Alexander Graham Bell *even though he had filed his application before constructing a working telephone* .... 'The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation.'" (*Id.* at 1644; citing *The Telephone Cases*, 126 U.S. 1, 535-536 (1888); emphasis added).

In early 2001, the USPTO published Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001). These Guidelines replaced the Revised Interim Utility Examination Guidelines that had been published in December 1999 (64 FR 71440; 1231 O.G. 136 (2000)); see also 65 FR 3425 (January 21, 2000). Under these Guidelines (see also Manual of Patent Examining Procedure § 2107), the Patent Examiner is required to assess the asserted utility to insure that it is *specific* (*i.e.*, well defined, not shared by all members of a broad class of invention, and not so vague as to be meaningless) and *substantial* (*i.e.* real world, practical utility, not a throwaway utility, that provides some immediate benefit to the public). The Examiner is also required to insure that the asserted utility is *credible* (*i.e.*, would be believed by a skilled worker in the relevant art). The required utility should either be disclosed in the application or be so apparent to

the skilled worker from the specification that it would be a well-established utility.

In 2005, after having had the new Utility Guidelines for about four years, the Federal Circuit appears to have complicated the long settled law on when an invention is complete in a case which examined the level of utility required to satisfy the enablement requirement (*Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005)). In an interference to determine priority of invention, Rasmusson sought the benefit of the first three priority dates of a series of nine applications that he had filed. Those applications claimed a method of treating prostrate cancer by using a selective 5-alpha reductase (5aR) inhibitor, and the same stated utility (treating prostate cancer) appeared in all nine consecutive priority applications. In Rasmusson's view, his priority applications satisfied both the utility and enablement („how to use") requirements. The Court, however, found that the stated utility was *not* supported by the first eight priority applications because it wasn't until the date of the ninth priority application that a person of skill in the art would have *recognized or believed that the invention would have the asserted utility*. The Court stated:

1. "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention ... must be taken as in compliance with the enabling requirement ... unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.' [quoting *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1970)] ... However, where there is 'no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects,' an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement." (*Id.* at 1323; citations omitted and emphases added).

The Rasmusson Court reasoned that if "mere plausibility" were the test for enablement, then applicants could unfairly obtain patent rights to "inventions" that were merely respectable guesses and, if such guesses later proved true, the applicant would be unjustly rewarded compared to another who actually demonstrated that the invention worked. While Rasmusson submitted evidence supporting credible use of "multi-active" 5aR inhibitors for treating prostate cancer at the earlier priority dates, the Board below had found that evidence insufficient to support a credible use for "selective" 5aR inhibitors, as "multi-active" 5aR inhibitors were believed to work by different mechanisms.

It is unclear how Rasmusson's holding – that an asserted utility is only enabling when one skilled in the art would recognize and accept it without question – accords with the mentioned long-stated legal precedence of the Federal Circuit and its predecessor, the CCPA, which has accepted post-filing date evidence that an original disclosure was enabled at the filing date.

That post-filing date evidence may be used to support the "how to make" and "how to use" prongs of enablement was maintained by the Federal Circuit in *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), citing and further stating with respect to *In re Marzocchi*:

1. "Even if one skilled in the art would have reasonably questioned the asserted utility, i.e., even if the PTO met its initial burden thereby shifting the burden to the applicants to offer rebuttal evidence, *applicants proffered sufficient evidence [post filing date] to convince one of skill in the art of the asserted utility.*" *Id.* at 1566-67.

Referring to post-filing date evidence of utility, the *Brana* Court stated that

2. "[Post-filing date evidence] can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification. It does not render an insufficient disclosure enabling, but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility)." *Id.* at page 1567 fn 19; citations omitted.

In summary, there appears to be a conflict between different Federal Circuit panels on the standard of enablement/credible utility required to support an invention date. In the face of such conflict, earlier decisions of the Federal Circuit are said to remain binding precedential law until such issues are revisited by a larger panel of the Federal Circuit sitting *en banc*.

Thus, while there are differences between the first-to-file and the first-to-invent patent system as regards the effective date for possession of the invention in the framework of patentability, both systems have established the same standards for completeness of an invention: performable is sufficient, performed is unnecessary; see also sections 2. and 4. *supra*. The holding of Rasmusson is not yet consolidated practice. That holding may be limited to situations of priority of invention contests in US interference practice when one or both parties rely on applications without a working example of the invention. Thus we will have to wait to see how the lower courts and the Federal Circuit apply Rasmusson in the future.

## 6. T 1329/04, "Factor-9/JOHN HOPKINS" of June 28, 2005

6.1 *T 1329/04* is a decision by Technical Board 3.3.8 that deals with the appeal of an applicant against the decision of the Examining Division to refuse the application for lack of inventive step (Article 56 EPC), lack of industrial applicability (Article 57 EPC), lack of enabling disclosure (Article 83 EPC) and lack of clarity (Article 84 EPC). Claim 1 of the Main Request before the Technical Board read:

- "1. A polynucleotide encoding a polypeptide selected from the group consisting of:
  - (a) a polynucleotide having the nucleic acid sequence of SEQ ID NO:3;
  - (b) a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:4;



- (c) a polynucleotide which is an RNA sequence corresponding to the polynucleotide of (a) or (b);
- (d) a polynucleotide encoding a fragment of the polypeptide encoded by any one of (a) to (c), which fragment causes growth and differentiation of oocytes; and
- (e) a polynucleotide which hybridises under stringent conditions with the polynucleotide of any one of (a) to (d) and encodes a polypeptide which causes growth and differentiation of oocytes."

Technical Board 3.3.8 only dealt with inventive step and denied it. The factual situation was the following: The application characterized the claimed polynucleotides as encoding a protein which was classified as being a member of the TGF-beta family, even though it only had 34 % sequence homology with known TGF-beta family members and only contained 6 out of the seven particularly spaced cysteine residues that were considered in the art as a key common structural motif of TGF-beta family members. The application also pointed out that the gene was predominantly expressed in ovarian tissue. Predictions were made about possible functions and uses of the encoded protein. However, no experimental evidence was provided in the application as filed supporting these predictions. To compensate for this, a post-published document was submitted which corroborated the predictions made in the application by actual data. They were correct.

The closest prior art disclosed the isolation of members of the TGF-beta family. The technical problem in view of the closest prior art was defined by Technical Board 3.3.8 as isolating a further member of the TGF-beta family. When assessing inventive step it became necessary to decide whether the subject matter as defined in the claims indeed solved this technical problem.

6.2 As mentioned above, there were no experimental data in the application which would have demonstrated that the GDF-9 protein encoded by the claimed polynucleotides indeed was a member of the TGF-beta family and indeed had the function causing the uses as predicted in the application. Technical Board 3.3.8 focused on the fact that GDF-9 did not show the characteristically high sequence homology with other members of the TGF-beta family (34 % homology did not satisfy them). Furthermore, to Board 3.3.8, the GDF-9 protein did not seem to be sufficiently related to the known proteins of the TGF-beta family because it did not have all seven cysteine residues with their characteristic spacing. There were only six. Thus, the Board concluded that the person skilled in the art could not have clearly and unambiguously considered the described GDF-9 protein as a further member of the TGF-beta family; *T 1329/04* at section 7. Since GDF-9 was far from fulfilling the standard criteria, it could not be attributed to any known subgroup of the TGF-beta family but could at best be considered as the first member of a yet unidentified subgroup; *T 1329/04* at section 8.

In this conclusion, Board 3.3.8 entirely ignored that in the application as filed the inventors were convinced that the GDF-9 protein belongs to the TGF-beta family and had certain functions causing certain uses – and that they were right. Irrespective of their disclosure, the Board took the position that "the application does not sufficiently identify this factor as a member of this family" because there was "not enough evidence in the application to make at least plausible" that the claimed polynucleotides solve the technical problem; *T 1329/04* at section 11.

Board 3.3.8 was of the opinion that the indications provided in the application about the hypothetical function and medical uses of the GDF-9 protein were mere speculations in the absence of experimental data; *T 1329/04* at sections 9 and 10. The Board disregarded the post-published confirmatory evidence provided by the applicant. The Board argued that it must be established *at the filing date* that the claimed subject matter is inventive. Otherwise, the assessment of inventive step could vary with time, which was held to be unacceptable; *T 1329/04* at section 12.

In summary, given the confirmatory evidence that was on file, Board 3.3.8 abandoned with this decision the "performable is sufficient" principle and required experimental evidence confirming a putative function or use *in the application as filed*. Only then it would be "plausible" that the technical problem has indeed been solved which means that only then there is a complete invention. This "plausibility approach" introduces a *subjective element* into the assessment of the performability of an invention that the case law never applied. Such a subjective criterion is dangerous, if the wrong addressee is chosen.

6.3 Technical Board 3.3.8 has indeed chosen the wrong addressee when taking the view that its subjective plausibility test is to be carried out by the average person skilled in the art:

... the skilled person was prepared to accept that a polypeptide belonged to the TGF-beta family if ...

*T 1329/04* at section 3.

The (average) person skilled in the art is the wrong addressee because the jurisprudence has long acknowledged that the knowledge of the inventor which actually lead to making the invention cannot be attributed to that person skilled in the art; *T 5/81*, "Production of hollow thermoplastic objects/SOLVAY". In this respect, *T 39/93*, "Polymer powders/ALLIED COLLOIDS LIMITED", stated that the person skilled in the art is not possessed of any inventive capability – which sets it apart from the inventor. In other words, if the inventor had had a flash of genius leading to the invention, it would neither be expected from the person skilled in the art that it would routinely have such a flash of genius – nor could it be reasonably expected from the person skilled in the art that it would always understand and believe in an invention originating from a flash of genius in the absence of experimental evidence. As a clear consequence, the person skilled in the art cannot be the base from which to judge plausibility of an inventive con-

tribution. It may simply not understand the invention and its implications. In fact, would the person skilled in the art be the base from which to judge plausibility, absurd results could be the consequence. This can be demonstrated by the following illustrative but not limiting examples:

*Example 1:* An inventor, a chemist, designs (only in a computer model) compound X. Because of her extraordinary capabilities and insight into structure/function relationships that go beyond those of a person of average skill in the art she predicts that this compound would be an excellent antagonist of a certain receptor known to be involved in brain tumors. Thus, the compound would be useful for treating such tumors. The average "person skilled in the art" would not have been able to make this prediction. The inventor files a patent application directed to compound X and its use in the treatment of brain tumors. When filing the application she has not yet synthesized the compound but she discloses a process for its production. She also did not yet carry out any experiments concerning the therapeutic use. However, later experiments show that all her predictions were correct, i.e. that compound X can be synthesized as predicted, and that it can indeed be used for treating brain tumors. The compound becomes a blockbuster.

According to the rationale of *T 1329/04* the inventor would not obtain any patent protection for her invention if at the filing date, in the absence of experimental data, her predictions were not plausible – subjectively – for the (average) person skilled in the art. Thus, the inventor would be deprived of her justified reward.

This is in clear contradiction to the established system! If the (average) person skilled in the art was not in a position to readily come up with the claimed subject matter, then this is a clear indication for inventive step and: experimental data in the application were not required. Analyzing the facts as in *T 1329/04* would actually result in a catch 22 situation: if plausible for the average person skilled in the art without experimental data, there would be no inventive step, if not plausible for the average person skilled in the art without experimental data there would either be lack of inventive step, too, or lack of enablement.

*Example 2:* Another inventor, an engineer, designs a new type of crane with a very unusual mode of action – but only on paper – and files a patent application. The Examiner, not familiar with the inventor's flash of genius and representing the average person skilled in the art with its common general knowledge, applies the *T 1329/04* plausibility test, is not convinced of the new mode of action and takes the position that the crane would not work. He therefore raises an objection for lack of enablement and for lack of inventive step because, in his subjective view, the technical problem cannot be solved.

The engineer cannot afford to have a model of his crane built. So he defends his position with scientific arguments.

The application is refused because the Examiner still cannot follow the engineer's thoughts. During appeal

proceedings the engineer finds a sponsor who finally builds a model of the crane and shows that it works advantageously, exactly as it has been predicted by the engineer in the application.

Applying the logic of *T 1329/04*, the engineer would again not get a patent for his crane because it was not plausible for the average person skilled in the art at the filing date (because of its limited capabilities in comparison to the inventor!) that the crane could work as described. The engineer would be caught in the same trap as our above chemist – only because of the subjective criterion introduced by Technical Board 3.3.8: wondering about what the average person skilled in the art would have thought and putting emphasis on the fact that there was no reduction to practice at the filing date.

*Example 3:* An "opposite" example could be based on the recent reports on fabricated scientific data concerning human stem cell lines which have even been published in one of the most respected scientific journals. Suppose, the scientists who made up their experiments would have filed a patent application and would have included the falsified experiments and results into the application as filed. Suppose further that the made up experiments and results would have been so plausible to the skilled person that it would immediately have been believed in them.

According to the rationale of *T 1329/04* that makes the whole "plausibility test" dependent on the average person skilled in the art's assessment at the filing date, the made up "invention" would have solved the technical problem at the filing date – albeit only subjectively. Moreover, since post-published documents, according to *T 1329/04*, are not to be taken into consideration when assessing whether the claimed subject matter indeed solves the technical problem or not, any later findings and publications demonstrating that the experiments and results actually had been made up and that the "invention" actually does not work could not change this assessment any more. Another unfair result, to say the least.

6.4 In section 12 of *T 1329/04* Technical Board 3.3.8 justified the rejection of post-published evidence for showing that the predictions of the application were correct by stating that considering post-published documents when assessing whether the technical problem has indeed been solved would lead to a situation where acknowledging a claimed subject-matter as a solution to a particular problem could vary with time. There was no need to be concerned in this respect. The result of considering whether a technical contribution is patentable may be a function of the evidence available at a certain point in time. Nevertheless, revocation of a patent in opposition or nullity proceedings has an *ex tunc* effect. Furthermore, whenever, e.g., a novelty destroying document may come up, objectively, the claim covering it has never been novel. Likewise, if evidence only available during opposition or nullity proceedings shows that the invention cannot be carried out in the entire area claimed and, therefore, enablement

has to be denied, objectively, there has never been enablement. In other words, whatever the level of realization is, the objective patentability of a performably disclosed invention never changes. Thus, to hold on to the established “performable is sufficient” principle does not mean that the assessment of patentability would vary with time in a relevant fashion. It simply guarantees a required flexibility by not pre-empting the future.

6.5 In summary, *T 1329/04* should not have abandoned the “performable is sufficient” principle and should not have replaced it by the subjective plausibility test to be done by the average person skilled in the art. This is because, by definition, the average person skilled in the art cannot always understand and appreciate why inventors think that what they claim actually works and solves a technical problem. Again, previous case law is explicit: the inventor should not be confused with the average person skilled in the art (see, e.g., *T 5/81*). The average person skilled in the art is *not* possessed of any inventive capability which is what sets it apart from the inventor (see, e.g., *T 39/93*). Thus, when consequently applying *T 1329/04*, inventors ahead of their time could not be successful in the EPO anymore. Such a policy is clearly hostile to substantive innovations.<sup>6</sup> The approach taken by the Board rather applies standards that are applied when referees assess whether a scientific article already has sufficient experimental basis for the conclusions that it takes. This, however, is not compatible with the established legal approach to assessing completeness of an invention. The consequent practice of such a drastic shift to a subjective “plausibility” assessment of the completeness of a disclosed invention – be it in context with industrial applicability, inventive step or enablement – would inevitably have the consequence that patentability would have to be denied for otherwise patentable inventions. We also have to understand that *T 1329/04* has put the applicant into an awkward position. As it disclosed a correct working hypothesis that the person skilled in the art would not have come up with – so the Board contends – the teaching would have been inventive, had it passed the new subjective plausibility test. The inventors were ahead of their time or had a flash of genius.

Thus, when an inventor correctly predicts a solution to a technical problem, when the disclosure can be performed without inventive effort and when post-pub-

lished evidence proves that the inventor was correct, patentability should not be denied solely because the inventor’s disclosure would not have passed the person skilled in the art’s plausibility test. The unfair results in our above examples are unacceptable.

6.6 The Board 3.3.8’s reliance on differences between the first-to-file and the first-to-invent patent system does not justify the proposed subjective plausibility test either.

In *T 1329/04* the appellant defended his case by arguing that in a first-to-file system as applicable in the EPO it should be allowable for the applicant to include speculations of possible functions and uses in his application because he is forced to cover any and all subject matter connected to its invention already at the filing date; *T 1329/04* at section 10.

The Board expressed the opposite opinion; *T 1329/04* at section 10. It took the position that in a first-to-file system the (earlier) filing date, not the date at which the invention was made determines to whom of several persons having made an invention independently of each other, the right to a European patent belongs. The Board stated that it is particularly important in such a system that the application allows the reader to – subjectively, as we have seen – conclude that the invention has been made, i.e. that the problem has indeed been solved, not merely put forward at the filing date of the application.

This reasoning of the Board is based on a misconception of the currently established first-to-file patent system (section 5, *supra*) in comparison to the first-to-invent patent system. A technical problem has been solved if the invention described in the patent application is complete, i.e. if it is described in a manner so as to enable the person skilled in the art to handle it in normal practice. In the EPO this required, according to the established case law, that all essential elements are provided in the application as filed.

In the first-to-invent patent system (section 5., *supra*) as it is currently established in the United States, the actual date allocated to the invention (which determines in interference proceedings to whom the invention belongs) is not the date on which the inventor finally demonstrated by way of experiments that his proposed solution indeed solves the technical problem. It is the “conception date”, i.e. the date on which the inventor for the first time had his idea in a provable manner (e.g., as a drawing on a napkin) and so complete that it only required diligence to reduce it to practice but no inventive effort any more. There may be a tendency in the United States to reconsider this policy for specific fact situations in interferences, as has been discussed in section 5, *supra*. However, no deviating general policy has become the established one yet. While international harmonization in intellectual property law is desirable, it appears to be improper for a Technical Board of the EPO to base any attempts for harmonization on new but not yet established trends in United States intellectual property practice rather than on established generally applicable principles, especially if such an attempt to harmon-

<sup>6</sup> In this context it is the Polymerase Chain Reaction (PCR) that comes to mind. The inventor, Cary Mullis, was awarded the Nobel price for this pioneering innovation. When Cary Mullis made the invention, those of average skill in the art did not understand PCR’s implications. As Cary Mullis described it in his article “The unusual origin of the polymerase chain reaction” in *Scientific American* in April 1990 on pages 36 to 43, it took another Nobel Prize laureate to do so. Only once PCR had revolutionized molecular biology, the argument was brought up that PCR was easy, straight forward and obvious from the prior art because of its striking simplicity (that makes it such a valuable tool for cloning, diagnostics and forensics); see also *T 78/96*, “Process for amplifying nucleic acid sequences/F. HOFFMANN-LA ROCHE AG” of October 30, 2003, on EP-B1 201 184, and *T 216/96*, “Process for amplifying, detecting and/or cloning nucleic acid sequences/F. HOFFMANN-LA ROCHE AG” of October 20, 2003, on EP-B1 200 362 (the latter two patents were the foundational European patents on PCR). What if an average person skilled in the art would have had to assess PCR’s value and implications at the time when Cary Mullis shared his concept with the scientific community for the first time?



ize would amount to abandoning established jurisprudence in the EPO<sup>7</sup>.

Thus, in a first-to-file patent system, as it is practiced at the EPO, the inventor already is at a disadvantage in comparison to the first-to-invent patent system as currently established in the United States because in determining who dominates the field only the filing date is relevant, not the conception date and because, logically, the filing date can only be later than the conception date. By the practice proposed in *T 1329/04*, the effective date of the first-to-file patent system would even be shifted further to the disadvantage of the inventor because he/she would actually need to provide experiments before he/she could file an effective application. Thus, at least at this time, *T 1329/04* is an improper attempt for adjustment and achieves the opposite – if anything.

### 7. Conclusions

The completeness of an invention is a fundamental requirement for patentability that results from Article 52 (1) EPC; introduction and section 2, *supra*.

In *T 1329/04* Technical Board 3.3.8 has proposed a subjective test for the completeness of an invention disclosed in a patent application; section 6.2, *supra*.

The test deviates from established jurisprudence in the EPO and at least the contracting state Germany; sections 2 and 4, *supra*. Even if there were contracting states in which experimental evidence would be required in order to acknowledge completeness of an invention, we suggest that this should not become the basis for the assessment of patentability in the EPO. This is because a situation would result in which the EPO would refuse patent applications for inventions that might well be patented in contracting states of the EPC. Patents granted by the EPO can still be invalidated in contracting states if their national law deviates from the practice of the EPO. However, there cannot be any patents in contracting states resulting from European patent applications that were refused. An example that supports our suggestion is the EPO's policy for granting patents for selection inventions. At least some of them would not be valid in Germany because Germany practices a different approach in the assessment of novelty. Would the EPO adopt Germany's standards in this respect, there would be hardly any patents any more for selection inventions that the EPO could grant. Furthermore, would the EPO adopt Germany's standards for granting patents on human DNA sequences, it could only grant purpose limited compound protection any more after the amendment of the German Patent act that became effective on February 28, 2005 (inserting a new § 1a); see also section 4, *supra*. The matter would become a question of whether the lowest or the highest common denominator between the contracting states should be chosen as a basis for the EPO's practice.

The test cannot be justified by reference to the EU Biotech Directive because it does not set out a require-

ment for having examples or a reduction to practice already at the relevant filing date; section 3, *supra*. The disclosure of a function is sufficient.

Because the subjective test is to be carried out by the average person skilled in the art, i.e., the wrong addressee, it leads to undesirable results; section 6.3, *supra*. The ingenuity of an inventor must not be punished by reducing it to the average level of skill in the art. Rather, it should be rewarded. This is only reliably possible when taking an "objective" rather than a "subjective" approach, as would also be in line with Moufang's commentary on Article 52 (1) EPC that was cited in section 2, *supra*.

The test is unnecessary to avoid any relevant variation in the assessment of patentability with time; section 6.4, *supra*.

The test is too scientific in terms of putting too much emphasis on the presence of scientific data rather than applying the traditional legal principles of conception of an enabling invention; section 6.5, *supra*.

The test would put inventors at further disadvantages in the first-to-file patent system over the currently established first-to-invent patent system. Effective filings would be further delayed by having to do (additional) experiments; section 6.6, *supra*.

In summary, *T 1329/04*'s newly proposed subjective test for completeness of an invention to be carried out by the (average) person skilled in the art should not be applied any further. Its results would frequently be inappropriate and it achieves the opposite of harmonization between the EPO, contracting states of the EPC and the United States of America. In terms of results of this subjective test, it is also important to note that practicing this test may also produce results for patentability requirements other than inventive step that are not compatible with the established system. Resulting from the central Article 52 (1) EPC, the patentability requirements are like a network. If the assessment of one of them is modified, there will inevitably be consequences for others. This is nicely documented by the same Board's decision *T 179/01* which demonstrates that by applying the subjective new test a DNA sequence disclosed in the art with an allocated function for which there is no experimental evidence would not be novelty destroying for a DNA claim covering the same sequence for the same function or any other function. Note that in this case there also was post-published evidence proving that the DNA sequence of the prior art indeed encoded a protein having the predicted function. Thus, applying the test proposed in *T 1329/04* consequently, would not only have the effect that complete inventions would become incomplete, it would also have the effect that relevant prior art would become irrelevant.

Practicing *T 1329/04* consequently would also provide an incentive for forum shopping by trying to influence the patent classification by selecting a particular kind of claim 1 so as to be assigned to a particular Technical Board rather than to another. Incompleteness of a complete invention should not depend on forum shopping. Furthermore, establishing two different lines of assessing

7 Note that *T 1329/04* does not evaluate in detail the current situation in the US. It merely assumes that the first-to-file system must be practiced in a certain way because of the first-to-invent system.

patentability in this respect would undermine any legal certainty.

All these problems can be avoided by continuing the traditional assessment of the completeness of an invention. Thus, when an inventor correctly predicts a solution to a technical problem, when the disclosure can be

performed without inventive effort and when post-published evidence proves that the inventor was correct, completeness of the invention should be accepted. The objective technical quality of an invention should still weigh more than formalism.

## Reform of European Pharmaceutical Law & Patent Protection

M. Krekora (PL)<sup>1</sup>

### Should patent attorneys know pharmaceutical law?

Yes, because since October the 30<sup>th</sup> 2005 European pharmaceutical law regulates the problem of patent infringement with regard to medicinal products.

Amendments to Directive 2001/82/EC<sup>2</sup> and 2001/83/EC<sup>3</sup> introduced something similar to the so called *Roche-Bolar Amendment*, as adopted in United States of America about 20 years ago. Article 13 (6) of amended Directive 2001/82/EC and Article 10 (6) of amended Directive 2001/83/EC state that conducting the necessary studies, tests and trials with a view to the application of paragraphs regulating preparation of "generic application for medicinal product" and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary protection certificates for medicinal products.

If we compare these provisions with authentic *Roche-Bolar Amendment*, which states that (35 USC § 271 (e) (1)) – *It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which*

*regulates the manufacture, use, or sale of drugs or veterinary biological products*, we can see that in spite of differences of the wording it leads to the same effect. It is legal to conduct tests and trials in order to prepare the application for marketing authorisation for a generic medicinal product before the expiry of the patent for original medicinal product.

But is it legal to submit such application to the regulatory authorities?

In United States it is not. Such action would be regarded as infringement of the patent under 35 USC § 271 (e) (2). However except for setting the effective date of the marketing authorisation after the expiry of the infringed patent and granting injunctive relief to prohibit the marketing of the generic product, the court may not award any monetary damages, if the generic product is not sold or imported into United States. So even if at the first sight these provisions look very restrictive, they are quite "generic friendly".

In European Union the situation is not so clear. If in the national law of a Member State there is not a provision directly stating that filing an application for a marketing authorisation constitutes an infringement, we can only rely on courts' judgements with regard to this problem.

In *Upjohn v. Kerfoot*<sup>4</sup> the English court ruled that filing of the application for marketing authorisation did not constitute an infringement of the patent on condition that the necessary tests and trials had been carried outside the United Kingdom (it was before the amendment of pharmaceutical directives) and the application was not accompanied by samples of the product.

But in some Member States it is impossible to obtain marketing authorisation for a medicinal product without submitting samples. According to the judgement of the European Court of Justice (ECJ) dated the 9<sup>th</sup> July 1997 in the case *Generics BV v Smith Kline & French Laboratories Ltd*<sup>5</sup>, if it is necessary to submit samples, the applicant shall wait till the expiry of the patent. In this case the ECJ ruled that the court is entitled to issue an injunction prohibiting the applicant to introduce its generic product

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2 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Veterinary Medicinal Products (Official Journal L -311, 28/11/2004, p. 1 – 66)

3 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use (Official Journal L – 311, 28/11/2004, p. 67 – 128)

4 [1988] FSR 1.

5 Case C-316/95 ECR [1997] I-03929.

into the market for a certain period of time, even if the patent for the original product already expired. Such period shall be equal to the actual period which the applicant would have needed to obtain the marketing authorisation if he had applied for it after expiry of the patent. It means that this period may be longer than 210 days (according to the respective provisions of Directive 2001/82/EC and 2001/83/EC the marketing authorisation procedure shall last not longer than 210 days). In the said ruling this period was equal to 14 month, what makes much more than regulatory 210 days.

Although we can consider this judgement as quite restrictive we should remember that in the European Union, unlike in USA, the holder of the patent for original product is not informed about filing an application for a marketing authorisation for a generic medicinal product. The whole procedure is confidential, so he can find out about that only when the information about marketing authorisation is published. And it is quite late, because it often happens when the patent protection is over. So the possibility to stop the marketing of the product after patent expiration constitutes a really effective mean of enforcement of industrial property rights.

Taking into account the above and the wording of the respective provisions of Directive 2001/82/EC and 2001/83/EC as amended, we can conclude that after 30<sup>th</sup> October 2005 it is legal to conduct tests and trials in

the territory of European Union and then to submit an application for marketing authorisation, but it is illegal to submit samples before the expiration of the patent for original medicinal product, unless rules of national law of a Member State, where the application is filed, are less restrictive.

In Poland such rules are less restrictive; moreover they are in force for a longer time than those of European Union law. Article 69 (1) (4) of Polish Industrial Property Law<sup>6</sup> states that it is not an infringement of the patent to use the invention, to the necessary extent, for any activities essential for obtaining marketing authorisation, in particular for medicinal products.

First of all we can see that this provision relates not only to medicinal products, but also to all products that may not be marketed without special license granted by public authorities. Secondly this provision directly allows use of the invention for all activities connected with obtaining marketing authorisation. So such activities include not only tests and trials but also filing an application and submitting the samples.

So in Poland the situation with regard to the scope of patent protection has not changed since the 30<sup>th</sup> of October 2005. But in many EU Member States the amendments made to both directives mean that the national patent law must be changed (or already has been changed) in order to implement new provisions.

## Begründung der Definitionsmethode zur Prüfung erfinderischer Tätigkeit

S. V. Kulhavy\* (CH)

- I. In den Richtlinien beschriebene amtliche Prüfungsmethoden
- II. Kritik der Methoden
- III. Die Definition einer naheliegenden Lösung
- IV. Schaffung neuer technischer Lösungen
- V. Zwei grundlegende Fragen betreffend die Definitionsmethode
- VI. Die Lage der Grenze zu den Erfindungen
- VII. „Bekannt“ in der Definition einer naheliegenden Lösung
- VIII. Der maßgebende Stand der Technik
- IX. Recherche im Stand der Technik
- X. Das Wissen und Können des Fachmanns
- XI. Der Unterschied zum Stand der Technik
- XII. Das Schlusswort

### Zusammenfassung

In den „Richtlinien für die Prüfung im Europäischen Patentamt“ sind mehrere Methoden zur Prüfung erfinderischer Tätigkeit bei Lösungen von Aufgaben bzw. Problemen beschrieben. Es handelt sich beispielsweise um den sogenannten Aufgabe-Lösungs-Ansatz, um die Anwendung von Anzeichen usw. Diese Methoden stellen auf das Wissen und Können eines Fachmanns ab, wobei der Umfang dieses Wissens und Könnens in den „Richtlinien“ anhand von Ausdrücken mit unklarer bzw. unscharfer Bedeutung umschrieben ist. Gemäß den „Richtlinien“ kann es jedoch auch Fälle geben, in denen es zweckmäßig ist, auf das Wissen und Können von Personengruppen, beispielsweise eines Forschungs- oder Produktionsteams

<sup>6</sup> Dziennik Ustaw (Official Journal of Republic of Poland) dated 2003, No 119 (1117)

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bei der Prüfung erfinderischer Tätigkeit zu denken als an eine Einzelperson. Diese Fülle von Prüfungsmethoden, von maßgebenden Fachleuten und von unbestimmten Ausdrücken stiftet Verwirrung, beispielsweise dann, wenn eine Lösung nach der einen der amtlichen Methoden eine Erfindung darstellt und nach einer anderen der amtlichen Methoden nicht.

Der Verfasser dieses Beitrags entwarf eine Methode zur Prüfung erfinderischer Tätigkeit, welche die genannten Nachteile nicht aufweist und anhand welcher man genau entscheiden kann, ob eine Lösung eine Erfindung darstellt oder nicht. Im Zusammenhang mit der Benützung dieser sogenannten Definitionsmethode tauchten jedoch zwei Fragen betreffend die Grundlagen dieser Definitionsmethode auf. Diese Fragen werden in diesem Beitrag beantwortet.

### *I. In den Richtlinien beschriebene amtliche Prüfungsmethoden*

In den „Richtlinien“<sup>1</sup> sind mehrere Methoden zur Prüfung erfinderischer Tätigkeit bei Lösungen von Aufgaben bzw. Problemen beschrieben. Es handelt sich beispielsweise um den sogenannten Aufgabe-Lösungs-Ansatz, um could/would approach, um die Anwendung von Anzeichen usw. Diesen Prüfungsmethoden ist gemeinsam, dass sie neben anderem auch auf das Wissen und das Können eines Fachmanns abstellen. Die Eigenschaften dieses Fachmanns sind in den „Richtlinien“<sup>1</sup> unter 9.3 wie folgt umschrieben: „Es ist zu unterstellen, dass es sich bei dem ‚Fachmann‘ um einen Mann der Praxis handelt, der darüber unterrichtet ist, was zu einem bestimmten Zeitpunkt zum allgemein üblichen Wissensstand auf dem betreffenden Gebiet gehört. Es ist auch zu unterstellen, dass er zu allem, was zum Stand der Technik gehört, insbesondere den im Recherchenbericht angegebenen Dokumenten, Zugang hatte und über die normalen Mittel und Fähigkeiten für routinemäßige Arbeiten und Versuche verfügte. .... Es kann auch Fälle geben, in denen es zweckmäßig ist, eher an Personengruppen, beispielsweise ein Forschungs- oder Produktionsteam zu denken als an eine Einzelperson. Dies könnte beispielsweise für gewisse fortgeschrittene Technologien wie Datenverarbeitung- oder Telefonanlagen und für hochspezialisierte Verfahren wie die kommerzielle Produktion integrierter Schaltungen oder komplexer chemischer Stoffe zutreffen.“

### *II. Kritik der Methoden*

Früher kam man bei der Prüfung erfinderischer Tätigkeit mit den erwähnten Anzeichen aus. Danach kam der Aufgabe-Lösungs-Ansatz. Zuletzt kam das could/would approach. Wie ist die Situation, wenn eine geprüfte Lösung gemäß einer der amtlichen Methoden als Erfindung gelten kann, während sie gemäß einer anderen der amtlichen Methoden nicht als Erfindung betrachtet wird? Neuerdings kann man bei der Prüfung der erfinderischen Tätigkeit auch auf das Wissen und Können einer Personengruppe abstellen. Wenn man der Beur-

teilung der erfinderischen Tätigkeit das geballte Wissen und Können eines Forschungsteams zugrunde legt, dann kann eine Lösung, welche eine Einzelperson ersonnen hatte und zum Patentieren angemeldet hat, nie auf einer erfinderischen Tätigkeit beruhen. Denn eine Einzelperson kann nie so viel Wissen und Können besitzen wie eine Gruppe von Forschern auf dem Gebiet der beurteilten Lösung. Bekanntlich werden aber die meisten Erfindungen durch Einzelpersonen hervorgebracht. Den Organen vom EPA steht es frei, Forschergruppen auch auf anderen als auf den in den „Richtlinien“ genannten Gebieten der Technik als Massstab für die Beurteilung von Erfindungen zu verwendenden. Dies erhöht nicht nur weiter die Rechtsunsicherheit, welche auf diesem Gebiet derzeit bereits herrscht, sondern das EPA könnte sich selbst durch die Anwendung dieser Prüfungsmethode bei der Erteilung von Patenten behindern.

Der Fachmann als Einzelperson kann gemäß den „Richtlinien“ auch weiterhin als Massstab für die Beurteilung der erfinderischen Tätigkeit benutzt werden. Dabei kann sein Wissen gemäß den „Richtlinien“ über den Inhalt des Recherchenberichts hinaus ausgedehnt werden, indem ihm die Kenntnis auch des „allgemein üblichen Wissensstands“ zugestanden wird, und indem er auch „zu allem, was zum Stand der Technik gehört, insbesondere den im Recherchenbericht angegebenen Dokumenten, Zugang hatte“. Andererseits wird sein Wissen in den „Richtlinien“ beschnitten, indem ihm das Wissen nur auf „dem betreffenden Gebiet“ zugestanden wird, was ein offensichtlicher Widerspruch zu dem ist, was im vorstehenden Satz beschrieben ist. Welches ist das betreffende Gebiet? Das Können des Fachmanns wird ebenfalls beschnitten, indem er nur über „die normalen Mittel und Fähigkeiten für routinemäßige Arbeiten und Versuche verfügt“. Was gilt als normal und was als routinemäßig?

Hieraus kann man ersehen, dass die Anleitung zur Prüfung erfinderischer Tätigkeit, welche sich in den „Richtlinien“ befindet, nicht nur eine Menge unbestimmter Ausdrücke enthält, sondern dass die Anleitung auch einen Mix aus Methoden zur Prüfung erfinderischer Tätigkeit sowie einen Mix aus übertriebener, untertriebener und widersprüchlicher Anforderungen an die erfinderische Tätigkeit enthält. Hieraus kann sich jeder das auswählen, was ihm passt. Diese Sache hat jedoch einen Haken. Die Prüfer, die Einspruchsabteilungen und insbesondere die Beschwerdekammern sitzen dabei, wie man volkstümlich sagt, am längeren Hebel, sodass sie unter solchen Umständen für ihren Standpunkt in den „Richtlinien“ immer eine ausreichende Stützung finden. Eine Partei, welche eine entgegengesetzte Meinung vertreten würde, hat keine Aussicht auf Erfolg, weil die Anleitung in den „Richtlinien“ keinen Fixpunkt enthält, wo man als Gegenseite einhaken könnte.

Man könnte noch lange Kritik an den amtlicherseits ausgegebenen Weisungen zur Prüfung erfinderischer Tätigkeit üben. Der Eindruck des Verfassers dieses Beitrags geht dahin, das, je länger das Europäische Patentamt bestehen wird, desto mehr Methoden zur Prüfung erfinderischer Tätigkeit zum Vorschein kommen werden.

<sup>1</sup> „Richtlinien für die Prüfung im Europäischen Patentamt“, 2003, Teil C, S. 65 ff.



Wenn nichts geschieht, dann ist es nicht ausgeschlossen, dass es in der nächsten Ausgabe der „Richtlinien“ noch einige Methoden mehr zur Prüfung erfinderischer Tätigkeit geben wird, wodurch die Rechtsunsicherheit nur noch zunehmen würde. Das Thema früher Erfindungshöhe und derzeit erfinderische Tätigkeit war immer ein sehr schwieriges Thema, aber eine solche Rhapsodie von Methoden und von unbestimmten Ausdrücken bei der Prüfung dieses dritten Merkmals einer Erfindung gab es wohl noch nie.

### III. Die Definition einer naheliegenden Lösung

Der Autor dieses Beitrags publizierte<sup>2</sup> eine Methode zur Prüfung erfinderischer Tätigkeit, bei welcher die Grenze zwischen dem oberen Rand der Zone der naheliegenden Lösungen und dem Raum der Erfindungen scharf definiert ist. Dies bedeutet, dass diese Prüfungsmethode ermöglicht, über die erfinderische Tätigkeit bei einer beurteilten Lösung klar bzw. verstandesmäßig und genau zu entscheiden, ohne dass vage bzw. unbestimmte Begriffe ausgelegt werden müssen. Diese Methode beruht auf der Definition<sup>3</sup> einer naheliegenden Lösung, welche wie folgt lautet:

„Eine Lösung ergibt sich in naheliegender Weise aus dem Stand der Technik, wenn ein bekanntes technisches Mittel aufgrund der bei diesem Mittel bereits bekannten technischen Eigenschaften zur Lösung einer Aufgabe bzw. eines Problems verwendet wird.“

Diese Definition einer naheliegenden Lösung ergab sich aus der Analyse einer großen Anzahl von bereits entschiedenen Fällen. Wenn eine gewerblich anwendbare und neue Lösung nicht unter die Definition einer naheliegenden Lösung fällt, dann konnte sich diese neue Lösung aus dem Stand der Technik nur in einer nicht naheliegenden Weise ergeben. Eine solche Lösung beruht auf einer erfinderischen Tätigkeit (Art. 56 EPÜe). Eine gewerblich anwendbare und neue Lösung kann, wie dies aus der Definition einer naheliegenden Lösung hervorgeht, über die obere Grenze der Zone der naheliegenden Lösungen hinausgehen und somit eine Erfindung darstellen, wenn das technische Mittel neu ist oder/und wenn die Eigenschaft des lösungsgemäß verwendeten, bekannten technischen Mittels bei diesem Mittel entdeckt und bei diesem technischen Mittel daher neu ist. Falls das technische Mittel neu ist, dann liegt eine Kombinationserfindung vor. Falls die Eigenschaft des lösungsgemäß verwendeten, bekannten technischen Mittels bei diesem entdeckt und bei diesem daher neu ist, dann liegt eine An- bzw. Verwendungserfindung vor. Beispiele für diese und weitere Arten von Lösungen sind im Buch<sup>4</sup> des Verfassers dieses Beitrags anhand der Definition der naheliegenden Lösung im Einzelnen besprochen.

So einfach und, man kann dies wohl mit Recht sagen, auch klar wird gemäß dieser Methode über Erfindungen

entschieden. Wir wollen diese Methode kurz Definitionsmethode oder noch kürzer D-Methode nennen.

### IV. Schaffung neuer technischer Lösungen

Eine Erläuterung, warum es nur die zwei genannten Grundarten von Erfindungen gibt, liegt außerhalb des Rahmens dieses Beitrags. Der interessierte Leser findet Näheres zu diesem Thema in einem früher veröffentlichten Artikel<sup>5</sup> des Verfassers dieses Beitrags. Im soeben genannten Artikel des Verfassers dieses Beitrags ist auch Schritt für Schritt beschrieben, wie neue technische Lösungen, darunter fallen auch Erfindungen, entstehen können. In diesem Artikel ist auch erläutert, dass und wie man die Schaffung neuer Lösungen den Computern anvertrauen kann. Wenn die Grenze zum Raum der Erfindungen rationell wirklich nicht erfassbar wäre, wie dies die „Richtlinien“ annehmen, dann wäre es gar nicht möglich, Schritt für Schritt zu beschreiben, wie Erfindungen entstehen, und ein diesbezügliches Computerprogramm zu schreiben. Denn ein Computerprogramm kann bekanntlich nur dann geschrieben werden, wenn sich das betreffende Verfahren in einzelne, rationell erfassbare Schritte zerlegen lässt. Angesichts des Inhaltes dieses zuletzt genannten Artikels<sup>5</sup> gelten die Ansichten vom EPA darüber, wann eine Erfindung vorliegt, als veraltet.

### V. Zwei grundlegende Fragen betreffend die Definitionsmethode

Wie erwähnt, legt die Definition einer naheliegenden Lösung den oberen Rand der Zone der naheliegenden Lösungen fest, oberhalb welchem sich der Raum der Erfindungen befindet. Im Zusammenhang damit tauchten zwei Fragen auf. Man hat erstens gefragt, wodurch die Lage der Grenze zum Raum der Erfindungen, wie sie durch die Definition einer naheliegenden Lösung festgelegt ist, begründet ist. Zweitens hat man gefragt, weshalb diese Grenze scharf sein soll. Die Schärfe der Grenze zu den Erfindungen hängt nämlich davon ab, wem das technische Mittel und die Eigenschaften der bekannten technischen Mittel bekannt sein sollen, die in der Definition genannt sind. Wenn die Grenze des Wissens und des Könnens des Fachmanns so unscharf wäre, wie dies in den „Richtlinien“ beschrieben ist, dann wäre der Verlauf der Grenze zu den Erfindungen dementsprechend unscharf. Folglich wären wir mit der Definitionsmethode nur dort, wo wir mit den Prüfungsmethoden des Europäischen Patentamtes heutzutage sind.

### VI. Die Lage der Grenze zu den Erfindungen

Die Antwort auf die Frage, warum die Grenze zu den Erfindungen gerade dort liegen soll, wo die Definition einer naheliegenden Lösung sie festlegt, wird unter gesellschaftspolitischen Aspekten beantwortet.

Probleme entstehen im Zusammenhang mit Objekten, welche Sachen oder Verfahren sein können. Nachdem ein Problem entstand bzw. nachdem eine zu lösende Aufgabe formuliert wurde, sucht man zunächst im Stand

<sup>2</sup> epi Information 3/1998, S. 110 ff.

<sup>3</sup> epi Information 3/1998, S. 111.

<sup>4</sup> S. KULHAVY „Materielle Prüfung von Erfindungen“, 1978, ISBN 3-85732-100-8

<sup>5</sup> epi Information 2/2004, S. 65 ff.



der Technik ein technisches Mittel, das Eigenschaften hat, die dieses Mittel zur Lösung des Problems bzw. der Aufgabe prädestinieren. Denn es ist am Naheliegendsten, sich im Stand der Technik zunächst umzuschauen, ob es dort ein technisches Mittel gibt, welches die zur Lösung der Aufgabe bzw. des Problems geeigneten Eigenschaften besitzt. Wenn es gelingt, beispielsweise anhand einer Recherche im Stand der Technik, zumindest ein technisches Mittel aufgrund der bei diesem Mittel bereits bekannten technischen Eigenschaften zu finden, welche dieses Mittel zur Lösung der Aufgabe bzw. des Problems prädestinieren, dann wendet man dieses technische Mittel am betreffenden Objekt an. Eine Recherche im Stand der Technik ist nicht sonderlich teuer. Da das gefundene technische Mittel zum ersten mal mit dem Objekt zusammengeführt worden ist, gilt diese Lösung der Aufgabe bzw. des Problems als neu. Sie weist einen Unterschied<sup>1</sup> gegenüber dem Stand der Technik auf. Deswegen kann diese Lösung geprüft werden, ob sie bzw. der Unterschied sich aus dem Stand der Technik in naheliegender Weise ergab oder nicht. Lösungen, bei welchen das verwendete technische Mittel aufgrund seiner technischen Eigenschaften im Stand der Technik gefunden worden ist, ergaben sich gemäß der Definition einer naheliegenden Lösung in naheliegender Weise aus dem Stand der Technik, und sie liegen deswegen innerhalb der Zone der naheliegenden Lösungen. Wegen Art. 56 EPUe beruhen solche neue Lösungen nicht auf einer erfinderischen Tätigkeit. Für solche Lösungen werden daher keine Patente im Sinne von Art. 52, Abs. 1 EPUe erteilt.

Das Glück, dass man zumindest ein technisches Mittel aufgrund der bei diesem Mittel bereits bekannten technischen Eigenschaften im Stand der Technik findet, muss man nicht immer haben. Heutzutage gibt es immer noch genug Probleme, welche ihrer Lösung harren. Dies deswegen, weil man im Stand der Technik kein technisches Mittel aufgrund der bei diesem Mittel bereits bekannten technischen Eigenschaften finden konnte, welches zur Lösung eines dieser Probleme verwendbar wäre. Wie dies seit mehr als hundert Jahren bekannt ist, erfordert die Lösung solcher Probleme oft einen großen Aufwand, u.a. auch einen finanziellen. Nachdem jemand eine Lösung eines solchen Problems hervorgebracht und der Öffentlichkeit vorgestellt hat, könnten die Wettbewerber diese Lösung kopieren und sich in dieser Weise einen großen Entwicklungsaufwand ersparen. Dies würde Personen bzw. Firmen demotivieren, in Lösungen schwierig lösbarer, aber für die Gesellschaft dennoch wichtiger Probleme Geld zu investieren. Um Leute und Firmen zu solchen Investitionen zu motivieren, hat man seinerzeit den modernen Patentschutz eingeführt. Dieser Patentschutz schützt diejenigen Lösungen, welche über die obere Grenze der Zone der naheliegenden Lösungen hinausgehen und sich daher nicht definitionsgemäß in naheliegender Weise aus dem Stand der Technik ergaben – Art. 56 EPUe. Solche Lösungen werden als Erfindungen gemäß Art. 52, Abs. 1 EPUe betrachtet und sie werden durch Patente geschützt.

### *VII. „Bekannt“ in der Definition einer naheliegenden Lösung*

In der Definition einer naheliegenden Lösung kommt das Wort bekannt im Zusammenhang mit dem verwendeten technischen Mittel und im Zusammenhang mit seinen technischen Eigenschaften vor. Man kann fragen, wem bekannt. Wenn die Antwort auf diese Frage dem Fachmann mit den in den „Richtlinien“ beschriebenen Eigenschaften lauten würde, dann wären wir, wie dies bereits erwähnt worden ist, auch mit der Definitionsmethode nur dort, wo sich die offizielle Lehre heutzutage befindet. Denn während der Prüfung auf erfinderische Tätigkeit müsste man auch weiterhin und immer wieder die Frage stellen, was zum Wissen und Können des Fachmanns des einschlägigen Gebiets im jeweils geprüften Fall gehören konnte usw.

„Bekannt“ bedeutet im Rahmen der Definitionsmethode soviel wie zum Stand der Technik gehörend. „Bekannt“ ist somit nicht auf eine Person bezogen, gleichgültig, ob diese Person eine reale oder eine fiktive Person ist. Der Stand der Technik ist im Art. 54, Abs. 2 EPUe wie folgt definiert: „Den Stand der Technik bildet alles, was vor dem Anmeldetag der europäischen Patentanmeldung der Öffentlichkeit durch schriftliche oder mündliche Beschreibung, durch Benutzung oder in sonstiger Weise zugänglich gemacht worden ist.“

### *VIII. Der maßgebende Stand der Technik*

Der Inhalt des im Art. 54, Abs. 2 EPUe definierten Standes der Technik ist für die Beurteilung erfinderischer Tätigkeit bei der betreffenden Lösung maßgebend. Deswegen werden wir den Stand der Technik gemäß Art. 54, Abs. 2 EPUe als maßgebenden Stand der Technik nennen.

Im Patentwesen gibt es nämlich noch einen anderen Stand der Technik, welcher in gewissen Fällen eine Rolle spielen kann. Der maßgebende Stand der Technik enthält nur Informationen, welche bis zum Anmelde- oder Prioritätstag der beurteilten Lösung der Öffentlichkeit zugänglich gemacht worden sind. Nach dem Anmelde- oder Prioritätstag entwickelt sich der Stand der Technik jedoch weiter, sodass der Stand der Technik beispielsweise im Zeitpunkt der Beurteilung einer neuen Lösung mehr Informationen beinhaltet als der für diese Lösung maßgebende Stand der Technik. Diesen sich nach dem Anmelde- oder Prioritätstag weiter entwickelnden Stand der Technik wollen wir als allgemeinen Stand der Technik nennen.

### *IX. Recherche im Stand der Technik*

Der Inhalt des maßgebenden Standes der Technik lässt sich durch eine Neuheitsrecherche mit dem Stichtag Anmelde- oder Prioritätsdatum ermitteln. Das Resultat dieser Recherche erscheint in einem Recherchenbericht. Im Recherchenbericht sind als Resultat der Recherche Dokumente des Standes der Technik genannt, welche für die Beurteilung erfinderischer Tätigkeit der betreffenden Lösung relevant sind. Alles, was in diesen Dokumenten offenbart ist, gilt für die beurteilte Lösung als bekannt. Zum Inhalt des maßgebenden Standes der

Technik, d.h. zum Inhalt der ermittelten Dokumente gehören Informationen über die Ausgestaltung von Sachen und Verfahren, welche lösungsgemäß als technische Mittel verwendbar sind, sowie Informationen über die bei solchen Sachen und Verfahren bekannten technischen Eigenschaften. Der Inhalt des jeweiligen Dokuments des Standes der Technik ist schriftlich bzw. auch bildlich festgelegt. Folglich kann man anhand des schriftlich bzw. auch bildlich festgelegten Recherchenresultats eindeutig entscheiden, ob das lösungsgemäß verwendete technische Mittel angesichts dieses Recherchenresultats bekannt war und wenn ja, ob auch die lösungsgemäß ausgenützten technischen Eigenschaften desselben bei diesem technischen Mittel gemäß dem Recherchenresultat bereits bekannt waren. Deswegen dürfen wir behaupten, dass die Prüfung erfinderischer Tätigkeit anhand der Definitionsmethode und der Entscheidung darüber von subjektiven Urteilen frei sind und dass die Grenze zum Raum der Erfindungen eindeutig, scharf und beweisbar definiert ist. „Bekannt“ bedeutet im Rahmen der Definitionsmethode soviel wie zum maßgebenden Stand der Technik gehörend.

#### *X. Das Wissen und Können des Fachmanns*

Die derzeit offiziell geltende Erfindungslehre stellt meistens auf das Wissen und das Können bzw. auf die Fähigkeiten des durchschnittlich gut ausgebildeten Fachmanns des einschlägigen Gebiets der Technik oder dgl. ab. Dies deswegen, weil es angeblich keine Erfindungen geben könnte, wenn der Fachmann auf allen Gebieten der Technik ‚alles‘ wissen und können würde. Indem die derzeit offiziell geltende Erfindungslehre das Wissen und das Können des Fachmanns gegen oben hin beschneidet, findet sie oberhalb dieses beschnittenen Wissens und Könnens des Fachmanns den Raum für die Erfindungen. Da die derzeit geltende offizielle Lehre die obere Grenze des beschnittenen Wissens und Könnens des Fachmanns jedoch nach Belieben setzen kann, wie dies vorstehend anhand der Prüfungsmethoden vom EPA beispielsweise dargelegt worden ist, ist die obere Grenze der Zone der naheliegenden Lösungen und somit auch

die Grenze zum Raum der Erfindungen gemäß der derzeit offiziell geltenden Lehre verschwommen, unscharf, unbestimmt usw.

#### *XI. Der Unterschied zum Stand der Technik*

Die Definitionsmethode kommt ohne die genannten Abstriche am Wissen und Können des Fachmanns aus. Man kann die Frage stellen, wie Erfindungen möglich sind, wenn die sonst vorgeschriebenen Abstriche am Wissen und Können des Fachmanns nicht gemacht werden? Gemäß der vorliegenden Lehre weiß bzw. kennt „man“ bzw. der Fachmann nur das ‚alles‘, was zum maßgebenden Stand der Technik gehört. Eine Lösung, wenn sie nach der Durchführung einer Neuheitsrecherche im Stand der Technik als neu gilt, beinhaltet etwas, womit sie über den maßgebenden Stand der Technik hinausgeht. Dieses „Etwas“ stellt bei der geprüften Lösung einen Unterschied<sup>1</sup> zu ihrem maßgebenden Stand der Technik dar. Dieser Unterschied wird anhand der Definition einer naheliegenden Lösung geprüft, ob er sich aus dem maßgebenden Stand der Technik in naheliegender Weise ergab oder nicht. Wenn nicht, dann beruht der Unterschied bzw. die beurteilte Lösung auf einer erfinderischen Tätigkeit, und ein Patent kann für eine solche Lösung erteilt werden. In dieser Weise sind Erfindungen möglich, auch wenn keine sonst vorgeschriebenen Abstriche am Wissen und Können des Fachmanns gemacht worden sind.

#### *XII. Das Schlusswort*

Dies ist die Lösung des seit mehr als hundert Jahren bestehenden Rätsels betreffend die Lage und den genauen Verlauf der Grenze zwischen den Erfindungen und den naheliegenden und daher nicht patentwürdigen Lösungen. Die interessierte Öffentlichkeit sollte vom EPA verlangen, dass das EPA die erfinderische Tätigkeit der Lösungen anhand dieser einfachen und leicht verständlichen Methode prüft. Nach Ansicht des Verfassers dieses Beitrags hat die interessierte Öffentlichkeit das Recht darauf zu verstehen, warum das EPA bestimmte Lösungen für Erfindungen hält und andere nicht.

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- Der Kurs versteht sich als letzte Etappe vor der Eignungsprüfung und als Ergänzung zu eigentlichen Ausbildungskursen
- Die Lehrfunktion des Kurses beschränkt sich demgemäss auf das Durcharbeiten konkret gestellter Prüfungsaufgaben der Teile A bis D und die Instruktion der Prüfungstechnik durch erfahrene und beim EPA zugelassene Vertreter
- Die Aufgaben werden nach Wunsch auf deutsch, englisch oder französisch gestellt und können auch in der entsprechenden Sprache bearbeitet werden
- Die Bewertung erfolgt anonym anhand der bei der Eignungsprüfung angewandten Kriterien
- Der Kurs ist aus drei zeitlich getrennten Modulen aufgebaut, die auch einzeln belegt werden können und je die Teile A bis D der Europäischen Eignungsprüfung enthalten (Teilprüfungskandidaten können auch nur die Teile A/B oder C/D belegen, wobei die entsprechende Kursgebühr auf die Hälfte reduziert wird)

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- **Anmeldeschluss:** **01.09.2006**
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