epi Information

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Institute of Professional Representatives before the European Patent Office

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Editorial

T. Johnson (GB)

There is a popular radio programme in the U.K. called „Just a Minute". Four panellists are asked in turn by a Chairman to speak for one minute on a topic (previously unknown) given them by the Chairman. Each contestant has to speak with relevance to the topic and *inter alia* without hesitation, or repetition. If the speaking contestant errs, the other contestants can interrupt. Points are awarded for valid interruptions and for being the speaker at the end of the minute allotted to the topic.

The programme is a comedy programme perhaps peculiar to the so_called British sense of humor.

„What?" dear reader, you may say, has this to do with the EPC?

My answer is „Minutes" those reports issued according to Rule 124EPC by a Board following Oral Proceedings, and which are provided to the party(ies) to the proceedings.

As someone who has written Minutes of countless meetings, I know that their production can be a thankless task, and I venture none more so than following Oral Proceedings, where often track has to be kept of countless Requests.

But are we alone thinking that, since the Written Decision is also issued and that this is invariably detailed yet germane to the proceedings in question, Minutes are superfluous, not to say in some cases irrelevant. In our experience, they seem to be getting shorter, and without meaningful input. We know of one case where the Minutes of a 10-hour Oral Proceeding were just ten lines long, – one line per hour!

Should the Minute be up?

On a different note we take a minute to welcome Mr. Benoît Battistelli who has been appointed the next Chairman of the Administrative Council. We wish him well for his three year term starting on 5th March, 2009. At the same time, we also wish the outgoing Chairman, Mr. Roland Grossenbacher, every good wish for the future.

Nächster Redaktionsschluss 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 **11. Mai 2009**. Die Dokumente, die veröffentlicht werden sollen, müssen bis zum diesem Datum im Sekretariat eingegangen sein.

Die Ausgabe 2-2009 wird auf der *epi* Website ab Ende Juni 2009 on-line verfügbar sein. Bitte beachten Sie, dass Sie das Heft Mitte Juli 2009 erhalten werden.

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 **11 May 2009**. Documents for publication should have reached the Secretariat by this date.

Issue 2-2009 will be available on-line on the *epi* website by the end of June 2009. Kindly note that your personal copy will reach you by mid-Juli 2009.

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 **11 mai 2009**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

L'édition 2-2009 sera disponible en ligne sur le site de l'*epi* à la fin de du mois de juin 2009. Merci de noter que vous recevrez votre numéro mi-juillet 2009.

Report of the Disciplinary Committee

P. Rosenich (LI)

Chairman

1. epi Disciplinary Committee Fixed Chambers

As from October 2005 the Chambers were:

Chamber Kinsella	GB
Chamber Monain	FR
Chamber Katschinka	DE
Chamber Fröhling	GB
Chamber Norgaard	GB
Chamber Rosenich	GB, DE

As from October 2008 the Chambers are:

Chamber Kinsella	GB
Chamber Monain	FR
Chamber Markó	DE
Chamber Fröhling	GB
Chamber Norgaard	GB
Chamber Rosenich	DE,GB
Chamber Gil Vega	GB
Chamber Pop	FR

A second French speaking Chamber (Chamber Pop) was installed immediately after the elections for the Disciplinary Committee.

A further English speaking Chamber (Chamber Gil-Vega) was installed in order to cope with the increasing number of complaints.

As the Chambers have been now increased to 8 (from 6) and some Countries have still not nominated a representative for our Committee, some of the Chambers do not have a Substitute member. So far, this has luckily not resulted in either administration problems, or problems regarding the function of these Chambers.

It is problematic, however, when Members of our Committee and Chambers respectively are moved to other bodies, like to the Disciplinary Board, and no fresh members (as replacements) are available to substitute for these leaving members.

2. Meeting of Disciplinary Committee

As mentioned above, it is problematic when the substitution of members takes time to finalise. In one case an important member of our Chamber and Committee will leave his function by 1st January 2009 because he will be delegated to the Disciplinary Board. Hopefully the coming Council meeting will allow election of a new member for the respective country of said Member. However, as new members can be elected only by Council, this means that the new incoming member will not be able not participate in our annual DC-meeting (which takes place just before the Council meeting). These meetings are especially useful for new members in order to get as quickly as possible into their functions as full members of our Chambers.

For that reason Council was asked, if it could approve a „preliminary participation" of a proposed new Member at a DC-meeting.

Of course such „preliminary participation" would only work if there is only one candidate from the respective country available (or nominated).

If Council decided not in the negative and DC found that such invitations are possible at the discretion of the Chairman of DC.

3. Meeting of Disciplinary Committee – for Information only

The DC discussed a number of topics in its meeting and reported the outcome of these discussions directly at the Council.

Mr. Katschinka as a very long standing retired member and, as a Chairman of a DC's Chamber, was invited to participate in the DC-Meeting to report about his experiences. However it appears that he could not attend, as he was still on holiday at the date of our meeting.

4. New Chairman of the Disciplinary Board

The Chairman of the DC met the new Chairman of the Disciplinary Board, Mr. Hans-Christian Haugg of EPO. Further amendments of our Regulations have been declared possible and it was agreed that both Chairmen will consult on this issue.

It was also briefly mentioned that EPO have seen, in the past, only a very few cases of problematic reactions or behaviour of representatives during oral proceedings. The Chairman of DC offered that the DC could look into this matter to see whether we are able to receive complaints from the EPO.

5. New cases in 2008 – Call for Action of Council and Board

The DC faces a significant increase in the number of cases before its Chambers (more than 10, as of October 2008). This is a further reason why the epi Council and Board should allow any and all measures possible to assist the DC in recruiting the full possible number of Members (namely one Member from every EPC State)

6. Delivery of a Decision of a Chamber of the Disciplinary Committee

In one case the decision of one of the Chambers of this Committee was returned as not deliverable. As of today it is not clear whether this is a procedural trick of the defendant or just a postal problem. Hopefully the Chairman of DC can report more fully at the next Council meeting. In the meantime DC decided that in such cases the local members of DC in the respective countries should intervene as a first measure.

7. Next Meeting of Disciplinary Committee

Depending on the requested decision under Section 2 above, the next DC-meeting is planned for autumn 2009. Council found it not necessary that the DC meeting is connected timely to the Council, and Council accepted that further training in Mediation for the members, especially for fresh members, should be organized.

8. Elections within DC

DC reelected its present Officers.

epi Tutorials 2009

PQC (Professional Qualifying Committee of the *epi*) developed last year a new approach for the *epi* Tutorials based on the past 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 disseminate this knowledge a tutors meeting is scheduled in the summer. Those tutors who have attended the ‚Tutors Meeting' 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 *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 3 to 5 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 6 July for the summer tutorial, and by 7 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 2007 and 2008 papers will be considered. The papers can be downloaded from the EPO website *http://www.epo.org/patents/learning/qualifying-examination/training.html*

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 on the number of candidates. The candidates provide their own travel expenses as well as the travel expenses of their tutors. All candidates and tutors will be requested to fill out an evaluation form.

Candidates will be informed by their tutors about the time and place of the meeting.

Summer tutorial	Sending drafts to tutors by 17 August 2009
Autumn tutorial	Sending drafts to tutors by 16 October 2009

Fees for the tutorial:
180,00 € per paper for non-*epi* students
90,00 € per paper for *epi* students

For candidates who do not need a copy of the papers from the *epi* Secretariat, the fees are:
150,00 € per paper for non-*epi* students
75,00 € per paper for *epi* students

The registration form can be downloaded from the *epi* website *info@patentepi.com*
http://216.92.57.242/patentepi/english/300/320/

For further information, please contact the *epi* Secretariat Tel.: +49 89 242052-0

Next Board and Council Meetings

Board Meetings

79th Board meeting on 25 April 2009 in Toulouse (FR)
80th Board meeting on 12 September 2009 in Ljubljana (SI)
81st Board meeting on 28 November 2009 in Munich (DE)

Council Meetings

66th Council meeting on 23 May 2009 in Luxembourg (LU)
67th Council meeting on 10 October 2009 in Düsseldorf (DE)

Update of the European Patent Attorneys database

For the attention of all *epi* members

Kindly note the following contact data of the Legal Division of the EPO:

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Please send any change of contact details to the European Patent Office so that the list of professional representatives can be kept up to date. Be aware that the list of professional representatives, kept by the EPO, is the list used by the *epi*. Therefore, to make sure that *epi* mailings as well as e-mail correspondence reach you at the correct address, please inform the EPO Directorate 5.2.4 of any change in your contact details.

Thank you for your cooperation.

LIST OF PROFESSIONAL REPRESENTATIVES AS OF 31.12.2008

by their place of business or employment in the Contracting States

No.	Contr. State	Total Repr.	% of Tot/Repr.
1	AT	116	1,24
2	BE	155	1,66
3	BG	78	0,83
4	CH	403	4,31
5	CY	13	0,14
6	CZ	112	1,20
7	DE	3118	33,33
8	DK	173	1,85
9	EE	29	0,31
10	ES	162	1,73
11	FI	153	1,64
12	FR	827	8,84
13	GB	1827	19,53
14	GR	29	0,31
15	HR	27	0,29
16	HU	112	1,20
17	IE	55	0,59
18	IS	22	0,24
19	IT	367	3,92
20	LI	11	0,12
21	LT	32	0,34
22	LU	19	0,20
23	LV	21	0,22
24	MC	2	0,02
25	MT	8	0,09
26	NL	399	4,26
27	NO	102	1,09
28	PL	381	4,07
29	PT	46	0,49
30	RO	80	0,86
31	SE	302	3,23
32	SI	31	0,33
33	SK	40	0,43
34	TR	104	1,11
	Total	9356	100,00

Problems arising from Rule 164 EPC

E. A. Kennington[1] (GB)

Rule 164 EPC (relating to regional processing of PCT applications) reads as follows:

Rule 164

Consideration of unity by the European Patent Office

(1) Where the European Patent Office considers that the application documents which are to serve as the basis for the supplementary search do not meet the requirements of unity of invention, a supplementary search report shall be drawn up on those parts of the application which relate to the invention, or the group of inventions within the meaning of Article 82, first mentioned in the claims.

(2) Where the examining division finds that the application documents on which the European grant procedure is to be based do not meet the requirements of unity of invention, or protection is sought for an invention not covered by the international search report or, as the case may be, by the supplementary search report, it shall invite the applicant to limit the application to one invention covered by the international search report or the supplementary search report.

This has the effect of putting the applicant for any PCT application that does not have the EPO as the International Searching Authority at a significant procedural disadvantage compared with applicants for an EP-direct application or for a PCT application for which the EPO is the ISA, in the case that the EPO concludes that the claims lack unity. This is most easily seen by considering the following hypothetical example.

Hypothetical Example

Imagine four patent applications, all identical and all filed on the same day:

Application 1 is filed as a European Patent Application;
Application 2 is filed as a PCT application with the EPO as International Searching Authority;
Application 3 is filed as a PCT application with the Austrian Patent Office as International Searching Authority;
Application 4 is filed as a PCT application with the USPTO as International Searching Authority.

The applications each have independent claims 1, 2 and 3, such that the EPO and the Austrian patent office raise objections of lack of unity but the USPTO does not. The effect of Rule 164 EPC means that different applications will be treated differently and the applicant will have more favourable options for amendment at the EPO in some cases than in others. The procedural treatment of the various applications is as follows:

Application 1 (Euro-direct)

When the Euro-direct application is searched, the EPO issues a partial search report and sets a deadline for the payment of additional search fees, in accordance with Rule 64 EPC. In the present hypothetical case, the applicant pays all additional search fees within the period, and all claims are searched. Consequently, a European Search Report is issued covering all claims. Additionally, in accordance with Guidelines B-XII, 6, item (iii), the search opinion covers all the inventions claimed.

In due course the applicant must amend the claims to overcome the objection of lack of unity. Since the European Search Report covers all claims, Rule 137(4) EPC (old Rule 86(4) EPC) permits the applicant to limit the application to any of claims 1, 2 and 3. If it has become clear in the meantime that claim 1 has no commercial value and that claim 2 is commercially important, the applicant can simply delete that claim (and claim 3 if necessary) and direct the application to claim 2.

Application 2 (Euro-PCT – ISA is EPO)

Since the EPO is the ISA for this application, an objection of lack of unity is raised in the International phase. In accordance with Rule 40 PCT, the applicant is given an opportunity to pay additional search fees. In the present hypothetical case, the applicant pays all additional search fees, and all claims are searched. Consequently, an International Search Report is issued covering all claims. Additionally, the accompanying written opinion covers all the inventions claimed (PCT Guidelines for Search and Examination, 17.59).

When the PCT application enters regional processing at the EPO, the EPO does not carry out a supplementary search, since it was itself the ISA. Inevitably it upholds the unity objection and the Euro-PCT application needs to be amended to overcome this. Since the International Search Report covers all claims and there is no supplementary search report, Rule 164(2) EPC permits the applicant to limit the application to any of claims 1, 2 and 3. If it has become clear that claim 1 has no commercial value and that claim 2 is commercially important, the applicant can simply delete claim 1 (and claim 3 if necessary) and direct the application to claim 2.

Application 3 (Euro-PCT – ISA is Austrian patent office)

The Austrian Patent Office is the ISA for this application, and like the EPO it raises an objection of lack of unity in the International Phase. In accordance with Rule 40 PCT, the applicant is given an opportunity to pay additional search fees. In the present hypothetical case, the appli-

1 E. A. Kennington, European Patent Attorney (Scott & York Intellectual Property). This article represents the personal view of the author only.

cant pays all additional search fees, and all claims are searched. Consequently, an International Search Report is issued covering all claims. Additionally, the accompanying written opinion covers all the inventions claimed (PCT Guidelines for Search and Examination, 17.59).

When the PCT application enters regional processing at the EPO, the EPO carries out a supplementary search. Inevitably, it also considers that there is a lack of unity. In accordance with Rule 164(1) EPC, it does not issue an invitation to pay additional search fees, but simply restricts the supplementary search report to the first invention mentioned in the claims (in this case, claim 1). In due course, the Euro-PCT application must to be amended to overcome this. Since the supplementary search report only covers the invention of claim 1, Rule 164(2) EPC requires the applicant to limit the application to this invention regardless of the fact that the International Search Report covers all claims. If it has become clear that claim 1 has no commercial value and that claim 2 is commercially important, the applicant cannot direct the application to claim 2. Claim 2 can only be protected by filing a divisional application, at the additional cost of several thousand Euro (probably over €3000 in extra official fees alone, before adding any professional charges) and a delay of several years. In the meantime, the applicant is left with the original Euro-PCT application, which is now redundant and useless since it can only be directed to commercially valueless claim 1. This is in spite of the fact that the applicant paid all additional search fees when given the opportunity, and the International Search Report covers all claims.

Application 4 (Euro-PCT – ISA is USPTO)

The United States Patent & Trademark Office is the ISA for this application. Unlike the EPO and the Austrian Patent Office, it does not raise an objection of lack of unity in the International Phase. Therefore there is no invitation to pay additional search fees and an International Search Report is issued covering all claims. Additionally, the accompanying written opinion covers all the inventions claimed (PCT Guidelines for Search and Examination, 17.59).

When the PCT application enters regional processing at the EPO, the EPO carries out a supplementary search. It considers that there is a lack of unity. In accordance with Rule 164(1) EPC, it does not issue an invitation to pay additional search fees, but simply restricts the supplementary search report to the first invention mentioned in the claims (in this case, claim 1). In due course, the Euro-PCT application must be amended to overcome this. Since the supplementary search report only covers the invention of claim 1, Rule 164(2) EPC requires the applicant to limit the application to this invention regardless of the fact that the International Search Report covers all claims. If it has become clear that claim 1 has no commercial value and that claim 2 is commercially important, the applicant cannot direct the application to claim 2. Claim 2 can only be protected by filing a divisional application, at the additional cost of several thousand Euro (probably over €3000 in extra official fees alone, before adding any professional charges) and a delay of several years. In the mean time, the applicant is left with the original Euro-PCT application, which is now redundant and useless since it can only be directed to commercially valueless claim 1. This is in spite of the fact that the International Search Report covers all claims and the applicant was never given an opportunity to pay any additional search fees.

Effects of Rule 164(2) in the Hypothetical Example

Rule 164(2) EPC allows the applicants for applications 1 and 2 (Euro-direct and Euro-PCT – ISA is EP) complete freedom to select any of the claimed inventions for further prosecution. However, if there is a supplementary search, Rule 164(1) prevents the applicant from getting the supplementary search to cover the second and subsequent inventions by paying additional search fees. This means that Rule 164(2) denies the applicants for applications 3 and 4 (Euro-PCT – ISA is AT, and Euro-PCT – ISA is US) the freedom to select whichever of the claimed inventions they wish for further prosecution. Thus, if it is realised at a late stage that the invention of claim 1 is not commercially the most valuable, the applicants for applications 1 and 2 can switch to one of the other independent claims while continuing with the same application, but under the same circumstances the applicants for applications 3 and 4 have to file a divisional application at an additional cost of several thousand Euro and a delay of several years. This provides the applicants for applications 1 and 2 with a significant procedural advantage over the applicants for applications 3 and 4. In this respect, the EPO is penalising some applicants for using the PCT route instead of the Euro-direct route. Additionally, it is treating some PCT applicants more favourably than others, on the basis of which office acts as ISA.

This consequence of the rule has been widely recognised in the European Patent Attorney profession. Several firms have recommended that all PCT applications should be reviewed as a matter of course before entry to EP regional phase, and should be amended if necessary under Rule 161 EPC to ensure that the commercially most valuable independent claim is presented as claim 1 (and, in case of ex post facto lack of unity, the most commercially important dependent claim is presented as claim 2). This policy helps to some extent, but it inevitably increases the complexity and cost to applicants at the stage of regional phase entry. Furthermore, the existence of a strategy to ameliorate discriminatory treatment is not the same as the removal of the discriminatory treatment, and the provision remains a pitfall for the unwary. In any case, if the relative commercial value of the different claims is only appreciated after entry into the EPO regional phase, an applicant for a Euro-PCT application where the ISA is the EPO (application 2 in the hypothetical example above) is still in a better position than PCT applicants with any other ISA.

A further problem, which has actually occurred in our office, arises from the application of Rule 164(2) to

Euro-PCT applications pending at the time when EPC 2000 came into force. In some cases, such applications entered EPO regional processing before Rule 164 was published, but the supplementary search was not carried out until after Rule 164 came into force. As a result, the deadline for amending the claims on entry into regional processing passed before anyone knew that the option of requesting further searches in the case of lack of unity (under old Rule 112) would be withdrawn. A finding of lack of unity in the supplementary search report has now left the applicant unable to direct the application to the claims of its choice, but at the time when action could have been taken to avoid this result, by putting the most commercially important claims first, no-one knew that there was any purpose in making such an amendment.

Background and History of Rule 164 EPC

Current Rule 164 replaces previous Rule 112, which originated as Rule 104b (which entered into force on 1 Feb 1978, i. e. before the first EPO or PCT application had been filed). There does not seem to have been any long-standing intention to change this rule, since Rule 164 was introduced at a late stage in the preparations for implementing EPC 2000, apparently with very little prior discussion or scrutiny.

In preparation for the coming into force of EPC 2000, draft rules were put out for consultation in June 2002. Following revisions, the rules were adopted by a decision of the Administrative Council of the EPO on 12 December 2002 (CA/D 14/02, published in Special Edition No. 1 of OJEPO 2003). At that stage, nothing corresponding to current Rule 164 was proposed. The 2002 adopted rules retained previous Rule 112 with only editorial amendments.

The new rule was first put forward in a set of proposed revisions to the 2002 rules, made in August 2006 (CA/PL 17/06), which also introduced the new rule numbers for the first time. It appears that the EPO considered the change from old rule 112 to new rule 164 to be non-controversial. Its comments on the proposed changes were as follows:

1. *Many practical problems have arisen within the framework of current Rule 112 EPC. The rule does not address all possible scenarios, e.g. not the situation where non-unity is only introduced by amendments filed on entry into the European phase. Also the case where after amendment on entry into the European phase the application is unitary, but nevertheless relates to an invention not searched, is not covered. Especially in the situation where there is no supplementary search and Rule 112 has to be applied by the examining division, there is no straightforward procedure. Applicants consider a Rule 112 communication as a first communication by the examining division and respond by e.g. contesting the findings or filing further amendments. This causes considerable delays.*
2. *The EPO believes that the principle should be that examination should only be carried out on inventions covered either by the international search report or by the supplementary search report, in line with G 2/92 (OJ EPO 1993, 591). Under the proposal, the procedure will be simplified and the opportunity to have multiple inventions searched within the framework of one application will be limited to the international phase. On entry into the European phase, non-unitary subject matter should be deleted.*
3. *The proposal does not involve any loss of rights for the applicant. The result is just that the applicant will have to use the appropriate way of having any further inventions searched and examined by filing divisional applications. This will bring the Euro-PCT procedure in line with the Euro-direct procedure.*

The 2006 proposals were not put out for public consultation. The amendments to the rules (amongst other matters) were debated in two meetings of the Committee on Patent Law on 19 to 21 September 2006 and on 2 November 2006. It appears from the minutes of those meetings (CA/PL PV30 and CA/PL PV31) that proposed Rule 164, and its changes from old Rule 112, were not discussed at all in those meetings. Comments from *epi* on the amendments to the rules were submitted in October 2006, but these focussed on other matters and did not mention new Rule 164. The final version of the rules (i. e. the rules now in force) were adopted by a decision of the Administrative council of the EPO on 7 December 2006

(The documents discussed in this section can be found on the EPO's website, in the legal texts section, under „documentation on the EPC revision 2000", page relating to Implementing Regulations, web address: http://www.epo.org/patents/law/legal-texts/epc2000/regulations.html.)

Discussion

The discrimination against Euro-PCT applicants whose International Searching Authority is not the EPO, depriving them of any opportunity to obtain the flexibility in choice of amendments during prosecution that can be obtained by those whose ISA is the EPO and by Euro-direct applicants, seems unfair and arbitrary. The applicants for applications 3 (Euro-PCT – ISA is AT) and 4 (Euro-PCT – ISA is US) in the Hypothetical Example above did not voluntarily abandon the right to prosecute any of the claims in their applications by choosing not to pay search fees when they were given the opportunity. They either paid the fees when given the opportunity (application 3) or were never given the opportunity (application 4).

In this respect, the situation is different from that in Enlarged Board of Appeal decision G02/92, mentioned in the EPO's comments. That decision was concerned solely with the situation where an applicant elected not to pay an additional search fee when given the opportunity. It is inherent in that decision that, when non-unity

is found, that applicant is given an opportunity to pay an additional fee and that such a fee would preserve the right to direct the application to any invention for which as fee had been paid. The fifth paragraph of part 2 of the Reasons for the Decision in G02/92 concludes *„Thus the payment by the applicant of further search fees in response to an invitation by the Search Division under Rule 46(1) EPC does not prejudice the applicant in any way. It simply gives him maximum subsequent flexibility in seeking protection for any or all of the further inventions to which his original application relates, in the light of the results of the search report."* It is precisely this flexibility that Rule 164 EPC denies to many PCT applicants.

The comments made by the EPO, at the time of first proposing the change from old Rule 112 to new Rule 164 in 2006, seem to be muddled when it comes to the effect of the rule change. In paragraph 3 of the comments (quoted above), both the first and the last sentences are wrong.

With respect to the last sentence of paragraph 3, the change does not bring the Euro-PCT procedure into line with the Euro-direct procedure but, on the contrary, makes the procedures less similar than they were previously. Although there were anomalies under the old system (in particular, old Rule 112 only applied in the case that a lack of unity objection in the International phase was followed by a failure to pay additional search fees), there were at least some circumstances in which such a PCT applicant could pay additional search fees to the EPO and preserve the right to choose any of the claimed inventions for further prosecution. It is now impossible for a PCT applicant whose ISA is not the EPO to obtain the procedural flexibility that is available to a direct EPO applicant. Thus effect of the change is the opposite of what was stated.

The first sentence of paragraph 3 is contradicted by the second sentence. The EPO's comments state that there is no loss of rights and then go on to say that the result is that the applicant will have to file a divisional application. Presumably, the comments were intended to mean that there is no loss of *substantive* rights. The EPO apparently did not consider the loss of procedural rights to be significant. However, procedural rights can be very important to applicants. It costs thousands of Euro to file a divisional application, and it delays the application procedure by several years. This is highly significant for almost all applicants (who will object to the increase in costs even if the delay does not worry them).

It is vitally important that the EPO acknowledges the importance of procedural issues. Patents are commercial assets, and the decision to apply for a patent is at least in part based on a balancing of the anticipated commercial benefits of the patent against the cost of obtaining it. Decisions not to proceed with an application, or to abandon rights by not filing a divisional application, are often taken on grounds of cost. Under these circumstances, a procedural change that substitutes a low cost procedure with one costing thousands of Euro constitutes a significant loss of rights.

As a matter of natural justice and good administration, the removal of a simple and cheap procedure, forcing applicants to follow a complicated and expensive one, should be objectively justified. However, the behaviour of the applicants for applications 3 and 4 in the Hypothetical Example above has given no justification for the loss of rights, unlike the case considered in decision G02/92. As noted above, they have not voluntarily abandoned the right to claim any of the originally-claimed inventions in the Euro-PCT application. They have either paid all fees when given the opportunity or have not been given the opportunity to pay the fees. Furthermore, many PCT applicants have no choice of ISA, so that it cannot be said that they voluntarily put themselves in this situation by choosing an ISA other than the EPO.

The EPO might argue that there is an objective justification for the refusal to allow the applicants for applications 3 and 4 to select any invention covered by the International Search Report, on the grounds that the EPO is only prepared to base its examination on a search report that the EPO itself drew up. However, this argument would fail on two points.

First, the old procedure of allowing Euro-PCT applicants to pay additional search fees had precisely the effect that the EPO did draw up a search report for the claims concerned. Any desire of the EPO only to rely on such a search report cannot justify the change embodied in Rule 164(1), which prevents such search reports from being drawn up for second and subsequent inventions.

Second, any insistence on a search report drawn up by the EPO is itself arbitrary and without an objective justification. The EPO used to accept search reports drawn up by various other Patent Offices. For applications filed before 1 July 2005, the EPO was prepared to rely on international search reports drawn up by the Austrian, Swedish and Spanish Patent Offices. In the case of the Austrian Patent Office, this arrangement dated back to a Decision of Administrative Council of 17 May 1979 (published in 1979 OJEPO, p 248). The arrangement was ended by a Decision of Administrative Council of 10 June 2005 (published at 2005 OJEPO, p422), as part of the changes arising from the introduction of Extended European Search Reports, i.e. search reports accompanied by a search opinion (draft official letter). For the first time, a supplementary search report would be drawn up even in the case of PCT applications searched by the Austrian, Swedish or Spanish Patent Offices. There was no suggestion that the EPO had come to find the quality of the searches performed by those offices to be inadequate, and the objective of this change appears to have been solely to provide a mechanism by which a search opinion could be provided by the EPO for all Euro-PCT cases where the EPO had not issued a corresponding opinion with the international search report. Thus, in the Hypothetical Example above the existence of a supplementary search report in the case of applicant 3 (ISA is Austrian Patent Office), pre-

venting reliance on the international search report, arises from considerations that are irrelevant to the quality of the international search report and which do not justify the refusal of the EPO to rely on this search report.

The only objective problem identified by the EPO is the specific situation where the ISA is the EPO (so that there is no supplementary search) and the application is amended on entry to the EPO regional phase to be directed to an invention not searched in the international phase. In this case the EPO is faced with unsearched claims and there is no procedure for getting those claims searched. This specific situation could be dealt with by an appropriate specific rule which does not impact adversely on PCT applicants whose ISA is not the EPO. It may be noted that in fact the present wording of Rule 164 has the surprising consequence that a Euro-PCT applicant whose ISA was the EPO now cannot amend the claims at entry to the EPO regional phase, so as to be directed to an invention not covered by the international search report, whereas any other Euro-PCT applicant can do so.

Consequently, there appears to be no objective rationale for treating some Euro-PCT applicants worse than Euro-direct applicants, and no objective reason why the EPO could not either rely on the international search report or alternatively provide an opportunity for an additional searching if a lack of unity is identified at the stage of the supplementary search report.

This situation, in which Rule 164 EPC puts some Euro-PCT applicants at a practical disadvantage compared with Euro-direct applicants, appears to go against the spirit of the PCT, which was intended to give applicants all the benefits of a regular national filing. However, it is perhaps not contrary to the actual provisions of the PCT, although it might be argued that there is a conflict with Article 11(3) PCT (PCT application shall have the effect of a regular national application) or Article 28(2) PCT (setting restrictions the scope of permitted amendments during national processing). Article 11(3) PCT is reflected in Article 153(2) EPC. Thus, if there was found to be a conflict with Article 11 (3) PCT, this would imply that Rule 164 is contrary to the EPC, and therefore *ultra vires*.

According to „epi Information" 2/2008, page 57, the European Patent Practice Committee of *epi* has proposed that Rule 164 should be amended to allow an additional search in the case that the claims were considered by the ISA to have unity of invention but the EPO finds lack of unity of invention. This would be useful but would not go far enough. Such a change, if adopted by the EPO, would deal with cases such as application 4 above (ISA is the USPTO), but would not deal with cases such as application 3 (ISA is the Austrian Patent Office). There seems to be no reason for considering a PCT applicant who paid all additional search fees to be less deserving. It would be better to allow all Euro-PCT applicants the opportunity to pay additional search fees

Conclusion and Recommendation

In conclusion, Rule 164 EPC is discriminatory and arbitrary in its effects and should be rewritten. It should either permit all Euro-PCT applicants to amend their claims on entry to the EPO regional phase so as to claim an invention outside the scope of the international search report, and have those amended claims searched, or it should prevent all Euro-PCT applicants from doing this. It should not, as at present, permit this if the ISA was not the EPO but prevent it if the ISA was the EPO. The rule should allow all Euro-PCT applicants the opportunity to select second and subsequent inventions for further prosecution, and not just those whose ISA was the EPO as at present, or at least it should deny this opportunity only in respect of claims not covered by the international search report owing to a voluntary decision not to pay additional search fees during the international phase. This could be done either by providing a mechanism for additional supplementary searching or by recognising the international search report. Such a rule would avoid the problems stated to occur with old Rule 112 while treating all applicants before the EPO fairly and equally.

The WARF Decision – There is more to an invention than its claims
G 02/06 – EBA Decision of 25 November 2008

S. J Mitchell[1] and G. W Schlich[2]

Summary

The WARF decision is out: the Enlarged Board of Appeal (EBA) has held that the invention required, at the time of the filing, destruction of an embryo. Whatever the claims covered, this inevitable embryo destruction meant the application had to be refused.

The Wisconsin Alumni Research Foundation (WARF) have had any hopes of obtaining European patent protection for their method for producing primate embryonic stem cells quashed. On 25 November 2008, the EBA of the European Patent Office (EPO) decided to finally reject their patent application [European patent application No. 96903512.1] on the grounds that it would be contrary to *ordre public* or morality under Article 53(a) of the European Patent Convention (EPC) to grant a patent for an invention that required the destruction of a human embryo.

WARF's application, dating from 1985, embraced claims to human embryonic stem cells *per se* and was refused at Examining Division level on the ground that it contravened Rule 28(c) EPC 2000 [previously Rule 23d(c) EPC 1973], which excludes the uses of embryos for industrial or commercial purposes from patentability. WARF appealed and in Decision T 1374/04 the Technical Board of Appeal (TBA) referred the case and, specifically, certain points of law to the EBA. The particular rule at issue echoes, and has its origins in, Article 6(2)(c) of the European Union's Biotechnology Directive [98/44/EC; 'the Directive'], prompting WARF *inter alia* to request that the referred points be further referred to the European Court of Justice (ECJ).

Whether to refer to ECJ?

The EBA was clear: this case could not be referred to the ECJ. Their decision states 'Neither the EPC nor the Implementing Regulations thereto make any provision for a referral by any instance of the EPO of questions of law to the ECJ'.

In reaching this decision, the EBA considered EC Treaty Article 234 then noted that while the EBA is a court or tribunal it is not a court or tribunal of an EU member state but of an international organisation not all of whose members are EU member states. EPC contracting states that are not EU member states cannot be presumed to have conferred jurisdiction to the ECJ. The EBA thus concluded it does not have the power to bind itself to an ECJ ruling.

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The Four Questions

The referral to the EBA was based on four questions, as recited in G 02/06, which are now discussed in turn.

Q1

Does rule 23d(c) apply to an application filed before entry into force of the rule?

Article 6(2)(c) of the Directive was implemented as Rule 28(c) EPC 2000 [previously Rule 23d(c) EPC 1973] on 1 September 1999. This raised the question of whether its specific exclusion of patents that involve the use of embryos for industrial or commercial purposes was retrospectively applicable to applications filed before this date, as was the case for the WARF application.

The EBA noted there were no transitional provisions. Hence the rule was seen as representing guidance on what is and is not patentable, with no suggestion that the rule has made unpatentable anything that was previously patentable. Specifically, there was no indication that hitherto the commercial exploitation of embryos was regarded as patentable.

In its submissions, WARF agreed, and so did the EPO President and most *amicus curiae* briefs. There seemed nothing more to say in relation to this question other than „Yes".

Q2

If the answer to questions 1 is yes, does Rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here: embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

The invention concerns primate embryonic stem cells, including human embryonic stem cell (hES) cells, which at the filing date had to be prepared from an embryo, said embryo being destroyed in the process.

Rule 28 EPC 2000 [previously Rule 23d EPC 1973] provides:

> Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
> (a) …
> (b) …
> (c) uses of human embryos for industrial or commercial purposes;
> (d) …

The question considered by the EBA was whether the invention falls within this provision. In interpreting the provision the EBA looked at the ordinary meaning to be given to the terms in context and in light of the object and purpose, including the preparatory documents of the Directive.

In the draft of 11 October 1997, the amended proposal for the Directive submitted by the Commission referred to 'methods in which human embryos are used', these methods being considered unpatentable. This was later revised on 26 February 1998 to read 'uses of human embryos for industrial or commercial purposes', which became the final text of the Directive and of Rule 28(c) EPC 2000 [previously Rule 23d(c) EPC 1973].

The straightforward reading of the words is that patenting is prohibited if a human embryo is used for industrial or commercial purposes. The EBA held this interpretation to be in line with the intention of the legislator, which was to avoid the commodification of human embryos, fulfilling the objective of the Directive to preserve human dignity.

This would appear on the surface to go against EC funding of research using human embryos. However, on page 7 of EC press release 11554/06 (Presse 215) of 24 July 2006, the Commission confirmed that it would continue to refuse to submit to the Regulatory Committee proposals for projects that necessarily involve the destruction of human embryos. The Commission also said in the same press release it would not be prevented from funding subsequent steps involving human embryonic stem cells. The Commission thus finds a distinction between funding for procedures to produce hES cells (not to be authorised) and funding for procedures that depend on the supply of hES cells from another source („OK, but don't tell us where you got 'em").

It was argued that WARF's claims do not specify a primary source of embryonic stem cells for further processing as being human embryos, which are necessarily destroyed in the process. Hence the claims do not require embryo destruction – could this enable allowance?

In its ruling, the EBA stated that the legislation refers to the whole invention not just to the claims. Before hES cell cultures are used, they have to be made and thus the teaching of the patent as a whole is relevant. The teaching of the patent requires destruction of the human embryo and this falls within the prohibition of Rule 28(c) EPC 2000.

The decision further commented that:

„To restrict the application of Rule 28(c) (formerly Rule 23d(c)) EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim."

WARF also argued that the legislative history of the rule meant that the scope of the exclusion had narrowed over time, and should be read accordingly. However, the EBA highlighted that this apparent narrowing was merely a clarification to distinguish uses referred to by Rule 28(c) EPC 2000 from others uses, for example, those that impart a benefit to the embryo. It would be hard to argue that a process that necessarily destroys an embryo could be beneficial!

WARF put forward another argument against the applicability of Rule 28(c) and attempted to define an embryo as being at least 14 days old – hES cells can be obtained from younger embryos. The EBA found this failed as there is no indication that this definition was or is a universally accepted one. In fact, some definitions, including those in UK and German Law, embrace embryos from conception onwards, including a fertilised egg.

Another line submitted by WARF was that obtaining a cell from an embryo in order to derive a stem cell line for research purposes was not an industrial or commercial act. The EBA rejected this.

The EBA held the legislators wanted to exclude inventions like the present one and in doing so have remained within the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sought to construct international rules for the protection of intellectual property. In this clear light there is no room for argument on questions such as the benefits of the invention for humanity, whether the benefits of the invention should be balanced against the prejudice to the embryo or at what point in time morality is to be judged (e.g. now or at the filing date?).

In conclusion, the answer is that the prohibition applies to the invention as a whole, not as defined in the claims, and that a patent is to be denied if carrying out the invention requires destruction of an embryo, regardless of the nature of the products obtained or claimed.

Q3

If the answer to question 1 or 2 is no does Article 53(a) EPC forbid patenting such claims?

The EBA decided that no answer was needed: the EBA had held that Rule 28(c) EPC 2000 [formerly Rule 23d(c) EPC 1973] is applicable in the present case and so it follows that Article 53(a) EPC forbids patenting of products that at the time of filing could be prepared exclusively by a method that involves the destruction of human embryos.

Q4

In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?

At the time of filing, the only methods for isolating hES cells involved the destruction of the embryo. Since then, hES cell lines have been deposited in stem cell banks and hES cells can be obtained and expanded from those deposits. In addition a technology has emerged that enables the production of cells with similar properties to hES cells (see Takahashi, K. and Yamanaka, S. Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. Cell 126:663-676, 2006). So-called induced pluripotent stem

(iPS) cells can be produced from less controversial fibroblast cells and could replace the need for the direct extraction of hES from embryos. The claims of the WARF application when taken together with iPS technology or cells from a stem cell bank enable the skilled person to fulfil the objectives of the invention without destroying a single embryo. This point was made by WARF.

In response, the EBA asserted that when assessing this rule, technical developments after the filing date cannot be taken into account. Just as an invention that is insufficiently described cannot be rescued by subsequent technical developments, neither can, in considering morality, the question of how the invention is required to be carried out. Any other conclusion would lead to legal uncertainty or be to the detriment of another who later comes up with an innocuous way of carrying out the invention. In this respect the decision emphasises a fundamental cornerstone to the patent system: the absolute nature of the content of the specification as filed.

The EBA was careful to specify that the decision is not concerned with the patentability of stem cells *per se*, merely with the patentability of inventions that inevitably require the destruction of an embryo, whether product or process inventions.

Decision

In a landmark decision, the EPO has thus finally and clearly rejected the appeal for the grant of a patent for an invention the carrying out of which necessarily (at the time of filing) destroys a human embryo. In doing so it has set clear guidelines for future cases, namely:

- there is no provision in the EPC for referral to the ECJ from decisions of the TBA or EBA;
- technical developments after the filing date cannot be taken into account when assessing whether the application falls foul of the morality provisions of the EPC;
- consideration of the invention as disclosed rather than as claimed is relevant for assessment of compliance with the EPC morality provisions;
- making a product with the intention of further research constitutes industrial exploitation of the invention; and
- the decision raises no objections to the patenting of human stem cells *per se*.

Role of the Patent Attorney

The comment of the EBA that skilful claim construction may be a dangerous thing to be guided by seems to go against the *raison d'etre* of patent attorneys, which is to find the right language to catch the desired claim scope whilst tiptoeing carefully around the prior art and complying with the requirement for a valid claim. But is there really no role for skilful claim drafting?

Consider the example of methods of diagnosis claims, which are not allowable under Article 53(a). These can be rendered allowable by the simple act of cutting out wording that includes as an essential feature of the claim that the method is carried out on the human or animal body, thus enabling valuable development of life-saving medical methods through the benefits of the patenting system.

We can, for example, compare the unallowable:

A method of diagnosis comprising

(a) extracting a tissue sample from a human body,

(b) subjecting the tissue sample to diagnosis procedure X …

with the allowable:

A method of diagnosis comprising

(a) providing a tissue sample, which has been extracted from a human body,

(b) subjecting the tissue sample to diagnosis procedure X …

Is it not clearly the case that the totality of the diagnosis process must at some stage involve taking a sample from the human or animal body, thus requiring a step carried out on the human or animal body? Under the EPO case law the invention does not, as a whole, relate to a method carried out on the human or animal body because the invention *as claimed* does not relate to a method carried out on the human or animal body. It could be argued that the diagnostic method could be carried out on tissue samples from a bank or on blood samples in long term storage, but they must have come from someone originally, mustn't they?

Deposit at the time of filing?

The decision begs the question of whether a deposit of a hES cell line under the Budapest Treaty in advance of the WARF filing would have helped – as others could have been directed to the cell line thus avoiding the need to destroy an(other) embryo to practice the invention. The answer seems to us that it might have made the key difference.

Effect of the decision on the industry

Already many observers have commentated on the impact of the decision. The consensus is growing: the law in Europe is clarified and future patent protection for methods and for human stem cells *per se* based upon cells obtained from deposited lines is relatively unaffected. If your current methodology does indeed use human embryos then make sure you include, on filing, disclosure of how to carry out the invention using cells from an acceptable source, such as a deposit.

Effect of the decision on pending applications

Given the comment that post-filed technical developments cannot be taken into account, it seems that pending applications are doomed or not dependent

upon their original disclosure. Regardless of the product or method claimed, if the only means of carrying out the invention disclosed requires embryo destruction then the invention will be refused in Europe. Claims to e.g. purified cardiac stem cells will fail if these are obtained by differentiation of hES cells obtained in turn from an embryo. But if a source of cells is included other than an embryo, such as adult or even foetal cells, the problem seems to be avoided.

Relevance to iPS cells

The decision seems to open the door to patents on cells and methods relating to iPS cells or cells obtained from iPS cells – no embryos are destroyed using this technology.

What next?

EPO examiners will have been waiting to examine cases held up by this referral and we now await the avalanche of new examination reports. We think we know what ours will say.

Invalidation proceedings as a counter-attack according to split litigation systems

A. Clerix (BE)[1]

Abstract

The present paper compares invalidation proceedings used as a defense in infringement proceedings by an alleged infringer for single track and dual track approaches. A first section provides an outline of different types of invalidation proceedings available. In the second section the single track and dual track approaches are discussed thereby evaluating their performance with respect to overall procedural efficiency in terms of cost and timing and to the quality of the judgment making process. The last section handles the interaction between single track and dual track approaches and jurisdiction in case of international legal disputes. Table 1 provides an overview of European countries in view of this comparison.

Invalidation proceedings

Invalidation proceedings relate to proceedings whereby the validity of a patent is questioned. This section discusses various types of invalidation proceedings that exist.

Invalidation proceedings can be initiated at a specialized administrative authority, i. e. a Patent Office, during a limited period after the patent has been granted by that authority typically 6 to 9 months as illustrated in figure 1b.

Known as opposition proceedings, these proceedings are initiated at the competent national or regional administrative authority. In case of a European Patent, opposition must be filed with the European Patent Office, while, when provided for by national law, an opposition against a national patent must be filed with the national Patent Office. Examples of countries providing an opposition procedure are Germany, Norway and Austria.

In those countries where the national Patent Office is only a registration office without performing a substantive examination of patentability of the patent application, no opposition procedures will be made available. Examples of such countries are Belgium, France and the Netherlands.

Invalidation proceedings can be initiated at a specialized administrative authority and/or legal authority, i. e. a court, once the patent is granted.

Known as nullity actions, certain countries only allow courts to handle these nullity actions, particular those countries where no substantive examination of a patent application is performed by a specialized administrative authority as illustrated in figure 1a. In these countries no opposition procedure exists and only a court is competent to deal with the question of validity during any moment of the lifetime of the patent. Belgium, France and the Netherlands are examples of such countries. As will be discussed in the next section, these countries are likely to apply the so-called single track approach when the questions of infringement and validity of a patent are simultaneously raised.

Other countries only allow a nullity action to be filed with a specialized administrative or legal authority. Examples of such countries are Germany (Federal Patent Court), the Czech Republic (Patent Office) and Austria (Patent Office).

As will be discussed in the next section, countries where a specialized authority decides on the validity of a patent, typically apply the dual track approach when the questions of infringement and validity of a patent are

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simultaneously raised. If these countries do have a dedicated administrative authority, i.e. a Patent Office, performing the substantive examination including the handling of oppositions as indicated above next to the authority handling nullity actions, procedural law is foreseen such that one can only start a nullity action before the nullity authority if there is no longer the possibility of filing an opposition before that dedicated administrative authority as illustrated in figure 1b. In Germany one can only approach the Federal Patent Court if no longer an opposition can be filed before the German Patent Office or before the European Patent Office.

Some countries, such as Denmark, allow invalidation proceedings to be initiated before court and/or before the Danish Patent Office. Here means are foreseen to suspend an invalidation proceeding at one authority until the other authority has a made a final decision on the question of validity.

In the previous types of invalidation proceedings the validity of a patent was questioned during a stand-alone action. Although any interested third party can start such stand-alone invalidity action, such action is typically initiated by a party wanting to weaken the patent position of the patent owner in order to, for example, prevent future infringement by that initiating partner or to reduce the business strength of the patent owner.

However, the validity of a patent will always be questioned during infringement proceedings. The alleged infringer will aim at having the patent declared invalid or at least partially revoked. The question of validity of the patent can then be raised as defense measure during the same proceedings dealing with the issue of alleged patent infringement. This is the case in Belgium, France and Italy.

Some countries don't allow the question of patent validity to be raised during the infringements proceedings itself, but require the alleged infringer to initiate a separate action with respect to the patent's validity. This separate action can be initiated before the same court, as is the case in the Netherlands and Sweden, thereby applying the single track approach. In some countries this separate action must be initiated before a specialized administrative or legal authority thereby applying the dual track approach. Examples of such countries are Germany where a court decides and Austria, where an administrative authority, i.e. the Patent Office, decides.

As various types of invalidation proceedings exist, in this paper one only focus on the invalidation proceedings initiated by an alleged infringer involved in infringement proceedings.

One has to keep in mind that different invalidation proceedings can be applied in parallel. For example when being involved in infringement proceedings, the alleged infringer can start an invalidity action for a national patent before the national legal and/or administrative authority whether or not as part of the infringement proceedings (see next section) and simultaneously file an opposition against the later filed European patent claiming priority of that national patent. Figures 1a-b below indicate the different invalidation actions as function of the lifetime of the patent.

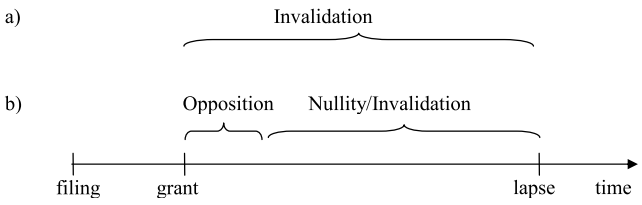

Figure 1: invalidity actions as function of a patent lifetime
a) only a court may deal with any validity issues
b) an administrative authority judges on patentability while the same (administrative) or another (legal) authority judges on validity

Infringement and invalidity: single track vs. dual track approach

In the previous section, reference was made to the so-called single track and dual track approach when raising the questions of infringement and validity of a patent. This section will explain the differences between both legal systems and (dis)advantages of each legal system.

The single track approach refers to legal systems whereby the question of validity and infringement of a patent are dealt with before the same authority as illustrated by figure 2.

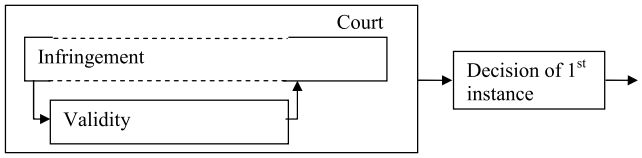

Figure 2: single track approach

As infringement issues are never dealt with by an administrative authority, only a legal authority i.e. a court will be competent to handle both questions. This authority can be a civil court or criminal court depending on whether civil and/or commercial matters or criminal matters are involved.

Depending on its competence, this legal authority may handle any civil legal matters as is the case in Belgium, may handle only civil legal matters related to intellectual property rights and/or commercial law as is the case of Spain or Portugal, or may only deal with proceedings which has as object patent matters thereby being a so-called patent court as is the case of the Netherlands and the UK. Some countries having a specialized administrative authority, i.e. a Patent Office, performing a substantive examination on patentability still opt for the single track approach, as is the case in the UK.

As discussed above the question of validity and of infringement can be initiated in the same proceeding as is the case in Belgium, or can be initiated as separate proceeding but before the same court as is the case in Sweden or the Netherlands. The single track approach doesn't prevent the alleged infringer from raising the question of validity before a specialized administrative authority. Depending on the timing and the legal provisions, he can still file an opposition with the competent national or regional administrative authority.

The dual track approach refers to legal systems whereby the question of validity and infringement of a patent must be dealt with before different authorities as illustrated by figures 3 and 4. The dual track system is also known as a split system or a bifurcated system.

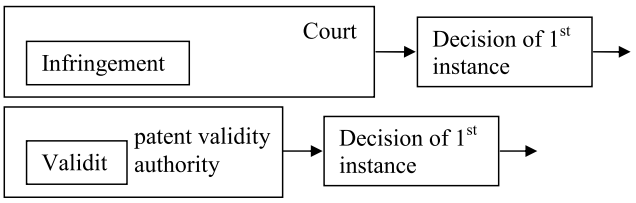

Figure 3: dual track approach with parallel proceedings

A legal authority, i.e. a court, will handle the question of patent infringement. This legal authority may handle any civil legal matters as is the case in Norway, or may only deal with matters regarding to intellectual property rights and/or commercial law as is the case in Austria.

Another authority, legal or administrative, will then decide on the validity of the patent. In Germany this patent authority is a legal authority namely the Federal Patent Court while in Austria, Bulgaria and the Czech Republic an administrative authority, i.e. the Patent Office, will judge on the validity of the patent.

Both legal systems, single track approach or dual track approach, have their strengths and weaknesses. Some of them are discussed below.

Timing

Because in a dual track approach, the questions of infringement and validity of the patent are handled before different authorities, there might be a concern regarding timing. In most dual track approaches the patent infringement authority can, e.g. Poland, or must, e.g. the Czech Republic and Hungary, await the outcome of the patent validity authority as illustrated by figure 4.

Only in Germany the patent infringement authority, i.e. one of the twelve District Courts, will typically not await the outcome of the patent validity authority, i.e. the Federal Patent Court in Munich as illustrated by figure 3. Hence in Germany the alleged infringer can loose the court case on infringement and be judged to infringe the patent, which will afterwards be declared invalid or partially revoked when the alleged infringer wins the court case on validity. This scenario is not unlikely as the German District Courts are reducing the period they need to deliver their decision on infringement to about the same period, i.e. typically 12 months, as the German Federal Patent Court needs to hand down a decision on validity. The German dual track approach is certainly in the favor of the patent owner, as the alleged infringer cannot effectively use the defence of invalidation proceedings.

In a single track approach, this timing is not an issue as the judge involved will first deal with the issue of patent validity and then decide on patent infringement. As these questions will be handled subsequently, the single track approach will take as much or even more time compared with the dual track approach, in particular compared with the German dual track approach.

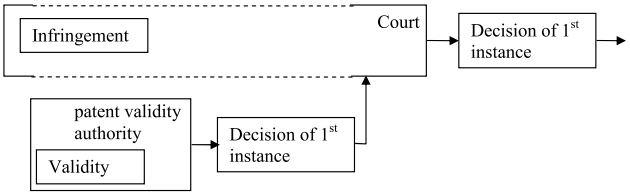

Figure 4: dual track approach with sequential proceedings

Costs

In a dual track approach, two proceedings have to be initiated, which proceedings can be running either in parallel as is the case in Germany (see figure 3), or in sequential order, e.g. as done in Austria (see figure 4). Having two proceedings may increase the legal costs compared to a single track approach as legal fees have be paid twice, two legal teams are involved and both proceedings need to be coordinated. Cost saving in a dual track approach however might be possible if the overall duration of the two proceedings is less that the duration of the single track approach. Both proceedings, infringement and validity, can be independently optimized for procedural efficiency, e.g. the technical skills of the judges of the patent validity authority can make the presence of technical experts during proceedings obsolete.

Expertise

As the patent validity authority in a dual track approach only has to deal with substantive patent law, he can acquire considerable expertise in judging on the validity of a patent compared to the single track approach. Typically technical judges will be members of the patent validity authority further increasing the expertise of the patent validity authority, which has a positive impact on the quality and the length of the invalidity proceedings.

Because in single track approaches patent cases can be dealt with before civil courts as well as before criminal courts, it is unlikely that the one court in the single track approach will be able to gain the same level of expertise on this matter compared to the patent authority in the dual track approach. An intermediate solution is to use in the single track approach specialized courts, in particular a patent court as is the case in e.g. the Netherlands, UK, such that a certain level of expertise can be built up.

Scope of Claims

Because in a dual track approach the patent validity authority will judge on the validity of all patents, a more consistent interpretation of claim scope in view of the prior art can be obtained throughout the patent system compared to the single track approach, where each civil or criminal court must interpret itself the claims of the particular patent involved. In a single track approach one tries to provide consistency in claim interpretation by appointing a limited number of courts, so-called specialized courts, even to the extent that only 1 or 2 courts are

exclusively competent for dealing with patent matters, as is the case e.g. in the Netherlands and UK.

As said above in the paragraph on timing, the final claim set used can be different when patent infringement proceedings and patent validity proceedings are running in parallel. Even if the claim set in both proceedings remains identical, the dual track approach may still lead to different views on the claim scope regarding patentability and infringement as different authorities, i.e. the patent validity authority and the patent infringement authority (court), are involved. This may result in the prior art being interpreted narrowly by the patent validity court while the claim scope may be construed broadly by the patent infringement court. As only one authority is involved in the single track approach, claims are more likely to be interpreted in a similar way when judging on patentability and when judging on infringement.

Scope of proceedings

A patent infringement case will, apart from the question of patent validity, also involve matters related to unfair competition, ownership, contractual aspects e.g. in licence deals, or may even involve other intellectual property rights such as Industrial Designs and Trademarks. In the single track approach the single legal authority involved can address these different aspects of the litigation between the patent owner and the alleged infringer. This is not possible in a dual track approach.

Conflicting decisions

As in the single track approach more then one court may be competent to judge on the validity of a patent, conflicting decisions on validity may arise if proceedings related to patent validity are initiated before different authorities. One can raise the issue of patent validity within the infringement proceedings and start in parallel a nullity action at another court. Such a situation cannot occur in a dual track approach as only one authority is competent to evaluate the patentability of the disputed patent. In single track approaches such situations can only be avoided if procedures regarding related actions (*lis pendes*) are in place.

Provisional Measures

Although in a dual track approach typically the patent infringement authority will suspend the infringement proceedings until the patent validity authority has made a decision, the patent infringement authority may still take provisional measures for safeguarding the interests of the patent owner. In a single track approach the court can take any necessary provisional

Jurisdiction

The question which legal authority is competent in a particular case is not always straightforward to answer unless contractual provisions are already in place between the disputing parties.

Within a country, procedural law has been established to help deciding the jurisdiction regarding actions occurring within the territory of that country involving its citizens or parties residing in that country. International private law, such as the Brussels I Regulation (EC No 44/2001) or the Lugano Convention, has been developed between European countries to decide where legal disputes between private parties of different nationality have to be heard and from which jurisdiction the law should be applied when deciding this legal dispute. The purpose of these national and international procedural law provisions is to avoid multiple, hence conflicting, decisions on the same matter between same parties. In the context of European patent litigation the relevant law is the international private law which will be shortly discussed below.

The main principle in these provisions is that the „claimant follows the defendant" (EC No 44/2001 Art. 2) such that it is the place of residence (domicile) of the defendant, i.e. the alleged infringer, that preferentially has jurisdiction over the infringement case. Given the broad definition of „domicile" (EC No 44/2001 Art. 60), an alleged infringing legal entity can be accorded more than one domicile such that, even for a single infringing party, the patent owner can select from several jurisdictions.

If the alleged infringers have different nationalities the claimant, i.e. the patent owner, can opt to start separate infringement proceedings against each of the alleged infringers individually in his respective place of residence. To avoid parallel court proceedings in different countries on similar subject matter (*lis pendens*), provisions are in place to make sure that only one court continues its proceedings while the other courts decline jurisdiction on this subject matter (EC No 44/2001 art 27).

Alternatively the patent owner can decide to start a single infringement proceeding against all the alleged infringers together thereby having the possibility to select the place of residence from any of the alleged infringers (EC No 44/2001 art 6§1).

If jurisdiction is established according to this principle, then infringement in different countries by an alleged infringer can be judged by the court selected.

A second principle in these provisions is that the place where the „harmful event", i.e. the infringement, took places determines which court has jurisdiction (EC No 44/2001 Art. 5§3). If infringement took places in different countries the claimant, i.e. the patent owner, can start separate infringement proceedings in each of these countries.

If jurisdiction is established according to this principle, then each national court selected can only judge on the infringement by an alleged infringer in that particular country.

Regarding infringement proceedings, these provisions provide clear guidelines on how to determine jurisdiction. However, if invalidation proceedings are initiated, things may become more complicated as another principle has to be applied known as „country of registration". In case of invalidity actions, each national court has exclusive jurisdiction over its national patents (which of course includes national counterparts of an inter-

national or regional patent application) (EC No 44/2001 art 22§4).

If the principle of „place of harmful event i.e. the infringing action on a national patent" is applied, then the local court having jurisdiction over the infringement action will also have jurisdiction over the invalidity proceedings. For the single track approach this means that the local court handles both infringement and invalidity proceedings. In the dual track approach the local court handles only the infringement proceedings and transfers the invalidity proceeding to the local patent invalidity authority.

If the principle „claimant follows the defendant" is used, then a problem may arise. The place of residence of an alleged infringer may not be within the territory where the monopoly of the infringed patent applies. It is not clear which principle; „claimant follows the defendant" or „country of registration", dominates if both infringement and invalidity are discussed.

If the court having jurisdiction over the infringement proceeding operates in a dual track approach, this court should only handle the infringement proceeding as would be the case if a national patent was be involved. The invalidity proceeding can be initiated at that national administrative or legal authority being competent for the infringed patent. Hence the principles of international private law can be applied. In GAT v. LuK (C-4/03 2006) the German District Court however felt competent to decide on the validity of a French patent, surprisingly as this court would have no jurisdiction if a German patent was at stake.

If the court having jurisdiction over the infringement proceedings operates in a single track approach, this court may feel competent to also decide on the validity of that, foreign, patent as it would be in case of infringement of a, local, patent.

However in GAT v. LuK (C-4/03 2006) the European Court of Justice found that exclusive jurisdiction on patent validity is with the courts of the country of registration when the validity of a patent is to be judged. This way the ECJ creates a dual track approach on European scale. As the authority judging on validity is located within a jurisdiction other than the court handling the infringement proceedings, there are no provisions about alignment of both proceedings; infringement and invalidity. The avocat-general of the European Court of Justice, Mr Geelhoed, suggested 3 possibilities to resolve this uncertainty: suspend the infringement proceeding, transfer the infringement proceeding and the validity proceedings to the jurisdiction competent to decide on the validity, make a decision on infringement if the alleged infringer is of bath faith, i.e. the counterclaim is without substance.

Table 1: list of countries indicating their membership of EU, EFTA and EPC.
If known, the table indicates for a given country whether infringement and validity of a patent can be dealt with before the same authority (single track) or must be dealt with before different authorities (dual track). In case of dual track approach the table indicates if infringement proceedings are suspended until a decision is made for the invalidation proceedings.
If known, the table indicates for a given country if specialized courts are designated to handle infringement cases.

Country	**EU***	**EFTA-***	**EPC**	**single or dual track**	**Location of specialized courts for infringement cases*** **
Austria			X	dual track: always suspension of infringement proceedings until APO** decides	Vienna
Belgium	X		X	single track	no
Bosnia-Herzogevina				single track	no
Bulgaria	X		X	dual track: always suspension of infringement proceedings until BPO decides	Sofia
Croatia			X	Single track	Commercial Courts *(Zagreb, Rijeka, Ozijek, Split)*
Cyprus	X		X	single track	no
Czech Republic	X		X	dual track: always suspension of infringement proceedings until CPO decides	Prague
Denmark	X		X	single track	Copenhagen
Estonia	X		X	single track	Tallinn
Finland	X		X	single track	Helsinki

France	X		X	single track	7 Tribunaux *(Bordeaux, Lille, Lyon, Marseille, Paris, Strasbourg, Toulouse)*
Germany	X		X	dual track: suspension of infringement proceedings while Federal Patent Court decides	12 District Courts *(Düsseldorf, Munich, Mannheim, Berlin, Braunschweig, Erfurt, Frankfurt, Hamburg, Leipzig Nuremberg, Magdeburg, Saarbrücken)*
Greece	X		X	single track	Athens, Thessaloniki
Hungary	X		X	dual track: always suspension of infringement proceedings until HPO decides	Budapest
Iceland		X	X	single track	Reykjavik
Ireland	X		X	single track	Dublin *(High Court, Commercial Court)*
Italy	X		X	single track	12 courts *(Bologna, Catania, Florence, Genoa, Milan, Naples, Palermo, Rome, Turin, Trieste and Venice)*
Latvia	X		X	single track	no
Liechtenstein		X	X	single track	Vaduz
Lithuania	X		X	single track	Vilnius
Luxembourg	X		X	single track	no
Norway		X	X	dual track: suspension of infringement proceedings may occur until Oslo district Court (nullity)/NPO (opposition) decides	no
Macedonia				single track	Skopje
Malta	X		X	single track	Valetta
Monaco			X	single track	Monaco (Industrial Property Tribunal)
Netherlands	X		X	single track	Den Haag (patent court)
Poland	X		X	dual track: suspension of infringement proceedings may occur until PPO office decides	no
Portugal	X		X	dual track: not clear if infringement proceedings are suspended until PPO decides	Commercial Courts
Romania	X		X	dual track: not clear if infringement proceedings are suspended until Court of Bukarest decides	no
Serbia				dual track: not clear if infringement proceedings are suspended until SPO decides	no
Slovakia	X		X	dual track: suspension of infringement proceedings may occur until SPO office decides	Bratislava, Banská Bystrica, Kosice
Slovenia	X		X	single track	no

Spain	X		X	single track	Commercial Courts (*Barcelona*)
Switzerland		X	X	single track	no
Sweden	X		X	single track	Stockholm
Turkey			X	single track	no *(unless in Ankara, Iszmir, Istanbul)*
United kingdom	X		X	single track	London *(Patents Court, Patents County Court)*

* EU and EFTA member states are bound by respectively the Brussels I regulation (EC No 44/2001 (2000)) and the Lugano Convention (1988). Both legal documents provide criteria to determine the appropriate jurisdiction in case of civil or commercial legal disputes involving parties from more than one member state. These legal documents further govern the recognition and enforcement of foreign judgments.

** *X*PO refers to the administrative authority responsible for patent matters in a given country *X*
e.g. APO refers to the Austrian Patent Office (Österreichische Patentamt)

*** This is the situation on 31/152008.
A specialized infringement court doesn't mean that this court is a patent court, i. e. only handling proceedings having as object patent matters. Most often these courts handle proceedings related to various types of Intellectual Property Rights and to commercial activities, such as unfair competition.
These specialized courts are often created when introducing the Community Trade Mark (EC No. 40/94 (1993)), whereby each EU member state had to create or designate specialized courts for proceedings concerning the Community trademark. Examples of such countries are Spain, Portugal and Greece.
If, for a given country, a number of courts can be selected, the location most renowned for patent matters is underlined.

Claim drafting for the EPC 2000

N. Fox (GB)[1]

Although the EPC 2000 was the first major revision of the European Patent Convention in over 30 years, the substantive changes to the law have been quite limited.[2] The only amendment which, on its face, would appear to have an impact on our drafting practices is new Article 54(5) EPC,[3] which expressly permits medical use claims in the form of: „Compound X for use in treating disease Y" where such treatment is not previously known. However, this paper argues that the overall effect of various innovations introduced by the EPC 2000 will have a far greater impact on our drafting and infringement practice than anyone would have expected.

EPO Excess Claims Fees

In December 2007, almost immediately after the EPC 2000 came into force, the EPO announced changes to the excess claims fees charged on European patent applications. Effective as of 1 April 2008, the EPO announced that instead of charging €45 for each claim in excess of 10, they would now charge €200 for each claim in excess of 15. The EPO also announced that from 1 April 2009, the excess claims fees for applications including more than 50 claims would further increase from € 200 for each claim in excess of 50 to €500 for each such claim.

Claims	Was	**From April 2008**	**From April 2009**
20	€ 450	€ **1,000**	€ **1,000**
30	€ 900	€ **3,000**	€ **3,000**
50	€ 1,800	€ **7,000**	€ **7,000**
75	€ 2,925	€ **12,000**	€ **19,500**
100	€ 4,050	€ **17,000**	€ **32,000**

The practical effect of the fee changes is to increase official fees on patent applications having more than 16 claims. As shown in the table above, compared with the old fees schedule, the cost of including 20 claims in an application has more than doubled. For 30 claims, costs have more than tripled. The size of the excess claims fees are now such that including more than 15 claims in any application will need to be commercially justified.

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2 For a detailed review of the EPC 2000 see *A Guide to the EPC 2000*, 2nd Edition, by Nicholas Fox, ISBN 97-8-090-393232-5, published by the Chartered Institute of Patent Attorneys, £30. Ordering information and sample pages available at: *http://www.epc2000guide.com*. Also available in French and German.

3 Article 54(5) EPC : Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

EPC 2000 to the Rescue

Fortunately, the EPO fee increases come at a time when legal reforms are reducing the importance of maintaining dependent claims in a European patent. Articles 105a–c EPC 2000 introduce a procedure for post-grant amendment for European patents. Under the new central limitation procedure, any granted European patent can be amended post-grant provided the amendments reduce the scope of the claims of the patent, are clear, are supported by the description and do not add matter.[4] Before the EPC 2000 came into effect, separate applications at the various national patent offices were required to amend a European patent post-grant. In many countries, for example in Sweden and France, such amendments were limited to restricting a patent's scope to that of a dependent claim. With the availability of central limitation at the EPO without such restrictions, it is no longer essential that all fall-back positions are included in the dependent claims at grant.

At the same time, the London Agreement has further increased the attraction of retaining fall-back positions within the description of a patent rather than including them as dependent claims. The London Agreement is an optional protocol under the EPC that is intended to reduce the amount of translation required to bring a European patent application into effect in the member states. As previously, when a European patent written in English is deemed in order for grant, an applicant must file translations of the claims into French and German with the EPO. Under the London Agreement, Germany, France, Switzerland and Liechtenstein[5] do not require any further translations to be submitted to bring the patent into effect in those countries. The patent can be brought into effect in Denmark, Sweden, Iceland, the Netherlands,[6] Lithuania[7], Slovenia and Latvia[8] by filing solely claims translations into national languages for those countries. A full translation of the description would only need to be submitted should the patent ever have to be litigated.[9] Minimising the number of dependent claims will therefore reduce the cost of translations.

Solving the Problem

Assuming that a set of claims has been drafted for filing at the USPTO, the claims should first be reviewed to identify any independent claims of essentially identical scope that effectively claim the same invention using different terminology. Such claims would face an objection by the EPO, which normally allows only a single independent claim per claim category (e.g. method, apparatus, disk claim, etc).[10]

The number of dependent claims can then be reduced without affecting scope by combining different options in a single claim, e.g. An A wherein the feature A is any one of X, Y or Z. Additionally, the number of claims can be reduced using multiple claim dependencies where appropriate. Thus, for example, a set of claims directed to a computer program on a carrier could be replaced by a single claim to a carrier carrying computer-implementable instructions that, when interpreted by a computer, cause the computer to perform a method in accordance with any of method claims 1-N.

If the total number of claims still exceeds 15, each of the dependent claims should be assessed in turn. Unless the claim, on its own, has commercial value (e.g. it forces a broader interpretation of another claim, or covers a specific commercial product, etc.), the claim language should instead be included at the end of the description together, if possible, with an indication of the advantage associated with the additional feature.[11] In this way, the feature can be reintroduced in prosecution if necessary, and the specification will include an indication as to why such a feature is advantageous and hence, might be inventive.

A Sting in the Tail

The effect of such an approach will be that in the future, granted patents will contain fewer claims. Fall-back positions of less importance may only appear in the description. Whilst this approach will benefit a patentee by reducing excess claims fees and translations costs, there is a significant downside to be considered.

When dependent claims were cheap and amendment opportunities limited, it was reasonable to suppose that the claims would identify most fall-back positions. If nothing of concern could be identified in the claims during a clearance search, then probably a patent could be dismissed as not giving rise to any infringement issues.[12] In contrast, in the future with far smaller claim sets, practitioners will have to study patent specifications in far greater detail to ensure that a potentially dangerous amendment is not lurking in the detail of the description.

4 Rule 95(2) EPC.

5 Similarly no claims translations are required in these countries when a patent application is granted in the other EPO official languages – London Agreement Article 1(1).

6 Croatia, Denmark, Iceland, the Netherlands and Sweden have all ratified the London Agreement and require a full translation of a European patent if the patent is granted in French or German. If a European patent is granted in English only the claims need to be translated.

7 Lithuania has not yet ratified the London Agreement. However, Lithuanian national law already only requires the filing of claims translations for a European patent to have effect in that country.

8 Latvia and Slovenia have ratified the London Agreement and only ever require claims to be translated into their national languages in order to have effect. This is the case regardless of the language a European patent is granted in.

9 London Agreement Article 2.

10 Rule 43(2) EPC.

11 Assessment of the commercial value of a dependent claim is an essential step as making changes to a patent post-grant can still have adverse consequences. Courts have an element of discretion as to whether remedies such as injunctions are granted and have the power to limit damages when a patent is amended after grant. Such issues are unlikely to arise when a post-grant amendment merely involves restriction of scope of a patent to that of a pre-existing dependent claim.

12 Strictly speaking this would not be the case in countries such as the UK which took a liberal approach to post-grant amendment allowing any features present in the description to be introduced into the claims post grant. Even so in general most reasonable fall back positions would find their way into the claims.

Zur Patentierbarkeit von Medizintechnik-Verfahren in Japan

S. R. Huebner[1]

Mit einer komplexen Entscheidungspraxis versucht das Europäische Patentamt bei der Patentierung medizinischer Verfahren den Spagat zwischen gesundheitspolitischen Vorgaben und Erfinderinteressen. Insbesondere bei in der Medizintechnik beeinträchtigt jedoch die Vielzahl von Überlegungen und Abwägungen, die gegenwärtig in die Beurteilung der Patentfähigkeit einfließen, die Vorhersagbarkeit der Entscheidungen. Im Gegensatz dazu gelingt es in der jüngeren japanischen Praxis, mit vergleichsweise einfachen formalen Kriterien zur Abgrenzung zwischen nicht patentierbaren medizinischen Verfahren und patentierbaren Betriebsverfahren medizinischer Geräte einen nicht unerheblichen Teil der in der Praxis auftretenden Fälle abzudecken. Allerdings verlangt dieser formalere Ansatz besondere Sorgfalt bei der Anspruchsformulierung.

Der Ausschluss medizinischer Verfahrenserfindungen in Japan

Anders als das Europäische Patentübereinkommen, das Diagnostizierverfahren sowie chirurgische und therapeutische Behandlungsverfahren ausdrücklich vom Patentschutz ausnimmt, kennt das japanische Patentrecht keine Sondervorschriften für medizinische Erfindungen. Stattdessen werden dort Einschränkungen der Patentierbarkeit auf medizinischem Gebiet aus der Erfordernis hergeleitet, dass eine Erfindung gewerblichen anwendbar sein muss. Anhand einer Analyse sowohl des japanischen Richterrechts, das sich auf dieser Grundlage entwickelt hat, als auch der europäischen und der US-Praxis wurden vor einigen Jahren Leitlinien erarbeitet, die inzwischen in die Prüfungsrichtlinien des Japanischen Patentamts Eingang gefunden haben. Das Ergebnis hat starke Parallelen zur europäischen Praxis, geht aber an wichtigen Stellen eigene Wege.

In Anlehnung an die Formulierung des Artikel 53 c) EPÜ werden „Verfahren zur chirurgischen oder therapeutischen Behandlung des menschlichen Körpers und Diagnostizierverfahren, die am menschlichen Körper vorgenommen werden" als nicht gewerblich anwendbar angesehen und von der Patentierbarkeit ausgeschlossen[2]. Für Verfahren, an denen medizinische Geräte beteiligt sind, gilt jedoch, dass sie nicht unter diesen Ausnahmetatbestand fallen und damit patentierbar sind, wenn sie lediglich die „Steuerung des Betriebs eines medizinischen Geräts" betreffen. Zwar kennt man auch in Europa eine ähnlich lautende Ausnahme von der Ausnahme des Artikel 53 c), jedoch ist deren Anwendungsbereich dadurch stark eingeschränkt, dass sie nach gängiger Praxis nur Betriebsverfahren erfasst, die in „keinerlei funktionellem Zusammenhang" mit einer vom Gerät am Körper vorgenommenen therapeutischen Wirkung stehen. So sah die Kammer zwar keinen funktionellen Zusammenhang bei einem Verfahren zur Durchflussmessung in einem Medikamentendosiergerät[3], das Betriebsverfahren eines Herzschrittmachers wurde aber als zwangsläufig nicht-patentierbares therapeutisches Behandlungsverfahren angesehen[4].

Anders in Japan: Dort ist die Grenze der Patentierbarkeit grundsätzlich erst erreicht, wenn eine von einem Arzt ausgeführte Tätigkeit oder die Wirkung des Geräts auf den menschlichen Körper unmittelbar in den Anspruch aufgenommen werden soll. Ohne Weiteres zulässig sind hingegen neben Anspruchsmerkmalen, die die internen Abläufe in dem medizinischen Gerät betreffen, auch solche, die Aktivitäten oder Funktionen des Geräts zum Gegenstand haben, einschließlich solcher, die auf den Patienten gerichtet sind. Dieser großzügigere Maßstab findet auf die üblichen Kategorien Chirurgie, Therapie und Diagnose gleichermaßen Anwendung. Nachfolgend soll dies anhand zweier Beispiele, die Verfahren im diagnostischen und im therapeutischen Bereich betreffen, genauer betrachtet werden.

Beispiel: Betriebsverfahren diagnostischer Geräte vs. Medizinische Diagnostizierverfahren

Der Stellungnahme der großen Beschwerdekammer G1/04 zufolge ist eine Erfindung nur dann als Diagnostizierverfahren anzusehen, wenn sie erfindungswesentliche Verfahrensschritte für alle Diagnosephasen umfasst, von der Datenerhebung bis zur „rein geistigen" Bestimmung einer Krankheit. Dadurch wird insbesondere erreicht, dass bildgebende Verfahren oder andere Verfahren, die lediglich die Ermittlung physiologischer Messwerte dienen, nicht unter den Patentierungsausschluss fallen. In Japan kommt man auf einem anderen Weg zu dem gleichen Ergebnis: Denn zwar gelten dort Verfahren bereits als Diagnostizierverfahren, wenn durch ein Messen der Struktur oder Funktion menschlicher Organe Daten erhoben werden, solange es „medizinischen Zwecken" dient, etwa dem Erkennen von Krankheiten oder dem Beurteilen der körperlichen Verfassung eines Patienten[5]. Dennoch sind medizinische Messverfahren im Allgemeinen auch dort patentierbar,

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2 Man beachte aber, dass die Formulierung anders als Artikel 53 c) EPÜ Tiere nicht mit einbezieht. Allerdings stellen die Richtlinien klar, dass ein am Tier auszuführendes Verfahren ebenfalls als nicht gewerblich anwendbar zu gelten hat, es sei denn, die Anwendung am Menschen wird ausdrücklich ausgenommen.

3 T 245/87, siehe auch die Kritik dazu in D.X. Thomas, „Patentability Problems in Medical Technology", IIC 2003 Heft 8 und T 426/89

4 T 426/89, siehe auch C. Heath, The Patentability of Medical Methods Under European Patent Law, Max Planck Institute for Intellectual Property, Competition and Tax Lawworking paper, 2004

5 kosmetische Zwecke werden hiervon nicht erfasst.

weil sie in die Kategorie der patentfähigen Betriebsverfahren medizinischer Geräte fallen. So geben die japanischen Prüfungsrichtlinien folgende Formulierung als Beispiel für einen zulässigen Anspruch an:

> (Zulässig) *Verfahren zum Steuern des Betriebs eines Magnetresonanztomographen, bei dem ein Steuermittel das Magnetresonanztomographen Sende- und Empfangsschaltkreise, eine Hochfrequenzspule und eine Gradientenspule steuert und das die Schritte umfasst: wiederholtes Abgeben von Impulsfolgen, während die Intensität eines Gradientenmagnetfelds in einer Phasencodierrichtung schrittweise vergrößert wird, wobei die Impulsfolge von der Hochfrequenzspule ausgesendet wird, die einen 90°-Impuls an einen Raum mit einem gleichförmigen Magnetfeld angibt, während die Gradientenspule ein Gradientenmagnetfeld in Scheibenrichtung erzeugt; Erzeugen eines Gradientenmagnetfelds vorbestimmter Stärke in Phasencodierrichtung durch die Gradientenspule; Aussenden eines 180°-Impulses durch die Hochfrequenzspule während die Gradientenspule ein Gradientenmagnetfeld in Scheibenrichtung erzeugt; und empfangen eines Magnetresonanzsignals von dem Körper eines Patienten während die Gradientenspule ein Gradientenmagnetfeld in Leserichtung erzeugt.*

Als nicht zulässig wird hingegen folgender leicht geänderter Anspruch angesehen:

> (Unzulässig) *Magnetresonanzbildgebungsverfahren mit Hilfe eines Magnetresonanztomographen, das die Schritte umfasst: Anordnen eines krebsverdächtigen Gewebes in einem Raum mit einem gleichförmigen Magnetfeld; wiederholtes Abgeben von Impulsfolgen, während die Intensität eines Gradientenmagnetfelds in einer Phasencodierrichtung schrittweise vergrößert wird, wobei beim Abgeben der Impulsfolge das Gewebe mit 90°-Impulsen bestrahlt wird und ein Gradientenmagnetfeld in Scheibenrichtung erzeugt wird; Erzeugen eines Gradientenmagnetfelds vorbestimmter Stärke in Phasencodierrichtung; Bestrahlen der Probe mit 180°-Impulsen, wobei ein Gradientenmagnetfeld in Scheibenrichtung erzeugt wird; und Messen des von dem betroffenen Gewebe ausgehenden Magnetresonanzsignals während der Erzeugung eines Gradientenmagnetfelds in Leserichtung.*

Der für die Entscheidung über die Patentierbarkeit wesentliche Unterschied zwischen diesen beiden Formulierungen liegt darin, dass der zweite Anspruch den Schritt des Anordnens der krebsverdächtigen Probe im Magnetfeld enthält. Dieser Schritt wird als eine ärztliche Tätigkeit angesehen und macht ihn dadurch zu einem nicht patentierbaren Diagnostizierverfahren. Durch Weglassen dieses Schritts wird der Anspruchsgegenstand zu einem reinen Betriebsverfahren und damit patentfähig.

Beispiel: Betriebsverfahren von Therapiegräten vs. therapeutische Behandlungsverfahren

Zu therapeutische Behandlungsverfahren zählen, ähnlich wie in Europa, sowohl Verfahren, bei denen durch physikalische Behandlung oder Medikamentengabe eine Krankheit behandelt wird, als auch gesundheitserhaltende und präventive Maßnahmen. Kommt bei der Therapie ein medizinisches Gerät zum Einsatz, gelten wiederum dieselben Grundsätze wie zuvor. Ein Anspruch, der ein Wirken auf den menschlichen Körper als Merkmal enthält ist unzulässig:

> (Unzulässig) *Verfahren zur elektrischen Stimulation mit einem Herzschrittmacher, bei dem durch ein Steuermittel des Herzschrittmachers gesteuert die Schritte ausgeführt werden: Vergleichen einer von einem Messmittel gemessenen Herzfrequenz mit einem Schwellenwert, der in einem Speichermittel gespeichert ist; Auslesen einer durchschnittlichen Herzfrequenz in einem Gleichgewichtszustand aus dem Speichermittel, wenn die Herzfrequenz kleiner als ein Schwellenwert ist; Berechnen der Differenz zwischen der durchschnittlichen Herzfrequenz und der gemessenen Herzfrequenz; und Bestimmen eines Pulsabstands aus der Differenz; Stimulieren einer Herzkammer mit des bestgelegten Pulsabstand Mittels eines Pulsgebers; und Konstanthalten der Herzfrequenz.*

Wegen der Verfahrensschritte des Stimulierens der Herzkammer und des Konstanthaltens der Herzfrequenz umfasst das beanspruchte Verfahren ein unmittelbares Wirken auf den menschlichen Körper und beschreibt damit ein nicht patentfähiges therapeutisches Behandlungsverfahren. Auf folgende Weise kann der Anspruch aber in ein patentierbares Betriebsverfahren umformuliert werden:

> (Zulässig) *Verfahren zum Steuern eines Herzschrittmachers, bei dem durch ein Steuermittel des Herzschrittmachers gesteuert die Schritte ausgeführt werden: Vergleichen einer von einem Messmittel gemessenen Herzfrequenz mit einem Schwellenwert, der in einem Speichermittel gespeichert ist; Auslesen einer durchschnittlichen Herzfrequenz in einem Gleichgewichtszustand aus dem Speichermittel, wenn die Herzfrequenz kleiner als ein Schwellenwert ist; Berechnen der Differenz zwischen der durchschnittlichen Herzfrequenz und der gemessenen Herzfrequenz; und Bestimmen eines Pulsabstands aus der Differenz; Erzeugen eines Impulses zum Stimulieren einer Herzkammer, mit dem festgelegten Pulsabstand mittels eines Pulsgebers.*

Hier wurde der Schritt des Stimulierens einer Herzkammer in eine auf den Impuls bezogene Zweckangabe „zum Stimulieren…" geändert. Diese Formulierung gilt als zulässig, weil die Zweckangabe nicht als Wirkung auf den menschlichen Körper angesehen wird, sondern lediglich als zulässige Charakterisierung des Impulses, der erzeugt wird. Durch diese Unterscheidung

gelingt es, zwischen Erfindungen zu unterscheiden, die im Ergreifen einer technischen Maßnahme bestehen, mit der eine bestimmte medizinische Wirkung hervorgerufen werden kann, und solchen Erfindungen, die im Hervorrufen der medizinischen Wirkung selbst liegen. Erstere sollen patentierbar sein, letztere nicht.

Die formalen Erwägungen des japanischen Ansatzes stehen in erkennbarem Kontrast zur europäischen Herangehensweise, bei der man zur Beurteilung der Patentierbarkeit von dem objektiven Zweck des Erfindungsmerkmals ausgeht und fragt, ob dieser möglicherweise therapeutisch ist. So wird in der Entscheidung T 329/94 ausdrücklich auf den anhand der Beschreibung und der Figuren ermittelten Zweck und die zwangsläufige Wirkung des Verfahrensschritts abgestellt, und in der Entscheidung T 789/96 fragt die Kammer danach, ob der technischen Aufgabe eine therapeutische Wirkung zukommt. Der sich hieraus ergebenden Interpretationsspielraum wird durch die pauschaleren japanischen Kriterien vermieden. Man kann kritisieren, dass sie dadurch den Umständen des Einzelfalls nicht immer gerecht werden. Dies wird jedoch im Interesse einer größeren Rechtssicherheit bei der Lösung des Dilemmas zwischen gesundheitspolitische Erwägungen den Interessen des Erfinders in Kauf genommen.

One patent too many in your portfolio? Why the interim findings of the European Commission's Pharmaceutical Sector Inquiry are essential reading for patent lawyers in all industry sectors.

B. Batchelor (GB) and S. Jones (GB)[1]

The broad ranging criticism of patenting practices in the interim report is likely to have an impact far beyond the pharmaceutical sector. The report characterises entirely standard patenting practices – patent portfolios, patent litigation, settlements and patenting second generation products – as suspect and potentially contrary to EC competition law. The final findings of the inquiry are likely to set the EC's policy and enforcement agenda on patents and their enforcement across all innovative industries for years to come. This article identifies the most troubling issues for patent practitioners, suggesting that the interim report suffers from significant analytical and legal flaws, as well as misunderstandings as to how the patent system works in practice.

Introduction

Few would have believed, in the early hours of 16 January 2008 as teams of DG Competition officials descended on the offices of innovative and generic pharmaceutical manufacturers, that the patent system was so firmly in the sights of the competition regulators. Using the 20,000 pages of documents retrieved from those companies, as well as three gigabytes of data requested over the 10 months that followed, officials drafted a 426 page interim report alleging that a range of practices – patent portfolios, litigation, settlements, promoting the use of patented second-generation products – had allegedly cost health systems €3 billion by delaying the entry of cheaper generics.[2] Further, allegedly dubious patent strategies could be the cause of innovative decline in the pharmaceutical sector. Amidst press reports that „Brussels condemns … use of patents,"[3] conduct which was hitherto second nature to patent lawyers and, indeed, business as usual across all innovative industry sectors, is now firmly under the spotlight. With the EU promising to launch fact finding studies into the use of IP as part of its *Industrial Property Rights Strategy for Europe*,[4] the interim report is essential reading for practitioners in all industries.

Initial reactions

Perhaps unsurprisingly, therefore, the findings caused some confusion among patent practitioners. Lord Justice

1 Bill Batchelor and Stephen Jones are partners of Baker & McKenzie LLP in Brussels and London respectively. Baker & McKenzie LLP represents EFPIA (the European Federation of Pharmaceutical Industries and Associations) in relation to the pharmaceutical sector inquiry. The views expressed in this article are the authors' personal views. A version of this article has previously appeared in *„Scrip"*.

2 *Pharmaceutical Sector Inquiry Preliminary Report*, DG Competition Staff Working Paper, 28 November 2008 (available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf)

3 Independent, 29 November 2008

4 *An Industrial Property Rights Strategy for Europe* COM(2008) 465/3 (Announcing studies of patent quality and the antitrust implications of IP and standard setting)

Jacob, one of the most eminent European patent lawyers and judge in the English Court of Appeal, speaking at DG Competition's launch of the interim report observed „there is absolutely nothing new in what [DG Competition] are reporting about." He cautioned regulators to „keep a sense of perspective." Antitrust lawyers also had real concerns. The interim report contained little or no legal analysis. There was no attempt to dissect the key legal issue which has long been the centre of heated debate at the IP/antitrust interface. That is, how do you reconcile the legal monopoly conferred by patents with the aims of competition law? The Competition Commissioner's opening statement warned of „cases against companies where there are indications that the antitrust rules may have been breached,"[5] a threat backed up by further dawn raids on innovator and generic companies on 24 and 25 November, just days before the launch of the interim report.[6] But the report offers no compliance guidance to patent practitioners whose daily business comprises many of the practices identified as „blocking tactics" in the report.

The truth about generic entry delay

What of the headline figure, the alleged €3 billion savings that would have been made had generics launched on day one after a medicine's loss of protection? The report is very carefully worded. It does indeed find that generics do not, on average, enter on day one. The delay was 6.6 months (weighted average) for all medicines examined, or under four months for top-value products. But reading the fine print, the report also concedes there may well be any number of reasons for this delay. It does not pin the sole blame on innovators, though one could be forgiven for thinking this, given the tenor of the rest of the report.

On the contrary, given the substantial regulatory and commercial hurdles to bringing even a generic medicine to market, these average times to entry – as little as 2.5 months in some countries – appear extremely short. By way of example, sharp eyed practitioners reading the report will spot that much of the period under review 2000-2006 was prior to introduction, at European level, of the *Bolar* testing exemption,[7] which would have prevented generics starting the testing needed for marketing authorisation in many European countries until after patent expiry. Equally, pharma specialists were quick to point out that the lengthy process of applying for marketing authorisation by generics could only have been begun after the innovator's regulatory data protection rights expired.[8] Small wonder then that generic companies have stated that regulatory delays „play a crucial role" in generic delays[9] and were „costing…European healthcare systems as much as EUR 100m per medicine per year."[10]

On closer examination the pattern of generic entry identified contradicts a blocking tactics theory. The report alleges blocking tactics are most prevalent against the top 30 most valuable medicines examined and that the incidence of the alleged tactics has in some cases quadrupled over the investigation period. Yet it finds generic entry is *quickest* and *getting faster* for precisely these high-value medicines. On that basis, it seems difficult to accept any theory of effective blocking strategies.

Patent portfolios

Turning now to the area of greatest interest to patent attorneys: the „toolbox" of blocking practices allegedly used by innovators. The first is patent portfolios. The report identifies one molecule with 1,300 related patents as the most egregious case. It also finds examples of patents filed near to expiry of the „primary patent" protecting a drug, the suggestion being that this somehow extends patent protection. However, it concedes that there is no general trend of a spike of patents near the time of primary patent expiry.

On analysis, the „1,300 patents" number turns out to be 800 (the remaining 500 are applications)[11] and, confusingly, counts separately each of the up to 27 national patents for the same invention across the EU (the EU 27 patent „family"). As the EPO comments, „this method of counting patents needlessly and artificially inflates applicable numbers, giving a distorted picture of the functioning of the system."[12] After adjustment, then, the real figure may be around 30 patent families (800 divided by 27), a number which would barely raise an eyebrow in high-tech industries, where thousands of patents can protect common consumer electronics.

5 *Antitrust: preliminary report of sector inquiry into pharmaceuticals, Opening remarks at press conference*, 28 November 2008, Neelie Kroes, European Commissioner for Competition Policy

6 Commission Press Release of 25 November 2008 *Commission confirms unannounced inspections of pharmaceutical companies*.

7 Europe's *Bolar* exemption (*Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984)) to permit testing by generic companies prior to the end of the patent term for the purpose of obtaining marketing authorisation was introduced under Article 10(6), Directive 2001/83 on the Community code relating to medicinal products for human use [2004] OJ L 311/67, as amended by Directive 2004/27/EC [2004] OJ L 136/34 to be implemented by EU Member States by 30 October 2005. The report examines drugs whose patents expired in the 2000-2007period. That is not to say that generic testing could not have occurred in countries with weaker patent protection or which recognised a testing defence prior to 2005.

8 Data exclusivity rules prevent the generic company relying on the innovator company's regulatory data for a period of between 6 or 10 years. Only after that data exclusivity right expires can the generic begin the authorization procedure. An amended data exclusivity regime now exists, but applies prospectively only to medicinal products for which an authorisation application was filed after 20 November 2005 under the mutual recognition procedure and after 30 October 2005 for the centralised procedure (Article 89, Regulation 726/2004 and Article 2, Directive 2004/27).

9 *EGA Response to the Public Consultation: DG Competition Pharmaceutical Sector Inquiry: Preliminary Report, Executive Summary*, 31 January 2009, p4 available at: http://www.egagenerics.com/doc/ega_pharma-inq_response_20090130-exsumm.pdf

10 *EGA Board of Directors urges early implementation of „Bolar provision" for Generics to ensure the future of European Research & Development*, EGA Press Release, 25 March 2004.

11 The report explains that it multiplied each patent application by the number of EU countries it designated. So 500 applications, divided by 27, is likely to be around 19 EPO patent applications.

12 *European Commission Pharmaceutical Sector Inquiry Preliminary Report – Comments From the EPO („EPO Comments on the Preliminary Report")*, p2

Particularly troubling is the view presented to DG Competition by the European Generic Medicines Association („EGA") that it should be illegal to patent and market second generation products which represent limited advances.[13] Aside from the degree of state intervention such a policy implies (should regulators or consumers decide on what is a valuable improvement?) it misunderstands, and would act as a deterrent to, the innovative process. At the outset of an R&D programme, how will a company know if the product will be a successful improvement on existing lines?

EC precedent, to the contrary, states that portfolios are lawful.[14] Trying to regulate patent portfolios through competition law, it is submitted, is fraught with dangers. Competition regulators cannot replace the views of the patent office or court on patent validity or dictate when a portfolio has one too many patents – are 799 patents lawful and the 800th illegal? How is a patent attorney to know when drafting an application, when filing it and when prosecuting it to grant? How is a patent attorney expected to know whether the company will have a dominant position in a related market at some indeterminate future moment and, if so, whether the addition to the portfolio would constitute illegal abuse of such a position? An overlay of competition regulation on an already complex patent system will tend to weaken intellectual property and chill innovation.

Patent litigation

The report makes much of the fact that innovators lost the majority of the 700 cases against generics that were litigated through to final judgement (62 % of 149 judgements), though it might be noted that they won 51 % of those they initiated. The European Patent Office („EPO") comes in for unsubstantiated criticism that it grants too many „weak" patents based on litigation statistics that, allegedly, showed the majority of litigated patents being revoked. The report is wrong here. In fact the litigation statistics show 28.8 % are revoked.[15] But that is beside the point. Since the vast majority of patents are never litigated and generics provoke litigation only on the most valuable patents where they consider there are the best chances of success, it is impossible to generalise from tiny sample of litigated cases to the entirety of the EPO's output. In fact, win/loss statistics of around 40-50 % are entirely to be expected and no different to the statistics for other sectors.[16]

From an antitrust perspective, there are significant legal obstacles to the Commission challenging an innovator for illegally vexatious litigation. Access to justice is a long established human right which the courts will not readily curtail. Such conduct is not illegal unless a dominant company makes a harassing claim that is not reasonably assertable and that is part of a plan to eliminate a competitor.[17] Moreover, it is submitted, competition law should not apply where the patent system already has ample remedies for clearing out bad patents. Generics need not launch at risk of suit, but can seek to clear the path prior to launch, by filing oppositions or applying for revocation or declarations of non-infringement.

Settlements

DG Competition has been closely briefed on the campaign by the US Federal Trade Commission against „reverse payments" or other „side deals" in settlement agreements. The allegation is that payments or benefits in kind transferred from innovators to generics as a *quid pro quo* for staying off the market are inherently suspicious. The report finds 20 such settlements in the EU involving €200 million in aggregate.

Again, there are methodological difficulties here. On closer analysis some of these allegedly restrictive agreements seem to assist generics, such as licensing or distribution arrangements. So, too, some of the payments are related to marketing, buy back of stock or contributions to legal costs. Such conduct does not seem to be *per se* unlawful.

Under EC competition law, there are real difficulties in prosecuting these cases and, indeed, notwithstanding the renewed efforts of the FTC, the tide in the US also appears to be turning against such challenges.[18] US courts reason that if a patent excludes all competition, then any *bona fide* settlement agreement that imposes restrictions on generics going no further than the patent can have no impact on competition. The key problem in these cases is that antitrust authorities cannot judge whether a patent is valid or invalid. The focus on particular features of settlements – side deals or reverse payments – cannot answer this fundamental question. The complex, drawn out and costly nature of patent disputes can lead to any number of good faith arrangements on which parties may seek to settle on commercially reasonable terms. Each case must be considered on its merits and antitrust second guessing should not deprive businesses of the opportunity to draw a line under litigation and move on.

13 *EGA Response to the Public Consultation: DG Competition Pharmaceutical Sector Inquiry: Preliminary Report, Executive Summary*, 31 January 2009, p4 available at: http://www.egagenerics.com/doc/ega_pharma-inq_response_20090130-exsumm.pdf

14 Case T-83/91 *Tetra Pak International SA v Commission* [1994] ECR II 755 („*Tetra Pak II*"), para. 242; compare, in the US, *Automatic Radio Mfg. Co. v Hazeltine Research, Inc.* 339 US 827, 834 (1950)).

15 Report, para. 393 and footnote 257 (28.8 % of patents are invalidated, being 27.5 % invalid and 1.3 % invalid and non-infringed, the remainder are non-infringement findings).

16 *Global Patent Litigation – Win Rates and Strategies*, Michael Elmer, May 31, 2007 (Patentee „win rate" ranging between 26 % (UK) and 55 % (France) across European jurisdictions Based on an informal survey in the absence of authoritative data sources)

17 Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937 (Questioning whether competition law should regulate such matters at all, given that access to justice constitutes a fundamental right and holding that, if applicable, the test must be that a claim in litigation is lawful unless undertaken by a dominant company where (i) it „cannot reasonably be considered to be an attempt to assert the right of the undertaking concerned and can therefore only serve to harass the opposing party" and (ii) is part of a plan to eliminate the competitor.)

18 *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056, 1075 and 1076 (11th Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 08-1097, 2008 WL 4570669 (Fed. Cir. Oct. 15, 2008).

Marketing and next-generation products

The final section of the report – which finds that marketing tactics and bringing out next generation patented products delay generics – is the most difficult to understand. It is no doubt true that many off patent products – 40 %, according to the report – are succeeded by second-generation medicines and, indeed, they are likely to be heavily marketed. But these practices are an essential part of vigorous competition. Next-generation products, with greater potency, fewer side-effects or reduced dosing regimens, offer competing and improved product choices. The EPO commentary is trenchant. Next generation products are an „express goal of the patent system" which is designed to „promote the creation of inventions built on other inventions, as demonstrated by the experimental use exception" and „follow-on invention also constitutes one of the underpinnings of the mandatory publication of applications."[19] There is, therefore, rightly no antitrust precedent which condemns second-generation products or their marketing.

Decline in innovative medicines

The interim report deals comparatively briefly with the development of new medicines. It notes a decline in new product launches – though the indice it uses, rather inexplicably, excludes important innovations such as vaccines – and speculates whether this may be caused by defensive patenting practices. When a patent will be considered „defensive" is ill defined, but it apparently means an unworked patent which serves only to block rivals. The report finds that innovators reported 1,100 instances of another company's patents blocking their R&D efforts and that in some cases innovators obtained patents solely to block competitors.

The report states that licensing where there are patent blocks is prevalent (being granted in 77 out of 99 licence requests) and licensing is only refused without good reason in two instances, there being only one case in which an R&D project was blocked. It makes no specific link between patent blocks and decline in innovation, merely stating that this might be a factor. It disregards extensive research identifying more intrusive use of cost-effectiveness assessments and other state pricing controls, increased regulatory burdens and technological challenges as the most likely cause of any decline in productivity, rather than reasons attributable to patent issues.[20]

The EPO's discomfort with a concept of „defensive patenting" is plain. „[A] cardinal principle of European patent law [is] that issues going to the intent of the applicant are irrelevant in terms of obtaining patent rights."[21] A subjective intent test would introduce damaging legal uncertainty into an objective system of patent grant. The innovator's intent will often be impossible to establish. In any research programme an innovator will have little idea as to which of the many compounds or other innovations it patents will ultimately prove technically or commercially viable. It will not want to hand research over to competitors while it is still possible the invention might be useful.

Ultimately, antitrust regulators face an uphill struggle in forcing companies to license out their intellectual property. Because forced licensing is highly damaging to innovation – no one will want to invest billions in R&D if they are forced to license the result to rivals – the law is at pains to state that it can only be required of a company with a dominant market position and then only in exceptional circumstances. The latest enforcement guidelines expressly identify harm to innovation as a defence to compulsory licensing claims.[22] It is, therefore, a highly fact-intensive inquiry to determine whether the high threshold for compulsory licensing is satisfied in any individual case.

The European patent and litigation systems

The interim report strongly advocates a single European patent court to streamline and reduce the costs of challenging patents, one part of the report with which Sir Robin Jacob agrees, and a subject which is dear to his heart; and a sentiment with which many patent attorneys and lawyers may also agree, provided that such a court can produce high quality, cost-effective and timely judgments. The absence of a Community Patent is also referred to, a subject on which there may be more mixed views.

There is criticism of the current opposition procedure at the EPO, and some of the comments in the interim report seem misconceived and based on misunderstandings and misconceptions; for example the statement that an average opposition in the pharmaceutical sector takes 3.6 years from initiation to final ruling including appeals, which the Commission thinks is a „long average duration" which „considerably limits companies' perspective to clarify the patent situation efficiently" would probably seem to most practitioners before the EPO to be very much an underestimate. However, it is hard not to agree with Sir Robin's view that opposition proceedings at the EPO do need to be speeded up.

No radical policy solutions are proposed by the report, though the EGA urges higher quality patents and the importation of US concepts such as a duty of candour in the European system. There seems, ultimately, to be a need for a mechanism to allow all disputes between innovator and generic, including claims of infringement, to be resolved well ahead of launch of the generic so as to eliminate the need for the innovator to seek interim injunctive relief.

19 *EPO Comments on the Preliminary Report*, p 3

20 *Scrip* 100 (2008). p35 („Why are drugs not getting through? As well as poor candidate selection, and the fact that drugs are spending more time in Phase II, attrition must be held accountable. … Of the projects for which companies have disclosed the reason for discontinuation, a startling 44 % of decisions were strategic, while just 28 % of programmes were dropped because of lack of efficacy and 11 % for poor side effects.")

21 *EPO Comments on the Preliminary Report*, p6

22 Guidance on the Commission's Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, 3 December 2008, paras. 88-89

Conclusion

The suggestion that practices considered up to now entirely legitimate and, indeed, pro-competitive in many innovative industries – patent portfolios, litigation, settlements, next-generation technologies or marketing of new products – can be potentially unlawful is of serious concern. Any intervention by the competition authorities needs to fully understand the risks to innovation which would be caused by an ill considered attack on the patent system. To echo the remarks of Sir Robin, „one should be very careful to avoid panic-driven or emotion-led changes, which could damage an important and beneficial part of industry". The conclusions of the final report on patenting practices are likely to influence the Commission's agenda for IP across all innovative industries and must be watched closely by the patents profession.

European Patent Attorney

C.E. Eder (CH)

Da das Wort „Patentanwalt" seit Jahrzehnten zwar in Deutschland und Österreich, nicht aber in andern deutschsprachigen Ländern ein den freiberuflich tätigen Patentanwälten vorbehaltener, durch ein nationales Gesetz geschützter Berufstitel ist, vertreten die Mitglieder der deutschen und österreichischen Patentanwaltskammer und mit ihnen auch andere Angehörige dieses Berufstandes die Ansicht, das *epi* habe keine Kompetenz, seinen Mitgliedern den Gebrauch des Titels „Europäischer Patentanwalt" zu gestatten.

Nach dem derzeitigen Stand der Verhandlungen im Schweizerischen Parlament kann erwartet werden, dass das Patentanwaltsgesetz im März 2009 beschlossen und im Verlauf des Jahres 2010 in Kraft treten wird. Nach dem Inkrafttreten

– darf
  a) der Berufstitel „Patentanwalt" in der Schweiz nur noch von denjenigen Personen benützt werden, die im schweizerischen Register der Patentanwälte eingetragen sind, und
  b) der Berufstitel „Europäischer Patentanwalt" nur von all den Personen, die in der Liste der beim EPA geführten Liste der zugelassenen Vertreter eingetragen und dadurch von Gesetzes wegen automatisch Mitglied des *epi* sind,
– und wird wegen Titelanmassung bestraft, wer einen der vorgenannten Titel unbefugterweise benützt.

Nachfolgend wird der Wortlaut der entsprechenden Artikel aus den kommenden *schweizerischen Patentanwaltsgesetz* wiedergegeben:

2. Abschnitt: Titelschutz
Art. 2 Patentanwältin oder Patentanwalt

Wer sich Patentanwältin oder Patentanwalt, conseil en brevets, consulente in brevetti oder patent attorney nennen will, muss die Voraussetzungen nach Absatz 2 erfüllen und im Patentanwaltsregister (Art. 11 ff..) eingetragen sein.

Art. 3 Europäische Patentanwältin oder europäischer Patentanwalt

Wer sich europäische Patentanwältin oder europäischer Patentanwalt, conseil en brevets européens, consulente in brevetti europei oder european patent attorney nennen will, muss in der beim Europäischen Patentamt geführten Liste der zugelassenen Vertreter eingetragen sein.

5. Abschnitt: Strafbestimmungen
Art. 15 Titelanmassung

Mit Busse wird bestraft, wer sich in seinen Geschäftspapieren, Anzeigen aller Art oder anderen für den geschäftlichen Verkehr in der Schweiz bestimmten Unterlagen:

a) Patentanwältin oder Patentanwalt, conseil en brevets, consulente in brevetti oder patent attorney nennt, ohne im Patentanwaltsregister eingetragen zu sein;

b) europäische Patentanwältin oder europäischer Patentanwalt, conseil en brevets européens, consulente in brevetti europei oder european patent attorney nennt oder einen damit verwechselbaren Titel verwendet, ohne in der beim Europäischen Patentamt geführten Liste der zugelassenen Vertreter eingetragen zu sein.

Unter diesen Umständen ist rechtzeitig vor dem Inkrafttreten des schweizerischen Patentanwaltsgesetzes zu überlegen, ob und allenfalls wie der Wortlaut des unter epi 4.2.3.2 publizierten „Beschluss des Rates zum Titel (Berufsbezeichnung)" zu ändern ist, damit nicht durch eine *epi*-Vorschrift den deutschen, den österreichischen, den französischen und den italienischen Berufsangehörigen etwas verboten wird, was den schweizerischen Berufsangehörigen durch das nationale Gesetz gestattet ist.

Procedural Law under the EPC 2000
Andrea Veronese and Peter Watchorn

Review by D. Harrison (GB)

That this book is a labour of love is evident not only from its dedication – in a non-official language! – but also from the immense attention paid to thoroughness and detail.

It claims in its subtitle to be „A practical guide for patent professionals and candidates for the European qualifying examination" and indeed it is; it follows the progress (or otherwise) of an application and then of a patent through the procedures of the EPC and the EPO, together with sections dealing with general fee-payment questions and „common provisions".

This is organized in a way so that a chapter devoted to a given phase is more or less self-contained, avoiding to a great extent any need to keep on referring back or forward to get the complete picture of the subject of interest. In each of these chapters sub-headings deal with specific topics, and in what appears to be a unique manner all relevant sources (Articles, Rules, Guidelines, Decisions and so forth) are laid out, with glosses or commentary, under each sub-heading. Though this involves a certain amount of duplication and the book runs to 600 pages, the result is something that is extremely easy to use for an instant reference, and one can imagine it becoming a must-have for candidates sitting the EQE.

For practitioners also? Yes, but with a slight caveat. The authors are both Examiners at the EPO, and Watchorn also has responsibilities in connection with the drafting of the Guidelines. So perhaps it is inevitable that although they raise a polite eyebrow at some Board decisions – for example, J 28/03[1] is mildly described as „remarkable", with the comment that it will be interesting to see if other Boards follow it – there seems to be no attention drawn to the places where the Guidelines could with justice be thought of as creative. For example, the statement in GL D-VII 2 that the effect of non-filing of a translation of a convention document when requested in opposition is that intermediate documents are taken to be part of the prior art is repeated without noting that there is no such – or indeed any – sanction provided in the EPC.

The practitioner faced with a difficult situation might find it necessary to dig a little deeper than what is found here; but that does not seriously detract from the everyday value of the contribution made by the book since he or she should always regard the Guidelines (which, be it remembered, are not law) with a healthy degree of scepticism.

As noted above, easy to use, with a good, detailed table of contents at the beginning and an index of Articles at the end; but an index of Rules would be an improvement and a table of cases a luxury.

Overall, a very considerable achievement.

1 No suspensive effect of an appeal filed against the grant of a patent for the purpose of filing a divisional, unless the appeal succeeds.

„Pagenberg/Beier, Lizenzverträge – License Agreements“[1]

Review by Prof. M. Lehmann[2]

Zweifelsohne gibt es auf dem Büchermarkt einige lesenswerte Formularrechtsbücher zum Gewerblichen Rechtsschutz und Urheberrecht. Aber es gibt nur einen „Pagenberg“, Lizenzverträge – License Agreements, der nunmehr in 6. Auflage, „vollständig überarbeitet und erweitert“, unter der Federführung von Pagenberg/Dietrich Beier/Abel, vormals Pagenberg/Geißler erschienen ist. Angeboten und kommentiert werden dabei nicht nur Vertragsmuster in synoptischer Darstellung, somit in deutscher und dazu korrespondierender englischer Fassung für die Lizenzierung von Patenten, Gebrauchsmustern, Know-how und Computersoftware sondern auch ausführliche Einführungen, „Vorbemerkungen“, in die Rechtsmaterien selbst, wobei insbesondere die „allgemeine Einführung“ von Pagenberg mit rund 140 Seiten außergewöhnlich zu bestechen vermag. Hier wird ausführlich das immer weniger gesetzlich transparent ausgestaltete Verhältnis von Kartellrecht, europäischem und deutschen, und Vertragsrecht erörtert. Dabei werden vor allem auch die einschlägigen Gruppenfreistellungsverordnungen, zum Beispiel für Technologietransfer – sowie für Forschungs- und Entwicklungs-Vereinbarungen, vorgestellt und praxisnah diskutiert. Die dafür unmittelbar relevanten, manchmal nicht unschwer auffindbaren Rechtsquellen, die europäischen GVO's, Leitlinien und Bekanntmachungen, sind im Anhang auf rund 200 Seiten wiederum in deutsch/englischer Fassung zusammengestellt und mit Internet-Zugangshinweisen abgedruckt worden, was die Handhabung dieses Werkes in der Praxis erheblich erleichtern dürfte. Was überhaupt die Online-Nutzung dieses Werkes angeht, stehen alle Texte des Vertragsmusters und die wesentlichen Materialien des Anhangs im Internet zum Download für jeden Leser und letztlich für jedermann bereit, der den „Zugangscode“ kennt: *http://www.service.heymanns.com*, Benutzername: pb, password: pb052007; dieser Hinweis sei hier gestattet.

Exemplarisch erwähnt und herausgegriffen werden sollen weiterhin aus den zahlreichen Mustervorschlägen, die Formulare für einen ausschließlichen Lizenzvertrag einschließlich von Geheimhaltungsvereinbarungen und Vorabverträgen über geheimes technisches Wissen (Know-how), für einen einfachen Lizenzvertrag, einen Gebrauchsmusterlizenzvertrag, einen Produktions- und Zuliefervertrag über patentgeschützte Gegenstände, einen Kooperationsvertrag einschließlich der Auswertung von Patenten, einen Entwicklungsvertrag, einen Forschungsauftrag mit Regelungen zur Behandlung von Erfindungen, einen Patentüberlassungsvertrag, sowie abschließend Software-Lizenzverträge und Software-Benutzungsverträge unter Einschluss der Probleme der Softwareerstellung. Alle Muster werden ausführlich erläutert und die einschlägige Rechtssprechung und Literatur wird dazu kommentierend in Fußnoten herangezogen. Selbst nach vollständiger Lektüre des Buches bleibt freilich eine rein rechtsdogmatische, zivilrechtliche Frage offen: Wie ist vertragstypologisch ein Lizenzvertrag einzuordnen? Als ein Vertrag eigener Art („sui generis“) würde Hilty sagen. Mit Fikentscher/Heinemann, Schuldrecht, 10. Aufl., Berlin 2006, Rdn. 980 ist aber die Rechtspacht gemäß § 581, Abs. 2, 535 ff.. BGB vorzuziehen. Was gewinnt man dadurch? Etwas mehr bürgerlich-rechtliche Struktur und gewisse Leitlinien, etwa bei der Rechtsmängelhaftung.

Fazit: Ein „mustergültiges“ Buch mit sachkundig erarbeiteten Formulierungsvorschlägen und Vertragsmustern, die häufig als das „Geheimwissen der Anwaltschaft“ betrachtet werden; somit ein absolutes „must“ für jeden Rechts- oder Patentanwalt sowie jeden interessierten Praktiker in der Wirtschaft, der mit Lizenzverträgen auf dem Gebiet des Gewerblichen Rechtsschutzes und Urheberrechts zu tun hat.

1 Carl Heymanns Verlag, Köln/München, 6. Aufl. 2008, 1067 S., € 148,00

2 Prof. Dr. jur. Michael Lehmann, Dipl.-Kfm., Universität und MPI, München

Comment on the article „Diamanten, Peanuts und Patente" published in issue 4/ 2008 of epi Information

K. Lundblad Pinnekamp (CH)

I would like to make a comment on and the thoughts about how the development of diamond synthesis by ASEA was pursued.

The ASEA project with von Platen started in 1949 and ASEA had hired a newly graduated chemist, Erik Lundblad to head the project. The project was based on equipment developed by von Platen and was conducted in his laboratories in Stockholm. Von Platen had many other projects on-going and was soon not actively participating in the project himself, but ASEA continued to make experiments and develop the process. In February 16, 1953, they succeeded in keeping pressure (83,000 atm) and temperature (2000oC) for an hour, without breaking the equipment. Analysis performed at Stockholm University detected small diamonds in the sample my father, Erik Lundblad had supplied.

The question of patenting the results came of course up, but the patent attorney dealing with the issue at that time replied that „this is only copying a natural process and can thus not be patented". Later, they were very surprised to see that GE had patented man-made diamonds. They were, however, always confident in the knowledge that they were first to succeed in synthesising diamond, but not first to publish.

The ASEA management could not see any direct use of the results for the company and decided to keep it secret, but supported continued development of the process. In 1961 ASEA had a plant in Robertsfors in the north of Sweden standing empty after having moved the glass fibre production to Falkenberg. It was then decided to start commercial diamond production in Robertsfors and Erik Lundblad became manager of the site. I remember when our family (I was eleven years at the time) moved up from the city of Stockholm to this small village in the north (around 200 km south of the Polar Circle). By that time they had learnt a lesson and were continuously applying for patents.

The Robertsfors plant became very successful; not least after de Beers some years later acquired part of the company and later took over the whole operations. Today the plant is owned by Element six.

My father left the diamond business in 1974 with an innumerable number of exciting experiences from the times with von Platen up to the patent conflicts with GE, which were eventually successfully concluded. When I in 1987 asked my father whether I should accept an offer to become a patent attorney and take over management of the ASEA patent department, he answered that I should definitely do so and that being a patent attorney is an important and exciting job. He continued his carrier in a different field at ASEA. Also his continued carrier in managing the ASEA generator division became very dramatic (a different story) and the number of exciting stories multiplied.

My father died 2004.

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