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Institut der beim Europäischen Patentamt zugelassenen Vertreter
Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

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Information

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Cover:
View from Ponte Vecchio
This picture painted by
Kate Donovan
(European Patent Attorney, DE),
was part of the **epi** Artists
Exhibition 2015 at the EPO, Munich

Kate Donovan

Kate Donovan ist zugelassene Vertreterin vor dem Europäischen Patentamt und arbeitet in der Patentabteilung von Nokia Networks in München. Im Alter von 18 Jahren stand Kate vor der schwierigen Entscheidung sich zwischen einem Kunststudium und dem Studium der Physik und Ingenieurswissenschaften zu entscheiden. Sie hat sich für die Physik entschieden und praktiziert in diesem Metier seit 12 Jahren glücklich als Patentanwältin. Darüber hinaus hat sie trotzdem weiterhin gemalt und ihre Liebe zur Kunst während ihrer Elternzeit nach der Geburt ihrer Tochter für sich wiederentdeckt. Außerdem hat die Malerei eine wichtige Rolle für Kate im Zuge der Rehabilitation von einer rheumatischen Arthritis gespielt und deshalb malt sie, so oft sie dazu die Zeit findet. Ihre größten künstlerischen Inspirationen sind Henri Mattisse, die Impressionisten and Kandinsky und die Blauen Reiter.

Kate Donovan is a European Patent Attorney and works in-house at Nokia Networks in Munich as IPR Counsel. At the age of 18, Kate had to make the difficult choice between studying art or physics and engineering. She chose physics and has spent 12 happy years practising as a patent attorney. However, she has continued to paint and rediscovered her love of art while on maternity leave after the birth of her daughter. Painting has also played in important role in Kate's rehabilitation from rheumatoid arthritis and she finds time to paint whenever she can. Her main artistic influences are Henri Matisse, Impressionism, and Kandinsky and the Blaue Reiter movement.

Kate Donovan est mandataire en brevets européens et travaille dans le département brevets de Nokia Networks à Munich. A l'âge de 18 ans, Kate a dû faire un choix difficile entre des études d'art et des études d'ingénieur en physique. Elle a choisi la physique et exerce avec bonheur depuis 12 ans le métier d'ingénieur brevet. Elle a néanmoins continué à peindre et a redécouvert son amour pour les arts durant son congé maternité après la naissance de sa fille. La peinture a également joué un rôle important lors de la rééducation de Kate à la suite d'une polyarthrite rhumatoïde, et elle peint dès qu'elle le peut. Ses principales influences artistiques sont Henri Matisse, l'impressionnisme, et Kandinsky et le mouvement artistique « Le Cavalier bleu ».

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Editorial

M. Névant (FR), Editorial Committee

En Marche ! (Moving forward!)

Marc Névant

My fellow countrymen may have the feeling, judging by the title of this editorial, that it is an ode to the glory of the recently elected French President. Not in the least!

The recent Council meeting in Warsaw (reported elsewhere in this issue) proved to be a long but successful journey that will carry momentum for our Institute. The Committees have now been appointed for a 3-year term, and, no doubt, they are active, along with the Board, in further advancing the influence of **epi** among major IP stakeholders.

The European Patent Organization elected a new President, Mr António Campinos, to succeed Mr Battistelli as President of the European Patent Office. Mr Campinos' term of office will commence on 01 July 2018. We wish Mr Campinos well in his new position, and we look forward to a further strengthened relationship with the EPO.

We also note with great interest that commencing in 2018, the EPO is implementing a new structure for handling oppositions: five directorates have been created, exclusively devoted to oppositions. We understand that the aim of the new structure is to harmonize the practice within the opposition divisions. This initiative, which is part of the Early Certainty programme, is to be applauded, and is a further step taken by the EPO to ensure that quality patents are granted and maintained.
We could not end this editorial without paying tribute to Terry Johnson, the former Chair of this Committee, whose Editorials have always been a source of inspiration. Thank you Terry for the opportunity to work with you. Together with the other members of the Editorial Committee, I wish you all the best for many years to come!

On that note, the Editorial Committee sincerely wishes all our readers a Happy Christmas and a Healthy and Prosperous 2018.

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 **16. Februar 2018**. 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 **16 February 2018**. 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 **16 février 2018**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

Report from the 83rd Council Meeting in Warsaw on 18 November 2017

T. Johnson (GB)

The President opened the meeting at 8.40am. The timetable and revised agenda were approved. The English version of the minutes of the previous meeting, C82 in Munich, was amended at line 365 concerning Professional Liability Insurance in all 38 Contracting States to read" Mr. Boff was against the **epi** assuming legal liability". With this and other minor amendments the minutes of C82 were approved.

Language of Minutes

One delegate suggested that Council Minutes should only be provided in English, with translations into German and French being provided later. Mr. Casalonga requested that the minutes be provided in the three official languages of the **epi** *ab initio*. Council decided to defer a decision on this to a later meeting.

Election of Committees

This being the meeting at which **epi** Committees were populated from those members of the Institute who had put themselves forward for election to Committees, the President reminded Council that where there was more than one candidate for a single Committee place it is the Council, not a Member State , which decides on the successful candidate.

Board/Library section of epi website

The Secretary General (SG) reported that it is now possible to access documents by date in the library section of the Institute website (as had been requested in the 97th Board meeting).






Reports

The previously circulated reports of the President, Vice-Presidents, and Secretary General were approved; The SG in addition informed Council orally that: (i) the next meeting, C84 in Valetta, Malta, would be the occasion to celebrate the 40th anniversary of the Institute, for which it was proposed to produce a commemorative booklet;

(ii) the Institute website was up and running and had the approval of members; and

(iii) the next Council meeting, C85 would be held in Helsinki on 10th November, 2018, with a pre-meeting seminar on 9th November, and meetings C 86 and 87 would be held in Sofia, BG, and Monaco in April and November respectively.

The Treasurer then spoke to his previously circulated report; in summary:

(i) There was no need to change the 2017 budget, which was almost balanced at -33k Euros;

(ii) new book-keeping software, Diamant, went 'live' in October 2017;

(iii) the legal status of the Institute as an international organisation having its seat in Munich needed to be established. To further this aim, Council agreed that a working group comprised of the Treasurer and members from the By-Laws Committee (BLC) should be set up to detail the main objectives and tasks of the Institute as set out in the Founding Regulation;

(iv) Revision of R154 EPC concerning streamlining of the annual subscription fee procedure would be placed before the Committee on Patent Law of the AC in 2018;

(v) the annual subscription for 2018 would **remain** at **190 Eur if paid before 1st May and 240 Eur if paid after 1st May**. The **epi** Studentship fee would also remain at 95 Eur for 2018;

(vi) New **epi** students: Mr. Thomsen reported on a new curriculum for new students, proposed by PEC for 2018, spread over 3 years. The elements for the 1st year were included in the 2018 budget and included a free webinar. Other elements included a reimbursement of 100 Euros per paper for tutors and student fees of 180 Euros per paper. Students would also receive a grant of 40 Euros towards a basic EPC commentary booklet. Further details of the various elements would be available in due course.

(vii) Professional Liability Insurance for members of the Institute: Mr. Thomsen advised Council that following Council's approval at C82 for carrying on with this initiative with effect from October 2017, a framework contract had been concluded between the **epi** and RMS, an insurance broker with authority from Lloyd's. As reported at C82, the contract requires a premiums' payment of 200,000 Euros per year, to be reached by October 2018. To date, more than 70,000 euros have been collected.

The contract offers two products: (a) an excess layer insurance of around 1.5M to 2.5 M Euros, taken over from a previous excess contract with AXA (cancelled as of 1st October, 2017), and (b) a liability insurance covering amounts of from 0 Euro to 5M Euros (there being applicable deductibles): to obtain a questionnaire form from RMS, visit:

http:// patentepi.com/en/professional-liability-insurance/product-information.html

(viii) Mr. Thomsen advised Council that the overall budget for the Institute for 2018 is planned to have a small deficit of -42,000 Euros.

The **epi**-Finances Committee confirmed that it approved all of the Treasurer's proposals.

Following a brief discussion, Council approved the Treasurer's report, and the PEC's proposals for 2018 for studentship.

Alberto Casado

The President then introduced Alberto Casado, Vice- President DG1 of the EPO who addressed Council on information on and changes at the EPO.

Mr.Casado informed Council that the EPO was the second largest intergovernmental institution in the EU. The Office has been granted ISO 9001, the Office's aims inter alia being to provide access for patent proprietors to the patent system internationally and to grant high quality patents.

Challenges for the EPO are *inter alia* to provide consistent growth, to handle the continuing trend for filing of applications for multi-disciplinary technically complex inventions, and to manage users' expectations in terms of cost and timelines. To meet these challenges the Office

aims by 2020 to increase efficiency, improve quality of granted patents, to improve timelines, to control costs, and to increase its influence internationally. To assist in these endeavours, about a thousand new Examiners have been recruited over the last ten years, and a sub-group of SACEPO is looking at raising quality and is consulting users in EU, USA, PRC, JP and RSK.

The EPO has been ranked the best PO in every IAM survey since 2010.

The new examiners follow a 2 year training programme, the total of 4,400 examiners being split into divisions of 3, and are provided with state -of -the-art tools including access to one of the world's largest databases (1bn records) and 50M original patent documents from Asia. It is aimed to reduce the searches' backlog by February, 2018 and examination time to 12 months on average by 2020 (at present it is 22.4 months). Patent grants in 2017 were about 100,000, and production in the first half of 2017 was up 4.8%.

In addition to working with other offices towards harmonisation, (148 WIPO member states use the EPO for ISA and IPEA), the internal priority going forward is to provide high quality/legally solid patents to provide legal certainty for users of the system and use of XML filing for increased efficiency. The aim is for an end-to-end granting process, for example each examining team will have an embedded formalities' officer.

Moreover, to cope with the increasing demand (up 18% since 2009) the EPO had in mind the introduction of a system for postponing the start of substantive examination by up to 3 years from filing (which could be curtailed by the filing of third party observations (TPOs).

The XML system is he advised hoped to be in place by 1st April, 2018; it would be predominantly pdf.

Finally, as regards UP/UPPC, Mr. Casado confirmed that DE, LV, SI and UK had Parliamentary approval for ratification.

There followed an extended Q and A session. On a question on quality control, Mr.Casado mentioned that SACEPO had requested meetings to discuss the topic, as a follow-up to this he was reminded that the **epi** had requested additional representation on SACEPO.

Another questioner queried the fact that when an applicant requests PACE the information is not published, which creates uncertainty for users. Mr.Casado replied that this would be looked into.

Following a question on extension countries, Mr. Casado replied that the EPO makes sure that such a country respects the EPO as such and that therefore the country accepts the responsibility of giving Eps effect in their territory.

In reply to a question on opt out under the UP on grant of an EP, Mr. Casado replied that the need to inform the UP Registrar was already in hand.

The President thanked Mr. Casado for his comprehensive presentation, endorsed with acclamation by Council.

Terms of Reference (ToRs)

Following Mr.Casado's address, Council considered ToRs as proposed to be amended or revised by the BLC. Thus for the EPPC, Council decided to rename the four technology groups under the EPPC umbrella as Technological Sub-Committees, and for the PCC that none of its members shall be a member of the Disciplinary Board of Appeal, Supervisory Board or Examination Board.

By- Laws

Arts. 18 and 50.1 of the By-Laws were amended by making it clear that there can be associate members of a Committee, but that such members do not have the right to attend meetings, but can be invited to do so by the Committee Chair, costs of/ for such attendance to be decided by the Treasurer.

Election of Committees

There was an extended discussion of, and voting for, members to populate the various Committees of the **epi**. The composition of the Committees as elected can be found elsewhere in this edition of **epi** Information, and on the website.

EPO proposals for enhancing the granting procedure

Chris Mercer, new chair of EPPC following the elevation of Francis Leyder to the Presidency, led, with the President, consideration of the EPO's proposals for bringing certainty with enhanced flexibility to the granting procedure, including the introduction of a procedure for deferred examination.

There was a lengthy discussion during which Mr. Mercer put forward several scenarios for consideration and voting concerning deferred examination, following which Council decided that the **epi**, via the EPPC, should write to the EPO to the effect that Council did not favour introduction of deferred examination under the EPC.

AOB: (i) Council approved a proposal that **epi** representatives having a meeting with the Supervisory Examination Board should consult with the PEC before any such meeting;

(ii) Mr. Casalonga for Litcom reported that as there is a delay in implementing UPPC systems, the 'sunrise' period might now begin in spring 2018. The system should be tested, and moreover the opt out provision might need at least 5 months per patent to implement. He proposed that a 'package' for opt out should be studied in cooperation with the OCC, and also that the **epi** should liaise with the Preparatory Committee and insist that the opt out provisions be tested before implementation.

Council approved these proposals.

(iii) The President advised Council that the Reporting Group would report to Council at C84 in Valetta. Meanwhile the composition of the group will remain as it is and will dealing only with Council matters and a new group will be established with the following members: Mr. Pereira da Cruz, Ms Vogelsang-Wenke, Mr Casey, Ms Allwarth and Mr Durán. This additional new group will deal with **epi** Secretariat matters.

Led by the President, Council observed a minute's silence in honour of Mr. Benatov, a founder member of the Bulgarian delegation and who had recently died.

Council thanked the Polish delegation members with acclamation for their efforts in organising a very successful meeting.

The President warmly thanked the Secretariat for their work in ensuring that the meeting, including voting, went as smoothly as it did. Council endorsed the President's words with acclamation.

The meeting closed at 19.17.

epi Artists Exhibition 2018

The **epi** Artists Exhibition of **epi** Artists has become a tradition in the cultural life of the **epi** and of the EPO. Opened for the first time in 1991, it was followed by further shows in 1994, 1996, 1998, 2000, 2003, 2006, 2009, 2012 and 2015. The interesting works on display have ranged from paintings to graphical and fine art works, such as ceramics, sophisticated watches and jewellery, and artistic textile creations. The exhibitions which were opened by the Presidents of the **epi** and of the EPO met with great interest. We hope that the forthcoming exhibition will be just as successful. It is planned to take place from

11 June to 22 June 2018
at
European Patent Office
PschorrHöfe building
Bayerstrasse 34, Munich.

A prerequisite for the exhibition is a large participation of artists from various countries. Therefore, all creative spirits among the **epi** membership are invited to participate. Please disseminate the information!

Please note that all contributions to the **epi** Artist Exhibition have to respect religions and beliefs, political views and take into consideration that children might be visiting the exhibition.

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Report of the By-Laws Committee (BLC)

P. Moutard (FR), Chair

1. BLC meetings and the topics discussed during these meetings

Since the C 82 Council meeting 3 BLC meetings took place, on 6 July, 7 September and 25 October 2017. The Chair of the Disciplinary Committee joined the meeting of 7 July by phone and participated to the meeting of 7 September 2017.

The main following topics were discussed during these meetings:

- amendments of the Terms of Reference (ToR) of the Committees, further to the decisions of the C82 Council meeting in Munich; the question of possible incompatibilities between certain committees or bodies of the **epi** was also discussed;
- further amendments to the article 18 BL, also further to C 82;
- creation of a recommendation collecting the list of conditions decided by the Council for certain committees;
- proposal from the internal auditors to amend Art.20 BL;
- proposal to amend Art.15.4 BL in view of an earlier sending of a summary and a list of the decisions to the **epi** members after each Council meeting.

We make here below a short presentation of the state of these different topics.

2. Amendments of the Terms of Reference (ToR) of the Committees, further to the decisions of the Council (C 82 Council meeting in Munich);

The Terms of Reference of the following committees were amended: By-Laws Committee, Online Communication Committee, Professional Education Committee, Professional Conduct Committee, European Patent Practice Committee, **epi**-Finances Committee.

To avoid conflicting situations between some committees or bodies the BLC has examined whether rules of mutual exclusion should be added to the Terms of Reference of some Committees. For example it could proposed that the members of the **epi**-Finances Committee cannot be at the same time member of the Board. The status of all **epi** Committees and bodies were checked accordingly and this topic is still under discussion. Corresponding proposals for amending the Terms of Reference of some committees will be presented to the 84th Council meeting in La Valette (C84).

3. Further amendments to art.18 BL.

This article, which in particular defines the duties of the committee members, was extensively discussed with Mr Paul Rosenich, Chair of the DC, to better take into account the particularities of this Committee.

First discussions were conducted on 6 July and continued during the meeting of 7 September. Final formal amendments were adopted during the meeting of 25 October.

The text of the proposed art.18 was adopted by the Council in Warsaw (C83).

4. Recommendation collecting the list of conditions decided by the Council for certain Committees

This list of recommendations was created based on the work of the Reporting Group presented during the Munich Council meeting C 82. It will be included in the Collection of Decisions.

5. Proposal from the Internal Auditors to amend Art.20 BL.

In order to improve the efficiency of their work, the Internal Auditors have proposed some amendments to art. 20 BL.

The text of the proposed art. 20 will be presented to the 84th Council meeting for decision in La Valette for decision.

6. Proposal to amend Art.15.4 BL in view of an earlier sending of the draft minutes to the Council members.

After each council meeting it is very difficult, if not impossible, to send as soon as convenient to all **epi** members a summary of the unapproved minutes and a list of the Council decisions (art. 15.4 BL).

The BLC has discussed this problem and drafted several proposals which will probably be presented to the 84th Council meeting in La Valette for decision.

Report of the European Patent Practice Committee (EPPC)

C. Mercer (GB), Chair

This report was completed on 26th October, 2017 and covers the period from the Munich Council meeting held on 24th and 25th April 2017 (C82) to date.

EPPC and its Structure

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.

During the period covered by this report, EPPC was organised with seven permanent Sub-Committees (EPC, Guidelines, MSBA, PCT, Trilateral & IP5, Quality and Unitary Patent). Additionally, *ad hoc* working groups were set up when the need arose. Two thematic groups had also been set up.

From the Warsaw Council meeting on 18th November, 2017 (C83), EPPC will consist of one full member per member state and will have the seven permanent Sub-Committees mentioned above. There will then be four thematic groups (ICT, Mechanics, Chemistry and Pharma). As usual, *ad hoc* working groups will be set up when the need arises.

The Previous Chair

This is the first report to Council from EPPC since Francis Leyder was elected President of **epi** at C82 and I have taken over as Chair of EPPC. Francis was an excellent Chair of EPPC, led us all with a great deal of energy and insight and provided us with the benefit of his encyclopaedic knowledge of everything to do with the EPC. He will be a hard act to follow.

EPPC Meeting

EPPC met on 25th and 26th April, 2017, immediately after C82.

At C82, Francis Leyder was elected as the new President of **epi** and stepped down as a member of EPPC so that a new member from Belgium could be elected by Council. As Francis had stepped down as an EPPC member, he could no longer be Chair of EPPC. Chris Mercer was elected to chair the Committee until C83 where the election of the members of the new EPPC will take place.

EPPC discussed its new structure (as recently approved by Council at C82) and had an exchange of views with Mr John Beatty (Director Patent Procedures Management, EPO) on non-unity matters and Early Certainty. Mr. Beatty has kindly provided us with copies of the slides he presented at the meeting and these slides can be found at http://patentepi.com/en/epi/forum/threads/171 (can be accessed by **epi** members after login).

EPPC further reviewed the PCT International Search and Preliminary Examination Guidelines. In particular, it analysed the examples concerning Unity of Invention provided in Chapter 10 with the aim of making proposals for the forthcoming Guidelines update. The Committee agreed to send further comments to Mr Emmanuel Samuelides (Chair of the PCT Sub-Committee), who committed to compile them all in a document to be sent to the EPO. This has now been completed, with input from a number of the members of EPPC, and the document has been sent to the EPO. A copy of the document is attached as Annex 1.This has been well received by the EPO, which intends to use it in its forthcoming discussions with WIPO.

Lastly, EPPC heard brief reports on meetings held with the EPO (including SACEPO Working Party on Quality and SACEPO Working Party on Rules meetings) and prepared for future internal meetings as well as further meetings with the EPO.

PAOC Meeting

EPPC's thematic group on pharma applications held its annual meeting with the Directors of the Cluster concerned with Pure and Applied Organic Chemistry (PAOC) in Munich on 16th May, 2017.

The examiners in this Cluster deal primarily with pharmaceutical chemistry but also with cosmetics and similar subjects as well as subjects overlapping with biotechnology. The EPO regards this meeting as very important, as can be seen from the fact that the meeting was attended by one Principal Director, one Director of Operations, 8 Directors and two Senior Experts. They were very well briefed and provided some very useful guidance on a number of topics. There were also 11 people from **epi**, including our President.

The organiser of this meeting, Ruurd Jorritsma, gathered a number of topics and designated one of **epi**'s members to present each topic. These were sent to the EPO well

in advance so that the EPO could prepare for the meeting. As a new feature this year, the EPO sent a number of topics to us for our comments. All these topics were discussed very frankly and we are grateful to the EPO for such good discussions.

The topics discussed included Article 53(c) in relation to methods of using a sub-assembly, non-surgical methods and the difference between cosmetic and therapeutic uses, PCT searches for methods of treatment, plausibility in pharma cases, Article 123(2) in relation to combining dependent claims and ranges, toxic priorities, procedural matters, both in general and specifically relating to opposition procedures, amendment of the description and unity of invention. A report of the meeting was published in **epi** Information 3/2017 on pages 12 to 15.

EPO-epi Partnership for Quality Meeting

The annual EPO-**epi** Partnership for Quality Meeting took place in the main EPO building on 18th May, 2017. The meeting was held as part of the 'Quality for Partnership' program, a continuous dialogue between **epi** and the EPO by means of which both organizations exchange their views and update each other on quality matters.

The delegation from the **epi** was composed of some members of the EPPC Sub-Committees on EPC and Quality and was headed by the **epi** President, Francis Leyder. The delegation from the EPO included Directors from DG 1 (Operations), DG 2 (Operational Support) and DG 5 (Legal/International Affairs) and was headed by Vice-President Raimund Lutz.

The EPO strongly stressed the importance of user feedback, remarking on the valuable contributions provided by **epi** in this regard. **epi** welcomed the opportunity to discuss further enhancements and seize the occasion to encourage its members to make use of the feedback mechanisms and bring their input.

The presentations and materials shown by the EPO have been kindly provided to the **epi** for further distribution among its members and can be accessed by **epi** members after login at http://patentepi.com/en/epi/forum/threads/171.

Meeting o fthe ICT Group of EPPC

The ICT group of EPPC met on 8 November 2017 the EPO directors in ICT field, and various matters pertaining to issues on eligibility and patentability of ICT applications have been collaboratively discussed. In particular, **epi** and EPO discussed eligibility and patentability of mathematical algorithms, GUIs, presentations of information and computer programs. Relevant parts of the Guidelines have been the object of feedback to the EPO by the **epi** with respect to actual practice. The meeting was concluded with the satisfaction of both parties.

Working Group on Article 123(2) EPC

A Working Group to study the application by the EPO, in particular the Boards of Appeal, of Article 123(2) EPC has been set up. This is chaired by Conor Boyce and will be looking to find examples of good and bad application of Article 123(2). Any input to this Working Group is most welcome.

Working Group on the Rules of Procedure of the Boards of Appeal

A Working Group to study the Rules of Procedure of the Boards of Appeal (RoP) has been setup. This is chaired by myself. It is aimed at looking at the present RoP to develop suggestions for amendment in advance of any changes being made by the Boards of Appeal Committee (BOAC) of the Administrative Council of the EPOrganisation (AC). Any input to this Working Group is also most welcome.

It became known to **epi** that the BOAC was going to discuss the RoP and so a letter was drafted, discussed at the 97th Board meeting and agreed with amendments requested by some participants. It was sent to Mr. Josefsson, the new President of the Boards of Appeal, with a copy to the President of the EPO. A copy of the letter can be found on the **epi** website.

After C83, the usual MSBA will take place at the new Boards of Appeal building in the Haar at the invitation of Mr. Josefsson. (MSBA used to be "Meeting of the members of SACEPO with the Boards of Appeal" but in recent years has changed to a meeting of invited representatives, mainly of **epi** and Business Europe, with selected members of the Boards. At the request of Mr. Josefsson, this year the **epi** delegation will be limited to five members, headed by Vice-President Vogelsang-Wenke.) A report on this meeting will be prepared in due course.

European patent with unitary effect in the participating Member States

The entry into force of the unitary patent system requires ratification or accession of 13 States party to the UPC Agreement, including Germany, France and the UK. The outcome of the "Brexit" referendum had created some uncertainty about the ratification by the UK, but these disappeared when the UK confirmed that it will be ratifying the UPCA and the necessary steps are being taken in the UK. However, the UPC/UP project has now been further delayed by a challenge to the UPC lodged with the German Constitutional Court. The Constitutional Court is waiting for comments from the German Gov-

ernment and a number of other organisations. The deadline for receiving these comments has been postponed from 31st October to 31st December. When the Constitutional Court will issue a decision is highly unpredictable. In light of this, the plans regarding entry into force of the unitary patent system have been put on hold.

In the period covered by this report, there have been two meetings of the Select Committee of the AC, one in The Hague and one in Munich. These have shown that the EPO is ready to implement its obligations under the UP Regulations and has been taking the necessary steps to ensure that data is transferrable between the EPO and the relevant member states. **epi** has been present at both of these meetings and continues to raise concerns about the top-up search for prior national rights (see also WPR report below), SPCs, the location of a (principal) place of business, training and payment of compensation.

The series of UP/UPC seminars initiated by **epi** resumed in May, with seminars in Copenhagen, Basel, Barcelona, Manchester, Brussels, Stockholm and Bern. Shortly before C83, there will be a seminar in Eindhoven. After this seminar, the programme will be suspended until the outcome of the challenge at the German Constitutional Court is known.

G1/16 (disclaimers)

The Working Group set up by EPPC to deal with this reference to the Enlarged Board (EB) finalised **epi**'s amicus curiae brief, which was filed with the EB. After its filing, the EB issued a communication setting out some preliminary views on the matter. **epi**'s Working Group prepared and filed a further submission. Oral proceedings on the referral were held and were attended by Gaby Leissler-Gerstl. A short report on the oral proceedings is present in the members' area of the **epi** website. A decision of the EB is now awaited. The brief and the submission are available on the EPO Register for this case.

Guidelines Sub-Committee

The Guidelines Sub-Committee met on 13th and 14th September, 2017 and went through the proposals from the EPO for amendment of the Guidelines, which was a very intensive effort. Some points were so complex that the discussion had to continue afterwards electronically. The Chair of the Sub-Committee has gathered together all the comments and has provided them to the EPO. A copy is available from the **epi** Secretariat if anyone would like to see them.

This year, the EPO chose to focus on amending the sections of the EPC Guidelines relating to "presentation of information" and timeliness. The amendments suggested by the EPO to the PCT Guidelines are mainly of a formal nature.

The Guidelines Sub-Committee aims to make the EPC and PCT Guidelines as clear and comprehensive as possible, to ensure that they reflect the EPC and case law and to ensure that the developed procedures are fair to all parties (applicants, patentees, opponents and third parties).

The SACEPO WPG will be held on 21st November, 2017.

SACEPO/WPR

A summary of the conclusions of the 16th Meeting of the SACEPO Working Party on Rules can be found on the **epi** website.

The 17th meeting of the SACEPO Working Party on Rules was held on 17th October, 2017. A brief note of the topics discussed can be found on the **epi** website.

One major topic was the proposal by the EPO to increase the appeal fee by about 20% but with no increase for SMEs and similar. The **epi** delegates spoke out against this and did so again at the recent meeting of the Budget and Finance Committee (BFC) of the AC (see EPO Finances Committee report). In light of the urgency of the matter, some members of EPPC and the EPO Finances Committee produced a letter which was sent to the AC. This was based on a previous submission made by **epi** in connection with the then proposals for reform of the Boards of Appeal. A copy of the letter can be found on the **epi** website.

Another major topic was "Early Certainty with Flexibility" which is addressed in a separate paper.

ICT Thematic Group

The ICT thematic group will be holding its annual meeting with the EPO on 8th November, 2017, just before C83.

Report of the **epi**-Finances Committee

M. Maikowski (DE), Chair

Michael Maikowski

The 79th Meeting of the **epi**-Finances Committee took place in Basel on 25 and 26 September 2017.

The meeting agenda included a number of topics relating to the financial management of **epi**'s affairs.

The Committee received reports from the Treasurer on

- performance relative to budget to date in 2017;
- the first draft of the budget for 2018;
- various projects and initiatives of the Treasurer; and
- the new activities for **epi** students.

Regarding the 2017 budget, the Committee agrees that the current deviation of the actual financial situation for 2017 from the budget does not justify a proposed adapted budget at Warsaw C83 Council meeting.

The Committee notes that the budget for 2018 is not yet finished. The first draft of the 2018 budget was however briefly discussed and approved by the Committee.

Regarding the VAT reimbursement process, the Committee acknowledges the difficulties encountered by **epi** to be exempt from VAT in some countries and approves the initiative of the Treasurer to improve the process in order to get a written upfront agreement of the service providers to apply the tax exemption on the later bill.

The Committee noted with approval that the implementation of the new DIAMANT bookkeeping software is well ahead of schedule and that the new software is scheduled to go live already in October 2017. It appears that this new bookkeeping software will substantially increase the efficiency of the bookkeeping processes in the **epi** Secretariat.

The investment strategy for the **epi** mandate to Julius Bär was presented and explained by the bankers of Julius Bär in charge of **epi**'s investment. The security measures were explained at length. The portfolio is structured very conservatively and yields a net performance of 1.84% YTD. After the presentation, the Committee agrees with the Treasurer and the bankers to continue with the current low risk profile.

Report of the Professional Education Committee

P. Rambelli (IT), Chair

According to the Survey on Training Needs for European Patent Attorneys, which was carried out by the EP Academy, in March 2017, with the **epi** support, the most preferred format for education events is a one-day seminar on specific topics.

Out of about 1500 European Patent Attorneys, who answered the Survey, about 800 selected the seminars as their preferred choice; interactive workshops, such as Examination Matters, organised by the EPO with the **epi** support, and live webinars (virtual classroom) were respectively the second and third choice.

The organisation of seminars falls under the competence of the Continued Professional Education Sub-Committee of PEC. In 2017, the **epi** was able to offer 12 seminars in 3 specific areas, namely:

- Opposition and Appeal (2 events): **epi** roadshow supported by the EPO,
- Unitary Patent and Unified Patent Court (8 events): **epi** roadshow partially with the EPO support, and
- Life of a Patent (2 events): **epi** roadshow supported by the EPO.

Overall the above-mentioned seminars were attended by about 725 participants including 612 **epi** members and 52 **epi** students.

Moreover, in the fourth quarter of 2017, a new roadshow on Guidelines 2Day, organised by the EPO with the **epi** support was successfully started in Munich; the roadshow includes in 2017 4 additional seminars in major European cities.

Whereas the organisation of seminars is indeed the core of the **epi** educational activity, in 2017 PEC also focused its efforts on the design of a training programme for EQE candidates, registered as **epi** Students. This student programme falls under the competence of the EQE candidates and **epi** Students Sub-Committee and of the **epi** Tutors Sub-Committee of PEC, who actively cooperated together in the project.

Training programme for epi student members

A draft training programme was defined at the **epi** Tutors'meeting which was held on 7 September 2017 and attended by 34 **epi** experts (tutors, coaches and speakers) and by members of the PEC Subcommittees "**epi** experts" and "EQE candidates".

The **epi** experts were called to act as an advisory board for the PEC in the development of an action plan for the implementation of a 3-year training programme for EQE candidates. The main aim of the 3-year training programme is to provide training in aspects not provided for by other service providers, to be made available as a benefit reserved to **epi** student members, thereby to make more attractive and foster the registration of EQE trainees, entering in the profession, as **epi** Students.

Details on the envisaged training programme are provided by Mrs. Margaret Mackett's report on the **epi** Tutor's meeting in this **epi** Information.

PEC is pleased to report that the basic concept of the training programme was approved by Council at the Council Meeting in Warsaw, although some adjustment may be needed in order to comply with financial and budget requirements.

Annual Meeting of EQE Tutors and Members of the Examination Committees

This traditional meeting, organised by the EP Academy with the **epi** cooperation, under the MoU, was held in Munich on 8 September 2017 and preceded by a networking event (dinner) on 7 September, hosted by the **epi**.

The meeting was organised according to the usual format including sessions for each EQE and pre-examination papers; for the first time a single session was held for A/B papers that, in 2017, for the first time, were drafted in a single technical field. The programme of the meeting included a presentation by Ms. Katerina Hartvichova and Ms. Margaret Mackett (PEC Sub-Committee Chairs) on the concept of "Mentoring EQE candidates", which aims at providing support and guidance for EQE candidates/ **epi** students in case where an EPA supervisor is not available to the candidate or in case the supervisor is unable or unwilling to provide such a support.

The possibility to implement the mentoring programme, initially for **epi** Students in need thereof, is under consideration by PEC; further developments could aim at the recognition of the mentoring programme as a means to fulfil the training requirements under Art. 11(2)(a)(i) REE.

EPO/epi work plan for 2018

The EPO/**epi** work plan for 2018, which is envisaged within the frame of Memorandum of Understanding with the EPO, was finalised at the Meeting of the MoU Paritary Committee, held on 4 October 2017.

The finalised programme shall include the following events:

- **Opposition and Appeal**: two seminars are envisaged in Budapest (24 April 2018) and Madrid (Q4, 2018); it is envisaged to implement a new series in 2019 when the new Rules of Procedure of the BoA will be implemented;
- **EQE Tutors**: Munich, September or October 2018;
- **Examination Matters**: Munich, 4 and 5 July 2018; the definition of topics for the workshops and speakers is under way; the **epi** will contribute two speakers;
- **Webinars "Life of a patent"**: a distance-learning course on basic aspects of the EPC;
- **Seminars "Life of a patent"**: two 2-days seminars in Athens and Ljubljana/Zagreb;
- **Guidelines2DAY**: the GL2DAY, which started on 5 October 2017, will be continued in Q1 and Q2 2018 in six locations; a new series in Q4/2018 is envisaged in four further cities;
- **UP/UPC**: the UP/UPC series in cooperation with the EPO is a presently stayed due to uncertainty on implementation of the new system; at least one seminar will be held in Bologna in Q2/2018; the parties have agreed to review the need for further seminars in 2018 depending upon developments in the implementation of the system;
- **Case Law** seminars: on proposal by PEC, the Academy has agreed to cooperate in the development of a new seminar series on "Case Law"; the programme, proposed by PEC, and approved by the Academy, shall include:
    - disclaimers,
    - clarity,
    - problem/solution approach;
    - Mock Oral Proceedings and
    - Case Law update.

Decision CD 07/2012 of the Disciplinary Committee

Headnote

Facts: The member provided opinions in support of an alleged infringer, under national court seizure procedures for patent infringement. The member had drafted the patent in question for a different entity, at a time when his current client was a co-inventor and owner of that entity. The patent had been sold to a new entity with part of the business. The complainant was also a co-inventor of the patent and R&D manager of the new entity. The complainant felt that the member breached his professional duty under CC Rule 4(f), by advising against the interests of his former client. The member in his defence considered that his client was always the same, and that the current proprietor had never been his client and was owed no duty of confidence. The member submitted that it would have been unreasonable of him to withhold assistance for his client, in the emergency situation created by the seizure. Furthermore, the case for infringement was so weak that any patent attorney could see non-infringement and the seizure action was clearly malicious.

Decision: A member should not give advice against the interests of a patent proprietor on a patent he himself has drafted and/or prosecuted. The member's actions were based on a subjective desire to advise his personal client, overlooking his professional duty to the new entity, the proprietor of the patent he had drafted. Within the terms of RD Article 3(2), (i) a patent or patent application constitutes "a particular matter" with which a member may deal, and (ii) the status of being "another client" is effectively inherited by each owner when the patent is transferred. Even if the drafting attorney and the current owner have never met, patents are by their very nature transferable property. In the present case, the patent was effectively transferred as part of an on-going business, and former colleagues found themselves in dispute. Other aspects of the defence were incompatible with one another and/or insufficient to override the fundamental duty. The Chamber issued a Reprimand to the member.

Procedure

Handling of the complaint is being conducted under the Regulation on Discipline for Professional Representatives before the European Patent Office of 21 October 1977 (hereinafter called the "Regulation on Discipline" or "RD"), and the Additional Rules of Procedure of the Disciplinary Committee adopted under RD Article 25 (hereinafter "Rules of Procedure" or "RPDC").

[…]

Summary of Facts

[…]

The Respondent's submissions

[…]

The Complainant's submissions

[…]

Considerations

The Chamber is to decide whether the conduct complained of constitutes a breach of the Rules of Professional conduct that are set out in the RD Articles 1, 2 and 3, with reference also to the recommendations made in the Code of Conduct. The complaint refers specifically to Article 4(f) of the Code, which is supplementary to RD Articles 2 and 3. According to RD Article 25(1), the Chamber is to examine the facts of its own motion, and shall not be restricted in this examination to the facts, evidence and arguments provided by the complainant and the relief sought. The following provisions have been identified in the written procedure as particularly relevant to the present case:

> RD Article 1(2): *A professional representative shall conduct himself in such a manner as not to prejudice the necessary confidence in his profession.*
>
> RD Article 3 (1): *A professional representative who is unwilling to accept a call upon his professional services or who withdraws his services shall forthwith inform the client. In the latter case, he shall take appropriate measures to enable the client to avoid detriment.*
>
> RD Article 3(2): *A professional representative shall refuse or withdraw his services if acceptance or continuation would necessitate his dealing with a particular matter on which he has represented or advised another client with opposing interests and the conflict has not been resolved.*
>
> Code of Conduct Article 4(f): *Supplementary to Articles 2 and 3 of the Disciplinary Regulation, a member shall not take any action against a particular matter which is being handled or has been handled by the Member or another person in his office, unless the client in the matter agrees to this action or unless the Member has no cognizance of the matter and is no longer in a position to take cognizance of it. The Member is not permitted to make use in the action of information obtained during the time the matter was previously handled, unless the information is public.*

In view of the large number of issues presented by the Respondent in his defence, the Chamber considered the following questions helpful in reaching a decision in the present case:

1. Would a professional representative *ordinarily* be in breach of his professional obligations, in providing an opinion on infringement of a patent, of which he has handled the drafting and/or prosecution, without consent of the owner of that patent?

2. If the answer to the first question is yes, then which circumstances, if any, create an exception in the present case?

Concerning the first question, the Chamber considers it beyond doubt that a professional representative is ordinarily in breach of the Code and also Article 3 (2) of the Regulation, in giving any advice on the scope of the patent that he has drafted, to anyone other than the owner. The question was raised, whether providing an opinion on non-infringement constitutes "acting against" the patent? In the correspondence the Respondent had drawn a distinction between acting "against" a patent by challenging its validity in a position of revocation proceedings, and merely giving an opinion of non-infringement. In the view of the Chamber, this distinction is false. The appreciation and presentation of arguments concerning infringement is just as subjective and potentially informed by "inside knowledge" as any presentation of arguments concerning validity. The author of the patent claim and description makes many fine judgements as to the precise wording and intended scope, leaving the claim with certain strengths and certain weaknesses that are not necessarily apparent to the outside reader.
As an aside at this point, the Chamber has no reason to doubt that the amendments made by the Respondent during the prosecution of the patent application were made in good faith, with the best interests of the applicant in mind. The Chamber agrees with the Respondent that it is a common part of the representative's function to restrict the scope of protection claimed, in order to overcome prior art and obtain grant of a patent. The Chamber agrees with the Respondent that the Complainant may exhibit a "biased view" in suggesting that the limitations were "urged" upon them by the Respondent. However the Chamber considers that it is a fact of life that clients and members of the public will form biased views from time to time. The rules of professional conduct have been designed so that members can avoid situations where clients can even begin to form such views, however unjustified those view may be.
Even if one were to concede that there are cases where determination of infringement is so clear on the face of the claim wording and the accused product that no reasonable patent attorney could conclude that infringement exists, the code forbids embarking on such an opinion. The Chamber believes that there are many cases where the scope of protection, when reviewed in the light of a certain accused product, has a surprising breadth. The attorney embarking on infringement advice has no way of knowing at the start whether such revelations will emerge. Therefore there can be no assessment before beginning the task, whether it is trivial or not. For this reason, the Articles of the regulation and the code of conduct are absolute: the representative "shall not take any action…; the representative "shall refuse…" (emphasis added).

As a matter of common sense, the Chamber finds that a particular patent application or patent in itself must constitute "a matter" within the meaning of CC Article 4(f). Given that the primary function of qualified representatives is to prepare and prosecute patent applications, it would be strange if those items were outside the definition of "matter" in the rules on discipline. Similarly, when a defendant can escape a patent either by proving non-infringement or by proving invalidity, it would be strange if the activities of the drafting attorney were restricted on one of these counts, but not on the other. In most jurisdictions within the EPC states, trial of infringement and validity issues is joined together in a single proceeding. Even in those countries with "bifurcated" proceedings, the legal and commercial advice behind-the-scenes will be integrated. It is noted that infringement generally arises as a question in national proceedings, and the Respondent in this case was acting primarily as a [...] national patent attorney, in providing his opinion to the court. Provided that he is acting in relation to a European patent, however, the conduct of a professional representative are governed by the rules and code. Moreover, it is noted that in the opinion document, the representative mentions his European patent attorney qualification, and not only his national one.

Turning to the second question posed above, numerous additional factors were thrown up by the Respondent in his defence, and these have all been considered carefully by the Chamber. Certain of these have been covered in the above reasoning already, for example the distinction between infringement and validity, and the distinction between an infringement problem generally, and one that is trivial to assess. Two of the factors potentially carry weight, and are considered now in more detail.

The first potentially distinguishing factor is that the party for whom the matter was previously handled, that is to say the patent applicant on whose behalf the drafting and prosecution were done, subsequently sold the patent application to another party, presently the Complainant. The Chamber finds that, on the evidence, the [new entity] was indeed for some time fully a client of the Respondent representative. If [the Respondent] intended otherwise, he would have to have taken specific steps to inform the Complainant for example at the time of [...]. This is true not only objectively, but importantly also from the perspective of the public, who see the respondent's name clearly on the patent application and patent as granted. However, the fact that [the new entity] was a client of the Respondent at this later stage of the application is not the main source of the bar arising under the cited Articles. Rather, it is the history of the Respondent in the drafting and prosecution of the application that creates the bar.

In the course of preparing a patent application, the drafting attorney, the inventors and management at the applicant company are all involved in confidential and privileged discussions, within a "circle of trust". RD Article 3 (2) and CC Article 4 (f) imply that working once within that circle of trust bars the representative from ever acting against the patent. The Chamber considers that the benefit of this pro-

tection inevitably must transfer with the patent right, when it is bought and sold, and that this must be true even when the party later seeking advice of the representative is the one that originally obtained and sold the patent. A patent right is, by its very nature, an item of legal property that can be bought and sold as a business asset. If it were to be the case that the purchaser of a patent or patent application should expect that the original drafting attorney, (with or without the assistance of the Seller) may turn up in public or in court one day criticising the patent and arguing against its scope or validity, the value of such property would go down, and public confidence in the profession would be undermined.

Within the terms of Article 3(2), the Chamber believes that the status of being "another client" is effectively inherited by each owner when the patent is transferred, even if the drafting attorney and the current owner have never met. While this is not explicit in the wording of the rules and code of conduct, for reasons argued above the alternative interpretation would not be compatible with the overall aims of the Regulation and the patent system.

[…]

In the present case, it seems clear from the evidence that the patent was indeed transferred as part of an on-going business activity, namely activities using the [...] technology, with associated brand names and personnel. The fact that, legally, the entity carrying on the business is not the same as the entity that created it is just a normal part of the structure of such transactions.

The second factor which the Chamber considered in detail as a possible exception to the general principle set out in question 1 above, was that of the requirement for urgent assistance in the context of the seizure procedure in [...]. It is difficult to reconcile the Respondent's position that he found the opinion of non-infringement to be trivially easy, such that any competent patent attorney would give the same opinion, yet he was not content to leave that assessment to the expert in the seizure procedure, and he was considering himself as the only qualified and available patent attorney to do the work. Clearly an awkward situation is created for the representative, when he has to refuse an instruction from a long-standing, personal client. Nevertheless, the rules are clear that refuse he must. There is an Article in the code of conduct, namely Article 4 (d) that permits an attorney to take necessary action to preserve the interests of the client, even if acting in a matter would conflict with the attorney's interests. This Article does not benefit the Respondent in the present case, however, because it creates an exception only when there is a conflict with the attorney's own interests, and not with the interests of a former client. Another reason why the Respondent cannot avail himself of CC Article 4 (d) is that the Article goes on to require that the representative take only the minimum action necessary to preserve the situation, and thereafter withdraws. From March 2011 to November 2012, the Respondent made no efforts to withdraw.

It is also far from clear that the giving of the non-infringement opinion was necessary to preserve rights in the seizure procedure. The Respondent explained at oral proceedings that the information sought in the procedure was information already available on [his client's] website, and that the seizure order should not be used to go "fishing" for other, commercially-sensitive information. However, none of his submission in the legal proceedings seems to have been directed to this point. Also, the Chamber finds a contradiction in the position of the Respondent that, on the one hand, he was the only person with the knowledge of the field necessary to assist [his client] in proving non-infringement, while at the same time, [the representative of the Complainant] should have been able to tell immediately from the website information and the wording of the claims that there was no infringement. Rather, it seems from the papers that the seizure procedure was made properly in order to obtain information about a product, in order to determine whether there was or was not infringement of the claims. The evidence shows that the expert who performed the seizure correctly identified the absence of two limitations, so that one may assume that the outcome of the seizure procedure would have been confirmation by all parties that there was no infringement. The motivation for the Respondent's intervention seems to have been only an instinct to help his client […], which must not be allowed to override professional obligations.

The Chamber notes that, even in cases of emergency, the Institute provides for members to seek confidential advice as to any cause of action they may be considering […]. In the present case, it appears rather that the Respondent never considered that he may have a conflict situation, or considered that the interests of his previous client could be overridden by obligations to a current client.

In addition to the Articles mentioned above, the Chamber considered whether the Respondent was in breach of RD Articles 1 (1), 1(2) and CC Articles 1(c) and 3(a).

Decision

The Chamber finds by unanimous opinion that the Respondent [..] has breached Article 3(2) of the Regulation on Discipline and Article 4(f) of the Code of Conduct for Professional Representatives before the European Patent Office. By a majority, the Chamber finds no breach of Article 1(2) of the Regulation on Discipline.

The Chamber issues a reprimand to [...].

Possibility of Appeal

[…]

Communication to Complainant

[…]

Publication

[…]

Report from epi Tutor's meeting on 7 September 2017 epi 3-Year Training plan

M. Mackett (GB), Chair (former epi Experts Subcommittee)

Aim of the meeting

To develop an action plan for the implementation of a 3-year training plan providing training in aspects not provided by other service providers.

Summary

The meeting was attended by 34 **epi** Tutors who were divided into 6 workshop groups (Training Plan (Year 1); Training Plan (Year 2); Training Plan (Year 3); Paper DII Training; Role of Supervisors & **epi** Student Forum) to discuss various aspects for providing a 3-year training plan. A leader was appointed for each workshop group.

Each workshop group discussed its assigned aspect and provided feedback to the other workshop groups. Following the feedback sessions, an action plan was devised.

The proposed 3-year training plan has now been approved by Council.

Action Plan

We appreciated that it would not be possible to implement all aspects of our action plan at the same time and we concentrated on what would be needed to implement the training plan for Year 1, and, what would be needed to prepare for implementation of the training plan for Years 2 & 3.

Time will be needed for implementation of the 3-year training plan, and, we propose implementation by year with time being taken for preparation of material for following year(s).

Year 1 training – proposed Implementation for September/October 2018

Seminars/webinars:

- an introductory seminar/webinar to advise students what they would be expected to do to pass the EQE and what is available in terms of guidance and support to get them to that stage
- seminar/webinar(s) on "Life of a patent module" discussing the use of patents and what the claims are used for

epi Student Forum:

- to provide support and guidance for **epi** Students by providing sections for each paper including the Pre-Exam
- to enable students to obtain answers to their questions posted in the forum, the questions being posted anonymously

Mentorship programme:

- to provide support and guidance for students in cases where supervisors are unable or unwilling to provide such support and guidance

Preparation for Paper DII training
Preparation for Year 2 training

Year 2 training - Proposed implementation for September/October 2019

Work/study groups:

- Workgroups for Paper A & B analysis
- Tutor-led case law discussion groups
- Establishment of study groups (where appropriate)
- Exercises leading into **epi** tutorials for Papers A & B

Webinar(s):

- Methodology & strategy for Pre-Exam
- Methodology & strategy for Papers A & B
- Methodology for finding answers

Mock Pre-Exam
Paper DII training (latter part of year)
Continuation of **epi** Student Forum
Continuation of Mentorship programme with same/different mentors

Preparation for Year 3 training

Year 3 training - proposed implementation for September/October 2020

Seminars/webinars:

- Paper C analysis
- How to deal with obscure points

Continuation of Paper DII training
Continuation of **epi** Student Forum
Continuation of Mentorship programme with same/different mentors
Continuation of **epi** Tutorials for Papers C & D
Mock EQE – Papers A, B, C & D (for papers being taken)
Repetition of Year 3 training for those sitting EQE in "modules"

Tutors' Report on the EQE 2017 Papers

L. Ferreira (PT), A. Hards (DE), M. Mackett (BE), H. Marsman (NL),
S. van Rijnswou (NL), and R. van Woudenberg (NL)

Each year in October, the European Patent Academy and the **epi** arrange a meeting between EQE tutors and the Examination Committees. The goals are to discuss last year's papers, to improve future EQE's by openly exchanging ideas and to help tutors prepare candidates for next year's exam.
The Examination Board has kindly given the tutors permission to publish their own report of the important points so that candidates can more easily find this information. In addition, the comments can greatly assist when reading and interpreting the official EQE Compendium.

This year's meeting was held in Munich, already on September 8. The participant list showed 80 registered participants (tutors and further registered EPO and **epi** members from the Academy, EQE Secretariat and **epi** Institute) and 14 registered Committee and Board members.

This Tutors' Report appears each year in the end of year edition of **epi** Information.

It contains the following sections:

1. Pass rates EQE 2017
2. General remarks
3. Paper A
4. Paper B
5. Paper C
6. Paper D
7. Pre-Exam

On behalf of the tutors present in Munich, I would like to thank all the members of the Examination Board and Committees for their openness, for listening to our opinions and comments, and for providing their feedback thereto. This meeting is our yearly opportunity to learn from each other. My thanks also to the tutors who asked questions and contributed to the discussions.

My special thanks to Luis Ferreira, Andrew Hards, Margaret Mackett, Harrie Marsman, and Sander van Rijnswou for finding time to prepare the individual paper summaries. As the A and B papers were for the first year common papers (the same for e/m and ch candidates), the summaries for the common A paper by and the common B paper were each made by two tutors, one with an e/m background and one with a chemistry background, such that the experiences from both technical backgrounds could be reflected in this report.
We all wish you good luck in 2018,
Roel van Woudenberg (Editor)

1) Pass rates EQE 2017

In 2017, 672 candidates out of 884 (76%) passed the Pre-Exam, and 595 out of 1665 candidates that took at least one paper passed the Main Exam. The official results for each paper, as published on the EQE website and dated 13 July 2017, are as follows:

EQE 2017	#Candidates	PASS	COMP.FAIL	FAIL
Pre-Exam	884	76,02%	--	23,98%*
A	859	55,06%	7,10%	37,83%
B	793	67,97%	12,61%	19,42%
C	1134	52,47%	10,14%	37,39%
D	1044	38,89%	13,41%	47,70%

*Note: These numbers do not include the results of any appeals. A pre-exam candidate appealed successfully (D 2/17) and got a pass after an initial fail after the DBA considered his appeal, in particular a translation issue with statement 18.2 – it is not known whether also candidates who did not file an appeal on this issue but in the light of these considerations would have passed, upgraded and informed accordingly, as was done in earlier years such as in 2015 (as published on the EQE Pre-Exam compendium pages in an "Addendum").

2) General remarks

Introductions

Introductions by Nicolas Favre (Chair of the Examination Board), Paolo Rambelli (**epi**) and Giovanni Arca (Academy) addressed several points of general interest and advocated some topics that were on the agenda. Giovanni Arca and Paolo Rambelli commented on the continuing changes in the EQE: the common A and B papers as of this year, the 30 minutes additional time awarded by the Supervisory Board for main exam papers to compensate the language disadvantage, the various amendments to Rule 28 IPREE for pre-registration. Giovanni mentioned supplementing class-room teaching with mentoring, next to the daily supervision. Paolo Rambelli remarked that the Candidate Support Programme has shown that coaching is an essential tool. Paolo Rambelli wants to increase **epi** studentship registration.

Other presentations

Katerina Hartvichova and Margaret Mackett, both from the Professional Education Committee from the **epi**, gave a presentation on mentoring (long-term support), tutoring (specific training events), and coaching (the last few months before

the exam): all three types of training support are needed, but not (necessarily) by the same person. **epi** Coaches have shown their value in the CSP; **epi** is setting up **epi** mentorship. Apart from looking for mentors, Katerina and Margaret called for our views on **epi** mentorship (refer to the **epi** forum).

3) Paper A by Andrew Hards and Margaret Mackett

EC I (AB) representatives: Wim van der Poel (EPO), Jens Sebastian (**epi**)

This is the first year for the new format where the technologies, chemistry and electricity/mechanics were combined to form general exam papers A and B, and it has taken the Examination Committee I between 3 and 4 years' work to prepare each of the papers.

We reported last year that this combination of technologies could be disadvantageous for students who major in chemistry, since the combined paper no longer focusses exclusively on chemical specialties, but also includes functional definitions of elements with mechanical interactions. In addition, students who major in electricity/mechanics will need to address the requirements i.e. for "essential features" and multiple independent claims.

Whilst at the annual Tutors' Meeting the critique was voiced that the new combined paper may no longer test the specialised techniques of each technical field, it was also pointed out that candidates from both chemistry and electricity/mechanics needed to adapt and master at least the basic aspects typical of either chemical and E/M prosecution.

This year's paper was about a dishwashing product, made up of several different detergent compositions wrapped in a polymer film where each detergent composition was required for only one interval or part of the dishwashing cycle. The crux of the invention was to provide different layers around the different detergent compositions, so that each layer dissolves during the relevant interval or part of the dishwashing cycle to release only the detergent composition required for that interval or part of the cycle.

Document D1 gave a brief description of a dishwashing tablet of two compositions (no packaging). Document D2 described a dishwashing tablet enclosed in a single pouch made of a PVA polymer film. The dishwashing product is also sold as either strips or a row of tablets.

From this, candidates should have come to the conclusion that simply claiming multiple layers of PVA film with the same thickness would not provide novelty over document D2, because for each tablet in a row or strip of tablets may be considered to have a double layer (one on the top and one on the bottom). Claims which were not novel did not attract any marks as usual.
Candidates were expected to consider the technical effects shown in the experiments and draft claims to the dishwashing product, which solves the problem of releasing dishwashing components at different intervals of the dishwashing cycle. The solution was to claim a dishwashing product comprising of at least two pouches made of PVA film, where the pouches should have different thicknesses.
A highly controversial point this year was the inclusion of features, which were explained by the applicant to be "essential". Especially, candidates not used to such restrictions, which are germane to the chemical field, of undoubtedly "necessary", but possibly implicit features, may have found the paper challenging. Thus, it was considered essential that the polymer is PVA and the film has a thickness of 10 to 50 microns; candidates who did not mention either were heavily penalized with losses of 16 and 8 marks respectively. A total of 35 marks were available for the independent product claim.

Furthermore, this year's paper is unusual as two independent process claims needed to be drafted in addition to an independent product claim and dependent claims. Normally, two independent claims of the same category are not allowed; this year, however, it was considered that two such claims were defendable under Rule 43(2) EPC. A total of 32 marks could be obtained for the process claims, whereby 10 marks are available for the general process and 22 marks for the rolling process.

A use claim could have earned an additional 2 marks with 15 marks being available for the dependent claims and 15 marks for the description.

An important point to note is that there were no "double" deductions for missing features in the independent product claim and the independent process claim(s). If a feature was missing from both claims, points were only deducted once.

In conclusion, Paper A 2017 had many aspects of a classic chemical-style paper, albeit without true chemical specialization aspects such as two-list issues or medical use claims, and thus, attention was needed for patterns such as essential feature and multiple independent process claims.

4) Paper B by Luis Ferreira and Harrie Marsman

EC I (AB) representatives: Nicolas Favre (**epi**), Andreas Böhm-Pélissier (EPO)

Wim van der Poel, Sebastian Jens, Andreas Böhm-Pélissier were present on part of EC I.

This year, we had the first combined A and B papers; combined in the sense of one paper for both the fields of mechanics and chemistry.

There was 30 minutes additional time; this is now made "official".

Passing rate: 68.0%, 12.6% compensable fail.

Main drafter Andreas Böhm-Pélissier gave the presentation.

The paper was on a pulse oxymeter for long-term monitoring of the 4 vital signs in a reliable and controllable manner.

The main challenges were time management, handling the prior art documents, managing the multiple embodiments and, of course, the amendments and argumentation.

Time management was not seen as demanding with the additional 30 minutes.

There were 3 prior art documents. One in the exact same technical field; one baby monitor and one more medical apparatus. However, D1 was not adapted for long time monitoring; D2 was not suitable for directly monitoring vital signals; D3 was mostly a sensor.

One embodiment was only described in the original claims of the application, not in the description and similarly one embodiment was only described in the description, not in the claims.

Three clarity objections were raised by the Examiner. The holding means was considered unclear; glove was only used in the claims, not in the description; and a trademark was used in the original claims and a clarity objection was raised to that fact.

It was needed to rather strictly follow the instructions of the client. This required in claim 1 to remove the "wireless" option, broadening the claim scope; this had to be argued even now the "essentiality test" is no longer mentioned in the Guidelines in the context of an intermediate generalisation. However, even if it is considered that the three-point or essentiality test is unhelpful or even unsuitable in this regard, it remains critical to argue any removal of a feature. Most candidates did so, providing a link to the Guidelines and arguing correctly.

In addition, the client wished to maintain the glove embodiment. One had to closely check and adapt the dependencies of the claims. board expressed the view that the three-point or essentiality test was unhelpful or even misleading (see also T 1118/10; compare also Guidelines H-V, 3.2.1 - June 2012 edition, which referred to the essentiality test in the context of an intermediate generalisation, and later versions, which no longer do.

For inventive step, there was a situation of two partial problems: one dealing with comfortable and reliable attachment, and one with a noise problem.

This required a quite detailed discussion of all three documents of the prior art. In particular, the combination of the closest prior art with all the other documents needed to be argued.

The client's suggested claim 1 was already novel and involved an inventive step. Only formal issues needed to be solved.

For the claims, one could get 30 marks.

It is not needed to amend the description and thus no marks were available for amending the description. There were no marks for a letter to the Applicant, for a letter to the marker, for dependent claims that are not explicitly requested by the client, for amending the description, for amendments against the wishes of the client, making introductory remarks, comments, and for requesting oral proceedings. Proposing alternative claim sets does not attract marks either. Of course, theoretically speaking, the possibility for divisional subject-matter remains for future papers.
There were very strict and detailed wishes and instructions of the client. The Examiner was clearly pointing to problems and the application was using clear wordings to assist to find the solution.

The feedback was that this paper B was fair. There was no difference in the passing rate for chemistry and mechanics candidates. There were hints in the paper and potential basis for amendments was also suggested by the client in the letter or in the draft claim set. For example, for added subject-matter, practically all the candidates did provide more than just listing paragraph numbers, by supplying reasons and explanation to support the amendments.

Like the last years, the argumentation and motivation is very important. You really need a structured approach to deal with all requirements. Support needs to be discussed by not only giving the exact part from which amendments come, but also why that can be amended, and in particular generalized. Clarity objections need to be discussed. And finally, the problem-solution approach must be followed in all steps.

5) Paper C - by Sander van Rijnswou

EC II representatives: Paolo Provvisionato (**epi**), Celia Martinez Rico (EPO), Joanne Moore (**epi**)

Present from the Exam Committee for Paper C were: Paolo Provvisionato (Paper C chairman), Joanne Moore (co-drafter; replacing the main drafter today), and Celia Martinez Rico (Paper C coordinator). Joanne Moore gave a presentation on paper C of 2017. During and after the presentation, questions from the tutors were answered. This report combines discussions that relate to the same part of the paper into a single section.

The Committee reported the following results:

Pass rate:	52.47%
Compensable fail:	10.14%
Fail:	37.39%

General

The candidates should not just use standard type of phrases. One should not just say that you can combine two documents. Instead, you should argue how and why you would modify one to arrive at the other.

In principle, only one correct attack per claim is needed. However, if the attack is weak -such as an Art.54(3) novelty attack-, there often is a second attack. According to the Committee, whether there is one or more is "a matter of understanding".

According to the Committee, it is a sign of the quality of the marking sheet that the two markers are often very close together. It is not a surprise if two markers give identical marks. The Committee explained that the examiner's report emphasizes what they would like to see. All those lines in the report were used to mark. It doesn't matter where the information turns up in the candidate's answer. The Committee thanked the bench-markers since they were used to test the marking scheme.

The Committee asked if the tutors were happy with the new way the marking results are summarized per claim. The majority was.

Effective dates and prior art

There were not many problems for the candidates. This section was straightforward. Also, the assessment of documents A2, A3, A5 and A6 did not give problems.

A tutor asked if it would be sufficient to give information such as dates without sentences but in a table. According to the Committee this would be enough, so long as it is understandable what the candidate meant, and as long as it is a reasoned answer. The reasoning why you give a date to a claim should be present. The marker cannot guess what is in the mind of the candidate.

Annex 4

Annex 4 is a non-patent article and is useful to claims 5-7 only. The "what, how and the circumstances" needed to be discussed. The document is too late to be prior art itself. It has been constructed so that it can only be used as evidence of public prior use. The document cannot be used as evidence of an oral disclosure. The document is not a written description of an oral disclosure. It was also not enough to explain that the cork screw was shown at the wine fair, since the composition of the coating cannot be seen. Candidates were expected to remark that it is the corkscrew sold at the wine fair which is the prior art and that a single sales makes all its features publicly available.

A4 is published after the filing date. Candidates were expected to recognize the public prior use by sale, and to cite the relevant portion of the Guidelines. Because of the sale, the composition of the coating is public. This is why oral disclosure is not enough.

If you miss everything of A4 in this section, you lost 5 marks. Some tutors had expected this aspect to be worth more. The Committee explained that only 50 points are available to give to those who are possibly fit to practice. It has to be balanced what to give points for. The Committee had expected most candidates to realize that A4 represents prior art by sale, but not many went into this. This was also taken into account. The balance between the general part and the attack part, may be different next year.

Priority documents

The letter of the client remarked that the priority applications were deemed withdrawn. In spite of it being in the client's letter, the Committee did not expect discussion of the withdrawal of the priorities. If the candidate did write something about it, it did not attract marks, although it could help to put the candidate in a better light.

According to the Committee: There is no more legal part in paper C. This is more for paper D. The instruction is to file a notice of opposition. It is not a requirement to write a letter. We try not to test legal questions for paper C. Although there may be a legal position that needs to be discussed, such as the admissibility of prior art (A4).

Opposition form

It is not compulsory to use the opposition form. This information can also be given without the form. The commission does remark that this is an important part: if you don't refer to the patent by number, or pay the opposition fee, then it does not matter how good you are, since the opposition is not validly filed.

Attacks

Claim 1.

The expected attack was A6+A2. All annexes referred to cork extraction devices, and were considered to lie in the same field. All have the same purpose: removing corks. How many features are in common – or rather, the one needing the least amount of structural modifications – determined the closest prior art. When discussing the closest prior art, an argumentation based on the most shared structural features was therefore expected.

A6 is the closest prior art because it needs the least amount of structural modifications.

Claim 2.

A5 is the closest prior art since it is of the same type: a lever type cork screw. A6 would not work because of the spring. A5 is the closest prior art despite the fact that there are two distinguishing features over A5.

In the context of claim 2, alternative solutions were discussed. In particular, how much the CPA impacts the answer.

According to the Committee: This relates to what is written in the Examiner's report, that other 'well-reasoned attacks' will attract marks. It means what it says. There are alternatives. We cannot write all variations that were possible. We use what the majority used for the Examiner's report. For example, consider A6 as CPA for claim 2. There were several answers like that. There is a strong problem to start with A6,

because of this spring. It is a technical hindrance. We considered such attacks if they at least acknowledged the problem with the spring. Those who were able to identify this, were considered and got marks.

Claim 3(1)
Features are already disclosed in A6.

Claim 3(2)
An article 123(2) attack was expected. There are two parts in A1 that disclose materials for the housing, and both needed to be discussed. Section [0008] had polyethylene but not the combination with levers. Section [0014] only discloses metal. Furthermore, it is mentioned that metal is needed for structural support, so plastic would not work. The support given by the housing was picked up well.

Claim 4.
The claim represents a different technical effect so partial problems were needed. The claim has an aesthetic and a technical effect. Both effects must be addressed for full marks. That the technical effect is achieved by a flower-shaped structural element does not take away its technical character.

Claims 5.
The Committee was not generous to people who said that A4 itself is prior art. An explanation how the composition is available to the public (by sale) and the features visible from the photograph is expected.

Claim 6-7.
The corkscrew sold is the closest prior art, not document A4 itself. Again, candidates often confused A4 as such, the fair (see – visible features only publicly available) and the sale (product and all its features publicly available).

6) Paper D by Roel van Woudenberg

EC III representatives: Dimitrios Roukounas (**epi**), Charlotte Nessmann (EPO), Simone Fausti (DI, EPO), Scott Roberts (DII, **epi**)

The Exam Committee was thankful for all the questions submitted prior to the meeting, even though not always positive. The Exam Committee answered all questions submitted, except for those relating to details about the marking and number of marks for specific alternative answers.

General – pass rates and design considerations

For D 2017 the rates for pass/ comp/ **pass+comp** / fail for paper D were 40%/ 14%/ **54%** / 46% of 1003 candidates. In 2017, the average score was 46, the maximum score 81.

In earlier years, the corresponding rates were 44%/ 11%/ **55%** / 45% in 2016, 55% / 11%/ **66%** / 34% in 2015 (about all-time high), and 39% / 9%/ **47%** / 53% in 2014. The pass+comp fail rate was thus similar in 2017 and 2016 (about 55%), despite the 30 minutes extra. The pass rate seems to be difficult to control.
The D 2017 has many more words than the two earlier Ds, which two earlier Ds suggested that the Ds has become shorter compared to the years before. For example, the DII 2017 has approx. 1330 words, compared to 870 in 2016, 970 in 2015, 1500 in 2014 and 1420 in 2013.

The Committee indicated that there is no target as to the number of words, but only as to the length of the paper in time – the paper is designed to do in 5 hours (with the Supervisory Board having given an extra 30 minutes to do it in). Understanding information is sometimes more easy with more words.

A tutor asked the Committee why no questions are drafted relating to the Rules of Procedure of the Board of Appeal, especially as more-and-more appeals fail due to non-compliance with the RPBA. There was a wide consensus among all tutors that it would be fair to asked questions about the RPBA. The Committee indicated that they will consider, but it will need some time as it is expected that the RPBA will change in the near future and it needs to settle first before questions can be included in the exam.

A tutor asked whether effects can be seem in the two parts of starting with the DII-part rather than the DI-part when sitting the exam. The Committee said that they cannot see from the answers where a candidate started but guessed that they will be equally successful.

DI-part
The DI-part had 6 questions, Q.1 of 6 marks, Q.2 of 6 mark, Q.3 of only 4 marks, Q.4 of 6 marks, Q.5 of 10 (!) marks and Q.6 of 8 marks.

The Committee indicated that the number of marks for question as an indication as to how much detail is needed. E.g., in Q.1, no individual details of all R.159 acts were needed – some do not relate to the topic of the question, others are already mentioned in the question. An "advise how to" is an indication to not give too much detail.

In DI, to help candidates, the Committee used wording from the official documents, e.g. the first two lines of Q.2-b) are from G 4/88. This sometimes leads to a question having more words than the average.

A tutor commented that the DI part has too many topics which are in daily life executed by formalities officers / patent administrators. The Committee responded by indicating that it may be true that formalities officers do some of the acts tested but it is relevant for the work of a patent attorney and the patent attorney bears the final responsibility.

There is no target as to the relative number of marks for EPC, international PCT and Euro-PCT.

Q.1 – Non-unity, entry for fast grant, extra search
PCT application, EPO = rO, EPO = ISA, no additional search fee paid after partial search report, IPRP with non-unity objection and positive opinion for first invention.

Q.2 – Transfer of patent during opposition, transfer of opponent status
Question 2-a) addressed the transfer of a EP patent during opposition proceedings from a US company D represented by Ms Y to another company D: the new company want to file amended claims by the final date set in summons to oral proceedings.

Question 2-b) addressed the transfer of opponent status from company B, together with all business assets, to company E represented by Mx X.

T 1421/05 was cited in the Examiner's report as legal basis for "Mr X has to file supporting evidence of the transfer and request that the EPO recognizes the transfer of opponent status to company E". T 1421/05 is not mentioned in the Guidelines (2016) and could only be found in the Case Law Book (2016) IV.C.2.2.3. The Committee indicated that the Case law Book is in the syllabus, and that the model answer is indicated to be a "possible solution", aims to be complete, and may have more than what is needed for full marks. I.e., there may be more answers that attract full marks. In this case, the reference to T 1421/05 was not needed for full marks.

Q.3 – Filing by reference
A situation that should have let quite straightforwardly to filing-by-reference. Much like D 2011, Question 5 (Icelandic earlier filing).

No marks were available for calculating the 12m term "as the question stated that the application had to be filed today". A tutor submitted that this seems to be in Consistent with Q.6-a): in Q.6-a) there were marks for legal basis and calculation of the 1 month period although also there the question asked what had to be done within one month.

The Committee commented that the dates are given to make straightforward that they are not needed, avoid speculation on postponements or so, indication of number of marks, 12 month period trivially correct as no R.134(1) needed: can just do what the client asks. Also in Q.6, the calculation was not needed for full marks, even though in the possible solution.

There was a discussion whether the question was unambiguously asking for the acts to be done only today, or also to acts incurred by those, but to be done later to secure a filing date – the certified copy of the earlier application (JP not excluder under R.40(3), OJ 2009, 486 / GL (2016) A-IV, 1.4.3.1)- and to get it into the procedure – the translation of the earlier application. Also, a tutor commented that the reference to a JP application rather than a En/Fr/De-language translation is a clear pointer to a candidate that he needs to discuss the effect of the JP language: non-standard facts must somehow appear in the answer. The Committee commented that they considered the question ("instructed to file today"; "how to proceed?") was just directed to the acts to be done today. The Committee also commented that bonus marks were available to discuss the translation, to award candidates for the time spend on it.

Q.4 – Admissibility and teaching of prior art, novelty and inventive step
Answering required a discussion of various type of prior art and how they could/could not be used in novelty and inventive step assessment. Not difficult, but easy to miss out some topics.

Q.5 – Priority under PCT: adding priority declaration, restoration before EPO as rO, recognition by EPO as dO
A 10-point PCT question, which will have scared off many candidates. However, the question tests R.26bis.1 and R.26bis.3 PCT (making/adding/correction priority declarations and restoration of priority before the rO) in detail but in a rather straightforward way when using the PCT Applicant's Guide and/or the Euro-PCT Guide.

Q.5-b – Legal basis PCT-EPC interrelationship
The comment in the general part of the Examiners report concerning the legal basis for the PCT-EPC interrelationship related in particular to this Q.5 (e.g., OJ 2007, 694 as legal basis for EPO using all due care in restoration as rO). It was noted that a reference to Art. 153(2) EPC was not needed with R.159(1) for full marks: a mere reference to R.159(1) EPC was sufficient – but it is good practice to in include the article.

Q.5-c – Legal basis all due care by EPO as rO
OJ 2007, 694 was given in the Examiners report as legal basis for EPO using all due care in restoration as Ro, but this reference was difficult to find. OJ 2007, 692 (first page of the OJ publication); Euro-PCT Guide (2017) 133; Euro-PCT Guide (2017) 135; and AG-IP Annex C EPO were exceptionally also accepted.

Q.6-a&b) – Fees on filing
Candidates were tested on fees on filing (filing fee incl page fee, search fee), fee reduction due to nationality/residence and entity-type, fee reduction online vs paper.

Straightforward question. Main risk is missing the 1 page for the abstract.

Q6-a): Why was it needed to calculate the 1m expiry? The question already says that the filing needs to be today and the 1m is already given in the question (see also Q.3, where it was not required to confirm that the act could be done in time).

Q.6-c) – FP and AAD
Candidates were tested on the effect of a shortfall on the deposit account, the effect of replenishment, and how the missed payment resulting from the shortfall can be remedied. The ADA and/or AAD are almost every year on the EQE in

the last couple of years, but still many candidates do not prepare for them.

For full marks, it was needed to identify FP and its EPC articles, and the nature of the FP fee. No details were required as to how to pay it, i.e., not needed whether and how it could be paid under ADA, AAD or by bank transfer.

DII part

Very nice DII paper with dependent patents, various jurisdictions, opposition, product-by-process claims, transfer of priority, non-patent disclosures, Euro-PCT as potential Art.54(3) prior right, lost applications and further processing. The questions clearly and explicitly identify the topics a candidate needs to discuss.

Q1 could attract 35 marks (patent situation as/is: Q.1a 10 marks, Q.1b 5 marks, Q.1c 11 marks, Q.1d 9 marks, Q.2 18 marks (improvements) and Q.3 7 marks (FTO conclusions).

General comments from EC

The Exam Committee commented that this DII paper was a conventional paper with usual situations that could well be practice, requiring the candidate to analyse the situation as to novelty, inventive step, priority and validity of patent applications/patents, ownership of priority, practical measures, freedom-to-operate.

Abbreviations were given in the paper to simply the marking (uniform references).

Attention will continue to be given to short sentences and short phrases. Not planned to include any figures in the DII, as technical aspects are not tested and the attention could move away from what is wanted.

Q.1 - Outline the patent situation as it currently stands for beams having projections formed by a rolling process where:
a. the projections are of any shape;
b. the projections are of SHAPE-A;
c. the projections are of SHAPE-B;
d. the projections are of SHAPE-B1

The Committee commented that the term "patent situation" was also used in the past and refers to the patentability situation as it stands, which is a theme in every DII paper: identify applications, identify disclosures, discuss novelty, step, enablement and also their status (such as deemed to be withdrawn).

If a PCT application is still in the international phase, it a germ waiting the germinate. "Currently it may be regionalized and then…" EP: (Euro-PCT application, Art.54(3) effect).

If an EP application is /can be Art.54(3) against a Euro-PCT application, possible prior right effects in other jurisdictions need not be discussed.

All claims were formulated as product-by-process claims. This appeared not to be a major hurdle to scope of protection discussions, but its novelty discussion was not always done correctly: that required addressing that the claim is a claim to the product per se and does not get its novelty by the mere reference to the new process - the resulting product from the rolling process has distinguishable differences from the prior art beam made by a stamping process (no visible stress).

Q.2 "What can be done to improve our patent situation vis-à-vis CHINABEAM?"

The Committee remarked that a question asking about further processing is almost a gift. In Q.2, apart from requesting further processing, it is also needed to discuss how to get a grant: delete claim 2. So, not enough to say "respond to the R.71(3) and pay the FP fee", but need to answer with "do FP by filing the claims translations and the fees for grant and publishing, and pay the flat FP fee with 2m from the to be received loss-of-rights communication", or with "remedy the missed disapproval of the R.71(3) text by requesting FP by filing just the amendments, and the flat FP fee with 2m from the to be received loss-of-rights communication, and then wait for the next 71(3)".

It was noted that the Examiner's Report has an error on page 14 where it says "File third party observations with WIPO pointing out the invalid claim to priority in CB-PCT and citing the trade journal article dated 11 April 2016. The observations will be communicated to the EPO as ISA". Third party observations can only be filed after publication and the EPO as ISA will under ECfS normally have finished the ISR within 6m after CB-PCT is filed, so before its publication. They will thus not be communicated to the EPO as ISA but (later) to the EPO as dO.

Q.3 "Which types of metal beam are we or CHINABEAM free to produce, sell and use in the future?"

The Examiner's Report emphasizes: "Candidates are urged to ensure they answer the question posed. If a question asks for positive statements (e.g. what can be made, used and sold), discussing only negative statements (what a party can prevent) may risk not earning all available marks." and "A great number of other candidates elected to discuss how STEELCO can prevent CHINABEAM and vice versa without addressing the specific question: which types of metal beam are the companies free to produce, sell and use."

This year, a FTO analysis was needed with positive conclusions as to what both parties can do. No specific cross-licensing proposals were needed for full marks, but marks were awarded if a specific proposal was given.

7) Pre-Exam by Roel van Woudenberg

EC IV representatives: Stefan Kastel (**epi**), Francesco Rinaldi (EPO), Isabelle Caillet

The Exam Committee commented on questions submitted by tutors prior to the meeting and expressed their appreciation of the evaluation of the statements.

General – pass rates
884 candidates enrolled for the Pre-Exam 2017, out of which 860 also sat the paper (97%).
672 candidates passed, corresponding to 76% of all enrolled candidates and 78% of all candidates that sat the exam. Congratulations!
188 candidates failed, corresponding to 21% resp. 22%.
The pass rates are thus similar as in 2016 and 2015.

As in 2016, many candidates commented that they needed the full 4 hours and they reposted that only very few candidates left the exam room before the end – quite different from the years before 2015.

The Exam Committee commented that they give a lot of attention on keeping the difficulty level adequate and on the language, also for non-mother tongue language candidates. The consistent pass rates from 2015-2017 and stable pass rates of 75-80% show that the difficulty level is stable.

The pass rate is considerably lower for resitters (e.g., 105 Pre-Exam 2016 candidates were resitting: 53 passed, 52 failed again) and for multiple resitters (36 resitters that failed Pre-Exam 2015 and 2016: 17 passed, 19 failed again, of which 9 resitters failed Pre-Exam 2014, 2015 and 2016: 6 passed, 3 failed again).

The Exam Committee commented that the purpose of the pre-exam is an early start of preparation. Candidates need to study the EPC and PCT Articles and Rules, Guidelines and RFees, G-decisions and to do patent work; if they do all of this, they should be able to pass. The Guidelines pay a key role for candidates to give the right answer. Although the legal syllabus is the same as for the main exam, the difficulty level for the Pre-Exam is considerably lower than for the main exam: for the Pre-Exam, candidates need to recognize whether the situation is correct; in the DI-exam they need to formulate their answer.

General – Calendars: availability and style
For the Pre-Exams 2016 and 2017, the calendars were made available on the EQE website a few months (January 2016 and December 2016 resp.) before the exam by and under the responsibility of the Exam Secretariat. The Exam Committee does not know whether this will continue to be the case.

Legal part – introduction
The legal part covered a wide range of topics. Absent were standard topics as filing date and languages. Non-standard topics were, e.g., interlocutory revision, interruption, and second medical use.

Question 1 – state of the art and priority; novelty not tested
Good question, pre-exam type topic, right level, should not have imposed difficulties.
Some candidates confused state of the art and novelty: these candidates went wrong because they considered the catalogue not to be state of the art if it was earlier than the claim but the claim was novel. Error also made often in paper DII.

Question 2 – entry in the EP phase
Good question, pre-exam type topic, right level, should not have imposed difficulties, some have been in earlier exams (e.g., 2.1 with same wording).

Statement 2.1 (T) raised some comments of candidates on the DeltaPatents' Pre-Exam blog, as some candidates considered that the renewal fee fell due today (31m expiry), but that payment could be done up to 6m later with an additional fee, and for that reason answered F. However, the statement was whether the fees fall due ("requirement for entry", not what the time limit to pay them was.

Question 3 – pendency
Good question, pre-exam type topic, right level, should not have imposed difficulties.

Question 4 – formalities examination
Good question, pre-exam type topic, right level, most statements should not have imposed difficulties.

Statement 4.3 (T) is essentially the same as Pre-Exam 2014, statement 8.2. Difficulty with the statement is that R.6(1) EPC requires the translation to be filed within 2m of filing, but R.58 EPC –i.e., another "provision of the EPC"- provides for an invitation to file it within 2m from its notification without any sanction (esp. no additional fee). So, one may defend that "according to the provisions of the EPC", the translation does not need ("must") filed within 2m, but at least 10d+2m more are available; even more because the failure to file the translation within 2m from filing does not lead to a loss of rights. So, less-fit-to-practice candidates that are not aware of the formalities check invitation will surely answer T, whereas better-fit-to-practice candidates that know of the R.58 system had the risk to wrongly answer F.

Statement 4.3 (T): on the blog, some candidates suggested "must" as used in 4.3 having a different meaning than "shall" as used in R.6(1) and 2014-8.2. Also, some said that in French, "devoir" was used in 4.3 as well as in R.6(1). The Committee commented that this was extensively discussed before the exam in the Committee, and that "must" and "shall" are considered to mean exactly the same.

Question 5 – appeal
Good question, partly pre-exam type topic, 5.1-5.2 right level, 5.3-5.4 (too) difficult for pre-exam level.

Statement 5.4 was a hinting that 5.3 related to interlocutory revision.

Statement 5.4 (F) tests whether a certain submission will lead to the grant of interlocutory revision. This is a very difficult topic for candidates at pre-exam level and pre-exam

experience, but see above for the remarks about the difference between Pre-Exam and DI.

Question 6 – opposition
Good question, pre-exam type topic, 6.1-6.2 right level, 6.3-6.4 difficult for pre-exam level but fair.

Statements 6.3 and 6.4 are difficult, but they relate to key principles of first instance opposition proceedings and are documented well in the Guidelines.

Question 7 – amendments in opposition
Good question, pre-exam type topic, right level although difficult.

Statement 7.1 (F) tests the difference between admissibility and allowability. Pre-exam candidates find this a difficult conceptual difference.

Statement 7.2 (F) tests G 3/14 (extent of clarity examination of amendments in opposition) which was issued 24.03.2015, published Official Journal of Nov 2015 and in the Guidelines since the Nov 2015 edition, so it tests an important recent decision.

Question 8 – interruption
Good question, but quite difficult for a pre-exam type, esp. 8.4.

Interruption is an exotic topic that does not even occur frequently at the main exam paper D. It is a very difficult topic for candidates at pre-exam level and pre-exam experience. The Committee commented that interruption is not a typical topic, but the question has a clearly set-out situation and the Guidelines are very clear as to how to deal with it.

Question 9 – second medical use
Good question, pre-exam type topic except 9.1 (Swiss-type), in principle not difficult.

For the first time in the pre-exam, second medical use was tested. Some candidates considered this a too exotic topic, but second medical use is a key concept in the EPC and statements 9.2-9.4 are very straightforward tests of Art.53(c) and Art.54(4)&(5), which is also well-documented in the Guidelines. Also Swiss-type claims are mentioned in the Guidelines as a non-example.

It was discussed whether a claim "complies with a G-decision" (G2/08, Question 3) equates to testing "compliance with the requirements of the EPC", and whether this may have led candidates to answer wrongly.

Question 10 – international preliminary examination, and PCT Art.19
Good question, pre-exam type topics, not too difficult
Statements 10.1, 10.2 and 10.4 are standard topics for Art.34 and Art.19 PCT and should not have imposed any problems. However, as only very few demands and only very few Art.19 amendments are filed, candidates cannot base their answers on their practical experience.

Statement 10.3 (T) is difficult. R.66.6 PCT seems to give this right as an absolute right, but the OJ 2011, 532 par. 5 / Euro-PCT Guide (2017), 385 limits this as EPO allows only once, only by phone, and only after written submission. So, the applicant is entitled to oral communication, but under conditions and not unlimited – so one might also argue that the answer is F, as there is no such right anymore if already used. The Committee considered the statement to be unambiguous.

Claims analysis part
The claims analysis part related to toothbrushes for human use.

The client's application described that a drawback of known toothbrushes is that the users need to be trained by dentists in order to achieve optimum dental plaque removal. Remaining dental plaque can give rise to dental caries, which is highly undesirable.

The invention is presented as being based on the surprising finding that the amount of dental plague removal can be increased by transmitting additional vibrations to the bristles of the toothbrush, generated by an electric vibrator inside the brush body, preferably in the handle together with a controller and a battery. The controller acts as a switching device for selectively supplying electric energy from the battery to an electrically operated element, because the controller connects and disconnects the vibrator from the battery.

Four embodiments are described and shown in four figures. In some embodiments, the controller uses a push button to turn on&off the vibrations; in other embodiments, a pressure sensor in the bristle zone is used. Some embodiments have a replaceable brush and a connection section to connect it to the handle. A LED can be incorporated to emphasize the technical character, which makes users think that the toothbrush has a higher cleaning efficiency.
The toothbrushes must have a length of less than 30 cm, or between 18 and 25 cm when having a replaceable brush head for ergonomic reasons.

Two prior art documents were found by you (D1, D2); two more prior art documents were found by the EPO (D3, D4). The questions were related to three claim sets:

- Q11-13 to a first claim set composed of an independent claim and one dependent claim directed to a body of a toothbrush for increased dental plaque removal,
- Q14-17 to a second claim set composed of one independent claim and 4 dependent claims directed to a brush with a body comprising an electrically operated element, the electrically operated element being an electrically operated vibrator,

- Q18-20 related to one independent claim directed to a toothbrush with a body, [...], a connection section, the electrically operated element being an electrically operated vibrator, the connection section comprising a connection hole and a connection protrusion, and the toothbrush having a total length of between 18 and 25 cm.

Tested is scope of the claims, distinguishing features, role of dependent claims, novelty, selection inventions, claim feature issues such as "for example", extension of subject-matter including introduction of a undisclosed disclaimer (not allowed, D4 is not an Art.54(3)EPC prior right -- here it became clear why the dates were given), technical effects, formulation of two-part form, inventive step aspects such as closest prior art, formulation of the objective technical problem, considering to combine, and obviousness of the combination.

There were surprisingly few questions about closest prior art this year. The Committee commented that they are the most difficult to design, as they requires a really black-and-white situation for the Pre-Exam.

Question 17 – amendments
Amending the independent claim may give rise to Art.123(2) problems in the independent claim itself, or to the resulting dependent claims. The question does not specify what is done with the dependent claims while amending claim II. The Committee indicated that only the amendment to the independent claim itself has to be tested; no check is required whether the dependent claims are effected by the amendment to the independent claim in the Pre-Exam.

Statement 18.4 – Loudspeaker vs vibrator
D2 describes that, as long as a child holds the toothbrush in his hand, a sensor transmits a signal to a controller which energizes a music module. It plays a melody over a loudspeaker, the vibrations of which are converted intro vibrations of the air. In the German version, this sentence was phrased subtly different as "..spielt es über seinen Lautsprecher eine Melodie ab, deren Vibrationen…"

Statement 18.4 read "The technical feature "the electrically operated element is an electrically operated vibrator located in the handle" distinguishes claim III from document D2". The answer to statement 18.4 relied on whether D2's "loudspeaker, the vibrations of which are converted intro vibrations of the air" could be considered a type of "electrically operated vibrator".

This topic got an extensive discussion on the DeltaPatents' blog, including a discussion on the differences between the English and the German wording.

The Committee commented that the exams need all to be translated in 3 different languages, all with the same meaning and difficulty level. Many checks are done on the translations, but some differences sometimes occur. Decision D 2/17 is noted by the Committee, and prevents the Committee from commenting in 18.4 now. Also the Examination Board could at this point (and still in early November) take note of D 2/17, but could not comment as to whether other candidates that failed due to 18.4 would be "promoted" as they were in, e.g., 2015 (see Addendum to the Examiner's Report on the EQE Compendium pages).

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Thank you for your cooperation.

Image Processing and Generation from a Patent Perspective

Michael M. Fischer (DE),
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With the advent of smart phones at the latest, the field of image processing and generation has become ubiquitous in our daily lives. Our smartphones recognize faces and improve colors if we take pictures on a dull day. While the field is interesting from a technical perspective last but not least by its different fields of industrial applications (e.g. finding the teats of a milk animal as in **T 754/03**) and its close relationship to the field of artificial intelligence and mathematics, especially the latter makes the field challenging for the patent practitioner. Inventions in the field of image processing and generation belong to the computer-implemented inventions which face many obstacles on both sides of the patent world: patentability and enforceability. The author of this article has dealt with hundreds of inventions in this field and wants to share his knowledge with the interested reader. The first part of the article defines the technical field, the second part deals with patentability before the EPO and the third part deals with the enforceability of patents in this technical field. The article is rounded off by a conclusion as a fourth part.

A. Nomenclature

(Digital) image processing means the use of computer algorithms to perform image processing on (digital) images. It typically deals with classification of images, feature extraction and pattern recognition. It typically uses digital image transformations (applying kernels, masks to images, etc.) as a first step to extract features from an image and then applies approaches from artificial intelligence (neural networks, etc.) for subsequent classification. In this article, the term "image processing" also encompasses the field of image compression which uses computer algorithms to reduce the cost for storage and transmission of images. The term "image generation" is sometimes synonymously used with the term computer graphics and denotes the creation/rendering (texturing, colouring, etc.) of images (or films) using a computer. It should be noted that the International Patent Classification makes a distinction between image processing (without compression) and generation under class G06T ("image data processing or generation, in general") on one hand and image compression, which is primarily dealt with under class H03M (coding, decoding or code conversion in general) and partly under class H04N (pictorial communication, e.g. television), on the other hand.[1]

1 The interrelation between image processing and image compression can be seen from the fact that Board 3.5.04 deals with appeals from both G06T and H04N.

B. Patentability before the EPO

Without any doubt, the milestone decision in the field of image processing is the VICOM decision (T 208/84) from the year 1986. The method relates to "a method of digitally processing images in the form of a two-dimensional data array having elements arranged in rows and columns in which an operator matrix of a size substantially smaller than the size of the data array is convolved with the data array…". In other words, the method relates to a typical image processing method (as described above) which applies a mathematical operator (a kernel) to an image which is defined in the form of a two-dimensional data array. The headnotes of the decision read:

"I. Even if the idea underlying an invention may be considered to reside in a mathematical method a claim directed to a technical process in which the method is used does not seek protection for the mathematical method as such.

II. A computer of known type set up to operate according to a new program cannot be considered as forming part of the state of the art as defined by Article 54(2) EPC.

III. A claim directed to a technical process which process is carried out under the control of a program (whether by means of hardware or software), cannot be regarded as relating to a computer program as such.

IV. A claim which can be considered as being directed to a computer set up to operate in accordance with a specified program (whether by means of hardware or software) for controlling or carrying out a technical process cannot be regarded as relating to a computer program as such."

Mathematical Methods & Programs for Computers

Headnote I , III and IV deal with two exclusions from patentability. Art. 52 (2) (a) EPC excludes mathematical methods and Art. 52 (2) (c) EPC excludes programs for computers from patentability. Art. 52(3) EPC clarifies that the exclusions only apply "to such subject-matter or activities as such". By these headnotes, decision **T 208/84** overruled the negative decision of the Examining Division which refused the patent application and opened up a liberal patent practice in the field of image processing in particular and in the field of computer implemented inventions in general.

The Board held that a "method for digitally filtering data" remains an abstract notion not distinguished from a mathematical method so long as it is not specified what physical entity is represented by the data and forms the subject of a technical process". According to the Board, the image data in the form of a two-dimensional data array do not seem to be an abstract notion. When examining whether the invention related to a mathematical method or a computer program as such (which would be non-patentable), the Board saw the basic difference between a non-patentable mathematical or algorithm and a patentable technical process in the fact that a mathematical method or mathematical algorithm is merely carried out on numbers and provides a result in numerical form whereas, if a mathematical method is used within a technical process, that process is carried on a physical entity, in the specific case a stored image, by some technical means implementing the method and provides as its result a certain change in this physical entity. Although the author of this article agrees with the Board's point of view, an image could equally be regarded as an abstract entity since it is nothing else than stored pixel values (numbers).

Similarly, a method of encoding audio information in a communication system may aim to reduce distortion induced by channel noise. Although the idea underlying such a method may be considered to reside in a mathematical method, the encoding method as a whole is not a mathematical method as such, and hence is not excluded from patentability by Art. 52 (2) (a) and Art. 52(3) EPC. A method of encrypting/decrypting or signing electronic communications may be regarded as a technical method, even if it is essentially based on a mathematical method (see **T 1326/06**).

In this context **T 1227/05** should be mentioned which says that a procedural step (e.g. a mathematical algorithm) may contribute to the technical character of a claimed method only if it serves an adequately defined technical purpose of the method. In particular, specific technical applications of computer-implemented simulation methods, even if involving mathematical formulae, are to be regarded as modern technical methods which form an essential part of the fabrication process. Such simulation methods cannot be denied a technical effect merely on the ground that they do not yet incorporate the physical end product. However, the meta-specification of an undefined technical purpose (for example, the simulation of a "technical system"), could not be considered adequate.

It should be mentioned that the decision **T 208/84** comes to the conclusion that the method defined in claim 1 is not barred from patent protection under Art. 52 (2) (a), (c) and 52 (3) EPC but does not deal with novelty and inventive step. This is due to the fact that the decision was rendered long before the COMVIK approach (**T 641/00**) which says that if a claim contains at least one technical feature, it is not excluded from patentability under Art. 52 EPC any more. One can, however, assume that the Board considered enhancing or restoring an image, without adding to its information content to be a technical effect.

Industrial Application

Although this was not disputed by the Examining Division or the Applicant, the Board held that claim 1 also complied with the requirement of industrial application (Art. 57 EPC) by saying:

"Clearly a method for obtaining and/or reproducing an image of a physical object or even an image of a simulated object (as in computer-aided design/computer-aided manufacturing (CAD/CAM) systems) may be used e.g. in investigating properties of the object or designing an industrial article and is therefore susceptible of industrial application. Similarly, a method for enhancing or restoring such an image, without adding to its informational content, has to be considered as susceptible of industrial application within the meaning of Article 57 EPC."

Moreover, the Board held that it does not make any difference whether an invention is embodied in hardware or in software:

"In arriving at this conclusion the Board has additionally considered that making a distinction between embodiments of the same invention carried out in hardware or in software is inappropriate as it can fairly be said that the choice between these two possibilities is not of an essential nature but is based on technical and economical considerations which bear no relationship to the inventive concept as such. Generally speaking, an invention which would be patentable in accordance with conventional patentability criteria should not be excluded from protection by the mere fact that for its implementation modern technical means in the form of a computer program are used. Decisive is what technical contribution the invention as defined in the claim when considered as a whole makes to the known art. Finally, it would seem illogical to grant protection for a technical process controlled by a suitably programmed computer but not for the computer itself when set up to execute the control."

Presentation of Information

Unfortunately, **T 208/84** and other decisions in the field of image processing and generation do not make any comments on "presentation of information" as an exclusion from patentability under Art. 52 (2) (d) EPC. The reason is probably that there is no doubt that an image itself is defined as nothing more than a pure representation of information. This means that generally speaking an image (at least if it does not show any technical features) obtained by an image processing method, or in particular an image compression method, is excluded from patentability under Art. 52 (2) (d) EPC.

Let's have a look at the following claim set:

1. A method of processing an image by applying the steps…
2. An image obtained by the method of claim 1.

In other words, claim 2 would not be allowed in the above claim set. However, Art. 64 (2) EPC stipulates that if the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process. The author of this article is of the opinion that Art. 64 (2) EPC may be regarded as a backdoor to circumvent Art. 52 (2) (d) EPC (before national courts in infringement proceedings).

Typically, Art. 64 (2) EPC is applied to pharmaceutical products obtained by a novel and inventive process. However, Art. 64 (2) EPC is formulated so broadly that it can also be read – without much discussion – on images obtained by an image processing method. Visser writes: "Art. 64 (2) EPC extends the protection conferred by a process patent to the products obtained directly by the process, even if the products are not patentable per se. Hence, the protection may extend to a known product (not patentable under Art. 52 (1) EPC)... The non-patentability of the product does not affect the examination of the process claim, because Art. 64 (2) EPC does not belong to the requirements of the EPC on patentability to be examined (Art. 52-57 EPC) but to the provisions concerning the effects of patents and patent applications to be applied by national courts deciding on infringement. (G1/98 r.4)"[2]

This means that although claim 2 above would not be allowed, someone who has a European patent for claim 1, could sue someone else for infringement of his patent if the person merely shows/displays images obtained by the method of claim 1. Without any doubts a far reaching effect.

Inventive Step

In order to demonstrate the presence of an inventive step, a technical effect based on the distinguishing feature(s) has to be identified. Typical technical effects in the field of image processing are to increase sharpness of an image, increase contrast of an image, improve contours, improve saturation of colour, improve quantitative measurement of defects in a manufacturing process, improve accuracy of measurement of defects, allow for faster object tracking, etc. In **T 2124/08**, the problem of "improving user-friendliness" was also accepted. In the field of image compression, the technical effects are typically to reduce the amount of storage, reduce the processing time or reduce the transmission time. Please note that these technical effects are only acceptable since image compression is considered to be technical.

However, **T 1954/08** referred to decision **T 1227/05**, point 3.2.5 (supra) which held that (the sole) processing speed was not a suitable criterion for distinguishing between technical and non-technical method steps since it was always possible to conceive of a slower algorithm than the one claimed. Similarly, the sole amount of memory a computer-implemented algorithm requires is equally unsuitable for determining whether or not a method step contributes to the solution of a technical problem since it is always possible to imagine an algorithm demanding more memory. As mentioned above, the innovative potential of the algorithmic scheme can be left aside since it does not serve any technical purpose and, thus, does not contribute to the technical character of the claimed method and cannot enter into the examination for an inventive step.

Also in **T 42/10** it was held that processing speed is not a suitable criterion. "The appellant's third argument is that factor graphs, and the associated message passing algorithm, are technical. They address the technical problem of speeding up computation.

In its full generality, speed of computation is a mathematical problem. It may be the case that a computer has a particular processor that is particularly good, or particularly poor, at some (class of) operations. Recasting a mathematical method so as to take advantage of what the processor does quickly, or to avoid what it does slowly, might involve technical considerations. In such a case, the recast method, when performed on that particular processor, might not be "just" mathematical but also be technical. However, not all recasting of mathematical methods in order to increase speed are technical. In the days when people looked up trigonometric functions in tables, recasting a method so as to reduce the number of times the tables had to be consulted might speed up computation, but nothing technical was happening.

The appellant has not provided any evidence that there really is an increase in speed of computation. There is no analysis of the complexity of any prior art method of performing the same sort of calculation, and there is none of the complexity using factor graphs. Nor has the appellant provided any evidence for its assertion that the increase in speed would only be obtained on a computer, whereas calculations by hand would be slower. However, the Board also considers that, even if the increase in speed were established, it would not be an increase which solved a technical problem, and that is enough to reject the argument. According to the application (paragraph [0068] as published), it does not matter

2 D. Visser, "The Annotated European Patent Convention", 21st edition, H. Tel Publisher, 2013, p.134

what sort of technical apparatus is used to perform the calculations. What matters is only the ability to carry out the necessary steps. It follows from that, that any improvement in speed is inherent in the method of calculation. It does not result from exploiting ability or avoiding some lack in the computer. At best, if the appellant is correct, and there is an increase in speed which only occurs on computers, it is a matter of abstract computer science."

T 42/10 also relates to a case (Gale`s application) from the UK for an algorithm for faster calculation of square roots which was not deemed patentable since it did not solve a technical problem. The increase in computation speed was not deemed a technical effect.

"The Board's approach to assessing questions of what is and what is not technical about a computer-implemented method, in this case, asks the same questions as Nicholls LJ in Re Gale's Application. The first is: what does the method as a whole do, and does it produce an overall technical result? The second is: if there is no overall technical result, does the method at least have a technical effect within the computer? If both questions are answered in the negative, no technical problem has been solved and there can be no inventive step."

A. Enforceability

On the one hand, patents relating to image processing methods which define a particular image operator applied on an image may be difficult to enforce due to problems that relate to the detection of the infringement of the claimed method. Since the image processing method is implemented in software, it is hard to detect whether the software infringes the claimed method or not. Normally, some form of decompilation or step-by-step analysis is required. (An interesting decision is **T 2440/12** which does not deal with infringement but with a prior use of software. The prior use was in the form of sales of a software product that embodied the claimed invention. This was undisputed between the parties. In the Board's view, it can be rather convincingly argued that the mere fact that any interested (and skilled) person who acquired the software product would be able to see how the input data was processed and understand how the method implemented by the software was carried out. By executing the program line-by-line, a skilled person would be able to see how the input data was processed and understand how the method implemented by the software product was carried out step-by-step. The information provided by the stepwise execution of the software product represented a form of disclosure of a specific embodiment of this method.)

On the other hand, the field of image/video compression is dominated by many standards which are covered by patents (MPEG, H.264, JPEG, GIF, etc.). An essential patent or standard-essential patent (SEP) is a patent that claims an invention that must be used to comply with a technical standard. Companies involved in the development of image compression methods often file their patent applications before they share their knowledge with other members in the standards organization. Should the patent be granted and also become part of a compression standard, then the patent proprietor could ask for royalties from all members who wish to use the standard. (As the patent has become part of a standard, there are presumably many who wish to use it.) Standards organizations, therefore, often require members to disclose and grant licenses to their patents and pending patent applications that cover a standard that the organization is developing. If a standards organization fails to get licenses to all patents that are essential to complying with a standard, owners of the unlicensed patents may demand or sue for royalties from companies that adopt the standard. This happened to the GIF and JPEG standards, for example.

Determining which patents are essential to a particular standard can be complex. Standardisation organizations require licences of essential patents to be on fair, reasonable, and non-discriminatory (FRAND) terms.

B. Conclusion

The field of image processing and generation is susceptible to patent protection in Europe (and many other jurisdictions). Whether a patent will be granted depends on the fact whether the claimed invention is novel and inventive vis-à-vis the prior art. However, since the field is closely related to mathematics, care has to be taken not to direct the claims to the mathematical method per se (which should not be a problem since images are not considered to be abstract). An interesting (and unanswered) question arises whether an image processed by an image processing method is protected under Art. 64 (2) EPC. At least in the field of image/video compression, enforceability (i.e. detection of infringement) of a patent is often not a problem at least if it relates to a standard. In such cases, it can often be determined that someone uses a standard and thereby automatically infringes the patent.

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Notes on R. 43 (2) EPC

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Rule 43 (2) EPC stipulates that a European patent application may contain more than one independent claim in the same category (product, process, apparatus or use) **only if** the subject-matter of the application involves (a) a plurality of interrelated products, (b) different uses of a product or apparatus, (c) alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim.

1. Interrelated methods, apparatuses or uses

Regarding R. 43 (2) (a) EPC, the Guidelines F –IV-3.2 explain:
"The following are examples of typical situations falling within the scope of the exceptions from the principle of one independent claim per category:

(i)
Examples of a plurality of interrelated products (Rule 43(2)(a))

- plug and socket
- transmitter – receiver
- intermediate(s) and final chemical product
- gene – gene construct – host – protein – medicament

For the purpose of Rule 43 (2) (a), the term "interrelated" is interpreted to mean "different objects that complement each other or work together". In addition, Rule 43(2)(a) can be interpreted as covering apparatus claims, since the term "products" is considered to include apparatuses. Likewise, it may include systems, sub-systems and sub-units of such systems, as long as these entities are interrelated. Interrelated methods claims may also fall under the exception of Rule 43(2)(a)."

Although not covered by the wording of R. 43 (2) (a) EPC, the Guidelines explain that interrelated method/process claims are also covered by R. 43 (2) (a) EPC. Analogously to the transmitter-receiver example above, one could think of a claim set containing "a method for encoding data" and "a method for decoding data". Hence, the Administrative Council should amend R. 43 (2) (a) EPC to "(a) a plurality of interrelated products **or processes [methods]**" or even more comprehensively to "(a) a plurality of interrelated products, **processes [methods], apparatuses or uses**".

2. "Method of manufacturing" and "Method of operating"

Another situation in which the EPO typically allows two method claims, although this situation is not covered by the exhaustive list ("only if") of exceptions of R. 43 (2) EPC, is the case in which the same inventive concept (Art. 82 EPC) comes into effect in a "method of manufacturing apparatus A, comprising the steps of…" and in a "method of operating apparatus A, comprising the steps of…". For example, the EPO typically allows a claim set containing

1 A method of manufacturing semiconductor device A, comprising…
2. A method of operating semiconductor device A, comprising…

According to the author of this article, this situation is not covered by the wording of R. 43 (2) (a) EPC (even if it referred to interrelated methods or processes) since according to the Guidelines the term "interrelated" is interpreted to mean "different objects that complement each other or work together". It should be mentioned that neither the Guidelines nor the case law of the Boards of Appeal deal with the situation above. However, the Boards of Appeal appear to construe the exception mentioned in R. 43 (2) (a) EPC quite narrowly, see **T 671/07** and **T 1232/07**. Certainly the exceptions of R. 43 (2) (b) EPC and R. 43 (2) (c) EPC do not apply to the situation above. Hence, a fourth exception should be added to R. 43 (2) EPC or at least the situation above should be added to the Guidelines.

3. Computer-implemented inventions

The author of this article welcomes the clarification in the Guidelines under F IV-3.2 that four independent claims are allowable in the context of computer-implemented inventions.

1. Method of operating a data-processing system comprising steps A, B, …
2. A data-processing apparatus/system comprising means for carrying out said method
3. A computer program [product] adapted to perform said method
4. A computer-readable storage medium/data carrier comprising said program.

However, it is not quite clear which of the three exceptions of R. 43 (2) EPC allows four independent claims in this case.

Incidentally, the EPO recently confirmed the patentability of electrical signals in its decision **T 533/09**. The Technical Board of Appeal 3.4.01 held that under the EPC the notion of invention was not linked to "tangible" (in the sense of "material") subject-matter. Electrical signals, the intensity of which could be measured at any time, in fact fell within the definition of "physical entity". This decision is in line with the much earlier decision **T 163/85** (Colour television signal/BBC) of 14 March 1989 which stated that a color television signal characterized by technical features of the system in which it occurred did not fall within the exclusions of Article 52(2)(d) EPC. Hence, we can add a claim such as:

5. An electrical signal embodied on a carrier wave and propagated on an electrical medium, the electrical signal comprising the computer program of claim 3.

Regarding the number of independent claims in computer-implemented inventions, please see also the examples given in the Guidelines F-IV 3.9.1 and 3.9.2.

4. 3D Printing

Many experts believe that the next industrial revolution will be based on 3D-Printing (sometimes referred to as "Additive Manufacturing") which enables the production of a three dimensional object from a digital file. Design files from which an object is printed can either be produced by the user, for example using CAD-type software, downloaded from an online source, or obtained from a 3D scanner. The technology enables copying and sharing of any printed products like the copying and sharing of music and film files in recent times. Hence, it seems to be advisable that the patent claims should include a claim covering the design file itself (i.e. usually called "a computer-readable medium" in Europe):

1. A product, comprising …
2. A method of manufacturing, comprising…
3. A computer-readable medium having computer-executable instructions adapted to cause a 3D printer to print the product of claim 1.

Although the author of this article does not see any hindrance regarding the allowability of such a claim set in Europe, he is not aware of any European case law that would explicitly allow such a claim set. It would be helpful if the Guidelines or the Boards of Appeal provided some clarification in this regard in the near future.

5. Conclusion

Although it is common practice of the EPO, and also covered by the Guidelines, to allow several independent claims in cases which are not covered by the exhaustive list of exceptions of R. 43 (2) EPC, the Boards of Appeal seem to construe the term "interrelated" in R. 43 (2) (a) EPC quite narrowly in the sense of "complementing each other". Recent developments in 3D-Printing require creative approaches to claim drafting and represent a challenge to R. 43 (2) EPC and the Guidelines.

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Next Board and Council Meetings

Board Meetings

99th Board Meeting in Munich (DE) on 9 February 2018
100th Board Meeting in Malta (MT) on 13 April 2018

Council Meetings

84th Council Meeting in Malta (MT) on 14 April 2018
85th Council meeting in Helsinki (FI) on 10 November 2018

Abstract: In recent years, new clinical transparency rules were introduced by authorities around the world (including Europe and the US) and also self-imposed by pharmaceutical companies. They require the early publication that a clinical trial is conducted long before any clinical trial results become available. Accordingly, there is a tension between the regulatory requirement of posting clinical trials and the associated prior art effect, and the patentability requirement of including respective clinical data in the original application to support enablement and inventive step. Are the new clinical trial transparency rules a deterrent for innovation? An applicant may indeed have difficulties to secure patent protection for inventions related to the clinical trial, whether or not a patent application is filed before or after the registration of the clinical trial. The following review focuses on the patenting situation in Europe and discusses possible filing strategies to approach the obstacles.

Gefährdet die neue Transparenz bei klinischen Studien den Patentschutz von Innovationen?

Lorenz Kallenbach (DE) & Marco Vallazza (DE)
Deutsche und Europäische Patentanwälte

1 Einleitung

In den letzten Jahren wurden weltweit neue Transparenzregeln sowohl von staatlicher Seite als auch selbstverpflichtend durch Unternehmen eingeführt. Im Zuge dessen werden klinische Studiendesigns frühzeitig registriert und bereits kurz danach publiziert, d.h. bevor klinische Ergebnisse vorliegen. Dies führt zu patentrechtlichen Schwierigkeiten. Da es nicht mehr möglich ist, die Ergebnisse einer klinischen Studie in eine Patentanmeldung aufzunehmen, ohne dass die Veröffentlichung über die Durchführung der klinischen Studie der Anmeldung als Stand der Technik entgegensteht, wird die Wahl eines geeigneten Anmeldezeitpunkt zur Herausforderung.

Im Folgenden wird näher beleuchtet, welche patentrechtlichen Konsequenzen eine Einreichung der europäischen Patentanmeldung vor bzw. nach der Veröffentlichung der Studienregistrierung haben kann. Insbesondere wird auf zwei Arten von Patentansprüchen eingegangen, die im Hinblick auf einen potenziell schutzwürdigen Gegenstand klinischer Studien von besonderer Relevanz sind: medizinische Verwendungsansprüche sowie Produktansprüche, die den in der klinischen Studie verwendeten Wirkstoff betreffen.

2 Einreichung einer Europäischen Patentanmeldung betreffend den Gegenstand einer klinischen Studie vor der Studienregistrierung

2.1 Offenbarung

2.1.1 Medizinischer Verwendungsanspruch

Gemäß T 609/02 ist die Erzielung der beanspruchten therapeutischen Wirkung bei einem medizinischen Verwendungsanspruch als funktionales Merkmal des Anspruchs zu betrachten. Somit muss die Eignung des Einzelwirkstoffs bzw. Kombinationspräparates für die medizinische Verwendung in der ursprünglichen Anmeldung plausibel beschrieben sein, um die Erfordernisse von Art. 83 EPÜ zu erfüllen (T 1823/11, siehe Gründe 3.2.1).

In früheren Entscheidungen der Beschwerdekammern des Europäischen Patentamts (EPA) wurde eine ausreichende Offenbarung der medizinischen Verwendung auch ohne jegliche (prä-)klinische Daten in der Ursprungsanmeldung akzeptiert, sofern die positive Kenntnis des Fachmanns über die medizinische Eignung gegeben ist, wobei auf den Stand der Technik – ggf. i.V.m. nachveröffentlichten Beweismitteln – verwiesen werden kann (T 1364/08). Auch wenn diese Grundsätze weiterhin Bestand haben, erscheint es zunehmend schwierig, das Erfordernis der Glaubhaftmachung der medizinischen Verwendung ohne (prä-)klinische Daten in der Ursprungsanmeldung zu erfüllen. Beispielhaft hierfür stehen die jüngst ergangenen Entscheidungen T 488/16 (hier wurde die Glaubhaftmachung unter Art. 56 EPÜ behandelt, da es sich um einen Produktanspruch handelte; jedoch sollten die Erfordernisse der Glaubhaftmachung identisch zu denen unter Art. 83 EPÜ sein) und T 1868/16.

In der Regel liegen entsprechende präklinische Daten für die medizinische Verwendung von Einzelwirkstoffen vor, die die Glaubhaftmachung der medizinischen Wirksamkeit in entsprechenden Anmeldungen, die vor der Studienregistrierung eingereicht werden, stützen. Somit wird Art. 83 EPÜ für die Monotherapie regelmäßig eine überwindbare Hürde darstellen, selbst wenn man den strengeren Maßstab anlegt, der (prä-)klinische Daten in der Ursprungsanmeldung verlangt.

Im Unterschied zum Einzelwirkstoff gestaltet sich das Bereitstellen präklinischer Daten für Kombinationswirkstoffe schwierig. In der Praxis fehlt es z.B. an aussagekräftigen Modellsystemen, die kombinatorische Effekte belegen, oder die Präklinik wird aus verschiedenen Gründen übersprungen und stattdessen direkt in eine klinische Phase-Ib/II-Studie eingestiegen (z.B. aufgrund eines Zeitvorteils oder vorhandener Literaturdaten zum Klasseneffekt).

Trotz des möglichen Fehlens präklinischer Daten, würde die ausreichende Offenbarung im Falle der medizinischen Verwendung von Kombinationen keine allzu große Hürde darstellen, wenn man dem Gedanken der T 1616/09 folgt, dass die Kombinationstherapie bereits dadurch glaubhaft gemacht ist, dass die entsprechende Verwendung für zumindest einen enthaltenen Wirkstoff bekannt oder glaubhaft ist (siehe Gründe 6.2.2).

Die neuere Entscheidung T 2506/12 wirft die Frage auf, ob die Überlegungen, die aus der T 1616/09 folgen, nicht zu kurz fassen. Es sei einleitend angemerkt, dass die Entscheidung T 2506/12 die ausreichende Offenbarung des Standes der Technik betrifft, wobei sich deren Untersuchung nicht von der Untersuchung der ausreichenden Offenbarung der ursprünglichen Patentanmeldung unterscheiden sollte, wenn der postulierte einheitliche Standard der Entscheidung T 1437/07 Anwendung findet (siehe Gründe 25).

Gemäß der Entscheidung T 2506/12 umfasst eine therapeutische Behandlung nicht nur die Effektivität der Behandlung, sondern auch eine akzeptable Sicherheit (siehe Gründe 2.8). Zunächst bestätigte die Kammer, dass von der bekannten Effektivität der Einzelwirkstoffe auf eine effektive Behandlung durch das Kombinationspräparat zu schließen ist (siehe Gründe 2.11). Obwohl weiterhin bekannt war, dass der zugelassene Wirkstoff PLD akzeptable Sicherheit zeigt und auch für den weiteren Wirkstoff ET-743 keine Sicherheitsbedenken in den vorläufigen Ergebnissen einer Phase-II-Studie diskutiert wurden (siehe Gründe 2.9 und 2.10), war die Kammer der Auffassung, dass die Sicherheit des Kombinationspräparats hierdurch nicht bereits plausibel erscheint (siehe Gründe 2.12). Interessant ist, dass die regulatorischen Behörden, die die Durchführung der in der Entscheidung erwähnten Phase-I-Studie genehmigt hatten, offenbar nicht solch große Sicherheitsbedenken bezüglich des Kombinationspräparats hatten, um die Studiendurchführung nicht abzusegnen.

Wenn man der Einschätzung der Kammer in dieser Entscheidung folgt, wäre die therapeutische Behandlung nicht nur mittels eines Kombinationswirkstoffs, sondern auch mittels eines Einzelwirkstoffs nicht ausreichend offenbart, wenn es an entsprechenden Daten fehlt, die die Sicherheit der Therapie glaubhaft machen. Ebenso wenig könnte man sich, wenn man die Patentanmeldung bereits vor der Veröffentlichung der Durchführung einer Phase-I-Studie einreicht, in der Ursprungsoffenbarung auf die Ergebnisse einer solchen Studie stützen, obwohl es in einer Phase-I-Studie genau darum geht, die Sicherheit eines Wirkstoffs zu untersuchen (T 2506/12, Gründe 2.12). Somit müsste man sich z.B. auf präklinische Daten, die Wirkmechanismen, die keine überlappende Toxizität erwarten lassen, Sicherheitsdaten von strukturell/mechanistisch-ähnlichen Molekülen oder klinische Daten einer anderen Indikation stützen, die – im Idealfall – Einzug in die Ursprungsoffenbarung finden sollten.

Es ist momentan noch unklar, in welche Richtung sich die Rechtsprechung entwickelt, da mit T 1616/09 und T 2506/12 zwei einzelne, gegenteilige Entscheidungen vorliegen.

2.1.2 Auf den Wirkstoff gerichteter Produktanspruch

Für einen Produktanspruch, unabhängig, ob dieser ein Mono- oder Kombinationspräparat betrifft, stellt die ausreichende Offenbarung i.d.R. eine niedrige Hürde dar, da es hierfür genügt, dass die Herstellung des Produkts ausreichend offenbart ist und man somit nicht auf die Ergebnisse einer etwaigen klinischen Studie angewiesen ist (T 1616/09, Schlagwort).

2.2 Begründung des Prioritätsrechts

Voraussetzung von Prioritätsrecht und dessen Inanspruchnahme ist die Anmeldung derselben Erfindung (Art. 87(1) EPÜ), was bedeutet, dass die Priorität anzuerkennen ist, wenn der Fachmann den Gegenstand des Anspruchs unter Heranziehung des allgemeinen Fachwissens unmittelbar und eindeutig der früheren Anmeldung als Ganzes entnehmen kann (G 2/98). Außerdem muss das Prioritätsdokument eine nacharbeitbare Offenbarung enthalten (T 81/87).

Wie durch die Entscheidung T 903/05 bestätigt, sind erfinderische Tätigkeitsüberlegungen für die Prioritätsfrage unerheblich. In dieser Entscheidung waren experimentelle Daten, die laut Einsprechendem für die Glaubhaftmachung der Lösung des technischen Problems erforderlich waren, erst in der Nachanmeldung enthalten. Laut Einsprechendem stand dies der wirksamen Inanspruchnahme der Priorität im Wege. Gemäß der Kammer gibt es jedoch für die wirksame Inanspruch-

nahme der Priorität keine über die Frage der nacharbeitbaren Offenbarung hinausgehende Erfordernisse, wie beispielsweise das Vorliegen experimenteller Daten in der Prioritätsanmeldung, die glaubhaft machen, dass die Erfindung das technische Problem tatsächlich löst. Wenn dieser Entscheidung gefolgt wird, könnten während des Prioritätsjahres generierte (klinische) Daten die erfinderische Tätigkeit des beanspruchten Gegenstands der Nachanmeldung stützen, solange dieser bereits ohne solche Daten in der Prioritätsanmeldung ausreichend offenbart ist.

Ob der Entscheidung T 903/05 tatsächlich gefolgt wird, ist jedoch fraglich, da es paradox erscheint, dass man unter Wahrung des Prioritätsdatums die Erfindung nachträglich vervollkommnen kann. In diese Richtung deutet auch die Entscheidung T 2165/08, in welcher modifizierte Oligonukleotide als Produkt beansprucht wurden. Hier wurde es aufgrund der Abwesenheit relevanter experimenteller Daten in der Prioritätsanmeldung als nicht glaubhaft angesehen, dass die beanspruchten Oligonukleotide tatsächlich den in der Beschreibung allgemein offenbarten technischen Effekt besitzen. Daher wurden die in der Nachanmeldung beanspruchten Oligonukleotide als in der Prioritätsanmeldung nicht offenbart angesehen und die wirksame Inanspruchnahme der Priorität verneint. Auch wenn die patentrechtliche Bewertung dieser Entscheidung im Hinblick auf die Offenbarung des Anspruchsgegenstands in der Prioritätsanmeldung schwer nachvollziehbar ist, scheint sie den Gedanken zu bestätigen, dass eine Erfindung nicht das Prioritätsdatum genießen und sich gleichzeitig auf einen erst in der Nachanmeldung glaubhaft gemachten Effekt stützen kann.

Die wirksame Inanspruchnahme der Priorität ist demnach zweifelhaft, wenn die Prioritätsanmeldung keine Daten enthält, die den Anspruchsgegenstand stützen.

2.3 Neuheit

Neuheit ist im Lichte der nachveröffentlichten Studienregistrierung gegeben, unabhängig davon, ob das Produkt oder dessen medizinische Verwendung beansprucht wird.

2.4 Erfinderische Tätigkeit

2.4.1 Medizinischer Verwendungsanspruch

Auch wenn Daten in der ursprünglichen Anmeldung nicht in jedem Fall notwendig sind, um die erfinderische Tätigkeit von medizinischen Verwendungsansprüchen zu begründen (T 158/96, T 1364/08), werden sie oftmals angebracht sein, ggf. im Nachhinein (T 715/03), um die Lösung des technischen Problems der medizinischen Verwendung glaubhaft zu belegen, insbesondere wenn das technische Problem eine Verbesserung gegenüber dem Stand der Technik fordert. Beispielsweise dürfte ein neues Dosierungsschema in vielen Fällen sogar klinische Daten benötigen, um eine Verbesserung gegenüber einem bekannten Dosierungsschema zu belegen und nicht als naheliegende Alternative zu gelten.

Das Einreichen der Anmeldung vor Veröffentlichung der Durchführung einer entsprechenden klinischen Studie bringt die Schwierigkeit mit sich, dass etwaige klinische Daten, welche die erfinderische Tätigkeit stützen könnten, zum Zeitpunkt der Anmeldung nicht vorliegen und auch nicht in allen Fällen nachgereicht werden können. Denn ob die beanspruchte Lösung die Aufgabe tatsächlich löst, d.h. ob der beanspruchte Gegenstand tatsächlich die gewünschte Wirkung erzielt, ist nach T 1329/04 auf der Grundlage der ursprünglichen Offenbarung zu prüfen. Nachträglich veröffentlichte Beweisstücke dafür, dass der beanspruchte Gegenstand die gestellte Aufgabe löst, werden berücksichtigt, wenn anhand der im Patent enthaltenen Offenbarung bereits glaubhaft erscheint, dass die Aufgabe tatsächlich gelöst wird. Ob eine Ursprungsoffenbarung die gestellte Aufgabe glaubhaft löst, ist eine Einzelfallentscheidung.

Die Anforderungen unter Art. 83 EPÜ bezüglich der Glaubhaftmachung der medizinischen Verwendung (siehe Abschnitt 2.1.1) sollten ebenso für die Glaubhaftmachung der gestellten Aufgabe unter Art. 56 EPÜ gelten (T 60/89, siehe Gründe 3.2.5).
Hiernach besteht das Risiko, dass das Fehlen entsprechender Daten in der Ursprungsanmeldung, die die Monotherapie (und einen ggf. vorliegenden verbesserten Effekt) stützen, dazu führt, dass das technische Problem nicht glaubhaft gelöst ist. Das Risiko, dass entsprechende Daten nicht nachträglich akzeptiert werden, erscheint besonders hoch, wenn nicht nur Daten für die Monotherapie fehlen, sondern auch keine Wirkungen im Stand der Technik sich schlüssig auf den beanspruchten Gegenstand lesen (T 665/05, T 108/09, T 1760/11).

Bei Kombinationstherapien könnte die Glaubhaftmachung, dass die Aufgabe gelöst ist, eine niedrigere Hürde sein, weil Daten – die für die Kombinationstherapie vor Studienbeginn oft nicht vorliegen – möglicherweise nicht erforderlich sind, um die Lösung des technischen Problems glaubhaft zu machen, solange die medizinische Verwendung der Monopräparate bereits bekannt ist (siehe Abschnitt 2.1.1, T 1616/09, aber: T 2506/12).

Zu untersuchen ist weiterhin, inwiefern eine bekannte Monotherapie auch die Lösung des technischen Problems der Kombinationstherapie glaubhaft macht, die einen verbesserten Effekt gegenüber der Monotherapie betrifft, wie z.B. einen additiven oder gar synergistischen Effekt. Die Entscheidung T 1642/07 deutet darauf hin, dass theoretische Ausführungen zur verstärkten Wirksamkeit und ein prophetisches Beispiel für die Glaubhaftmachung eines additiven Effekts genügen können (zumindest so lange der Stand der Technik an einem solchen Effekt nicht zweifeln lässt) und das technische

Problem tatsächlich gelöst worden ist (siehe Gründe 18 und 20-23). Ein verbesserter Effekt wäre damit auch ohne entsprechende Daten in der Ursprungsanmeldung glaubhaft gemacht (als Grundvoraussetzung dafür, diesen Effekt mit weiteren Daten zu untermauern), wenn im Studiendesign der ursprünglichen Anmeldung von einer effektiven Behandlung die Rede ist, insbesondere wenn die Einzelwirkstoffe in derselben Indikation nachweislich therapeutisch aktiv sind.

Womöglich wird diese Faustregel nicht einen synergistischen Effekt des Kombinationswirkstoffs glaubhaft machen. Das wird durch die Entscheidung T 1243/12 bestätigt. In diesem Fall ging es um die therapeutische Behandlung mit einem Kombinationswirkstoff, und der Anmelder stützte sich auf ein nachveröffentlichtes Dokument als Beweismittel für einen synergistischen Effekt des Kombinationswirkstoffs. Da dieser Effekt jedoch nicht in der Ursprungsanmeldung beschrieben war und dementsprechend auch nicht glaubhaft gemacht wurde, entschied die Kammer, dass die Lehre des nachveröffentlichten Dokuments nicht für die Formulierung des technischen Problems herangezogen werden kann (siehe Gründe 8-12).

2.4.2 Auf den Wirkstoff gerichteter Produktanspruch

Bei einem Produktanspruch für einen Einzelwirkstoff gilt für die Glaubhaftmachung eines technischen Effekts das im vorigen Abschnitt 2.4.1 Gesagte ebenso, also, dass (prä-)klinische Daten regelmäßig in der Ursprungsanmeldung erforderlich sind, um die Lösung des technischen Problems glaubhaft zu machen. Ein strenger Maßstab wurde insbesondere in der Entscheidung T 488/16 diktiert. Die Glaubhaftmachung des technischen Effekts betreffend die therapeutische Wirkung wurde hier verneint, obwohl die Ursprungsanmeldung diesen Effekt des Einzelwirkstoffs beschrieb und Assays erwähnt, die dies bestätigt haben, ohne dass die Rohdaten hierzu gezeigt worden sind.

Bei Kombinationswirkstoffen ist der Fall wiederum, analog zu dem bereits Gesagten, regelmäßig anders gelagert. So wurde es in den Entscheidungen T 294/07 und T 45/12 (siehe Gründe 3.4.3) für die Glaubhaftmachung unter Art. 56 EPÜ als ausreichend erachtet, dass die ursprüngliche Anmeldung einen verbesserten Effekt der Kombination beschreibt, ohne dass entsprechende Daten gezeigt worden sind.

Mit der erfinderischen Tätigkeit könnte es allerdings zu Problemen kommen, wenn man vor einer entsprechenden klinischen Studie ohne deren Daten eine Anmeldung einreicht und die Entscheidung T 2506/12 durchgreift (siehe Abschnitt 2.4.1), oder wenn man sich für die Diskussion der erfinderischen Tätigkeit der Kombinationswirkstoffe auf einen synergistischen Effekt beziehen möchte, um gegenüber den Einzelwirkstoffen erfinderisch zu sein (siehe auch Abschnitt 2.4.1 bezüglich der Möglichkeit, Daten nachzureichen).

2.5 Erstes Zwischenfazit

Das Einreichen der Patentanmeldung vor der Veröffentlichung der Studienregistrierung hat zur Folge, dass die ursprüngliche Anmeldung ohne die aus der Studie resultierenden Ergebnisse auskommen muss. Dies kann negative Konsequenzen bezüglich einer ausreichenden Offenbarung und/oder erfinderischen Tätigkeit haben, insbesondere für solche Erfindungen, deren technischer Effekt/Vorteil erst durch klinische Daten ersichtlich wird (z.B. die Sicherheit einer medizinischen Verwendung oder die Überlegenheit eines neuen Dosierungsschemas), und für Erfindungen, die die Präklinik oftmals überspringen (z.B. Kombinationswirkstoffe). Die erfinderische Tätigkeit könnte sich in manchen Fällen durch das Nachreichen solch klinischer Daten stützen lassen, was sich jedoch im Lichte der Rechtsprechung möglicherweise schwierig gestaltet (T 1329/04, T 1791/11, T 1814/11, T 1243/12, T 488/16). Vor diesem Hintergrund befürwortet die Internationale Vereinigung für den Schutz des Geistigen Eigentums (AIPPI) in einem AIPPI Position Paper (The Standing Committee on Pharma and Biotechnology, 13.04.2017) einen weltweit einheitlichen Standard, der nachträgliche Beweismittel für die Bewertung der erfinderischen Tätigkeit erlaubt.

3 Einrichung einer Europäischen Patentanmeldung betreffend den Gegenstand einer klinischen Studie nach der Studienregistrierung

3.1 Offenbarung

Im Unterschied zur Patentanmeldung, die vor dieser Veröffentlichung eingereicht wird, kann die nach dieser Veröffentlichung eingereichte Anmeldung insofern besser gestellt sein, als dass sie die klinischen Daten ebenjener Studie in der Ursprungsanmeldung beinhalten könnte, die die ausreichende Offenbarung weiter stützen. Damit ist eine ausreichende Offenbarung gemäß der oben zitierten Kriterien sowohl von Verwendungs- als auch Produktanspruch erleichtert.

3.2 Neuheit

Eine Offenbarung ist nach ständiger Rechtsprechung nur dann neuheitsschädlich, wenn die darin enthaltene Lehre ausreichend offenbart ist (siehe die in Abschnitt 2.1 dargestellten Prinzipien). Was bedeutet dies im Falle der Vorveröffentlichung der Durchführung einer klinischen Studie?

3.2.1 Medizinischer Verwendungsanspruch

Gemäß etablierter Rechtsprechung ist die therapeutische Verwendung eines Einzelwirkstoffs neu gegenüber einer Vorveröffentlichung über die Durchführung einer entsprechenden klinischen Studie, wenn die Ankündigung einer solchen Studie nicht den Behandlungserfolg explizit oder implizit offenbart (T 158/96, siehe Schlagwort).

In anderen Worten, die im Stand der Technik unzureichende Offenbarung der medizinischen Verwendung des Wirkstoffs führt dazu, dass dieser nicht neuheitsschädlich ist. Weder in T 158/96 (kein allgemein anerkannter, pharmakologischer Test für obsessiv-kompulsive Erkrankungen vorhanden) noch in T 385/07 (kein Zelltyp des beanspruchten Krankheitsbildes verwendet) wurden die vorveröffentlichten präklinischen Daten als ausreichende Offenbarung einer therapeutischen Wirkung angesehen, während in T 715/03 nicht einmal der aufgrund der Durchführung einer Phase-II-Studie implizierte Abschluss einer Phase-I-Studie die therapeutische Wirkung belegte, sondern lediglich Sicherheit und Verträglichkeit der Therapie.

Das bedeutet nicht, dass grundsätzlich klinische Daten zum Nachweis der therapeutischen Wirkung notwendig wären, um die medizinische Verwendung einer späteren Anmeldung vorwegzunehmen, sondern nur, wenn im Einzelfall die Offenbarung von Präklinik oder eines allgemein anerkannten, erwiesenen Zusammenhangs zwischen den aufgezeigten physiologischen Aktivitäten und der Erkrankung versagt. Insofern ist der EPA-Standard unter Art. 83 EPÜ für die Qualifizierung als Stand der Technik nach Art. 54 EPÜ (T 158/96, T 385/07, T 715/03) und die Bewertung der Patentierbarkeit nach Art. 83 EPÜ (T 1364/08, T 1616/09) identisch (T 1437/07), d.h. in beiden Fällen sind klinische Daten zum Nachweis der therapeutischen Wirkung nicht unbedingt notwendig.

Entsprechend wurde in der Entscheidung T 1616/09 für die ausreichende Offenbarung der beanspruchten medizinischen Verwendung des Kombinationswirkstoffs geschlussfolgert, dass diese aufgrund der vorbeschriebenen medizinischen Verwendung der Einzelwirkstoffe gegeben ist. Dies sollte im Lichte der Entscheidung T 1437/07 analog für den Stand der Technik gelten (siehe Abschnitt 2.1.1 oben). Somit könnte die Vorveröffentlichung über die Durchführung der klinischen Studie mit einer Kombinationstherapie für die beanspruchte Verwendung dieser Kombination neuheitsschädlich sein, ohne dass in der Vorveröffentlichung eine Aussage über den Behandlungserfolg durch die Kombination getroffen wird.

Einen möglichen Ausweg für dieses Dilemma könnte die erwähnte Entscheidung T 2506/12 bieten (siehe Abschnitt 2.1.1), wonach für die ausreichende Offenbarung einer medizinischen Verwendung eines Kombinationswirkstoffs neben der therapeutischen Wirkung auch die Sicherheit der Verwendung glaubhaft zu machen ist, was in dieser Entscheidung durch die zitierten Vorveröffentlichungen nicht plausibel dargelegt war.

Sollte dagegen die Sicherheit der Kombinationstherapie bereits in einer anderen medizinischen Indikation gezeigt worden und somit möglicherweise auch die Sicherheit der in der Studienregistrierung genannten neuen Indikation glaubhaft sein, ließe sich die Neuheit des medizinischen Verwendungsanspruchs ggf. herstellen, indem man dem Anspruch technische Merkmale hinzufügt, die nicht in der Veröffentlichung über die Durchführung der klinischen Studie enthalten und – im Hinblick auf die erfinderische Tätigkeit (siehe Abschnitt 3.3.1) – mit einem technischen Effekt verbunden sind. Dies könnte u.U. eine nähere Spezifikation der medizinischen Verwendung selbst sein (T 1859/08). Von besonderem Interesse sind solche Merkmale, die für die Sicherheit und Wirksamkeit des Wirkstoffs von Bedeutung sind, so dass ein Generika-/Biosimilarhersteller durch die regulatorische Behörde daran gehindert werden könnte, entsprechende Hinweise aus dem Beipackzettel zu entfernen. Bei der Europäischen Arzneimittel-Agentur (EMA) darf der Abschnitt zur Sicherheit normalerweise nicht verändert werden, selbst beim Entfernen einer Indikation insgesamt. Somit verhält sich die EMA ähnlich wie die U.S. Food and Drug Administration (FDA) (siehe z.B. die Entscheidung der FDA vom 17.01.2017 bezüglich des Produkts Xyrem, in der bestätigt wird, dass gewisse sicherheitsrelevante Informationen, die in diesem Fall auch patentrechtlich geschützt waren, nicht aus der Packungsbeilage der Generika gestrichen werden dürfen). Ist es beispielsweise notwendig, die Dosierung eines oder beider Wirkstoffe bei einer therapeutischen Kombination anzupassen, kann diese neue Dosierungsanleitung nicht nur in einer Patentanmeldung beansprucht, sondern auch Bestandteil des Abschnitts zur Sicherheit und Wirksamkeit des Wirkstoffs bzw. der Kombination im Beipackzettel werden. Wenn das Label des Generika-/Biosimilarherstellers diese Aussagen über die angepasste Dosierung gemäß den Vorgaben der EMA und FDA enthalten muss, könnte sich der Generikum-/Biosimilarhersteller in einer unentrinnbaren Falle aus regulatorischen und patentrechtlichen Zwängen befinden und müsste den Ablauf des entsprechenden Patents abwarten. Ob, gleichsam wie in den USA, auch in Europa eine solche Erwähnung im Abschnitt zur Sicherheit für die Bejahung der Patentverletzung ausreichend ist, bleibt abzuwarten, da es hierzu – dem Wissen der Autoren nach – noch keine Entscheidung gibt.

3.2.2 Auf den Wirkstoff gerichteter Produktanspruch

Ob ein Produktanspruch durch die Veröffentlichung der Durchführung einer klinischen Studie vorweggenommen ist, hängt davon ab, ob der Wirkstoff in dieser Veröffentlichung oder bereits durch vorherige Publikationen ausreichend offenbart wurde. Wie bereits beschrieben, erfordert dies insbesondere, dass die Herstellung des Wirkstoffs und dessen Struktur ausreichend offenbart sind. Hieran könnte es beispielsweise mangeln, wenn in der Publikation über die klinische Studie lediglich eine interne Bezeichnung des Wirkstoffs verwendet wird.

In der Praxis wird man eine entsprechende Patentanmeldung, die den Einzelwirkstoff schützen soll, einreichen, bevor klinische Studien durchgeführt werden. Die Fall-

konstellation, dass ein Produktanspruch – gerichtet auf einen Einzelwirkstoff – erst nach der Veröffentlichung der Durchführung einer klinischen Studie eingereicht wird, ist also im Normalfall rein hypothetisch.

Bei Kombinationswirkstoffen werden die Strukturen der Einzelwirkstoffe sowie deren Herstellungsmöglichkeiten i.d.R. bekannt sein, wenn eine entsprechende Studie zum Kombinationsprodukt durchgeführt wird, weshalb eine Veröffentlichung hierüber neuheitsschädlich ist.

3.3 Erfinderische Tätigkeit

Für die erfinderische Tätigkeit ist es im Hinblick auf die Veröffentlichung der Durchführung einer klinischen Studie fraglich, ob diese den beanspruchten Gegenstand nahelegt. Es ist insbesondere zu untersuchen, ob der Fachmann in Anbetracht der Lehre aus der vorveröffentlichten Studienregistrierung sich in einer Einbahnstraßen-Situation befindet, eine angemessene Erfolgserwartung hat oder zumindest – einer "Try and see"-Haltung folgend – einen routinemäßigen Versuch unternommen hätte und in naheliegender Weise zum beanspruchten Resultat gelangen würde (T 293/07).

3.3.1 Medizinischer Verwendungsanspruch

In verfügbaren Entscheidungen betreffend klinische Studien von Einzelwirkstoffen als Stand der Technik wurde die erfinderische Tätigkeit entsprechender medizinischer Verwendungsansprüche bejaht, da der Stand der Technik nicht beschrieb, dass tatsächlich eine therapeutische Aktivität vorliegt (T 385/07), und diese Aktivität auch nicht aufgrund der Struktur oder Aktivitätsklasse nahegelegt war (T 715/03). In anderen Fällen (ohne dass hierauf in der Beschwerde weiter explizit eingegangen wurde (T 158/96)) hatte die Prüfungsabteilung die erfinderische Tätigkeit im weiteren Prüfungsverfahren anerkannt. Eine Ausnahme stellt die Entscheidung T 1364/08 dar, in der eine „Try and see"-Situation bejaht wurde. Je nach den Umständen des Einzelfalls könnte die Bewertung der erfinderischen Tätigkeit von Monotherapien also anders ausfallen.

Bei Kombinationstherapien könnte die Situation allgemein anders aussehen. Wenn überhaupt die Neuheit der medizinischen Verwendung anerkannt wird (siehe Abschnitt 3.2.1), scheint die Vorveröffentlichung über die Durchführung einer diesbezüglichen klinischen Studie auch für die erfinderische Tätigkeit eine nur schwer zu überwindende Hürde darzustellen, da bekannte Monotherapien regelmäßig angemessene Erfolgsaussichten für eine entsprechende Kombinationstherapie liefern werden (T 725/11, T 2506/12 [siehe Gründe 3.7, 3.9, 3.10, 3.12, 3.15], Einspruchsverfahren zu T 1853/16).

Wie bereits in Abschnitt 3.2.1 erwähnt, ließe sich die Patentfähigkeit eines medizinischen Verwendungsanspruchs wiederum allgemein stärken, indem weitere Merkmale in den Anspruch aufgenommen werden, die nicht in der Veröffentlichung über die Durchführung der klinischen Studie genannt (beispielsweise eine Dosierungsanweisung) und mit einem relevanten technischen Effekt verbunden sind.

3.3.2 Auf den Wirkstoff gerichteter Produktanspruch

Im Regelfall ist die erfinderische Tätigkeitsdiskussion für den auf den Wirkstoff gerichteten Produktanspruch nicht relevant, da bereits keine Neuheit besteht, wenn die Patentanmeldung erst nach der Veröffentlichung einer entsprechenden Studienregistrierung eingereicht wird.

3.4 Zweites Zwischenfazit

Die nach der Veröffentlichung über die Durchführung einer entsprechenden klinischen Studie eingereichte Patentanmeldung hat den potentiellen Vorteil, dass sie die Ergebnisse der klinischen Studie beinhalten kann, die die ausreichende Offenbarung und erfinderische Tätigkeit jeweils stützen können. Gleichzeitig hat man den Nachteil, dass diese Veröffentlichung jetzt der Patentanmeldung als Stand der Technik entgegensteht. Dies wird oftmals dazu führen, dass Produktansprüche (egal ob Einzel- oder Kombinationswirkstoff) bereits nicht neu sind und für medizinische Verwendungsansprüche (insbesondere Kombinationstherapien) die erfinderische Tätigkeit eine hohe Hürde darstellt. Als einen Ausweg für die medizinischen Verwendungsansprüche könnte man versuchen, deren Patentfähigkeit zu stärken, indem man dem Anspruch Merkmale hinzufügt, die nicht in der Vorveröffentlichung der Durchführung der klinischen Studie erwähnt werden (ob für die Mono- oder Kombinationstherapie). Hierbei ist darauf zu achten, solche Merkmale zu wählen, die mit einem relevanten technischen Effekt verbunden sind und dem Patentinhaber einen ausreichenden Schutzumfang bieten. Ein solches Merkmal könnte beispielsweise eine Dosierungsanweisung sein, welche regelmäßig einen essentiellen Bestandteil der Zulassung für eine bestimmte Indikation darstellt und nicht von Generika-/Biosimilarherstellern aus der Packungsbeilage entfernt werden kann, ohne die Indikation insgesamt zu entfernen.

4 SCHLUSSFOLGERUNG

Die aktuellen regulatorischen Erfordernisse der frühzeitigen Registrierung und Publikation des Studienprotokolls stellen eine neue Hürde für die Patentierbarkeit von pharmazeutischen Innovationen dar. Wie hoch diese Hürde ausfällt, hängt in Europa maßgeblich vom Zeitpunkt der Einreichung der Patentanmeldung, vom Anspruchsgegenstand und von der Anspruchskategorie ab.

4.1 Einzelwirkstoffe

Wenn vor der Registrierung eingereicht wird und zumindest präklinische Daten für den Einzelwirkstoff vorhanden sind, kann die Patentierbarkeit des Einzelwirkstoffs (ob Produkt- oder medizinischer Verwendungsanspruch) gegeben sein. Im Hinblick auf die Entscheidung T

2506/12 könnte es für den Zweck der ausreichenden Offenbarung einer medizinischen Verwendung ratsam sein, neben der Glaubhaftmachung der effektiven Behandlung zusätzlich auf die Sicherheit des Wirkstoffs in der Ursprungsanmeldung einzugehen und beispielsweise bei einer Anmeldung, die auf die zweite medizinische Indikation gerichtet ist, auf klinische Daten der ersten medizinischen Verwendung zu verweisen.

Fehlen dagegen solche (prä-)klinischen Daten, könnte man das Einreichen einer auf die Monotherapie-gerichteten Patentanmeldung aufschieben, um die entsprechenden Ergebnisse der klinischen Studie in die Ursprungsanmeldung aufzunehmen. Auch wenn man damit in Kauf nimmt, dass die Studienregistrierung zum Stand der Technik für solch eine Anmeldung wird, scheint die erfinderische Tätigkeit gegenüber dieser Veröffentlichung zumindest für die medizinische Verwendung des Einzelwirkstoffs in vielen Fällen eine überwindbare Hürde (umso mehr, wenn man der medizinischen Verwendung weitere Merkmale hinzufügt, die nicht in der Veröffentlichung der klinischen Studie genannt werden).

Schließlich könnte man für die Monotherapie auch eine Doppelstrategie erwägen: eine erste Einreichung vor der Studienregistrierung, gefolgt von einer späteren Einreichung, die die Daten aus der klinischen Studie umfasst. Für den Fall, dass bereits die erste Anmeldung als ausreichend offenbart gilt, würde ein Einreichungsdatum vor Studienregistrierung gesichert und die Studienregistrierung somit nicht für die Diskussion der erfinderischen Tätigkeit relevant. Die zweite Anmeldung könnte fallen gelassen werden, sofern ihr Gegenstand nicht über die erste Anmeldung hinausgeht. Wenn die erste Anmeldung jedoch als nicht ausreichend offenbart gilt, wäre man mit der zweiten Anmeldung im Hinblick auf die ausreichende Offenbarung besser gestellt, da man auf die Daten der klinischen Studie zurückgreifen kann. Um die Patentfähigkeit der zweiten Anmeldung nicht zu gefährden, ist bei dieser Strategie zu beachten, dass vorzugsweise die zweite Anmeldung vor Veröffentlichung der ersten Anmeldung eingereicht wird (wenn die erste Anmeldung als nicht ausreichend offenbart gilt, wäre sie auch nicht für die Neuheit der zweiten Anmeldung nach Art. 54(3) EPÜ relevant) oder – sofern die zweite Anmeldung erst nach Veröffentlichung der ersten Anmeldung eingereicht wird, weil die klinischen Daten vorher nicht verfügbar sind – die erste Anmeldung den Stand der Technik nicht weiter anreichert. Folglich ist bereits zum Zeitpunkt der ersten Anmeldung zu berücksichtigen, wann mit klinischen Daten für die zweite Anmeldung zu rechnen ist, um den Offenbarungsgehalt der ersten Anmeldung entsprechend anzupassen.

4.2 Kombinationswirkstoffe

Anders gestaltet sich die Situation bei Kombinationswirkstoffen, die gerade in der Krebsbehandlung von steigendem Interesse sind, um Tumorzellen die Fluchtmöglichkeiten abzuscheiden. Wird hierbei das körpereigne Immunsystem adressiert, wie es im aufstrebenden Gebiet der Immunonkologie der Fall ist, sind oftmals keine geeigneten Modellsysteme zur Hand, um die Immunantwort in der Präklinik widerzuspiegeln. Wird vor der Registrierung der klinischen Kombinationsstudie eine Patentanmeldung eingereicht, könnte trotzdem die Glaubhaftmachung der medizinischen Verwendung gegeben sein, wenn die entsprechende Therapie mit einem der Einzelwirkstoffe bereits bekannt ist. Im Lichte der Entscheidung T 2506/12 sollte die Patentanmeldung – neben der Effektivität – auch die Sicherheit der Therapie diskutieren, beispielsweise, indem man beschreibt, dass aufgrund der Wirkmechanismen der Monopräparate nicht mit einer überlappenden Toxizität zu rechnen ist. Wird auf diese Weise die ausreichende Offenbarung der medizinischen Verwendung glaubhaft gemacht und gezeigt, dass der beanspruchte Gegenstand die gestellte Aufgabe löst, ist das Nachreichen von Daten für die erfinderische Tätigkeit erleichtert. In diesem Zusammenhang ist es zu begrüßen, dass sich die AIPPI für einen großzügigeren Umgang mit nachveröffentlichten Beweismitteln für erfinderische Tätigkeitsüberlegungen ausspricht (siehe AIPPI Position Paper, Conclusions, The Standing Committee on Pharma and Biotechnology, 13.04.2017).

Das Einreichen einer auf Kombinationstherapie oder -produkt gerichteten Anmeldung nach Studienregistrierung erscheint dagegen nicht vielversprechend, selbst wenn sich entsprechende klinische Daten in der Patentanmeldung finden. Wenn es überhaupt gelingt, die Neuheit gegenüber der Publikation über die Durchführung der klinischen Studie herzustellen, bleibt die erfinderische Tätigkeit in den meisten Fällen angreifbar, weil diese Publikation als Stand der Technik eine angemessene Erfolgserwartung hervorrufen kann (wiederum davon ausgehend, dass zumindest einer der Einzelwirkstoffe für die entsprechende medizinische Verwendung vorbeschrieben ist).

Wird die Anmeldung, die auf die medizinische Verwendung des Kombinationswirkstoffs gerichtet ist, trotzdem erst nach der Veröffentlichung der entsprechenden Studienregistrierung eingereicht, sollte man wiederum die Möglichkeit erwägen, Merkmale in den Anspruch aufzunehmen, die nicht in dieser Veröffentlichung erwähnt werden. Insbesondere sind solche Merkmale zu bevorzugen, die mit einem technischen Effekt assoziiert sind und einen effektiven Schutzumfang gewährleisten, wie z.B. Merkmale, die essentielle Bestandteile der Packungsbeilage sind.

4.3 Globale Patentstrategie

Diese Empfehlungen hinsichtlich einer frühzeitigen Einreichung der Patentanmeldung bzw. einer Fokussierung auf bisher unveröffentlichte Anspruchsmerkmale stehen im Einklang mit einer weltweiten Patentstrategie, die

die Erfordernisse anderer Jurisdiktionen nicht vernachlässigen darf. Beispielsweise muss in den USA der therapeutische Effekt in einer Veröffentlichung nicht glaubhaft gemacht werden, damit diese für einen entsprechenden Anspruch als neuheitsschädlich gilt. Eine US-Patentanmeldung sollte folglich entweder vor der Veröffentlichung über die Durchführung einer entsprechenden klinischen Studie eingereicht werden, oder – wenn erst hinterher und nach Ablauf der Neuheitsschonfrist eingereicht wird – weitere Anspruchsmerkmale umfassen, die nicht vorveröffentlicht sind und zur Patentierbarkeit beitragen. Die erstgenannte Variante ist auch deswegen praktikabel, da das US-Patentamt weniger strenge Anforderungen hat, was das nachträgliche Einreichen von Daten anbelangt.

4.4 Regulatorische Exklusivität

Da es aus patentrechtlicher Sicht aufgrund der neuen Transparenzregeln keinen idealen Einreichungszeitpunkt mehr gibt (d.h. ein Einreichen mit den Daten aus der klinischen Studie bevor die Durchführung derselben veröffentlicht wird), wäre abschließend für Europa anzuregen, dass ein Ausgleich für die gestiegenen Patentierungsanforderungen geschaffen wird. Das könnte eine regulatorische Exklusivität für jede weitere Zulassung sein, die einer klinischen Studie bedarf – ähnlich der dreijährigen Exklusivität, die es in den USA unter dem Hatch-Waxman-Act für dieses Szenario gibt.

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CONCLUSION

New regulatory requirements, which demand the early registration and publication of clinical study designs, raise the bar for patenting pharmaceutical inventions. The particular challenge that an applicant faces depends on the filing date of the patent application (i.e., filing before or after the clinical study posting), whether the application is directed to a single agent or a combination product, and if a product or the medical use thereof is claimed.

Regarding single-agent drug products, preclinical data usually exists before a clinical trial is registered and will in many cases be required to sufficiently support patentability of an earlier filed patent application relating to the product or medical use thereof. If preclinical data is not available for the single-agent drug product, one should consider waiting for the clinical trial data before filing the patent application, as the clinical trial registration, which is devoid of this data, is a hurdle that in many cases can be overcome (especially if the claim is formulated as a medical use).

The situation tends to be different for combination products, which oftentimes lack preclinical data when a respective clinical trial is registered. Such lack of data, however, is not necessarily detrimental to the patentability of patent applications that are filed prior to the clinical-trial publication and are related to combination products or therapies, as long as at least one of the active pharmaceutical ingredients is already known (e.g., for the same medical use). Quite the contrary, it may be warranted to file such patent applications prior to the clinical trial registration even in the absence of supporting preclinical data, since a later filed application may not be patentable in view of the pre-published clinical trial registration and the pre-known active pharmaceutical ingredient(s).

Concerning patent applications relating to the medical use of a single-agent drug or combination product, which are filed after the clinical trial registration, patentability may be strengthened by including claim features that are not yet disclosed in the clinical trial registration and associated with a relevant technical effect. Ideally, such feature should also be an integral part of the drug label.

The authors' recommendation of filing early or relying on undisclosed features is in line with a global patent strategy, especially since the U.S. Patent and Trademark Office (USPTO) considers the study publication as novelty-destroying for a later-filed patent application, which relates to such subject-matter. In addition, the USPTO takes a lenient approach regarding the submission of data after the initial filing date, such as clinical trial data, to support non-obviousness.

Interruption of the proceedings due to insolvency before the EPO and UPC

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The initiation of insolvency proceedings gives rise to multiple conflicts related to the overlap between the mechanisms that are specific to patent granting and opposition procedure and those that are specific to bankruptcy law. To coordinate the provisions outlined in both patent law, on the one hand, and bankruptcy law, on the other hand, is not easy and may result in the risk of loss of IP rights if not properly managed. Analysis of the interaction between bankruptcy law and IP rights assists with possibly avoiding the entanglement that may result from disputes between these two legal disciplines.

1. Interruption of the proceedings due to insolvency: Rule 142 (1)(b) EPC

Rule 142 (1)(b) EPC provides for the interruption of the proceedings if *the applicant for or proprietor of a European patent, as a result of some action taken against his property, being prevented by legal reasons from continuing the proceedings before the European Patent Office.*

The *rationale* of the Rule is to protect parties who are not able to act in the proceedings for defined legal reasons against a loss of rights which could otherwise occur, until such time as the EPO can resume the proceedings[1].

As a consequence, *"The time limits, other than the time limit for making a request for examination and the time limit for paying the renewal fees, in force as regards the applicant for or proprietor of the patent at the date of interruption of the proceedings shall begin again as from the day on which the proceedings are resumed. If such date is less than two months before the end of the period within which the request for examination must be filed, such a request may be filed up to the end of two months after such date"*.

Rule 142 (2) also states that, *"when (…) the European Patent Office has been informed of the identity of the person authorized to continue the proceedings before the European Patent Office, it shall communicate to such person and to any interested third party that the proceedings shall be resumed as from a date to be fixed by the European Patent Office"*.

1 EUROPEAN PATENT OFFICE; Travaux Préparatoires EPC 1973, Rule 90. Available at: http://webserv.epo.org/projects/babylon/tpepc73.nsf/0/486CEA2649C2CBD5C12574490026021F/$File/Rule90eTPEPC1973.pdf

2. Which types of insolvency interrupts the procedure?

Decisions from the Board of Appeal (BoA) constantly reiterate that the decisive criterion for interruption under R. 142(1)(b) EPC is whether the action against the property was such as to make it legally impossible for the applicant to continue with the proceedings.

In decision **J 26/95** the BoA held that, in the absence of specific circumstances, proceedings against the applicant under Chapter 11 of the US Bankruptcy Code did not interrupt proceedings before the EPO because it did not constitute a case where, as a result of such action, it was impossible for the debtor to continue the proceedings. On the contrary, it was found that the nature of proceedings under Chapter 11 allowed the debtor to continue conducting his business. The BoA, with similar arguments, reached the same conclusion in **J 11/98**, in relation to the payment of **renewal fees** that were due.

The BoA regarded **(J 10/94)** as being analogous to a case of legal impossibility whereby the applicant, as a consequence of an action against his property, an order via a French Court to freeze the bank accounts, resulted *de facto* in the insolvency of the applicant since he did not have at his disposal any remaining property by means of which he could have affected the required payment. In such a case, however, it was to be determined whether the actions taken against his property effectively made it impossible for the applicant to continue the proceedings, irrespective of the nature of the action (judicial or contractual).

In **J 11/95**, the BoA held that the applicant who had been declared bankrupt but still continued the proceedings before the EPO even after that event, was apparently not prevented by legal reasons from continuing *other* proceedings before the EPO. Therefore, the BoA held that under these circumstances, despite the bankruptcy, it was not legally impossible for the applicant to file also the priority document within the two-month period from the Office´s invitation in that sense.

The BoA reached a similar conclusion in **T 1533/07** and declared that, in the event of death or legal incapacity of an opponent, Rule 84(2) EPC[2] cannot be considered as analogous to Rule 142(1)(b) EPC because the insolvency administrator appointed by the Court is entitled to continue the proceedings before the EPO.

Therefore, both the EPC legal framework, and EPO practice, confirm that if the applicant is prevented from acting in relation to the properties affected by the insolvency, the procedure before the EPO will be interrupted, regardless of the definition of such an action, namely bankruptcy, receivership or a Court order prevents *de facto* the applicant to continue with the patent procedure (J 10/94; J 7/83). Consequently, reorganization procedures such as chapter 11 proceedings in the US, or comparable proceedings according to European national laws, do not cause the interruption of proceedings because they do not legally prevent the applicant from continuing his business.

3. When is the procedure interrupted?

The Guidelines[3] clarify that the interruption in case of insolvency under EPC is, in principle, adopted *ex officio* by the European Patent Office and the entry in the register has only declarative effect[4]. Therefore, the interruption under R 142 (1)(b) EPC has a retroactive effect from the date of the occurrence of the insolvency event[5].

For instance, in **J 16/05** the BoA also considered that since the intention of the rule is to protect parties who are not able to act in the proceedings for the defined legal reasons against a loss of rights which would otherwise occur, interruption may be declared even though in this case the event occurred two years prior. Keeping the above in mind, the BoA pointed out that due to reason of legal certainty, this can only be applied if the applicant acted in good faith and cooperated in the proceedings by informing the Office when they were aware of facts justifying an interruption.

4. Are there any formal requirements?

According to the Guidelines for examination, the Legal Division is responsible for bearing interruptions and resumptions[6].

In **J 9/90** the BoA held that for R 142(1)(b) EPC to be applied, the registered applicant, recorded in the Register of European Patents, and the insolvent person (here a limited company), must be **legally identical**.

In that regard, in **J 16/05**, in relation to the interruption and the payment of the renewal fees, the BoA held that a simple change of name of the applicant does not alter the identity of the legal person and is therefore entitled to request the interruption of proceedings pursuant to R 142(1)(b) EPC.

5. What can be interrupted?

It appears that the intention of R 142 (4) EPC is that generally all time limits may be interrupted, including time limits set for filing and paying filing, examination, grant, and appeals fees and annuities. This has been confirmed by various decisions from the BoA, though the Board clarified that for some of those time limits different consequences apply *(see point 6)*.

Keeping in mind the general principles of R. 142 (1)(b) EPC, some BoA cases shall be addressed in greater detail:

a) Examples in which the BoA declared the interruption of proceedings under R. 142 (1)(b) EPC

- Examination Fee: In **J 7/83** the BoA addressed the issue of interruption of proceedings with regard to the time limit prescribed for payment of the examination fee. In particular, the BoA held that the bankruptcy proceedings where parties had been placed under receivership according to French Law lead to interruption of proceeding pursuant to R142(1)(b) EPC[7].
- Renewal Fees: In **J 902/87** the BoA confirmed that the payment date for renewal fees and the six-month period for paying the renewal fee together with an additional fee referred to in Art. 86 EPC 1973, R. 90(4) EPC 1973, which had fallen due during the period of the representative's or applicant's incapacity, can be affected by interruption.
- National and designation fee: In J 10/94 the BoA held that if the conditions of Rule 142 (1)(b) EPC are satisfied, the time limit for the payment of national fee and designation fees are interrupted and will start to run integrally on the date of resumption of the proceedings.
- Appeals: To date, the possibility to interrupt the time limit for filing the notice of **appeal**, as well as the petition for review, has not been an object of a decision of the BoA, at least the author has not found any such decision. However, in order to assess whether time limits set for the appeal proceedings may be interrupted or not under R. 142(1)(b), two considerations can be made: firstly,

2 IMPLEMENTING REGULATION EUROPEAN PATENT CONVENTION, R 84 (2) EPC: *"In the event of the death or legal incapacity of an opponent, the opposition proceedings may be continued by the European Patent Office of its own motion, even without the participation of the heirs or legal representatives. The same shall apply where the opposition is withdrawn"*.

3 EUROPEAN PATENT OFFICE, Guidelines for examination, Part. E, VII. Available at: http://www.epo.org/law-practice/legal-texts/html/guidelines/e/e_vi_1_1.htm.

4 This statement has been confirmed by Decision J 16/05 of the EPO BoA.

5 It should be noted that "event" does not necessarily mean "declaration of bankruptcy". See Decisions J 26/95; J 9 10/94; J 7/83.

6 Decision of the President of the EPO of 21 November 2013. OFFICIAL JOURNAL EUROPEAN PATENT OFFICE (OJ EPO), 2013, 600. However in Decision T 0854/12 it was recognized the competence of the Technical BoA to deal with interruption of procedures issues.

7 The BoA refers to the previous R.90 (1)(b) EPC, which after the adoption of the amended Implementing Regulations to the EPC 2000 on the 13.12. 2007, remained unchanged but under Rule 142 (1)(b)

the wording of R. 142 (4) EPC, which refers to "*any periods*" and, secondly, like oppositions, appeals could derive from "*inter partes*" proceedings. In light of the former, it could therefore be assumed that the time limits for appeal proceedings may be interrupted for the *applicant* and the *patent proprietor*. However, it seems that the time limits of an appeal may not be interrupted if the appeal was filed by an opponent who was declared insolvent (see discussion below about the interruption of the opposition proceedings).

b) Examples in which the BoA denied the interruption of proceedings under R. 142 (1)(b) EPC

- Primarily it should be noted that, whilst the nine-month opposition period is not interrupted, oral proceedings may not start if the applicant is prevented from acting[8]. However, if a receiver has been appointed, proceedings may be continued under its direction.
- Insolvency of the patent holder: in **T 0854/12** the BoA held that the interruption of **opposition proceedings** under the meaning of Rule 142 (1)(b) EPC applies to cases in which the patent holder, whom was not initially limited in the course of the proceedings, is then "*prevented from continuing the procedure*". In that case, the BoA held that the provision could not be applied because the patent, via the consent of the insolvency administrator, had been transferred to an already restricted patent holder, wherein the insolvency administrator was not limited to his power of authority.
- Insolvency of the opponent: Similarly, if during the opposition period the opponent is prevented from acting as a consequence of an action taken against his property, there is no interruption of the procedure (**T 1533/07**). Indeed, R. 142 (1)(b) EPC clearly states that the "*the applicant for or proprietor of a European patent*" is the entitled person to request the interruption of proceedings.

6. What are the consequences?

Pursuant to R 142 (4) EPC, all EPO communications and decisions that have been issued during the interrupted period are deemed null and void and will be notified anew after the resumption of proceedings.

The resumption of time limits begins, in their original length, from the day on which proceedings are resumed. Contrary to that, the time limit for filing the request for examination is only suspended from the date of interruption of the proceedings. Therefore it resumes for the remainder of the time limit or at least for the two-months before the period wherein the request must be filed.

In **J 7/83** the BoA held that R142 (4) EPC did not indicated an exception to the general principle that all time limits are interrupted, but only specified how time limits had to be calculated. Thus, in J 7/83 the time limit under Art 94(2) EPC 1973 for payment of the examination fee was suspended from the date on which payments were discontinued by court order, up to the date on which examination proceedings are resumed.

Likewise, in **J 902/87** the BoA stated that such an interpretation could not be applied to **renewal fees**, whereby the EPC did not prescribe a time limit for payment, rather dates on which they fell due. Hence, the only time limit affecting renewal fees that may possibly be suspended is the six-month grace period for paying the renewal fee together with an additional fee referred to in R. 51 EPC. The BoA also clarified that Art. 142 (4) EPC had to be interpreted as deferring, until the date proceedings are resumed, the payment date for renewal fees which had fallen due during the period of the representative's or applicant's incapacity.

The BoA reached a similar conclusion in **J 09/94**, in relation to the **request for examination**. In this case, the BoA considered that the deadline to pay the examination fee was suspended and that the period shall begin to run, from the resumption of the procedure, either for the remaining period or for the minimum period of two months provided in Rule 142(4) EPC. The reason for such a conclusion is that the examination request is not deemed to have been filed until the examination fee has been paid. Therefore, in the event the applicant has submitted the examination request but is prevented from acting upon payment of the examination fee, the time limit is suspended.

It may be concluded that in case of interruption, time limits begin, with their original duration, on the day on which proceedings are resumed, whereas, in case of *suspension*, the time limits are suspended from the date of interruption of the proceedings, and would resume for the remaining time period or, for at least the two-months before prescribed by R 142(4) EPC.

7. Unified Patent Court (UPC)

Irrespective of the present delay with implementation of the new Unitary Patent System, the Author would like to provide a short overview on bankruptcy situations before the UPC. In this context, two aspects should be kept in mind: Firstly, in contrast to the standard situation of EP prosecution of patent applications, a suit in front of the UPC is rather an exceptional situation for most

8 EUROPEAN PATENT OFFICE, Travaux Prépatatoires, BR/60/70; point 61. Available at: http://webserv.epo.org/projects/babylon/tpepc73.nsf/0/97749182A6C8F2D3C1257BD800277E70/$File/BR%2060%20e%2070.pdf

proprietors, alleged infringers or nullity plaintiffs. Secondly, unlike the average duration of a patent grant at the EPO, the Rules of Procedure envisage a timeframe of 12 to 15 months in each instance until a decision is rendered. It remains to be seen whether this timeframe can be adhered to by the UPC, but in any case it seems likely that the issue of interruption of the proceedings before the UPC will have a minor impact as compared to proceedings under the EPC.

Rule 311 of the 18th UPC draft of 15 March 2017[9] refers to the interruption of the proceedings due to insolvency of the party. According to this Rule, "*if a party is declared insolvent under the law applicable to the insolvency proceedings the Court shall stay the proceedings up to three months". As a consequence, "proceedings may be stayed until the competent national authority or person dealing with the insolvency has decided whether to continue the proceedings or not*". The Rule also states that "*where the competent national authority or person dealing with the insolvency decides not to continue the proceedings, the Court may decide, upon a reasoned request by the other party, that the proceedings should be continued in accordance with the applicable national insolvency law*".

Therefore, under the UPC, interruption applies only to insolvency declared under the law applicable to the insolvency proceedings, leaving open the question whether it could be also applicable to cases where the party, as a consequence of an action against its property, would result in *de facto* insolvency because he does not have any remaining property at his disposal.

Moreover, under the UPC, interruption due to insolvency may be applied to both parties. On the contrary, before the EPO, in decision T 1533/07 the interruption of the proceedings requested by the opponent was denied.

According to Rule 311(2) UPC, "*Proceedings may also be stayed at the request of a temporary administrator who has been appointed before a party is declared insolvent*". This also seems to differ from the proceedings before the EPO, considering that with decisions T 1533/07 and T 854/12 the BoA denied the interruption of proceedings in the presence of an insolvency administrator appointed by law.

Finally, Rule 311(4) UPC states that "*if proceedings are continued, the effect of a decision of the Court as regards the insolvent party in the action shall be determined by the law applicable to the insolvency proceedings*".

Rule 311 UPC is, however, silent on the issue concerning calculation of time limits after resumption of the proceedings.

Further, as the UPC has not yet been introduced, there is currently no reference to case law addressing the above-mentioned rule and, due to the likely little impact of interruption in these procedures, it may take some time until a judgement under Rule 311 UPC will be rendered by the UP Court.

8. Conclusion

In conclusion, interruption of proceedings under R 142(1)(b) EPC applies when the applicant or patent proprietor is prevented to act as a consequence of an action against his property that legally or factually impedes him to continue with the patent proceedings. From this moment, and with few exceptions (i.e. opposition period), all time limits shall be interrupted and they will then begin, with their original length, on the day on which the proceedings are resumed. Due to specific provisions, the time limit to file the request for examination and the renewal fees are only suspended, which implies that from the resumption of the procedure the time limit will begin to run either for the remainder of the time limit or for at least two months. Interruption does not apply in the event of insolvency of an opponent.

Under the UPC rules, both parties can request that the proceedings be interrupted. Interruption could also be granted at the insolvency administrator´s request. In any case, interruption applies only to insolvency declared under the law applicable to the insolvency proceedings and it stays the proceedings up to a maximum of three months.

9 UNIFIED PATENT COURT, UPC Rules of procedure 18th Draft. Available at: https://www.unified-patent-court.org/sites/default/files/upc_rules_of_procedure_18th_draft_15_march_2017_final_clear.pdf

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