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Institut des mandataires agréés près l'Office européen des brevets

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Information

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Cover:
Florale Impression I
2014, 70 x 90 cm
This picture painted by
Mr. Markus Böckhorst
(European Patent Attorney, DE)
was part of the **epi** Artists
Exhibition 2015 at the EPO, Munich

Markus Böckhorst

Nach Berufsausbildung und Abitur, Studiumabschluss an der TU-München zum Dipl.-Ing. (Univ). Danach Eintritt in die Patentabteilung der Siemens AG und dort tätig als European Patent Attorney bzw. Patentassessor. Zwischenzeitlich Diploma in „Patent Litigation in Europe" an der Université de Strasbourg. Zurzeit patentrechtliche Betreuung eines Teils der Healthcare-Sparte der Siemens AG als Senior IP Counsel. Berufsbegleitend seit 1975 Beschäftigung mit der Bildhauerei sowie der konkreten und abstrakten Malerei. Studienaufenthalte bei Hansjörg Gartner, Peter Casagrande und Egon Stöckle, sowie wiederholt längere Aufenthalte an der Europäischen Kunstakademie Trier unter anderem bei den Dozenten Joe Allen, Claude Mancini und Christine Henn. Begleitend dazu zahlreiche Gruppen- und Einzelausstellungen. Mitglied im Berufsverband Bildender Künstler.
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After having successfully completed the professional training and high school graduation, graduation as Diploma Engineer (TU Munich). Afterwards entry into the patent division of the Siemens AG, working there as a European Patent Attorney, respectively Patent Assessor. Meanwhile degree in "Patent Litigation in Europe" (Université de Strasbourg). Currently patent law related support of one part of the Healthcare division of the Siemens AG as a senior IP Counsel.
Alongside work since 1975 occupation with sculpture and concrete and abstract painting. Several studies by Hansjörg Gartner, Peter Casagrande and Egon Stöckle, as well as several longer stays at the European Art Academy in Trier studying under Joe Allen, Claude Mancini and Christine Henn inter alia.
To accompany this numerous group and individual Artists Exhibitions. Member of the professional organisation of fine artists.
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Après une formation professionnelle et un baccalauréat, diplôme de fin d'études à l'université technique de Munich en tant qu'ingénieur diplômé à l'université. Puis Avocat Européen des brevets ou assesseur en brevets auprès du département Brevets de Siemens AG. Entre-temps diplôme « Contentieux des Brevets en Europe » à l'université de Strasbourg. Actuellement soutien en matière de brevets auprès de la division Santé de Siemens AG en tant que Conseil Senior en Propriété Intellectuelle.
Parallèlement à son activité professionnelle, sculpture et peinture concrète et abstraite depuis 1975. Séjours d'études auprès de Hansjörg Gartner, Peter Casagrande et Egon Stöckle, ainsi que plusieurs longs séjours à l'Académie Européenne des Beaux-Arts de Trèves auprès, entre autres, des maîtres de conférences Joe Allen, Claude Mancini et Christine Henn. Parallèlement de nombreuses expositions de groupes ou individuelles. Membre de l'association professionnelle des artistes des beaux-arts.
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Editorial

T. Johnson (GB), Editorial Committee

No profession is, we suggest, entirely without jargon. It is a kind of shorthand which allows for ease of communication between the members of the profession. Our profession is not immune, for example "adapted to", "suitable for", "characterised in that" could be said to be jargon, or "patentese", the meaning of which we are sure our members explain to their clients.
We are prompted to reflect on the topic of jargon as we recently came across another term which to us is jargon, namely "Millennials".

With apologies to those of our readers well familiar with the term, which seems also to be called the Millennial Generation or Generation Y, we could find no precise date for the start and end of the generation, the general consensus being that it covers birth years ranging from the early 1980s to the late 1990s or early 2000s.

We came across the term in a report on Millennials presented to the recent World Economic Forum. The report, which covered Millennials operating in 29 countries, both developing and developed, showed that two thirds of Millennials expressed a desire to leave their current employers by the end of 2020. The report also shows that Millennials want business to shift its purpose, i.e. to concentrate more on people, products and purpose and less on profits. According to the report too, Millennials also want to have their 'leadership' qualities enhanced, and recognised, by employers.

With no pejorative intent towards Millennials, we find these results of the report (which we have summarised) a little disturbing. If it is true for our profession, employers will have to go through repeated extensive and expensive training of new recruits to replace those Millennials who leave if we are to provide an ongoing high quality body of professionals well-equipped to serve the needs of applicants.

Hopefully most of the recruits to our profession are in for the long haul. We are sure too that employers in our profession are well aware of the Millennials problems highlighted in the report and are actively taking steps to engender loyalty in their staff and trainees.

This is the first issue of **epi** Information in its new electronic guise. We on the Editorial Committee hope that our readers will appreciate and enjoy the new format. The Editorial Committee will continue to try not to lapse into jargon, at least not too often!

Nächster Redaktionsschluss für **epi** Information	Next deadline for **epi** Information	Prochaine date limite pour **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 **13. Mai 2016**. Die Dokumente, die veröffentlicht werden sollen, müssen bis zum diesem Datum im Sekretariat eingegangen sein.	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 **13th May 2016**. Documents for publication should have reached the Secretariat by this date.	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 **13 mai 2016**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

Report of the European Patent Practice Committee (EPPC)

F. Leyder (BE), Chair

This report completed on 4 March 2016 covers the period since my previous report dated 22 November 2015 published in **epi** Information 4/2015.
The EPPC is the largest committee of the **epi**, but also the one with the broadest remit: it has to consider and discuss all questions pertaining to, or connected with, practice under (1) the EPC, (2) the PCT, and (3) "the future EU Patent Regulation", including any revision thereof, except all questions reserved for the Biotech Committee.
The EPPC is presently organised with six permanent sub-committees (EPC, Guidelines, MSBA, PCT, Trilateral & IP5, and Unitary Patent). Additionally, *ad hoc* working groups are set up when the need arises. Thematic groups are also being set up.

1. Independence of the Boards of Appeal

The EPO organised an online user consultation inviting users to express their views on the different reform elements. The summary can be downloaded from the EPO website: http://www.epo.org/law-practice/consultation/completed.html
In preparation of the December 2015 meeting of the Administrative Council, a document CA/98/15 was submitted by the EPO "The Orientations for the structural reform of the EPO Boards of Appeal". Comments were filed by **epi**, which can be found by following the link at the end of this page: http://patentepi.com/en/epi-reports/news.html. Document CA/98/15 was however withdrawn.

2. MSBA 22

The meeting planned on 7.10.2015 unfortunately had to be cancelled. The next (22nd) consultative meeting of user representatives with the Boards of Appeal (MSBA i.e. Meeting of SACEPO with the Boards of Appeal) will be convened after the summer holidays. In the meantime, suggestions of topics for discussion are more than ever welcome.

3. European Patent with Unitary Effect in the Participating Member States

The 18th SC meeting was held on 15 December 2015. The whole package, comprising the level of renewal fees and the distribution key, was adopted:
– Rules relating to Unitary Patent Protection (RUPP)
– Rules relating to Fees for Unitary Patent Protection (RFeesUPP)
– Budgetary and Financial Rules (BFR)
and
– Rules relating to the Distribution of Fees amongst the participating Member States (RDF) The latter was however not made public.

The 19th SC meeting will be held on 15 March 2016. Some details of the implementation will be discussed, and a chairman and deputy will be elected for the next term.

Francis Leyder

4. Committee on Patent Law

The 46th meeting of the Committee on Patent Law (CPL46) will take place on 12 May 2016.
It will in particular deal with two topics for which the delegations of the Member States have been invited to report on the situation in their country: the last day of validity of a European patent (a topic raised by **epi** in view of the future jurisdiction of the UPC on non-unitary patents) and the patentability of plants obtained by essentially biological processes (a topic for the Biotech Committee).

5. Symposium on Article 84 EPC

The EPO Academy organized a Symposium on Article 84 EPC in The Hague on 14 January 2016. **epi** was represented by six members, three from the EPPC and three appointed by PEC. The EPO started with an overview of the law (DG5) and the current practice (DG1). US, Japanese and European perspectives were then introduced, the last one by **epi** (M. Honkasalo had accepted the challenge). In the afternoon, the participants were divided into four break-out sessions: mechanics, electrophysics, chemistry and biotechnology. The results of these sessions were presented in the final plenary session and debated in a round-table discussion. As a result of the Symposium, the EPO plans to enrich and improve the Guidelines, for example by adding examples provided by the participants and discussed during the day.

6. SACEPO/WPR 14

As reported earlier, the 13th meeting of the SACEPO Working Party on Rules was held on 17 November 2015.
The EPO has processed the users' "wish list" for rule amendments into different categories, and informed us that the list will be closed item for the moment, but some suggestions will be reviewed when appropriate.
The main item on the agenda was the presentation of ideas

to "simplify" the procedures. As mentioned in the supporting document received one week before the meeting, "The need for a revision of the complexity of the procedures in place at the EPO was seen by EPO management in order to ensure a harmonised and sustainable practice under both the EPC and the PCT while fostering efficiency for users and examiners." Some proposals having a direct impact on users had been presented during the meeting. During the Council meeting in Cologne, some of these proposals could be very briefly presented and discussed. Discussions continued inside the EPPC, and the EPPC provided on 22 January 2016 written comments on some seven proposals how the EPO plans to "simplify" processes. The most discussed proposal relates to auxiliary requests and oral proceedings in the examination phase: whether to allow any auxiliary requests in response to summons, whether to process only the main request in the oral proceedings.

We have received the invitation to the 14th meeting of the Working Party on Rules, to be held on 7 April 2016, but had not received the agenda at the time of finalizing this report.

7. Meeting with VP1

In the EPO, Mr. Minnoye is the Vice-President in charge of Directorate-General 1 (Operations), responsible for search, examination and oppositions. Many issues were discussed during the meeting on 9 February 2016.

The extension of "top-up" searches to cover prior national rights is under preparation: the same search will be conducted in pre-translated documents, and it is intended to provide a simple list (the examiner will not look at the additional hits).

Some of the proposals to "simplify" processes (mentioned in the report on SACEPO/WPR) were also discussed. In particular, the EPO is working on internal procedures, the target being to reach a decision within 15 months in opposition proceedings after the opposition period has ended: requests for extensions of the period for responding to the notice of opposition would no longer be granted automatically, and the summons would be issued within three months of the response. Also the EPO will suspend examination of applications when a renewal fee is not paid, the effect of any PACE request re-starting when it is paid, and any oral proceeding being rescheduled if time permits (more than one month).

8. EPPC Meeting

The EPPC met on 16-17 February 2016. The main topics discussed were:

- The EPO proposals to "simplify" processes (mentioned in the above report on SACEPO/WPR).
- The new e-filing tools: the EPO had kindly offered to demonstrate these, in particular web-form filing that the EPO wishes us to increasingly use instead of fax in order to improve the quality of the documents received. Two Key Account Managers made the presentation, and we seized this opportunity to learn about their too little known role. A third EPO speaker was Mr Wierzejewski[1] of the Patent Procedures Management Directorate, who discussed the OCR processes.
- The annual Guidelines review process, with feedback provided by the Committee on specific topics raised by the Vice-Chair in charge of the Sub-Committee.
- The archiving of old EPC versions: this was in reaction to an EPO user survey to which **epi** was, surprisingly to me, not invited to participate. Several uses of such archive were identified, which will be passed to the EPO.
- The draft amicus curiae brief in case G1/15: the Committee agreed on the main principles of the brief. The final version was filed on 29 February 2016.
- Enquiries regarding national legislation at the request of the President: the chairman introduced several topics for which a contribution is requested in writing from the EPPC members (or, where applicable, from those representing countries participating in the unitary patent system), with the aim of posting the results on the **epi** website.
  1. Preventing double protection with a unitary and non-unitary patent.
  2. Protection conferred by non-unitary vs unitary patents.
  3. Delayed 'validation' where the request for unitary effect is refused.
  4. Payment of renewal fees in case of a successful petition for review.

  The President had also asked information about the closure of the national route, which was obtained orally.
- A proposal by T. Jackson (published in **epi** Information 1/2016) to amend the wording of communications according to Rule 71(3) and Article 97(1): the Committee generally agreed with most of the proposal, but was of the opinion that further investigation was required.

9. Meeting of JPAA with epi

During the meeting of 18 February 2016, I made a short presentation of the unitary patent system, which has since been posted on the **epi** website.

10. ICT Thematic Group

The ICT Thematic Group of the EPPC (information and communications technology) has again met with the EPO Directors in the field of ICT on 2 December 2015. The meeting addressed questions on the number and scope of European searches specifically in the CII field (computer implemented inventions), as well as on the applicability of many clarity objections in this field. The EPO explained its

1 Mr Wierzejewski is well known to us as the author of a poster "Recent procedural changes" downloadable from the **epi** website in the Documents/member section (last edition dated 14.07.2015).

modus operandi with large filers and outlined further initiatives to improve efficiency and quality. Both sides again considered the meeting fruitful, and the timing of the next meeting has already been agreed.

11. PCT WG9

The PCT Working Group will next meet in Geneva from 17 to 20 May 2016. No details were known about the discussion topics at the time of finalising this report.

12. PfQ

At the time of finalising this report, the date of the next Partnership for Quality meeting had not yet been set. It could regretfully not be combined with the EPPC meeting of 16-17 February 2016.

Report of the By-Laws Committee (BLC)

P. Moutard (FR), Chair

Most of the work performed by the By-Laws Committee (BLC) since the last report follows from the decision taken during the Council meeting (C79) in Cologne (15 November 2015). We present here below the different topics which were discussed during a BLC meeting on 2 March 2016.

1. epi 4.2.2.2 : Professional Designation (The Title "European Patent Attorney" in Several National Languages)

It was agreed during C79 (15 November 2015) that the BLC will provide a new proposal for the next Council meeting (C80) in Athens (23 April 2016) regarding the professional designation ("European Patent Attorney").

Paolo Gerli (BLC member) has performed further work on this topic. Italy, Switzerland and San Marino have agreed on the title in Italian language and Sweden and Finland on the title in Finnish language. But it seems that the position of the Dutch and Flemish still needs to be clarified, the same applies to Cyprus, Greece and Turkey.

Paolo Gerli will present an amended draft of **epi** 4.2.2.2 during the next Council meeting (C80) in Athens.

2. Guidelines of the Editorial Committee

The BLC discussed whether these guidelines for authors set up by the Editorial Committee are in line with the terms of reference of the Editorial Committee or not.
The BLC was recently informed that the Editorial Committee intends to propose an amendment of its terms of reference during the next Council meeting in Athens (C80).

Therefore, it was agreed to wait for the presentation of the new terms of reference of the Editorial Committee in the frame of C80 before undertaking anything with respect to the guidelines for authors.

3. Further to Decision 4 of C79 (Cologne) to Reduce the Composition of the Board and to Include Invited Guests (see report of the Reporting Group to the Council in View of C79, §1, pages 2-5): Is Any Amendments of the BL Needed?

3.a. The BLC reviewed Articles 7.2, 7.3, 8, 9 and 10 of the BL. It seems that no amendment of the BL is needed, except may be Art. 10.8 BL where committee chairs could be mentioned as possible third parties invited to Board meetings.
3.b. The BLC is also preparing a proposal for a new recommendation in Chapter 3.2 of the Collection of Decisions, concerning the new composition of the Board and the invited guests. The report of the Reporting Group of the second accumulated file of Cologne provides the basis for such a recommendation.
3.c. It has also been observed that two different quorums apply for a Board and a Presidium meeting (A.11 BL). Since the Board is now reduced, and has a composition very similar to that of the Presidium, there is a possibility to organize a Presidium and then a Board meeting successively at a same place (thereby saving costs). However different quorums apply, which means that there could be situations where the Presidium can meet but not the Board (and vice versa).
This situation will be explained to the Council during the next Council meeting (C80).
3.d. Art. 8.2 BL was also discussed in view of the amendments made to Art.5.2 BL (Hamburg, C 73) so that the term of office of a council member no longer ceases in case of a change of constituency or electorate. The former rule still applies to Board members, since, according to Art..8.2 BL, the term of office of a Board member still ceases in case of a change of constituency or electorate. The By-Laws Committee has not prepared any amendment to this stricter rule since it seems more justified for Board members than for Council members who are not Board members.
This situation will also be explained to the Council during the next Council meeting (C80).

4. Designation of Rapporteurs in Committees

At the C79 meeting in Cologne, Council approved to establish the position of a "rapporteur" in committees. Further to this decision, there is no need to amend the BL since the proposal of the Reporting Group is in line with Art.18 BL. However a recommendation will be drafted, which will be included in Chapter 3.3 of the collection of decisions on the basis of the proposal of the Reporting Group.

5. Double Signature

The double signature topic was extensively discussed during the BLC meeting on 2 March 2016, together with the Internal Auditors and the **epi** Treasurer.

Starting from the draft presented during C 79 (Cologne), a new draft of Art. 17A was elaborated, which includes:
- a reference to the budget approved by the Council, like in Art.15.2 BL and Art.16 BL,
- the possibility for the President to co-sign an employment contract;
- the opening and closing of bank and postal giro accounts in the list of operations for which a double signature is required;
- the possibility for contracts with a lower value (between 5000 € and 20000 €) to be co-signed by an appointed person of the Secretariat, provided the appointment of such person is signed by the Treasurer and either the President or the Secretary General, the extent and duration of such an appointment being laid down in writing.

Furthermore it will be specified:
- in Art.17 BL: that its last sentence (possibility for the President, the Secretary General and the Treasurer to delegate powers to Secretariat staff and any other employee of the **epi**) does not apply the new A.17A BL, so that the possibilities to delegate any power to sign any contract will be limited to those contracts with a value between 5000 € and 20000 €;
- in Art.13, 15 and 16 BL that the competences of the President, the Secretary General and the Treasurer are subject to the limitations of Art. 17A BL.

For contracts with a value below 5000 €, the usual provisions of Art.13, 15 and 16 BL still apply.
A new draft of Art. 17A BL including the above amendments will be presented in C80 in Athens.

6. Discussions Further to the Work of the Reporting Group

The Treasurer submitted to the BLC the result of some recent work conducted by the Reporting Group. A draft amendment of Art. 7(4) of the Founding Regulation was elaborated in order to implement possible new rules of representation in the Council.
Furthermore, a few days before the meeting of March 2, some other proposals were presented to the BLC, also resulting from the work of the Reporting Group, concerning the possibility of organizing electronic Council meetings, the duties of Council members, the election and the duties of committee members and the rights and duties of a committee chair. The BLC commented these proposals but this topic could not be discussed during the meeting of March 2, for lack of time.

Report of the Committee on EPO Finances

J. Boff (GB), Chair

Jim Boff

EPO Fees

A paper was discussed at the October meeting of the Budget and Finance Committee (BFC) proposing a 1% increase in all fees other than the International search fee and preliminary examination fee. The average rate of increase across all fees would be around 0.8%. **epi** spoke against automatic fee adjustments but rather asked for periodic review of fees and fee structure to ensure that the fees remained appropriate, and for more notice and consultation on fee changes.
epi also pointed out that the budgeted increase in the number of pending applications automatically would give the EPO more of an increase in income than the 1% proposed, since renewal fees on pending application are such a large part of the Office's income, and forecast to grow by around 4% between 2015 and 2016.
The proposal for the fee increase was approved by the BFC and later by Administrative Council, and will come into force 1st April 2016.

Financial Health

The Office is to undertake reviews of the financial position of the EPO.

Select Committee

A meeting of the Select Committee approved the Top 4 fee schedule, to the acclaim of the user representatives present.

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Minutes of meeting of epi Biotech Committee with EPO Directors on 12 October 2015

S. Wright (GB), Secretary

Simon Wright

The following topics were discussed during the meeting.

1. Stem cells

The patentability of hES cells is governed by Rule 28c, the main decision being G2/06 (WARF). There was a question mark over whether downstream products are excluded following C-34/10 CJEU which seemed to suggest that it was irrelevant at which time an embryo may have been destroyed. The Chung paper published on 10 January 2008 provides a method of obtaining hES cells without destruction of the embryo and so from that date a person skilled in the art (PSA) could rely upon this method to obtain hES cells in a non-destructive manner.

The definition of an "embryo" appeared to be anything that would develop into a human being, and potentially included a parthenote (a cell where division is kick-started by a chemical or electrical method). However, more recently, there had been a UK Patent Application (applicant: ISCC), refused by the UK Patent Office. This was appealed to the UK High Court who then referred various questions to the CJEU, which gave clarification that parthenotes are not embryos (C-364/13). That means that the use of parthenotes to obtain embryonic stem cells does not involve destruction of an embryo, nor even use of such. So the question then is when was the first disclosure of parthenotes allowing a PSA to obtain hES cells without embryo destruction or use? The EPO has decided that this is in Patent Application WO 03/046141 (ACT) published on 5 June 2003. As this enables the obtaining of hES from parthenotes, EP applications filed after this date concerning hES cells will now be allowable. The description will have to be adapted accordingly in each case, to ensure that destructive embryo use is not contemplated as a method of performing the invention.

The first examination reports issued by the EPO regarding the issue, will include this information and why there has been an EPO change of policy (C-364/13 CJEU). There will, however, not be an official statement from the EPO. However the EPO will publicise this change of practice in future presentations, and in particular Aliki Nichogiannopoulou will be in the UK to give a talk on this matter. There will be new Guidelines in the beginning of November, saying that CJEU cases may be persuasive on the EPO, even if not legally binding.

2. Plants and Tomato and Broccoli Cases G2/12 and G3/13

This decision confirmed that plant products and plant material other than a plant variety produced by an essentially biological process are patentable. The EU Biotech directive allows such plant products other than plant varieties. *The exclusion from patentability of essentially biological processes for the production of plants does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit or plant parts. This applies even if the only method available at the filing date for generating the claimed plants or plant material is an essentially biological process for the production of plants, and also if the claimed product is defined in terms of such a process.*

3. Myriad in the US

It was noted that there has been a recent Australian decision on the Myriad case too. The EPC and the EU Biotech Directive are very clear about the patentability of human genes and there are numerous decisions from the technical Boards confirming and interpreting both. The EPO does not expect the problems the US and Australia are experiencing.

4. Antibodies

The EPO said that they are updating their internal harmonisation notes, but the public had no access to these. The **epi** noted that Examiners appear to rely on internal harmonisation notes, but of course these are not provided to attorneys.
The EPO's general policy is that if an antibody is claimed it needs a surprising effect: just another antibody is usually regarded *prima facie* as obvious. The topic of patenting antibodies may be included in the next examination matters, or there may be a separate workshop.
Thus, one needs some surprising effect or to demonstrate there has been some difficulty in producing the antibody (for example, if the antigen is poorly immunogenic or difficult to generate).

5. Sequence Listings

Unfortunately Maria Fotaki was not able to be present. The EPO sends all sequences disclosed in the patent appli-

cation to the European Bioinformatics Institute (EBI) which makes them available online, both for European A and B publications and for PCT published applications where EPO is the ISA. It was noted, as an aside, that the US Patent Office only sends the sequences to the NCBI when the granted B specification is published.

As for sequence alignments in Office Actions, the Examiners have received no general instructions on this because it might generate too much paperwork. However, any *ad hoc* request will be taken into account and the alignments provided by the examiner when it is needed for a better understanding of the objection.

6. Pharmacogenomics

The EPO had more good news for the **epi**. This effectively concerns further medical uses for subgroups of patients defined by a biomarker. In the past such claims needed to contain an active diagnostic step in order to be considered novel. Based on more recent case law, the EPO has reviewed its internal harmonisation notes. Claims in this area are now construed to implicitly include the selection (step) of patients as a limiting feature. For example, if a subgroup of patients to be treated is defined by allele X and the prior art does not disclose any test for that allele, the claim will be regarded as novel, even if the prior art discloses a large patient population which – albeit untested for – included patients with that allele. The policy also extends beyond alleles to patient groups characterized by expression profiles and methylation patterns. Further case law from the Boards of Appeal has to confirm this approach.

7. Medical Uses

In decision T1570/09 of May the competent board considered that there is not any legal reason for granting in a single set of claims both an independent Swiss-type claim and an independent Article 54(5) EPC 2000 type claim for the same medical indication of the same substance.
T1021/11 (June 2015) confirms the practice currently followed by the examining divisions that both types of formats are actually allowable.

In T0826/12, the board confirmed that a claim constructed in a manner resembling a Swiss-type claim but only specifying that the medicament is in the form of a capsule for administration to a patient "in need thereof", does not define a second medical use and is not to be considered as a Swiss-type claim. In this respect, it was noted in the meeting that the wording "*in need thereof*" which is insisted upon by the US PTO is not required by the EPO, and it does not define the disease or patient.

8. Sequence Listings

It was commented that BISSAP is not widely used, and users instead prefer Patentin. Users cannot use BISSAP in the USA, and therefore Applicants will not prepare a second separate sequence listing for the US from the rest of the world. The EPO is reviewing the tools for the submission of sequence listings.

9. Search for Life

This is an initiative where the Applicant could re-run their own search as part of a larger IT project (roadmap) within the EPO. This may now come later, it is a small cog in a large machine.

10. Non-Unity

One of the **epi** members raised the issue of the EPO not being sufficiently applicant-friendly when raising non-unity objections – especially in the field of Biotech when more than one invention can be searched without extra search effort. Reference was made to point 2.2 of Chapter VII of Part B of the EPO Examination Guidelines.
The EPO explained that indeed examiners can and regularly do decide to search more than one or even all identified inventions for one search fee in those specific cases where no extra search effort is required for the further inventions and this extra effort does not justify the payment of an additional search fee. Examiners are encouraged to adopt a pragmatic approach in this regard.

The EPO presented statistics concerning the years 2010 to 2015; no final numbers were available for 2015, though.
In general, the statistics show a very positive trend with respect to the number of files for which non-unity objections were raised and the number of identified inventions per file.
In Biotech, the rate of non-unity objections in search has gone down from 24% in 2010 to 19% in 2015 (up to September).
The *mean* number of inventions per file has decreased slightly and remains around 18 for Biotech. However, this mean number is skewed by the cases with an exceptionally high number of inventions per file. This taken into account, the *median* number in Biotech is 5, not so different to the EPO average.

The mean number of inventions paid for by applicants is 1.4 in Biotech versus 1.5 for EPO, slightly more are paid for in the PCT procedure.
The cases in Biotech with exceptionally high number of inventions per file have gone down by 2/3 between 2010 and 2015.
Between 2010 and 2015, the rate of protests in PCT non-unity cases has continuously decreased from about 5.5% to 2.5% (currently a mere 16 cases per year).
In Biotech, continuous efforts are being taken and initiatives are being started to support even further harmonisation between examiners concerning their approach to non-unity.
It was pointed out by the **epi** that sometimes no extra documents are cited when additional search fees are paid.

The **epi** noted that the a posteriori objections are often the worst problem, because we do not know what prior art the EPO is going to find, and we do not know how claim 1 is going to be split up. As soon as there is a lack of novelty attack then the claims fragment, but it is difficult to predict how this is going to be decided, and once it has been decided, it is very difficult to change.
The EPO said that the applicants are free to present arguments for regrouping the inventions when paying the additional search fees.
With regard to the PCT protest procedure, the EPO stated that non-unity expert examiners are present in each directorate and will be assigned to the protest board by the director.
The protest success rate for PCTs was about 25-30%.

11. Added Matter

There was a brief discussion of existing guidelines. The emphasis should be on what the person skilled in the art would understand from the specification, however.

12. Other Matters

The next meeting is going to be scheduled for May or June 2016. The EPO requested that they receive the agenda from the **epi** sooner.
Victor Kaas suggested some changes to the format which were widely welcomed. The EPO would like to discuss Applicant filing strategies, and when they choose to use the PCT, the EPO and national cases. We can also talk about clients, and promising technical fields.
We could also mix up attendees, so instead of having one side of the table with **epi** and the other side EPO, we are mingled, making for a friendlier (and less them and us) atmosphere. We can also expand the agenda beyond formal questions, and if need be somebody could give a short presentation with a few slides.
We could also discuss promotion of EPO services and fees, for example comparing the fee structure with the other IP5. This should of course be seen as independent from the EPO, maybe a brochure could be produced. PCT direct appears to have been rarely used in the biotech sector.

Electoral Committee – Open Position

M. Müller (CH), Chair

Every three years, the over 11000 **epi** members from 38 states elect the approx. 140 members of the Council of the Institute. The elections are managed by the **epi** Electoral Committee (EC) and by the **epi** Secretariat. Prior to the election there is a nomination phase in which the list of candidates for each country is determined. The entire process is in transition: in 2014 for the first time the election was done by internet voting (by an external voting service provider), whereas the nomination process was revised but still done on paper. For the 2017 election, we are currently planning to have the nomination process done via the **epi** website. This will be an initial investment, with the goal of improving efficiency and transparency of the process.

The Electoral Committee has three members. Two are standing for re-election and so we are looking for a third member. Members of the Electoral Committe should have at least one, preferably both, of:
– Experience with the organisation of elections on a communal or higher level.
– An affinity for working with computer tools, in order to safely, reliably and efficiently implement the nomination and election.

A committment for remaining in the Committee for more than just one election is expected, in order to ensure continuity.
Members of the Electoral Committee may of course not be themselves candidates for election to the Council.

What's in it?

Taking responsiblility in a job that is not spectacular but vital for a functioning democratic process. Working in and for an international organisation.

What's next?

The members for the Electoral Committee will be elected by Council at its meeting on April 23, 2016. The next election will take place in February 2017, with work for the nomination phase beginning in the summer of 2016.

If you are interested and want to know more about the job, please write or phone the current chair of the Electoral Committee:

Dr. Markus Müller
Frei Patent Attorneys, Zürich, Switzerland
Phone: +41 44 396 20 60
E-mail: markus.a.mueller@frei-patent.ch

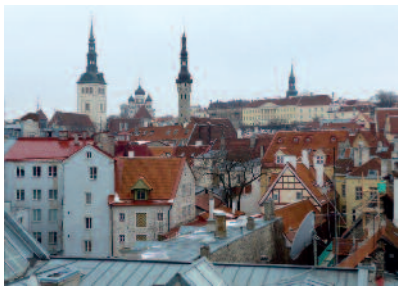
Note: You can also find – rather detailed – information on the **epi** website page on Rules and Regulations (patentepi.com/en/the-institute/rules-and-regulations.html), where you can download the Collection of Decisions. Therein, see the documents "3.1.3 Rules for Election of Council" and "3.3.3.2 Terms of Reference of the Electoral Committee".

94th Board Meeting in Tallinn

38 out of 41 Board members together with Mr Giorgio Checcacci (Chair of the Professional Conduct Committee) and Mr Maarten Nollen (member of the Editorial Committee) attended the 94th Board meeting in Tallinn (EE). The minutes of the 93rd Board Meeting were adopted with minor amendments raised at the meeting. The Treasurer announced a more positive balance than expected before and satisfactory financial results for 2016. As initiated by the President, Board exchanged points of view on how to change EQE. Mr Mercer on behalf of the Reporting Group presented to Board one proposal of reduction of the size of Council, as well as an alternative proposal suggested by Mr Laurent Nuss (FR). The positions of the member states have been mostly in favour of Proposal 1 developed by the Reporting Group. The Reporting Group discussion was carried on by Mr Francis Leyder on implementing electronic ballots by Council. Ms Marjut Honkasalo, on behalf of Mr Antero Virkkala (Chair of the Online Communication Committee), briefed Board on the problems arising from eDrex, i. e. the electronic Druckexemplar generated by the EPO by means of OCR. Mr Simon Wright (Secretary of the Biotech Committee) presented a report about the latest development such as the amicus curiae letter in the Ariosa v Sequenom case and gave an overview on national laws on nucleic acid sequences. Mr Maarten Nollen of the Editorial Committee gave a presentation on the communication programme and on the **epi** communication plans using the **epi** website and **epi** Information. Then, a short update on CSP (Candidate Support Project) by Ms Mihaela Teodorescu underlining a high passing rate for the EQE 2015 was followed by Mr Giorgio Checcacci's report on the recent PCC meeting from 9th March in Munich and his information about the current status of ongoing PCC projects (UPC Code of Conduct, Revision of Code of Conduct, CPE). Finally, Mr Paolo Rambelli (Chair of the Professional Education Committee) informed Board about the upcoming signature of the Memorandum of Understanding between EPO and **epi** and presented the Guidelines2day/Art. 84 EPC Roadshow in 2016 and 2017. Finally, Mr Peter Thomsen (CH) on behalf of the Swiss delegation presented a proposal of amendment of the **epi** decision on the use of professional titles.

The Board meeting was followed by an official reception and dinner on Saturday with high-ranking invited guests and IP experts such as Ms Kai Härmand (Deputy Secretary General, Legislative Policy Department of the Estonian Ministry of Justice), Mr Margus Viher (Director General of the Estonian Patent Office) and Mr Almar Sehver (President of the Estonian Patent Attorneys' Association).









epi Seminar "Opposition and Appeal" in Paris

C. Mulder (NL)

On 2 March 2016 Marcus Müller (member of the Boards of Appeal of the European Patent Office) and Cees Mulder (European patent attorney and associate professor of intellectual property law at Maastricht University) gave another successful Opposition and Appeal seminar in Paris for an audience of around 70 patent attorneys. The seminar was moderated by Jérome Collin.

The cycle of **epi** Opposition and Appeal seminars supported by the EPO started in December 2013 in Milano on request of Paolo Rambelli. Since then the seminars have been given more than 10 times at various locations all over Europe (including Barcelona, Eindhoven, Helsinki, London, Munich, Oslo, Stockholm and Warsaw).

The format of the seminar is that Marcus Müller takes the lead in presenting the seminar and that Cees Mulder acts as an aide with questions and remarks. This collaboration stimulates the attendees to also ask questions. This makes the seminars very vivid and stimulating for the audience as well as for the speakers. A lot of practical and tactical advice is given by the two speakers. For instance, Cees Mulder gives practical advice how to behave and act in oral proceedings and he also gives a presentation how to draft patent applications with the aim of preventing problems later on in opposition and appeal.

Usually, the seminars are moderated by the local **epi** PEC member. The **epi** organises the event in a friendly and professional manner.

In 2016 more Opposition and Appeal seminars have been scheduled: on 14 June in Zurich and on 27 September in Copenhagen.

Marcus Müller (DE)

- Member of the Boards of Appeal
- Deputy Chairman of Board 3.3.09 of the European Patent Office (Munich) 2010-Present
- Patent examiner at the European Patent Office (Munich) 2000-2009
- European Patent Attorney (trainee) at AkzoNobel (Arnhem, NL) 1997-2000

Cees Mulder (NL)

- European Patent Attorney 1999-Present
- Associate Professor of Intellectual Property Law (Maastricht University) 2009-Present

Previous experience

- Founding Partner of DeltaPatents (Eindhoven, NL) 2001-2009
- Philips Electronics (Eindhoven, NL) 1982-2001

epi Roadshow on UP/UPC Registration for Munich is open!

B. Riffert, **epi** Secretariat

The seminars will provide knowledge of both systems to allow **epi** members to work with the systems and to advise clients on strategic choices, for example on opting out of the Unified Patent Court (UPC), and unitary patent (UP) versus classical individual state validation. A number of the seminars (relating to the new UPC agreement and the changes in the EPC to accommodate the UP) will be held jointly with the EPO, with expert speakers from both the **epi** and the EPO.

The content of the seminar series focuses on:

- The way to European patents with unitary effect
- The legal framework, including overview of EU Regulations
- The Rules related to Unitary Patent Protection (RUPP)
- Annuity fees
- UPC: procedure, court structure, jurisdiction, territorial scope
- Current status of UPC agreement, timing, transitional phasing-in period, activities before entry into force
- Rules of Procedure; provisional measures, evidence, languages
- Costs and speed of proceedings
- Roles of Patent Attorneys within UPC, representation, privilege, UPC-register; opt-out, opt-in

Please be informed that the Education Team is currently finalising the dates in some countries.

The current schedule of the roadshow: http://patentepi.com/en/education-and-training/forthcoming-events.html

VESPA
Verband der freiberuflichen
Europäischen und Schweizer Patentanwälte

VIPS
Verband der Industriepatentanwälte
in der Schweiz

organisieren auch in diesem Jahr ein

PRÜFUNGSTRAINING FÜR DIE EUROPÄISCHE EIGNUNGSPRÜFUNG 2017

- Der Kurs versteht sich als letzte Etappe vor der Eignungsprüfung und als Ergänzung zu den eigentlichen Ausbildungskursen.
- Die Lehrfunktion des Kurses beschränkt sich demgemäss auf das Durcharbeiten konkret gestellter Prüfungsaufgaben der Teile A bis D und die Instruktion der Prüfungstechnik und -strategie durch erfahrene Europäische Patentanwälte.
- Die Aufgaben können nach Wunsch auf deutsch, englisch oder französisch bearbeitet werden, Modul 2 wird auf deutsch durchgeführt.
- Die Bewertung erfolgt vertraulich anhand der bei der Eignungsprüfung angewandten Kriterien. Eine schriftliche Korrektur wird abgegeben, Fragen an die Tutoren sind möglich.
- Der Kurs ist aus drei zeitlich getrennten Modulen aufgebaut (Module 1 und 3, jeweils einschliesslich Modul 2, können auch einzeln belegt werden) und umfasst je die Teile A bis D der Europäischen Eignungsprüfung.
- Teilprüfungskandidaten können auch einzelne Teile (A, B, C oder D) belegen, wobei die Kursgebühr entsprechend reduziert wird.
- An den Modulen 2 und 3 können auch Resitter teilnehmen (auch an einzelnen Teilen), deren nicht bestandene Prüfungsarbeiten (2016) wir im Rahmen von Modul 3 schriftlich kommentieren.

Aufteilung des Kurses:

Modul 1 (ab Juni 2016)
Die Kandidaten erarbeiten zu Hause schriftlich Lösungen zu den Prüfungsaufgaben des Jahres 2015. Die eingegangenen Arbeiten werden schriftlich korrigiert, bewertet und den Kandidaten wieder zugestellt, die Kandidaten können nach Erhalt der Korrekturen den Tutoren Fragen stellen und an Modul 2 teilnehmen.
Anmeldeschluss Modul 1 (und 2): 01.06.2016

Modul 2 (September 2016)
Vorstellen von Prüfungstechnik und -strategien für die einzelnen Teile. Ausführliche Besprechung der Fragen zu Prüfungsaufgaben 2015 und, wo erwünscht, Fehleranalyse der Kandidatenarbeiten.

Modul 3 (Anfang November 2016)
Die Kandidaten können zur Vorbereitung an Modul 2 teilnehmen. Modul 3 umfasst die Durchführung einer simulierten, dreitägigen Prüfung mit den Prüfungsaufgaben von 2016. Die an Modul 2 erarbeitete Strategie kann gezielt in Modul 3 geübt werden. Die Lösungen der Kandidaten werden korrigiert, bewertet und den Kandidaten zugestellt. Die Kandidaten können nach Erhalt der Bewertung zu ihren Aufgaben den Tutoren Fragen stellen.
Anmeldeschluss Modul 3 (und 2): 01.09.2016

- **Kursgebühr Modul 1 (inkl. Modul 2 für alle Teile A-D): CHF 600.-**
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Contact Data of Legal and Unitary Patent Division

Update of the European Patent Attorneys database

Please send any change of contact details using EPO Form 52301 (Request for changes in the list of professional representatives: http://www.epo.org/applying/online-services/representatives.html) to the European Patent Office so that the list of professional representatives can be kept up to date. The list of professional representatives, kept by the EPO, is also the list used by **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 523 of any change in your contact details.
Kindly note the following contact data of the Legal and Unitary Patent Division of the EPO (Dir. 5.2.3):

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legaldivision@epo.org
www.epo.org

Thank you for your cooperation.

A Solution to eDrex OCR Problems

T. Jackson (GB), European Patent Attorney

In his article "*eDrex – the new T-Rex?*", **epi** Information 3/2015, pp104-106, Antero Virkkala highlights the risks for applicants and their representatives posed by the EPO's new "electronic Druckexemplar" (eDrex) process.

Instead of facsimile copies of the pages submitted by the applicant, the eDrex text intended for grant of a patent includes pages which have been processed by optical character recognition (OCR). These may therefore be subject to errors introduced during the OCR process.

Mr Virkkala shows how such OCR errors could have serious consequences, including loss of rights. This is despite the EPO's accuracy claims, and despite the best efforts of the applicant's representative to check the eDrex during the procedure under Rule 71(3) EPC.

Furthermore, he notes that in future the EPO is likely to favour "early OCR processing", under which all pages would be OCR-processed at the beginning of the examination, not just a few pages at the end of the examination which have amendments by the Examiner.

As Mr Virkkala points out, instead of a page-by-page check that the facsimile Druckexemplar corresponds to the representative's file copy, an eDrex dramatically increases the amount of checking required. It is now advisable to check the text character-by-character instead of page-by-page.

This article examines the legal background to these problems, and proposes a solution which could be easily implemented by simple changes to the wording of EPO communications.

Legal background

Article 70 EPC governs the authentic text of a European patent, but is mainly concerned with language issues. It is Rule 71a(1) EPC which enables us to determine exactly which version of the application text becomes the authentic text of the granted patent. This rule provides that the EPO's decision to grant a European patent "shall state which text of the European patent application forms the basis for the decision". The EPO does this in its standard form letter "Decision to Grant a European patent" (EPO Form 2006A).

For many years, that standard "Decision to Grant" Form 2006A has stated that the European patent is granted "with the title and supporting documents indicated in the communication pursuant to Rule 71(3) EPC". Thus, the authentic text of the patent is determined not by the EPC, but by the contents of two EPO communications.[1]

In particular, the communication under Rule 71(3) EPC (EPO Form 2004C) encloses the Druckexemplar, and sets out a detailed list of the pages contained within it, with their respective dates of filing. The applicant is deemed to approve this text by paying the required fees and filing translations of the claims (Rule 71(5) EPC). It is well understood that once approved, this will become the authentic text of the granted patent.

In Decision G 1/10, the Enlarged Board of Appeal considered whether Rule 140 EPC can be used to correct errors in the authentic text of a European patent after grant. The decision is clear: such correction is not possible. The applicant has the opportunity at the Rule 71(3) stage to ensure that the patent as granted is in the exact form he wants it to be. The burden lies with the applicant to check the text before approving it. Amongst the Enlarged Board's reasons was a concern for legal certainty for third parties.

Thus, once the applicant is deemed to have approved the text under Rule 71(5), and it has been granted, the only remedy is an appeal against the Decision to Grant, filed within two months of its date. Errors discovered subsequently cannot be corrected.

More recently, Decision T 1869/12 concerned a case in which the applicant's response to the Rule 71(3) communication requested (*inter alia*) deletion of amendments proposed by the Examining Division in the Druckexemplar. A subsequent EPO communication said that the applicant's request had been allowed, but enclosed copies of pages in which the Examining Division's amendments still remained. There was thus a discrepancy between the communication and the enclosed pages.

In an obiter dictum, the Board focused on what the Examining Division had intended to grant, rather than on what the applicant had approved. Despite the wording of the communication, it was clear that the Division intended to grant the patent with the amendments shown in the enclosed pages. Thus, while remitting the case back to the Examining Division for a properly reasoned decision, the Board made clear that the text could not be corrected as desired by the applicant.

1 Since July 2015, the "Decision to Grant" wording has been supplemented with a reference to a possible third EPO communication, the new information Form 2004W. This is issued if the applicant has requested amendments to the Rule 71(3) text, and waived the right to a further Rule 71(3) communication.

A possible solution to OCR problems?

In the latest Guidelines for Examination, effective November 2015, it seems that the EPO has recognised this OCR problem, and attempted to ameliorate it. Section H-VI, 4 includes the following:

> *Exceptionally, and in consideration of all relevant circumstances of the case, formatting/editing errors which were already contained in the text approved by the applicant may be corrected by the EPO of its own motion or at the request of the patent proprietor. Formatting/editing errors are alterations in the patent documents which occur during the preparation of the Druckexemplar and which are indicated neither by standard marks nor in Form 2004C or 2004W.*

While this is welcome, does it solve the problem?

It has been suggested that this new Guideline is based on the obiter dictum in Decision T 1869/12 above, which focused on what the Examining Division intended to grant. It can be argued that OCR errors are not intended by the Examining Division. So they can be corrected in the same way as printer's errors, to bring the granted text into agreement with what was intended.

This may work, but can we be sure? Will future Boards of Appeal always agree that OCR errors can be corrected, "exceptionally and in consideration of all relevant circumstances of the case"?

In T 1869/12 there was a discrepancy between the communication and the enclosed pages, but in the opinion of the Board it was clear how to resolve what the Examining Division intended. Currently, the communication under Rule 71(3) EPC refers both to pages as filed by the applicant on particular dates, and to the enclosed eDrex text. Which is the Examining Division's intention, if they differ? Will future Boards of Appeal always hold that OCR errors cannot have been intended, especially in future when the entire examination may have been based on a text which included those OCR errors? What if a future Board determines that the OCR-processed text had anyway been approved by the applicant, as required by G 1/10, irrespective of the Examining Division's intention?

A proposed additional solution

Consider the root of the problem:

- The authentic text approved by the applicant is defined by the content of two EPO communications.
- Currently those communications are worded to define the text not only by reference to pages filed by the applicant, but also by reference to the eDrex, which may contain OCR errors.
- Despite the new Guideline H-VI, 4, it is therefore still possible that the eDrex will be held to be the authentic text, including the OCR errors.
- That authentic text, when approved by the applicant, cannot be corrected if the OCR errors are discovered after grant (Decision G 1/10).

However, what if the wordings of the relevant EPO communications were altered, such that they defined the authentic text differently? What if they defined the text intended for grant in terms that definitely excluded any OCR errors? This would strengthen the new Guideline by removing the uncertainties.
Annexes 1 and 2 give proposals to do exactly that.[2]

The proposed wording of the Rule 71(3) communication (Form 2004C) sets out a detailed list of the pages supplied by the applicant and their respective dates of filing, as at present. But it makes clear that the accompanying eDrex is merely indicative. The eDrex helps the applicant to check the pages, but it is not itself intended to be the authentic text for grant of the patent.

Instead, the authentic text lies only in the pages that the applicant actually filed. So it does not include any OCR errors which may have inadvertently occurred in the production of the eDrex, or earlier in the examination process. If there are amendments by the Examining Division, these will be indicated in the eDrex by standard marks (Guidelines for Examination, C-V, Annex). The proposed wording of the Rule 71(3) communication refers to those standard marks. Thus, the authentic text will include any amendments which the Examining Division intended to make, but will exclude any OCR errors that they did not intend. At the same time, as emphasised by the Enlarged Board in Decision G 1/10, it is important that the authentic text continues to be precisely defined, since this provides legal certainty for third parties. As at present, the proposals ensure that the authentic text is clearly set out in the communication under Rule 71(3) EPC, which can be inspected by third parties.

The B1 publication of the patent will be merely indicative of the authentic text of the patent, and may contain inadvertent errors. These may be errors arising in the publication process after approval of the text, and also OCR errors introduced by the eDrex process. That is also similar to the present situation, where the B1 publication is merely indicative and may contain publication errors, compared to the authentic text. However, under the proposals, OCR errors no longer form part of the authentic text of the patent.

Decision G 1/10 will continue to apply. After grant, the proprietor will be unable to make corrections to the

2 The further information Form 2004W will likely also need corresponding amendments.

approved Rule 71(3) text under Rule 140 EPC. However, there will be no need to correct OCR errors after grant under that rule, because the approved authentic text will not suffer from them. If the applicant wishes, any OCR errors could instead be corrected by a simple request, in the same way as printer's errors.

Annex 1

Form 2004C – proposed amendments

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the Examining Division intends to grant a European patent on the basis of the above application, with the text and drawings filed by the applicant on the date or dates listed below, together with any amendments thereto by the Examining Division specifically mentioned below, and with the related bibliographic information as indicated below.

~~A~~ An indicative copy of the relevant documents is enclosed.

1.2 In the text for the Contracting States:

[List the Contracting States]

[List the page/claim numbers with their dates of receipt and dates of the applicant's letters, as at present]

With the following amendments to the above-mentioned documents proposed by the division and indicated by standard marks in the enclosed copy

[List the page and claim numbers which have been amended]

Comments

[Insert any comments and continue with the remaining text of the communication, as at present]

Annex 2

Form 2006A – proposed amendments

Decision to grant a European patent pursuant to Article 97(1) EPC

Following examination of European patent application No. _____ a European patent with the title ~~and the supporting documents~~ indicated in the communication pursuant to Rule 71(3) EPC (EPO Form 2004C) or in the information (EPO Form 2004W) dated _____ is hereby granted in respect of the designated Contracting States on the basis of the supporting documents filed by the applicant on the date or dates listed in the Form 2004C or 2004W, together with any amendments thereto specifically mentioned by the Examining Division in the Form 2004C or 2004W.

[Continue with bibliographic details and remaining wording, as at present.]

Post Brüstle Developments in EU Biotech Patent Law at the CJEU

H.P. Brack (CH)

Abstract: The Court of Justice of the European Union (CJEU) is expected to have an increasingly important role in patent matters in the future. This is because the EU countries and Parliament have agreed on a 'patent package' that lays the groundwork for the creation of unitary patent protection in the EU in the form of a European patent with unitary effect ('unitary patent') and a single specialized forum (the 'Unified Patent Court' or UPC) with exclusive jurisdiction for litigation relating to European patents and European patents with unitary effect.

The regulations on the unitary patent[1a] and on its language regime[1b] are legal instruments of the EU. Under Article 267 of the Treaty on the Functioning of the European Union[2] it is a primary role of the CJEU to interpret the Union law. Furthermore the Agreement on a Unified Patent Court[3] stipulates that the UPC is obliged, in the same way as a national court, to request preliminary rulings from the CJEU in order to clarify questions concerning the interpretation of EU law. Therefore it is clear that the CJEU will have an increasingly important role to play in patent matters in Europe, and it will be prudent for European patent attorneys to become familiar with its case law in the IP area.

As this case shows, national courts may unfortunately become bound to follow case law coming from the CJEU based on poor technical advice provided to the CJEU, or perhaps their lack of experience in the patent area, as some patent practitioners fear. Nonetheless this case also illustrates that such situations may be corrected by means of subsequent referrals to the CJEU.

Legal uncertainty resulting from CJEU case C-34/10 (Brüstle vs. Greenpeace): In an earlier paper on this topic in this journal[4], it was discussed how the CJEU in the case C-34/10[5] had provided clarification to the referring German Federal Court of Justice concerning the interpretation of several important aspects of the EU Directive 98/44/EC[6]. In particular, the CJEU specified how the term "embryo" should be defined and also how several exclusions from patentability related to that term should be interpreted.

The *Brüstle* Court at the CJEU held that „any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo';". In balancing the interests of society, the CJEU was careful to err on the side of broader basic rights protection at the expense of narrower industrial property rights protection. Although their decision generally received positive reviews from practitioners and the industry, it nonetheless soon became clear that the *Brüstle* decision C-34/10[5] had created some significant legal uncertainty on one aspect.

In particular, it remained unclear whether human 'parthenotes' should fall under the definition of a human embryo according to Directive 98/44[6]. It should be briefly noted that totipotent stem cells are the most versatile type of stem cell, and they are capable of developing into a complete, viable organism. In the case of parthenogenesis, chemicals are used to induce an egg to begin developing as if it had been fertilized, and the resulting egg (a parthenote) behaves like an early stage embryo. However because it contains no genetic material from a father, according to current scientific knowledge it cannot develop into a viable (human) fetus. Nonetheless the *Brüstle* court at the CJEU had equated human parthenotes with human embryos, and indicated that the definition of "human embryo" for the purposes of the Directive included human parthenotes. It will next be discussed how this apparent contradiction led to uncertainty in the interpretation of the Directive and a subsequent further referral to the CJEU from a national court for clarification.

Refusal of two GB patent applications - UK IPO BL O/316/12 (International Stem Cell Corporation): The issue in this decision[7] of the UK IPO was whether the Patent Applica-

1 (a) Regulation (EU) No 1257/2012 of the European Parliament and the Council of December 17, 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection and (b) Council Regulation (EU) No 1260/2012 of December 17, 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ EU L 361 of December 31, 2012, p. 1 and p. 89.

2 Consolidated version of the Treaty on the Functioning of the European Union – Part Six: Institutional and Financial Provisions - Title I: Institutional Provisions - Chapter 1: The institutions - Section 5: The Court of Justice of the European Union - Article 267 (ex Article 234 TEC), Official Journal EU C 115, of May 9, 2008, p. 164.

3 Agreement on a Unified Patent Court OJ EU C 175 of June 20, 2013, p. 1.

4 H.P. Brack, "The most important decisions of the EUEJ in patent matters", epi Information, 2/13, p. 54.

5 Judgment of the Court (Grand Chamber) of 18 October 2011, Brüstle v Greenpeace, available on-line, accessed 07.01.2016 at http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10

6 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ EU L 213, of July 30, 1998, p. 13.

7 UK IPO Patent Decision of 16 August 2012, BL number O/316/12, available on-line, accessed 01.01.2016 at https://www.ipo.gov.uk/p-challenge-decision-results/p-challenge-decision-results-bl?BL_Number=O/316/12

tions GB0621068.6 and GB0621069.4 complied with Schedule A2 of the UK Patents Act 1977[8], which was introduced into the Act in 2000 to implement articles 1-11 of Directive 98/44/EC[6].

The first ISCC patent application claims methods of producing pluripotent human stem cell lines from parthenogenetically-activated oocytes and stem cell lines produced according to the claimed method. The second ISCC patent application claims methods of producing synthetic cornea or corneal tissue involving the isolation of pluripotent stem cells from partenogenetically-activated oocytes as well as synthetic cornea or corneal tissue produced by these methods.

The UK IPO examiner's objection in his letter to the applicant[9] was that the claimed methods of producing stem cell lines, or synthetic corneas or corneal tissue, and/or the stem cell lines or synthetic corneas or corneal tissue thus produced, constitute uses of human embryos for industrial or commercial purposes, and they are thus excluded from patentability under Paragraph 3(d) of Schedule A2 of the Act. The core of the examiner's argument was that the parthenogenetically-activated oocytes produced in step (a) of claim 1 of either application, and/or the parthenogenetic blastocyst-like structures derived from them in the subsequent steps, fall within the definition of a "human embryo" for the purpose of Schedule A2 of the UK Patent Act. The examiner had given two main reasons for this argument; firstly, the decision of the CJEU in case C-34/10 *Brüstle* and, secondly, the definition of the term "embryo" provided by the UK Human Fertilisation and Embryology Act 1990[10], as amended by the Human Fertilisation and Embryology Act 2008 (the "HFE Act")[11], which defines an embryo as including "an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo."

The UK IPO hearing officer, concluded that the clear and unambiguous statement of the CJEU that human parthenotes were encompassed by the definition of "human embryos" left no choice but for the UK IPO to refuse both patent applications from ISCC, as they both claimed methods in which an unfertilised oocyte is activated by parthenogenesis and caused to develop into a parthenogenetic blastocyst-like structure and that this parthenogenetic blastocyst-like structure is then used (and necessarily destroyed by the disclosed methods for the mechanical separation of the inner cell mass) to produce stem cells and/or corneal tissue. In particular, he noted that if the parthenogenetically-activated oocyte and the parthenogenetic blastocyst-like structure constitute human embryos, then the claims of both applications relate to the unpatentable commercial or industrial use of a human embryo. In addition, the hearing officer stated that since he had decided that the parthenogenetic blastocyst-like structure is a human embryo as defined in Article 6(2)(c) of the Directive, any product-by-process and omnibus claims to stem cells, synthetic cornea or corneal tissue produced from it are also necessarily not patentable. The hearing officer felt there was no inconsistency between his conclusion that the various cell types used by and produced by the methods of the two patent applications were not capable of developing into a human being and his decision that nonetheless all of the claims of both patent applications related to unpatentable subject matter according to the Directive, thus necessitating their refusal.

Referral to the CJEU - UK Patents Court, International Stem Cell Corporation v Comptroller General of Patents, Case No. [2013] EWHC 807 (Ch): ISCC appealed the decision to refuse its patent applications to the Patents Court[12]. ISCC argued in its appeal brief that the test adopted by the CJEU in C 34-10 (*Brüstle*) was intended to exclude from patentability only those organisms capable of commencing and actually completing the process of development which leads to a human being. ISCC cited as supporting evidence for this line of argumentation the wording of the CJEU's test and its similar treatment of fertilised ova and non-fertilised ova subjected to somatic-cell nuclear transfer, as well as the BGH's final judgment after the CJEU's ruling in *Brüstle*. Thus ISCC argued that parthenogenetically-activated human oocytes would therefore only be excluded from patentability to the extent that they are capable of producing human totipotent cells, which would then have the capability to develop into a complete human being.

The Comptroller General argued that the CJEU's ruling in *Brüstle* was not clear with respect to the question whether the term 'human embryo' covers organisms capable of commencing the process of development of a human being irrespective of whether the process could be completed. Furthermore the Comptroller General argued that it was equally unclear as to whether or not the CJEU had in fact relied on inferior submissions reflecting an inaccurate current scientific understanding of the subject matter of parthenotes in their decision on that aspect.

It is noteworthy that the referring UK Patent Court presented its own view on this question in stating that if the parthenogenetically-activated oocytes at issue are incapable of developing into a human being, they should not be regarded as human embryos. Futhermore Judge Carr indicated that the factual matrix in the case before him was

8 UK Patents Act 1977, available on-line, accessed 01.01.2016 at http://www.legislation.gov.uk/ukpga/1977/37/contents

9 The UK IPO Examination Report of 3. August 2010, availablew on-line, accessed 12.01.2016 at https://www.ipo.gov.uk/p-ipsum/Document/ApplicationNumber/GB0621069.4/GCG6C52Jdms/GB2440333-20100803-Exam%20report%20%20Standard.pdf

10 UK Human Fertilisation and Embryology Act 1990, available on-line, accessed 01.01.2016 at http://www.legislation.gov.uk/ukpga/1990/37/contents

11 UK Human Fertilisation and Embryology Act 2008, available on-line, accessed 01.01.2016 at http://www.legislation.gov.uk/ukpga/2008/22/contents

12 UK High Court Of Justice, Chancery Division, Patents Court, Judgement of April 17, 2013, [2013] EWHC 807 (Ch), available on-line, accessed 01.01.2016 at http://www.bailii.org/ew/cases/EWHC/Ch/2013/807.html

quite different to that before the CJEU in *Brüstle*. In particular, genomic imprinting meant that in contrast to a fertilised ovum, there were no totipotent cells present in a parthenote, even in the first few cell divisions after activation. According to the current state of knowledge in the art, despite the superficial similarities in their initial development, parthenotes and fertilised ova were not identical at any stage. On this basis he felt there was clearly sufficient doubt as to the precise meaning of the ruling in *Brüstle*, and as to whether the CJEU would have come to the same conclusion as it did on parthenotes with the current facts, to justify making a further reference.

Therefore with his ruling on April 17, 2013 Judge Carr made a reference to the CJEU to clarify this issue by the following referred question[13]:

Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?

CJEU C-364/13, International Stem Cell Corp. v Comptroller General of Patents: Written observations were submitted in this case by the party ISCC, as well as the Member States FR, PL, PT, SE, and the UK and the Commission. A hearing was held on 29.04.2014 and ISCC, the UK, FR, SE and the Commission all made oral observations there.

The Opinion of the Advocate General (AG) from 17. July 2014: Pedro Cruz Villalón, the AG, stated[14] that the preliminary considerations in his opinion included both better current scientific knowledge concerning the developmental capabilities of parthenotes and the possibility to perhaps change these capabilities by means of future genetic manipulation technologies. The AG noted first of all that all parties and the referring court unanimously agreed that according to current scientific knowledge "genomic imprinting" and the lack of paternal DNA prevented human parthenotes from developing proper extra-embryonic tissue and thus to term. The agreement on this point contrasted with the diverging opinions of the parties and the referring court in the earlier *Brüstle* case.

Villalón noted that the referring court and parties in the present case nonetheless also agreed that the barrier presented by genomic imprinting might be surmountable in the future by unforeseen developments in genetic manipulation technologies. In addition, the PT and the UK governments noted in their submissions that the "tetraploid complementation" method had been used already to obtain viable adult descendants from mice parthenotes. However the patent applicant, ISCC, stated that such genetic manipulation changed the very nature of the parthenote in question. Furthermore the FR government had noted that such manipulation of human parthenotes would be illegal there, and the UK High Court noted that the pending amended claims of the ISCC patent applications excluded the possibility of such genetic manipulations.

The AG opined that therefore a critical point to consider was that the CJEU in their judgement in *Brüstle* had intended to primarily focus on the inherent capacity of various cells and multicellular organisms to develop into a human being. The AG stated that a close look at the judgment shows that the Court at the CJEU meant to inquire as to whether an unfertilised ovum has the inherent capacity of developing into a human being or not. The AG's opinion then seemed to indicate that the CJEU in *Brüstle* had not been provided with the best current scientific knowledge on this issue. Villalón pointed out that in *Brüstle* the Court had established a functional equivalence between fertilised ova, non-fertilised ova subjected to somatic-cell nuclear transfer and parthenotes, even though parthenotes, as is now apparent, are the only organisms among those three that cannot develop into human beings. The AG opined that if the Court had actually been aware of the fundamental difference between parthenotes and non-fertilised ova subjected to somatic-cell nuclear transfer and nonetheless wanted to establish a functional equivalence between the two organisms, it would certainly have discussed this difference in their judgement. Villalón thus stated[14]: "It is hence reasonable to assume that the observations submitted at the time in *Brüstle* caused the Court to have the impression that all three organisms possess the inherent capacity to develop into a human being. …" He contrasted that with the present ISCC case in which the referring court and the parties all unequivocally agreed that the submitted evidence on current scientific knowledge demonstrated that a parthenote does not, per se, have the required inherent capacity of developing into a human being and hence as such does not constitute a 'human embryo'.

AG Villalón proposed that the Court should answer the question referred as follows:

"Unfertilised human ova whose division and further development have been stimulated by parthenogenesis are not included in the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection

13 Reference for a preliminary ruling from High Court of Justice (Chancery Division) (United Kingdom) made on 28 June 2013 – International Stem Cell Corporation v Comptroller General of Patents (Case C-364/13), available on-line, accessed 12.01.2016 at http://curia.europa.eu/juris/document/document.jsf?text=&docid=140398&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=102572

14 Opinion Of Advocate General Cruz Villalón, delivered on 17 July 2014, Case C-364/13, International Stem Cell v. Comptroller General of Patents, accessed 03.01.2016 at http://curia.europa.eu/juris/document/document.jsf?text=&docid=15512&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=69363

of biotechnological inventions as long as they are not capable of developing into a human being and have not been genetically manipulated to acquire such a capacity."

AG Villalón emphasized that, in his view, even if human parthenotes are to be excluded from the concept of human embryos, the Directive does not prevent a Member State from excluding parthenotes or other organisms from patentability on the national level based on ethical and moral considerations.

The Decision of the ISCC Court at the CJEU from 18. December 2014: In their decision[15], the *ISCC* Court first specifically noted several aspects of the referral relevant to their answer to the referred question, as in the AG's opinion. First of all, that the referring court had stated that although a "parthenote" is capable of dividing and developing further, according to current scientific knowledge, human parthenotes can never develop to term because they lack paternal DNA. Second of all, the referring court had also stated that ISCC had amended its applications and their claims to exclude the possibility of using any method to overcome the inability of a parthenote to develop into a human being. Finally, according to the referring court, to exclude parthenotes from patentability does not strike an appropriate balance between encouraging biotechnology research by patent law and respect for the fundamental principles safeguarding the dignity and integrity of the person.

The *ISCC* Court then proceeded to reaffirm and clarify the key aspect of the earlier *Brüstle* decision in that "human embryos" meant being "capable of commencing the process of development of a human being". Firstly, the Court reaffirmed several points of the earlier *Brüstle* decision. The *ISCC* Court also emphasized that the concept of "human embryo" within the meaning of the Article 6(2)(c) of the Directive must be understood in a wide sense. The *ISCC* Court further stated that the *Brüstle* Court had specified that that classification must be applied to parthenotes because – although they are not strictly speaking the object of fertilisation – according to the written observations presented to the Court, parthenotes were just as capable of commencing the process of development of a human being as an embryo created by fertilisation of an ovum can do. Thus the *ISCC* Court concluded that it followed from the earlier *Brüstle* decision that a non-fertilised human ovum must be classified as a "human embryo" within the meaning of Article 6(2)(c) of the Directive in so far as the organism is "capable of commencing the process of development of a human being".

The *ISCC* Court went on to clarify however that the key aspect of "human embryos" was an "inherent capacity of developing into a human being" and that the term "human embryos" according to the Directive therefore excluded ovums lacking that capacity according to current scientific knowledge. Thus the *ISCC* Court concluded that the answer to the question referred is that Article 6 (2) (c) of Directive 98/44 must be interpreted as meaning that an unfertilised human ovum whose division and further development have been stimulated by parthenogenisis does not constitute a "human embryo", within the meaning of that provision, if, in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.

Grant of Patents, GB2431411B and GB2440333, by UK IPO on 4. November 2015[16,17]: The UK High Court made an Order on 22. January 2015 and a Consent Order on 29. April 2015 that resulted in both applications being remitted by the Comptroller to the Examiner for further examination, and they were both granted as patents.

Conclusion: This CJEU case, C-364/13 *ISCC*, illustrates how national courts may unfortunately become bound to follow case law coming from the CJEU based on poor technical advice provided to the CJEU, as was at least partially true concerning the alleged capabilities of pathenotes to develop into human beings in C-34/10 *Brüstle*. Nonetheless this case also illustrates that such situations may be corrected by means of subsequent referrals to the CJEU. Arguably the time required for such corrections is not overly unreasonable, as a total of slightly more than three years was required for a "correcting" judgment by the CJEU. Encouragingly the CJEU has also left considerable discretion to the national courts to determine what current scientific knowledge has to say concerning the ability of various types of organisms to develop into human beings or not.

After the EU patent package concerning unitary patent protection and the unified patent court comes into effect in the hopefully near future, it will be interesting to see whether or not there will be other examples of case law coming from the CJEU requiring correcting judgements as some patent practitioners fear.

Acknowledgement: Frederik Grever (NL) is thanked for his kind review of this manuscript.

15 Judgement Of The Court (Grand Chamber), 18. December 2014, Case C-364/13, International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks, accessed 03.01.2016 at http://curia.europa.eu/juris/document/document.jsf?text=&docid=160936&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=69363

16 Ipsum – Online Patent Information and Document Inspection Service, GB2431411 – Parthenogenic activation of human oocytes for the production of human embryonic stem cells, available on-line, accessed 12.01.2016 at https://www.ipo.gov.uk/p-ipsum/Case/PublicationNumber/GB2431411

17 Ipsum – Online Patent Information and Document Inspection Service, GB2440333 – Synthetic cornea from retinal stem cells derived from human parthenotes, available on-line, accessed 12.01.2016 at https://www.ipo.gov.uk/p-ipsum/Case/ApplicationNumber/GB0621069.4

Zusammenfassung

Der Gerichtshof der Europäischen Union (EuGH) erhält in der Zukunft im Bereich des Patentschutzes eine noch grössere Bedeutung. Grund dafür ist die Einigung der EU-Länder und des Europäischen Parlaments über das sogenannte Patentpaket, das die Grundlage für einen einheitlichen Patentschutz in der Europäischen Union in Form eines europäischen Patentes mit einheitlicher Wirkung schafft und die Errichtung eines Einheitlichen Patentgerichts (EPG) mit einer ausschließlichen Zuständigkeit für europäische Patente und europäische Patente mit einheitlicher Wirkung vorsieht.

Die Vorschriften über das einheitliche Patent und die Sprachregelungen sind Rechtsinstrumente der EU. Gemäss Artikel 267 des Vertrags über die Arbeitsweise der Europäischen Union ist der Gerichtshof der Europäischen Union für die Auslegung des Unionsrechts zuständig. Ausserdem sieht das Übereinkommen zur Schaffung eines einheitlichen Patentgerichts vor, dass das Einheitliche Patentgericht, wie jedes nationale Gericht, die korrekte Anwendung und einheitliche Auslegung des Unionsrechts sicherstellen muss, indem es den Gerichtshof der Europäischen Union um Vorabentscheidungen ersucht. Der EuGH wird somit eine immer wichtigere Rolle auf dem Gebiet der Patentsachen in Europa einnehmen, weshalb die European Patent Attorneys vor dem Europäischen Patentamt sich mit dessen Rechtsprechung im IP-Bereich vertraut machen sollten.

Wie der vorliegende Fall zeigt, müssen die nationalen Gerichte die Rechtsprechung des EuGH auch dann beachten, wenn ein Entscheid sich auf eine unkorrekte technische Begutachtung oder eine mangelnde Erfahrung im Patentbereich stützt. Dieser Fall veranschaulicht aber auch, dass solche Entscheide nachträglich, gestützt auf die Rechtsprechung des EuGH, berichtigt werden können.

Résumé

La Cour de justice de l'Union européenne (CJUE) devrait avoir un rôle plus important en matière de brevets à l'avenir. En effet, les pays de l'UE et le Parlement se sont entendus sur un «paquet de brevet» qui établit les bases pour la création d'une protection par brevet unitaire dans l'UE sous la forme d'un brevet européen à effet unitaire («brevet unitaire») et un seul forum spécialisé («Unified Patent Court» ou UPC, tribunal pour les brevets unitaires) ayant compétence exclusive pour les litiges en matière de brevets européens et les brevets européens à effet unitaire.

Le règlement sur le brevet unitaire et sur son régime linguistique sont des instruments juridiques de l'UE. Conformément à l'article 267 du traité sur le fonctionnement de l'Union européenne, la CJUE a pour vocation d'interpréter les lois de l'Union. En outre, l'accord sur un tribunal pour les brevets unitaires stipule que l'UPC est obligé, de la même manière qu'un tribunal national, de saisir la CJUE de questions préjudicielles afin de clarifier les questions concernant l'interprétation des lois de l'UE. Il est donc clair que la CJUE aura un rôle plus important à jouer en matière de brevets en Europe, et il sera prudent pour les conseils en brevets européens de se familiariser avec sa jurisprudence dans le domaine de la propriété intellectuelle.

Comme cette affaire le montre, les tribunaux nationaux peuvent malheureusement être tenus de suivre la jurisprudence de la CJUE établie sur la base de mauvais conseils techniques qui lui ont été fournis, ou éventuellement de leur manque d'expérience dans le domaine des brevets, comme le craignent certains conseils en brevets. Toutefois, ce cas illustre également que de telles situations peuvent être corrigées à l'aide de références ultérieures à la CJUE.

Next Board and Council Meetings

Board Meetings

95th Board meeting on 10 September 2016 in Amsterdam (NL)

Council Meetings

80th Council meeting on 23 April 2016 in Athens (GR)
81th Council meeting on 12 November 2016 in Berlin (DE)
82th Council meeting on 24/25 April 2017 in Munich (DE)

A New Scenario for Infringement of Second Medical Use Patents: Are Generics Liable when They Participate in Discount Contract Tenders?

Dr. K. Rüting (DE)

Recent decisions in the Netherlands, the UK, Denmark and Germany have shed light on the enforcement of second medical use patents.[1] One issue considered by the courts in their infringement analysis was the regulatory reimbursement practice of public health insurance companies under the different national laws. Courts in the Netherlands and Germany now held generics liable for indirect infringement of second medical use claims because they had participated in public tenders of health insurance companies, even though they had carved out the patented indications under a so-called "skinny label".[2] The ruling of the German court is of particular interest as it deviates from a (criticized but widely accepted) ruling of another German court which had *de facto* denied indirect infringement in case of second medical use claims.[3] This article focuses on the German perspective and outlines the new liability generics potentially face in particular in Germany, but potentially also in other jurisdictions that may take this approach as a guideline for developing their case law.[4]

1. Background

In cases where no patent for the compound or any first medical use exists or has already expired, second medical use patents provide for protection of a new (second) medical use of the compound, i.e. normally a new indication for treatment. The protection of such invention is problematic under the European Patent Convention (EPC) because (i) protection over the compound cannot be granted since it is already know and thus lacks novelty and (ii) the EPC prohibits patent methods of treatment of human by therapy[5]. The EPO initially established the practice of granting second medical use claims in the form of "Swiss-type" claims, i.e. "use of compound X for the manufacture of a pharmaceutical compound for the new therapeutic application Y".[6] The EPC has since been amended to allow purpose limited product claims also for the second (and further) medical use which are referred to as "EPC 2000 claims".[7] While these EPC 2000 claims replaced Swiss type claims which will no longer be granted,[8] there are still many years where Swiss-type claims will exist for infringement considerations. For national German patent, a "German-type" claim for the second medical use claim had been endorsed which claims the "use of compound X for the new therapeutic application Y".

Cross-label use of drugs comes into play when generic companies market their generic drug under a "skinny label" on which the patented indication is explicitly carved out.[9] Then, patent infringement is discussed when the generics undertake additional advertising activities for promoting the product also for the patented (but off-label) indication.

Apart from advertising, the turnover with generic drugs is also highly influenced by discount contracts between public health funds and generic companies. German law encourages negotiating such discount contracts for drugs.[10] Importantly, pharmacies are even legally obliged to *substitute* a drug or active substance prescribed by physicians with one of the drugs listed in a discount contract of the respective public health fund.[11] Pharmacists use special software enabling them to correctly comply with all rebate contracts. The substitution applies as long as the discounted drug and the original drug *overlap in at least one* indication for which a marketing authorization exists.[12] That means substitution of the originator drug against the discounted generic takes place for all indications, not only the indication where the databases show an overlap. This regulatory system of rebate contracts and mandatory substitution gives generics a backdoor for marketing their drugs for

1 Warner-Lambert Company, LLC v. Actavis Group PTC EHF, UK Court of Appeal, 2015 EWCA Civ 556; Novartis AG v. Sun Pharmaceutical Industry (Europe) B.V., The Hague Court of Appeal, 27 January 2015, Case No. 200.1 50.713/01; Maritime und Commercial Court Copenhagen, Judgement of 26 June 2015, Case no. A-6-15; Warner Lambert LLC v. Hexal AG et al., District Court of Hamburg, 2 April 2015, Case Nos. 327 O 67/15 (Hexal), 327 O 143/15 (1A Pharma), 315 O 24/15 (Ratiopharm), 327 O 132/15 (Glenmark) and 327 O 140/15 (Aliud Pharma).

2 Novartis AG v. Sun Pharmaceutical Industry (Europe) B.V., The Hague Court of Appeal, 27 January 2015, Case No. 200.1 50.713/01; Warner Lambert LLC v. Hexal AG et al., District Court of Hamburg, 2 April 2015, Case Nos. 327 O 67/15 (Hexal), 327 O 143/15 (1A Pharma), 315 O 24/15 (Ratiopharm), 327 O 132/15 (Glenmark) and 327 O 140/15 (Aliud Pharma).

3 District Court of Düsseldorf, 24 February 2004, Case No. 4a O 12/03, GRUR-RR 2004, 193 (196) – Ribavarin; District Court of Düsseldorf, 19 April 2011, Case No. 4a O 236/09.

4 In the US, for instance, the Hatch-Waxman Act provides generics with the possibility to carve out indications in the label to be approved by the FDA for which no approval is sought. Cf. 21 U.S.C. § 355(j)(2)(A)(viii). State law often requires that the cheapest product has to be handed out by pharmacies. The US Court of Appeals for the District of Columbia has confirmed this regulation, even though the court acknowledged that this law interferes with the interest of protecting the manufacturer of a pioneer drug. Bristol-Mayers Squibb Co. v. Shalala, 91 F.3d 1493 (D.C. Cir. 1986).

5 Art. 52 (4) EPC 1973; EPO Enlarged Board of Appeal, G 5/83.

6 The name "Swiss-type" goes back to the practice of the Swiss Patent Office which was later endorsed by the EPO.

7 Art. 54 (5) EPC 2000.

8 EPO Enlarged Board of Appeal, G 2/08.

9 Sec. 11a(1e) German Medicinal Products Act.

10 Sec. 130a (8) German Code of Social Law V.

11 Sec. 129 (1) sentences 1-3 German Code of Social Law V.

12 Sec. 129 (1) sentence 2 German Code of Social Law V.

the patented indication. Depending on the protected indication, this may significantly impact the turnover of both generics and originators.

2. German Law Prior to the "Lyrica" Case

Second medical use claims, *i.e.* Swiss-type and German type claims, are classified as method claims under German law, even though there has been tendency to regard them as a separate category of product claims.[13] When it comes to the question of infringement, however, courts leave this strict classification and treat them *de facto* as product claims with the limitation to the claimed use (*i.e.* the patented indication). Courts shift the acts relevant for infringement considerations to an earlier point in time, *i.e.* prior to the sale of the drugs by pharmacies.[14]

2.1 Direct Infringement

According to established case law, a drug manufacturer can be held liable for direct patent infringement if it produces and sells its generic drug with label instructions describing the patented use. Such instructions are typically laid out in the package leaflet. Under German law adding such label constitutes a so-called "manifested arrangement" (*sinnfällige Herrichtung*).[15] The reasoning for considering this as an infringing act is that the manufacturer has fulfilled all relevant acts for patent infringement by labeling the drug for the patented medical use. The final infringing act performed by the patient will occur more or less automatically, as the patient will follow the label instructions. According to the case law, the "manifested arrangement" for the claimed use can also happen in other ways, for instance, by confectioning, ready to use preparation or dosage of the drug.

If there are no label instructions but only separate advertising acts which promote the drug for the patented use in marketing materials, flyers and statements by sales people, it becomes more difficult for the patentee. In these scenarios, courts have been reluctant to find for direct patent infringement.[16] The advertisement measures have been regarded as insufficient to be a manifested arrangement of the drug for the patented use. The courts stated that it were uncertain whether the recipient of the marketing material would take notice of the advertised second medical use and thus, it were similarly uncertain whether infringement will actually take place.

13 Cf. Federal Supreme Court, 2005 GRUR 135 – Arzneimittelgebrauchsmuser; Bopp, in: Festschrift for Reimann, p. 13 (16); Kaess, in: Festschrift for v. Meibom, p. 191.
14 Federal Supreme Court, 1992 GRUR 305 – Heliumeinspeisung; Federal Supreme Court, 1990 GRUR 505 – geschlitzte Abdeckfolie.
15 Most recently Düsseldorf Court of Appeal, 7 August 2014, Case No. 2 U 8/14; Federal Supreme Court, 1983 GRUR 729 – Hydropyridin; Federal Supreme Court, 1977 GRUR 652 – Benzolsulfonylharnstoff); Hufnagel, 2014 GRUR 123 (125); Königer, Kompter, Ludwig, Lunze, Prinz zu Waldeck und Pyrmont, Schüssler, Wiegeleben, in: 2014 GRUR Int. 906 and Question 238 of AIPPI.
16 Most recently Düsseldorf Court of Appeal, 7 August 2014, Case No. 2 U 8/14; Düsseldorf Court of Appeal, 31 January 2013, Case No. 2 U 54/11 – Cistus Incanus.

Courts have not yet decided whether and how these principles apply to EPC 2000 claims which are not method but purpose-limited product claims. Given their character as product claims, a less concrete relation between the product and the intended purpose might be regarded as sufficient which could mean a different outcome regarding advertising acts. The German Federal Supreme Court, however, does not seem to distinguish between the different kinds of claim language as indicated in a decision related to patentability of a purpose-limited product claim.[17]

2.2 Indirect Infringement

Indirect infringement requires that the drug manufacturer must have known or it must have been obvious from the circumstances that the drug is (i) suitable and (ii) intended to be used for the patented second medical use. Given that the production of the drug as such is in the public domain because there is no longer patent protection for the compound or the first medical use and the patented use is not indicated in the label instructions, this subjective requirement is different to establish in practice. A mere potential cross-label use of the drug for patented indications is normally not sufficient. Rather, infringement considerations depend on the facts of the case and the evidence the patentee can present (e.g. information material provided to physicians, statements by sales persons on the cross-label use, increased amount of prescriptions and sales, etc.).

Apart from this subjective requirement, the question of liability of the drug manufacturer for indirect patent infringement depends on whether the seized court would follow the Düsseldorf "Ribavirin" decision.[18] The Ribavirin case-law says that only the offer or supply of a compound *for the purpose of being prepared for* the patented purpose may constitute indirect infringement. According to this decision, the supply of the drug *for immediate use* could not be considered as indirect infringement. In a later decision, the Düsseldorf Court of Appeal explicitly left open whether it might consider indirect infringement in such scenarios and thereby deviating from "Ribarvirin". Given some criticism in the literature, a change of the Düsseldorf case-law does not seem to be unlikely.[19]

3. The "Lyrica" Case

The recent German Lyrica cases so far been decided concern various preliminary injunction proceedings initiated by Warner Lambert against several generics.[20] The preliminary injunction proceedings have been decided and the

17 German Federal Supreme Court, 25 February 2014, Case No. X ZB 6/13 - Kollagenase II.
18 District Court of Düsseldorf, 24 February 2004, Case No. 4a O 12/03.
19 Haedicke, 2004 Mitt. 145 (147); Brandi-Dohrn, in: Festschrift for König, p. 33 (42).
20 *Warner Lambert LLC v. Hexal AG et al.*, District Court of Hamburg, 2 April 2015, Case Nos. 327 O 67/15 (Hexal), 327 O 143/15 (1A Pharma), 315 O 24/15 (Ratiopharm), 327 O 132/15 (Glenmark) and 327 O 140/15 (Aliud Pharma).

appeal is pending. The cases provide a typical procedural scenario for PI requests: Price erosion of the original product takes place due to the market entry of the generics and therefore the patentee has to fear that it cannot compensate its losses in the course of lengthy main proceedings. In addition, the validity of the patent at issue had been confirmed in an opposition before the EPO which is a further criterion supporting PI proceedings.

The patented indication was not mentioned in the package leaflet. In addition, the generics made use of the possibility to carve out the patented indications in the expert information which is directed to physicians and pharmacists. The German Medicinal Products Act provides generics explicitly with such option if patent law protection exists at the time of placing the drug on the market. Warner Lambert argued indirect infringement and attacked the generics for two behaviors: (1) participating in public tenders for discount contracts conducted by public health insurance companies without notifying the health insurance companies that the generics could not market their products for the patented indication and (2) notices in software for pharmacies and wholesalers without notifying them that the drug cannot be marketed for the patented indication.

The Hamburg court granted the preliminary injunction with regard to the participation in public tenders for rebate contracts. The court put emphasis on the fact that these tenders do not state the specific indication of the drug but only refer to the active substance (active pharmaceutical ingredient, API). Pharmacies handing over the drug to patients derive their information only from these rebate contracts, which similarly also only refer to the active substance. Neither the pharmacies nor the patients will consider patent infringement, and obviously do not even have the opportunity to do so. In fact, German public regulations even *mandatorily* require pharmacies to substitute a drug or active substance prescribed by physicians with one of the drugs listed in the discount contract of the individual public health fund. A substitution will take place as long as there is an overlap in one of the indications. The court concluded that taking part in these tenders without limiting the offer to the patent-free indications would constitute indirect infringement: An unlimited tender will result in an unlimited discount contract and thus in an unlimited entry in the database. Then, the pharmacies will more or less automatically sell the drug also for the patented indication.

The Hamburg court deviated from "Ribavirin" without providing detailed reasoning. Apparently, the Hamburg Court focuses on the already prepared drug and regards this as being sufficient for the manifested arrangement, at least when the generics participate in discount contracts at the same time. The Hamburg court rejected, however, Warner Lambert's request that the generics would have to give notice in software for pharmacies and wholesalers. The court reasoned that it had not been proven that the generics are responsible for the appearance in the pharmacy software.

4. Conclusion

The Hamburg court decision has established a new scenario for patent infringement by generics. It can be welcomed that the court has rejected the standard defense of generics that they could not be liable for indirect patent infringement due to the carve-out which in fact ignores the regulatory practice of substitution. Instead, generics need now to review their marketing activities towards public health funds.

By the same token, the court has established a new angle for pharmaceutical companies in reviewing potential liability of generics, namely by monitoring the bidding process of public health funds.

It also remains to be seen how the Hamburg Court of Appeal and the Düsseldorf courts will deal with this new approach. The first instance Hamburg court has applied a deliberate analysis of the practice of discount contracts by taking a self-confident decision which may lead to increased liabilities of generics for the use of the public reimbursement system. This may also have implications on other areas, namely the public bidding process and the procedure of tendering discount contracts. Parallel to the Hamburg court decision a regulatory decision of the Procurement Chamber of the Federal Cartel Office has been issued which emphasized that patent law is not preempted by regulatory law.[21] Instead, public health funds have to ensure that their tender process complies with patent law.

21 German Federal Cartel Office, 16 March 2015, Case No. VK 2-7/15.

A Review of the "Problem and Solution" Approach to Inventive Step under Article 56 EPC
Part 1 – The Correct Formulation of the Problem

A. Kennington

Part 1

This is the first part of a long article, which will be published in three parts in successive issues of **epi** Information.

This article provides a further discussion of the problem and solution approach to analysing inventive step. This discussion starts from the definition of inventive step in Article 56 EPC. In part 1 of the article, a rule is proposed for identifying whether the statement of the problem is correct, based on Article 56 EPC. This in turn leads to a reconsideration (in part 2 of the article) of the Comvik approach to the treatment of non-technical features in a claim. Finally, part 3 of the article makes a proposal to develop the Comvik approach by modifying one aspect of it.

The definition of inventive step is given in Article 56 EPC, and is based on obviousness having regard to the state of the art. On the other hand, the problem and solution approach is a tool for the analysis of inventive step and is not a definition. Consequently, the use of the problem and solution approach is only valid if it is conducted in a manner that is compatible with the definition of inventive step in Article 56.

Article 56 requires that lack of inventive step arises only if it is obvious to reach the claimed invention starting from the state of the art. Article 56 does not sanction the addition of any other information or consideration not contained in the state of the art. Therefore a line of reasoning fails to establish lack of inventive step if the path from the state of the art to the claimed invention is not obvious (or known), or if the path from the state of the art to the claimed invention relies on something extra in addition to the state of the art. If any stage in the path from state of the art to the claimed invention (whether using the problem and solution approach or any other approach) is not obvious, lack of inventive step is not established.

Consequently an argument of lack of inventive step, using the problem and solution approach, is only valid if both the problem is known or is obvious in view of the state of the art and the solution to the problem is obvious in view of the state of the art. The requirement that the problem should be known or obvious in view of the state of the art, which follows directly from Article 56 EPC, provides a way to identify whether the formulation of the problem is valid in any particular case. This may be helpful in order to resolve disagreements that may arise between parties (patentee and opponent, or applicant and examiner) over the correct formulation of the problem. It also implies that the practice of including novel non-technical features in the formulation of the problem is not correct.

Introduction

The problem and solution approach is used almost universally at the EPO in the examination of inventive step. Over the years, there has been extensive case law from the Boards of Appeal concerning the correct way to use this approach. However, difficulties can still arise. I believe that some of these difficulties can be avoided, and a clearer understanding of the principles that should underlie this approach can be obtained, from a review of the legal status of the problem and solution approach and a consideration of the provisions of the EPC relating to inventive step.

Inventive step is defined in the EPC by Article 56 as follows:

> *An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. …*

This is the only definition of inventive step given in the EPC. It does not mention the problem and solution approach. The test for inventive step, according to the EPC, is solely that the invention should not be obvious having regard to the state of the art.

The state of the art is in turn defined in the EPC by Article 54(2), which reads as follows:

> *The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.*

Thus an invention involves an inventive step if it is not obvious to a skilled person having regard to everything made available to the public (in any way) before the relevant date.

The problem addressed by the invention, and the solution provided to it, are not mentioned in the text of the EPC

itself, but are mentioned in three places in the Implementing Regulations of the EPC, in Rule 42 (content of the description), Rule 43 (form and content of the claims, in sub-rule (2) relating to multiple independent claims in the same category), and in Rule 47(1) (content of the abstract). Attention is normally focussed on Rule 42, the relevant part of which reads as follows

(1) The description shall:
…

(c) disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;
…

It should be borne in mind that this is a provision relating to disclosure in the description, and not the definition of inventive step.
Thus the wording of the EPC assumes that an invention will inevitably provide a solution to a problem, but it does not require the use of the problem and solution approach in assessing inventive step and it does not establish the problem and solution approach as a test for, or a definition of, inventive step. The only test for, and definition of, inventive step given in the EPC is that the invention is not obvious having regard to the state of the art (everything made available to the public).
These observations do not imply any criticism of the EPO for relying on the problem and solution approach. On the contrary, it is a highly useful method of analysis in assessing inventive step, and its use is widely approved in the case law of the Boards of Appeal. However, it is important that the problem and solution approach is regarded as a tool to be used in the assessment of inventive step, and not as a definition of inventive step that can be used as a substitute for the actual requirements of Article 56 EPC. Therefore care should be taken to ensure that the problem and solution approach is always implemented in a manner that is consistent with the requirements of Article 56 EPC.
Therefore a focus on the requirements of Article 56 EPC may be helpful in ensuring the correct formulation of the problem and may also be helpful in the selection of the starting point (the so-called "closest prior art") for the analysis of inventive step.

Formulation of the Problem

Often, an argument that a claimed invention is or is not inventive starts from a statement of the problem, and focuses on whether the claimed product or process is or is not an obvious solution to the problem, given the disclosure in the prior art. However, this approach does not correspond precisely to the requirements of Article 56 EPC. Article 56 EPC states that an invention has an inventive step if it is not obvious "having regard to the state of the art". It does not state that the invention has to avoid being obvious "having regard to the problem". Consequently, if an argument seeks to determine inventive step by asking whether the solution is obvious, it must be based on an appropriate formulation of the problem if it is to be in accordance with Article 56 EPC. If the problem is wrongly formulated, so as to contain the claimed solution or pointers to it, the solution may be obvious from the stated problem even if there is in fact an inventive step over the prior art. Therefore the problem and solution approach to inventive step can be misleading if the problem is not formulated correctly.

This issue is well known. Part G-VII, 5.2 of the Guidelines for Examination in the European Patent Office states, referring to Technical Board of Appeal decision T 229/85,

It is noted that the objective technical problem must be so formulated as not to contain pointers to the technical solution, since including part of a technical solution offered by an invention in the statement of the problem must, when the state of the art is assessed in terms of that problem, necessarily result in an ex post facto view being taken of inventive activity.

Similarly, Board of Appeal decision T 800/91 stated

In any case the formulated problem should be one which the skilled person would wish to solve knowing only the prior art: the problem should not be tendentiously formulated in a way that unfairly directs development towards the claimed solution. (Reasons for the Decision, part 6)

However, these exhortations from the Boards of Appeal do not provide an easy rule by which to determine whether a particular formulation of the problem is permissible. The problem and solution approach is supposed to be based on the "objective technical problem", that is determined by the difference between the closest prior art and the invention as claimed, but it is still not clear exactly how to formulate the problem without including pointers to the solution. It is not always easy to reconcile guidance from different Board of Appeal decisions.
For example, decision T 910/90 refers to the objective technical problem and states

Dabei kommt es nicht darauf an ob diese Aufgabe bereits im nächstkommenden Stand der Technik angesprochen ist, sondern darauf was der Fachmann beim Vergleich des nächskommenden Standes der Technik mit der Erfindung als Aufgabe objektiv erkennt. (Reasons for the Decision part 5.1)
(Unofficial translation – It does not matter whether this problem is already mentioned in the closest prior art, but rather what the skilled person objectively recognizes as the problem when comparing the closest prior art with the invention.)

while decision T 967/97 states

> *Der Aufgabe-Lösungs-Ansatz beruht im wesentlichen auf tatsächlichen Feststellungen über technische Aufgaben und Wege zu deren technischer Lösung, die dem Kenntnisstand und Können des Fachmanns objektiv, d. h. ohne Kenntnis der Patentanmeldung und der Erfindung, die sie zum Gegenstand hat, zum Prioritätszeitpunkt zuzurechnen waren. (Reasons for the Decision part 3.2)*
>
> *(Unofficial translation – The problem-solution approach is essentially based on actual findings about the technical problems and approaches to their technical solutions arising from the knowledge and skills that the skilled person possesses objectively, i.e. without any knowledge of the patent and the invention with which it is concerned, at the priority date).*

It seems that decision T 910/90 could imply that the problem can be formulated by taking the invention into account and there is no need for the skilled person to reach the problem starting only from the state of the art. If decision T 910/90 is interpreted in this way, it would appear to be incompatible with decision T 967/97. This illustrates some of the confusion that can still arise when trying to define the correct way to formulate the problem. Therefore, although it is well established that the formulation of the problem must not include pointers to the solution, there is still considerable scope for disagreement over what constitutes a pointer to the solution and considerable uncertainty over how to establish whether a formulation of the problem is permissible or not.

In seeking to clarify this point, I propose to start by suggesting that the formulation of the problem must not itself be inventive. This appears to be axiomatic. If the formulation of the problem is itself inventive then even an obvious solution to the problem would be an invention over the prior art. This point was appreciated in decision T 0002/83, which referred to the concept of the "problem invention" in which the invention lies in the identification or recognition of a problem, the solution being obvious once the problem is identified but not being obvious from the prior art alone. This was also recognised in the Guidelines for Examination in the European Patent Office up until 2009 in the discussion of the origin of an invention (originally in part C-IV, 9.4, and later in part C-IV, 11.6), but it has been removed from the 2010 edition onwards (where the relevant discussion was moved to part C-IV, 11.9. It is at part G-VII, 9 in the 2012 and subsequent editions).
More generally, the problem and solution approach seeks to establish that a claimed invention lacks inventive step by linking it to the state of the art by the chain "state of the art – problem – solution/invention". If this approach is to be consistent with Article 56 EPC, which requires obviousness over the state of the art, then each link in the chain must be obvious. If **every** link in the chain is obvious, the claimed invention lacks inventive step. If **any** link is not obvious, then the argument fails to show that the claimed invention lacks inventive step because it has not established obviousness having regard to the state of the art.

Therefore if one is seeking to test inventive step by asking whether the invention is an obvious solution to the problem, it is necessary to use an obvious formulation of the problem. This arises directly from to the definition of inventive step in Article 56 EPC. In this way, it is possible to derive the rule that the problem and solution analysis of inventive step is only valid if **the problem is formulated in such a way as to be obvious (or known) in view of the state of the art**.

In many cases, this rule will be relatively easy to apply, and it allows one to determine whether the problem has been correctly formulated or whether a pointer to the solution, or other impermissible matter, has inadvertently been incorporated into the formulation of the problem.

According to this proposed rule, if an analysis of inventive step uses the problem and solution approach, but the analysis relies on a problem that is not obvious having regard to the state of the art, then that analysis is not valid. In this case, it will be necessary to reformulate the problem. It will normally be possible to formulate a less ambitious problem that is obvious. In general, the problem "can I improve this?" will almost always be obvious even if there is no more specific obvious problem. The challenge then becomes to formulate a problem that is obvious over the state of the art, and which also has an obvious solution that leads to the claimed invention.

Combining Prior Art Disclosures

When applying this rule, it is worth remembering that Article 56 EPC refers to obviousness "having regard to the state of the art" in general, and not obviousness "when applying the state of the art to the closest prior art". Thus a problem may still be obvious having regard to the state of the art in general, even if it is not obvious from the starting point document alone. Suppose that an argument of lack of inventive step is being made, starting from document D1. When considering D1 in isolation, it may not be obvious that there is a problem with its technical disclosure. However, a consideration of D2 may make it obvious that there is a problem with D1, and the solution to that problem may also be obvious. In this case, both the problem and the solution are obvious having regard to the state of the art as a whole, and so there is no inventive step.

This point, that the problem needs only to be obvious in view of the state of the art as a whole, and does not need to be evident from the starting point disclosure, is similar to the conclusion of the US Supreme Court in *KSR v Teleflex*. In that case, a patent was attacked by saying that it

was obvious to solve a problem that arose in the disclosure of a first document by taking a feature from the disclosure of a second document. The Court of Appeals for the Federal Circuit rejected that argument on the grounds that the prior art documents did not address the precise problem that the patentee was trying to solve, and therefore the skilled person would not have a motivation to combine them. The Supreme Court reversed this conclusion, on the grounds that this approach to motivation was too restricted. Instead, any need or problem known in the relevant art can provide a reason for combining the features of the different prior art disclosures. Similarly, in the problem and solution analysis, the formulation of the problem can draw on any motivation that is known (or is obvious) to the skilled person having regard to the state of the art. It is not necessary that this motivation is present in the closest prior art. Additionally, it may be unrelated to any motivation or advantage mentioned in the patent or application in suit.

In principle, the problem and the solution may be made obvious by different prior art disclosures, but this situation requires that care should be taken to ensure that it is obvious to combine all the different disclosures. For example, if D1 discloses some particular arrangement, D2 may indicate that there is a problem with the arrangement of D1 but fail to suggest any solution. A third disclosure D3 may provide a solution to the problem. In this case, D1 is being combined with D2 to identify the problem and D1 is being combined with D3 to identify the solution. Consequently, D2 is being combined indirectly with D3, and it is necessary to ensure that there is nothing in the disclosures of D2 and D3 that would make their combination inventive. For example, D2 might indicate only that there is a difficulty with the arrangement of D1 in a particular context, and the disclosure of D3 might not apply in that context. In this case, the problem, if correctly formulated, would be a desire to modify D1 to overcome the difficulty in the context referred to in D2, since it is only this more restricted problem that is made obvious by the disclosure of D2. Consequently, it might not be obvious to adopt the solution proposed by D3.

In conclusion, the problem used in the problem and solution approach should itself be obvious, but it only needs to be obvious in view of the state of the art as a whole, and it is not necessary that the problem is obvious having regard to the closest prior art taken in isolation.

Selection of the Starting Point ("Closest Prior Art")

The problem and solution approach generally requires the identification of a single piece of prior art as the starting point. The problem then provides the motivation for the skilled person to modify the starting point. If an obvious problem motivates a skilled person to modify the starting point in an obvious manner so as to provide something falling within the scope of the claim, the claim lacks inventive step. The starting point is sometimes referred to as the "closest prior art", and it is possible to expend considerable effort in identifying which, out of several potential starting points, is the "closest". In my view, a consideration of Article 56 EPC shows that this may not always be necessary.

Article 56 EPC does not require that the invention should not be obvious "having regard to the closest prior art". It requires that the invention should not be obvious "having regard to the state of the art", and the state of the art is defined in Article 54 as everything made available to the public. Therefore, in order to establish obviousness it is merely necessary to start from the state of the art as a whole, and not from some particular "closest" prior disclosure. Thus, if there are several potential starting points for an obviousness argument, any of them can be used. If the claim is obvious starting from one item of prior art, then the claim lacks inventive step. It does not matter if the claim is not obvious starting from some other item of prior art, even if that other item of prior art is theoretically "closer". In practice, it may be possible to show an obvious path to the claimed invention from each of several starting points, in which case the claim lacks inventive step in view of each path separately (and any amendment needs to deal with all of them). See for example decisions T 0969/97 (Reasons part 3.2) and T 1514/05 (Reasons part 3.1.6).

Consequently, it can be seen that there is no need to conduct a lengthy analysis to determine which item of prior art is theoretically "closest", and there is no such thing as the "wrong" starting point. If a search reveals several potential starting points for an obviousness argument, it is permissible to consider each potential starting point in turn. If an obviousness argument can be made out starting from any one of them, the claim lacks inventive step, and it is not necessary to decide whether that particular starting point is the closest.

Although the technically closest prior art is often the most promising starting point, this may not be the case in some instances. For example, it may be the case that only a single, technically straightforward, modification to the disclosure of prior art X is necessary to reach the invention, but this modification is not obvious, whereas it may be necessary to make three modifications to the disclosure of prior art Y to reach the invention but all of these modifications are obvious to do. In this case, prior art X might be considered to be technically "closer", but prior art Y makes the better starting point for an analysis of inventive step. The definition of inventive step in Article 56 EPC, which refers only to obviousness having regard to the state of the art, makes it clear that an argument starting from prior art Y is acceptable. The concept of the "closest" prior art in the problem and solution approach can often be useful, but it should not become an artificial constraint on the selection of the starting point for an argument of lack of inventive step.

Treatment of Non-Technical Features

Earlier in this article a rule was proposed that the problem and solution analysis of inventive step is only valid if the problem is formulated in such a way as to be obvious (or known) in view of the state of the art. It is necessary to consider how this rule might affect the way in which non-technical features in a claim are treated during the assessment of inventive step.

As discussed in G03/08, the current approach at the EPO to the admissibility of claims containing non-technical features in a claim (sometimes called the "any hardware" approach) developed over time. It began in Board of Appeal decision T 1173/97 IBM (1 July 1998) with the initial break from the previous "technical contribution" approach and developed to the position set out in Board of Appeal decision T 0424/03 Microsoft (23 February 2006).

Alongside the "any hardware" approach to the admissibility of claims containing non-technical features, the EPO follows an approach to the inventive step of such claims that is often referred to as the Comvik approach, with reference to Board of Appeal decision T 0641/00 Comvik (26 September 2002). The Comvik approach requires that an inventive step can only be provided by technical features (or non-technical features that nevertheless combine with technical features to provide a technical effect). Therefore, under the problem and solution analysis, any non-technical features that do not contribute to a technical effect cannot be regarded as part of the solution to the problem.

Decision T 0641/00 Comvik proposed that non-technical features of a claim could be included in the problem, as a constraint that has to be met. The problem was formulated to include such features even though they were not known in the art. This practice of including novel non-technical features in the problem as a constraint to be met appears to be incompatible with the proposal above that the problem must be known or obvious having regard to the state of the art. Consequently, it is necessary to review the case law to understand how and why this practice arose, and whether it is really incompatible with the present proposal. This will be the subject of part 2 of this article.

To be continued

This article will be continued in the next **epi** Information.

Unintentional Abandonment?

J. P. Asquith (GB)

This article discusses the risks of claims being deemed abandoned under EPC Rule 162(4) as a result of reducing the number of claims on filing a Euro-PCT application. The absence of a decision on the correct interpretation of Rule 162(4) leaves room for legal uncertainty. Different interpretations of Rule 162(4) are discussed, together with some proposed amendments to Rule 162(4).

The Problem

On filing a Euro-PCT application it is common practice to reduce the number of claims to 15, thus avoiding the payment of claims fees (235 and 580 Euros for each claim in excess of 15 and 50 respectively).

But how cautious should a professional representative be when performing this seemingly straightforward step?

Rule 162(4) states: *"Where a claims fee is not paid in due time, the claim concerned shall be deemed to be abandoned."*

"The cautious seldom err."
Confucius (551 - 479 BC)

This rule seems to be open to at least two possible interpretations, as follows:

Interpretation 1

Claims which are present in the application at the time when claims fees are finally due for payment shall be deemed abandoned if claims fees are not paid for those claims.

Interpretation 2

Claims which are present in the application *at any time before* claims fees are finally due for payment shall be deemed abandoned if claims fees are not paid for those claims.

As far as the author is aware, there is no decision which conclusively determines whether Interpretation 1 or 2 is correct.

The most straightforward interpretation of Rule 162(4) would appear to be Interpretation 1, on the grounds that if claims have been deleted before the final deadline for payment of claims fees then no claims fees are "due" in respect of the deleted claims, and therefore it can be argued that abandonment of the deleted claims should not arise.

However, in support of Interpretation 2, it could be argued that the fact that a claim has been deleted is irrelevant, as Rule 162(4) says nothing about when the claim must be present in the application. Rule 162(4) can be interpreted as meaning that any claim for which a claims fee is not paid shall be deemed to be abandoned, regardless of whether the claim has been deleted or not.

Furthermore, abandonment is a serious matter. The consequences of abandonment in the present scenario are set out in Guideline E-VIII, 2.1.3, which states:

"Where a claims fee has not been paid in time, the claim concerned is deemed to be abandoned. Features of a claim

deemed to have been abandoned pursuant to Rule 162(4) and which are not otherwise to be found in the description or drawings cannot subsequently be reintroduced into the application and, in particular, into the claims."

Some possible solutions

In an effort to exercise caution, some professional representatives have suggested adopting one or more of the following strategies when reducing the number of claims on filing a Euro-PCT application.

1. Insert into the description statements of invention corresponding with the wording of any deleted claims.
2. Combine a number of dependent claims into a single dependent claim containing alternative clauses. For example, a dependent claim specifying that a feature is red and another dependent claim specifying that a feature is blue could be combined into a single dependent claim specifying that the feature is red or blue.
3. Add to the description a statement which makes clear that the description includes the subject-matter of all of the claims contained in the application as originally filed under the PCT.

The intention of such strategies is either to avoid the possibility of a claim being deemed abandoned under Rule 164(2), or to ensure that the claim could be reinstated if it were to be deemed abandoned.
However, the employment of such strategies is neither convenient for applicants nor conducive to the efficiency of the patent system as a whole, and we will therefore consider below what changes could be made to Rule 162(4) to avoid uncertainty. However, before doing so, let us look more closely at interpretations 1 and 2.

Interpretations of Rule 162(4)

Let us consider whether opportunities to make amendments before the deadline for payment of claims fees can teach us anything about the interpretation of Rule 162(4). PCT Article 41 states, "The applicant shall be given the opportunity to amend the claims, the description, and the drawings, before each elected Office within the prescribed time limit." As a result, in the case of a Euro-PCT application the applicant can file voluntary amendments before the 31 month deadline. There is a further opportunity to amend within the 6 month period set in the communication under Rules 161 and 162.
Imagine an international application in which claim 1 is for feature A and claim 16 is for feature A + B. On filing a Euro-PCT application, if claim 16 were deleted to avoid payment of a claims fee, then under Interpretation 2 above claim 16 would be deemed abandoned. However, claim 16 lies wholly within the scope of claim 1, and therefore, for logical consistency, we have to ask whether part of the scope of claim 1 would also have to be deemed abandoned. Suddenly issues relating to splitting a claim into two notional parts, reminiscent of those discussed in the recent referral to the Enlarged Board of Appeal in T 0557/14 (relating to "poisonous divisionals"), start to come to mind.

Further difficulties with Interpretation 2 can be identified by considering an international application in which the claims are amended many times either during international examination or in voluntary amendments before the EPO. Claims could be added, amended and deleted many times, eventually arriving at a set of 15 claims. On entry to the European regional phase no claims fees would be due, but under Interpretation 2 exactly which of the earlier claims would be deemed abandoned through failure to pay claims fees for those claims?

Consideration of problems of this sort allow one to argue that Interpretation 1 appears more logical than Interpretation 2. It also seems likely that if the EPO were inclined to follow Interpretation 2 there would, by now, have been a decision on the correct interpretation of Rule 162(4). However, in the absence of any actual decision on this point, total certainty on the correct interpretation of Rule 162(4) would appear not to be available.

The view from Directorate Patent Law / Dir. 5.2.1 European Patent Office

In an effort to clarify these issues the author entered into some correspondence with Directorate Patent Law at the EPO during 2014. Directorate Patent Law has kindly given permission for their opinion to be reproduced here, provided it is made clear that their opinion was given in reply to a general enquiry and that the information is not binding on the EPO in an individual case.
On this basis, the relevant portion of the opinion from Directorate Patent Law (abridged by the author) is reproduced below:

"... final assessment whether all claims fees due have been paid will (only) be made upon expiry of the six month additional period under Rule 162(2) 1st sentence EPC. Where the number of claims changes as a consequence of an amendment filed before expiry of this additional period (e.g. due to a deletion of claims), these amended claims will be the basis for calculating the amount of the claims fees to be paid (Rule 162(2) 2nd sentence EPC). The expiry of this additional period is decisive for the question of a deemed abandonment of claims under Rule 162(4) EPC in the (amended) application for which no claims fee was paid [emphasis added by the author]. The term "due time" in Rule 162(4) EPC, therefore, refers not to the period under Rules 159(1), 162(1) EPC, but to the additional period under Rule 162(2) EPC.

The consequences thereof can be clarified by the following examples:
(A) An international application comprises claims 1-25. Before expiry of the 31-month period, claims 21-25 are

deleted (i.e. an amended set containing 20 claims is filed within the 31-month period) and five claims fees (for claims 16-20) are paid.
(B) An international application comprises claims 1-25. After expiry of the 31-month period, but before expiry of the additional period under Rule 162(2) EPC, claims 21-25 are deleted (i.e. an amended set containing 20 claims is filed) and five claims fees (for claims 16-20) are paid.

In both examples (A) and (B) claims 21-25 are not deemed to be abandoned under Rule 162(4) EPC (note, however, the last paragraph below) because at the time of assessment under Rule 162(4) EPC (date of expiry of the additional period under Rule 162(2) EPC) there are no claims in the application documents for which claims fees must be paid and have not been paid.

By contrast, claims are deemed to be abandoned under Rule 162(4) EPC in the following example:

(C) An international application comprises claims 1-25. Before expiry of the additional period under Rule 162(2) EPC, no amendments are made and five claims fees (for claims 16-20) are paid. Claims 21-25, for which claims fees have not been paid within the period under Rule 162(2) EPC, are deemed to be abandoned under Rule 162(4) EPC, which will be communicated under Rule 112(1) EPC."

(D) An international application comprises claims 1-25. Before expiry of the additional period under Rule 162(2) EPC an amended set containing claims 1-22 is filed (e.g. on entry into the regional phase) and five claims fees (for claims 16-20) are paid (e.g. towards the end of the six-month period). Claims 21-22, for which claims fees have not been paid within the period under Rule 162(2) EPC, are deemed to be abandoned under Rule 162(4) EPC, which will be communicated under Rule 112(1) EPC.

The Guide for applicants – Part 2 ("Euro-PCT Guide") provides helpful explanations concerning claims fees for Euro-PCT applications in points 608-613, in particular point 609.

Suggested amendments to Rule 162(4)

It is helpful to set out the full wording of Rule 162.

Rule 162
Claims incurring fees
(1) If the application documents on which the European grant procedure is to be based comprise more than fifteen claims, claims fees shall be paid for the sixteenth and each subsequent claim as laid down in the Rules relating to Fees within the period under Rule 159, paragraph 1.
(2) If the claims fees are not paid in due time, they may still be paid within six months from a communication concerning the failure to observe the time limit. If within this period amended claims are filed, the claims fees due shall be computed on the basis of such amended claims.
(3) Any claims fees paid within the period under paragraph 1 and in excess of those due under paragraph 2, second sentence, shall be refunded.
(4) Where a claims fee is not paid in due time, the claim concerned shall be deemed to be abandoned.

In the author's submission, the legal uncertainty described above could be removed by amending Rule 162(4) in the following way, to correspond with Interpretation 1 above.

Rule 162(4): In respect of any claim which is present in the application at the end of the period under paragraph 2, where a claims fee is not paid in due time, the claim concerned shall be deemed to be abandoned.

This would make clear that only claims which were left in the application at the time when claims fees are finally due are deemed abandoned if the corresponding claims fees are not paid.
However, one might ask why Rule 162(4) refers to abandonment at all. The case law relating to abandonment in general indicates the need to take into account the "real intention" of the party (T 910/92), and the importance of "taking into account all the circumstances" (J 13/84). It does not follow that because an applicant has failed to pay claims fees for certain claims that the applicant wishes to abandon those claims. Therefore, in referring to abandonment, Rule 162(4) seems at odds with the tenor and spirit of decided case law on the subject of abandonment generally.
Furthermore, Rule 162(4) also seems rather at odds with the more relaxed provisions of Rule 164, which took effect from 1 November 2014, according to which an applicant for a Euro-PCT application now enjoys the freedom to pay a further search fee for any invention not yet searched. If the applicant chooses not to pay a further search fee the corresponding claims are not searched, but they may still be pursued in a divisional application. In contrast, an applicant who does not pay claims fees under Rule 162(4) runs the risk of abandonment of those claims, including the risk (if the claims are not otherwise supported by the description) of not being able to pursue a divisional application for those claims (Guideline C-IX, 1.3).
For these reasons it is submitted that Rule 164(2) could be amended in the following way for greater consistency with both decided case law and new Rule 164.

Rule 162(4): In respect of any claim which is present in the application at the end of the period under paragraph 2, where a claims fee is not paid in due time, the claim concerned ~~shall be deemed to be abandoned~~ may not be pursued further in the application.

This would allow an applicant to file a divisional application for such claims, even for features which, in the words of Guideline E-VIII, 2.1.3, *"are not otherwise to be found in the description or drawings"*.
This would seem a fairer and more logical outcome, which avoids the legal uncertainties discussed above.

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