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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:
Configured for engagement
This picture, photographed by Axel Remde
(European Patent Attorney, DE), was part of the **epi** Artists Exhibition 2018 at the EPO, Munich

Axel Remde

Axel Remde ist Elektroingenieur in vierter Generation mit Studium in Dresden und Karlsruhe. Nach seiner Promotion in Informatik arbeitete er über zehn Jahre in einem Schweizer Unternehmen der Medizinaltechnik. Dort war er zunächst in verschiedenen technisch /wissenschaftlichen Funktionen tätig. Die Auseinandersetzung mit Erfindungen und Patenten gewann dabei stetig an Bedeutung und mündete schliesslich in einen Wechsel in die Patentabteilung. In frühzeitiger Vorbereitung auf diesen Berufsweg hatte sich Axel Remde bereits in Kindertagen intensiv mit der Ermittlung des Standes der Technik durch Reverse Engineering befasst. Als zugelassener Vertreter vor dem Europäischen Patentamt und Schweizer Patentanwalt ist Axel Remde seit 2012 bei der Rentsch Partner AG in Zürich tätig.
Sein Interesse an der Fotografie begann zu Schülerzeiten und vertiefte sich in den letzten Jahren. Zu seinen Lieblingsmotiven zählen die Zeugnisse und zivilisatorischen Hinterlassenschaften vergangener Tage. Er arbeitet an mehreren offenen Serien, die er über einen längeren Zeitraum entwickelt.

Axel Remde, is a fourth generation electrical engineer, having studied Electrical Engineering at the University of Karlsruhe and the Dresden University of Technology. At an early age, he exhibited a considerable interest in technical matters by his love and practice of the technique of reverse engineering.
Following his successful doctoral thesis in Applied Computer Sciences, he worked for a Swiss medical technology company for approximately 10 years. Initially, he worked in different technical and scientific fields. Over time, his experience embraced inventions and associated patents which were steadily gaining importance. This experience resulted in a transfer to the patent department. He prepared for this career from an early stage by intensely studying the state of the art through Reverse Engineering.
As both a European and Swiss Patent Attorney, Axel has been working for the Swiss Law firm Rentsch Partner AG in Zurich since 2012. His keen interest in photography began at school and has deepened over time particularly in recent years. From a photographic perspective, his favourite subjects include abandoned technical equipment and production facilities.

Axel Remde, ingénieur électricien comme ses aïeux (il représente la 4è génération d'ingénieur), a fait ses études à Dresde et à Karlsruhe. Après sa thèse en informatique il a travaillé pendant plus de 10 ans dans une société suisse spécialisée en dispositifs médicaux. Il y a occupé pour commencer plusieurs fonctions techniques/scientifiques. La confrontation avec les inventions et les brevets a pris une importance croissante pour lui ce qui l'a amené à travailler au sein du département brevets. Il s'est préparé à sa carrière professionnelle de manière intensive dès son enfance en déterminant l'état de la technique par « rétro-ingénierie ». Depuis 2012 Axel Remde travaille comme mandataire en brevets européen et conseil en propriété industrielle suisse au sein du cabinet Rentsch Partner AG à Zurich. Son intérêt pour la photographie s'est manifesté dès l'école et s'est accru ces dernières années. Ses motifs favoris sont les témoignages et l'héritage des civilisations du passé. Il travaille sur plusieurs séries ouvertes qu'il développe au fil du temps.

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Editorial

M. Névant (FR), Editorial Committee

Adapt, improvise, overcome!

Marc Névant

2019 brings its own share of challenges that representatives will have to face.

Brexit is approaching fast, and the uncertainties surrounding the conditions of the exit generate worries on what commercial exchanges between the EU and the UK will look like in a few months. This might have an impact in the short- to mid-term on our activities because a slowdown of the economy in the EU zone could mean less innovation and hence fewer patent applications filed by European companies.

Another topic that could impact our work is the so-called "deferred examination" which the EPO is considering implementing. On this point we invite our members to read the reply filed, on behalf on **epi**, to the consultation initiated by the EPO. This reply is available on page 6 of this issue.

A further topic ahead of us is the revision of the rules of procedure of the Boards of Appeal. A comprehensive report on the user conference held last December 5th in Munich can be found on page 11 of this issue. It transpires from the report that the Boards intend to tighten the requirements for presenting new arguments/new requests at the appeal stage. It is also contemplated that decisions from the Boards can be in abridged form. While we certainly agree that an appeal should not be an opportunity to present a case afresh or to be a continuation of the opposition, one might wonder what the true purpose of the revision is. It cannot be ruled out that in a few months, decisions from the Boards will consist of two sentences only*: "The Board agrees with the findings of the examination division/ opposition division. The appeal is dismissed"*. We are not sure that this is what the Fathers of the Convention had in mind…

There are therefore reasons for concern. Yet we are confident that our daily practice will allow us to adapt to new situations, improvise (as we often have to do during oral proceedings) and eventually overcome difficulties. No doubt that Gunnery Sergeant Thomas Highway, a character played by Clint Eastwood in the movie "Heartbreak Ridge", would be pleased with that state of mind!

Last but not least (for those reading the editorial up to the end) our journal is continuing its transformation which started 3 years ago when the first digital issue was sent to our members. We have decided to change the structure/template of the journal, and we are also striving to improve the layout to make it a reader-friendly and "must read" journal. Time will tell whether our endeavours are successful…

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 **12. April 2019**. 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 **12 April 2019**. 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 **12 avril 2019**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

News from the Presidium

T. Tangena (NL), Past President, Deputy Secretary General

We live in interesting and challenging times. Very soon we should see what the Brexit will bring and how that influences the Unitary Patent (UP) and the Unified Patent Court (UPC). We also have the new President Campinos at the EPO, who started a discussion with users about his strategic plans for the next 4 years. In the Presidium we just finished 2 intensive days discussing and formulating **epi**'s reactions to these plans.

Thus, many external events influence our profession, but we also need to make up our own mind about what we European Patent Attorneys (EPAs) want with our own future. Last year in the Malta Council, we already started looking at the future of the profession. We did a follow-up in the Helsinki Council, where I lead a discussion about the future of the profession with Ann De Clercq (BE) and Mihaela Teodorescu (RO) as speakers, followed by a general discussion. The Council actively participated in these discussions, that can be summarized as follows:

Challenges for the future of the profession:

- In many countries there is not enough local European patent work given the present number of EPAs in those countries. This poses a serious threat for the future of the profession in those countries.
- In the future there will be less patent work because of worldwide harmonization and cooperation of Patent Offices, leading to simplified processes and possibly to mutual recognition of results of examinations and grants. The UP and UPC will certainly increase this trend. Council members feared that the remaining work will concentrate in a few States with already a lot of patent work, like the United Kingdom and Germany.
- On the other hand complexity is increasing, both from a technical as well as a legal point of view. For instance in Europe we have utility models, national patents, national patents via the EPC and with the UP/UPC we can also have UPs and European patents without unitary effect but with the possibility of an opt - out of the UPC. Also procedures to come to a patent are very complex with national routes, PCT, regional routes and highways to speed up and in the future maybe to slow down examination and grant.

Possible solutions that will influence the future of the profession:

- In many countries with little patent activity, EPAs can only survive by focusing also on other types of Intellectual Property, like trademarks. This will give some time to increase the number of locally originating patent applications. This increase can be stimulated with the help of the EPO and the National Patent Offices by promoting the benefits of the patent system more widely, especially to SMEs.

Tony Tangena

- In countries with sufficient patent activity EPAs can deal with the increasing complexity by becoming a specialist for instance in a specific technical area, in legal issues and in knowing the needs of specific businesses (Internationals vs SMEs, or universities). This will lead to more working in teams, where specialist EPAs rely on each other's knowhow. This could also mean that for instance administrative tasks or searches should be dealt with by specialized personnel or firms.
- EPAs in countries with a lot of patent work and EPAs in those that have not enough work can help each-other by outsourcing of work from countries with a lot of patent activity to countries with less local activity. Through the training that **epi** provided and especially through the Candidate Support Program we now have in many countries 'young' EPAs qualified through the EQE. So in most countries with less patent work the number of EPAs has grown and so there is further capacity to deal with patent work from others with the required quality. Such outsourcing should be profitable for both sides involved. Outsourcing is also important as it becomes more difficult to hire good technical people to start in the profession in countries with a lot of patent activity, since in general more patent activity means an active industry that also wants well-trained technical people.

So, in the years to come we will have to find solutions to the challenges, since it is very important that in all EPC countries local companies have the possibility to get local advice from EPAs on how to exploit innovations. There is a task for all of us to think about how we can realise this, so that Europe as a whole remains competitive and our profession remains successful.

Updates on epi Information

M. Nollen (BE), Chair of the Editorial Committee

Maarten Nollen

As Editorial Committee, we are most active in increasing the quality of epi Information. This is to inform you on the ongoing process.

New publication scheme

As of 2019, the publication scheme of epi Information is shifted. The publication dates will be in February, May, August and November. In this manner, we avoid publications just before Summer and around Christmas, which are very busy for many of us. Additionally, it allows us to present updates on practice well in due time before those enter into force, such as typically on 1 January or 1 April.

New order

In the current issue, the order of the contributions has been revised and several chapters have been introduced. We hope that the relevant content in epi Information is more accessible.

Regular authors

In response to our request in the preceding issue of epi Information, several people have taken up the invitation for becoming a regular author. Their contributions will appear as of the next issue. There is still space for some more regular authors, particularly with an interest to regularly report on Case law updates (Rules of Procedures, Enlarged Board (G-decisions and Review decisions), Chemistry, Pharma, Computer implemented inventions).

Regular authors are patent attorneys that provide such overview 4 times a year. What we have in mind for an overview:

- 1000-1500 words per contribution
- covering important updates, providing a summary and guidance and referring with link where to find the text of the update
- meeting the high standards of our profession as to quality and relevance
- addressing qualified European Patent Attorneys
- prepared by one author or a small team of authors

What we ask:

- commitment to be a regular author at least for one year, preferably for two years or more;
- willingness to provide the overview according to a format specified by the Editorial Committee
- sufficient background knowledge in the field, so as to give the guidance
- commitment to investigate independently (and/or with fellow authors) updates on a certain subject.

What we offer:

- publication in each issue of epi Information as regular author, with email address in a footnote
- opportunity to become a leading and well-known expert on the topic
- review of the contribution by the Editorial Committee

If you are willing to become regular author, please send an email to editorialcommittee@patentepi.com.

Further information can be obtained from Maarten Nollen, Arnold & Siedsma (tel 0032-2-7376290)

Increased Flexibility in the Timing of the Examination Process

The following article reproduces the reply filed, on behalf of epi, to the online user consultation launched by the EPO at the end of last year on the possibility that would be offered to applicants to postpone examination

C. Mercer (GB)

Question 1: Would you be in favour of a procedural option for postponing examination of a European patent application and, if so, could you explain why? No

Comments/reasons/examples: This reply is filed on behalf of the Institute of Professional Representatives before the European Patent Office (**epi**). **epi** has considered this question a number of times and its Council has consistently decided that it is not in favour of any form of deferred examination. **epi** notes that deferred examination was considered during the drafting of EPC 1973 but was rejected. Moreover, in the drafting of EPC 2000, Article 95 EPC 1973, which was on a related topic, was deleted. It therefore appears that the legislators are against any proposal for deferring examination. **epi** continues to hold the position that there should be NO system for deferring examination.

Question 2: In your view, would a postponed examination system benefit the European patent system? Could you explain why?: No

Comments/reasons/examples: Any proposal to defer examination would lead to increased legal uncertainty. This would be to the

detriment of the system as a whole and would in particular be to the detriment of third parties who are adversely affected by any continued legal uncertainty. It may also be to the detriment of any applicant using such a system as it may be held by the EU Commission to be anti-competitive as it might enable the applicant to maintain an advantageous market position on the basis of an unexamined application. It also seems to be contrary to the objectives of the EPO which aims to provide early, not delayed, certainty.

Question 3: In your view, what might be the economic and business impact of a postponed examination system? Comments/reasons/examples: The economic and business impact of a deferred examination system would be a significant reduction in competition and a hindrance to further research and development. In order to decide on whether it can enter a particular market, a technology-based company needs to know how other parties' patents will affect its plans. If the grant of patents is deferred, such companies will not be able to decide whether to enter the market and so competition will be reduced. If such a company wants to clarify the situation, it will need to do the work the EPO is paid to do by filing third party observations (TPOs). Thus, a financial burden is placed on such companies but no such burden is placed on applicants. The same is true if a competitor is trying to develop an improved product or process. Research into such improved products or processes will be inhibited by the existence of unexamined applications. Thus, the business and economic impact is negative.

Question 4: In your view, would such a system influence applicants'/patentees' behaviour in filing patent applications or enforcing patents and, if so, how? Yes
Comments/reasons/examples: Applicants already have a number of options for conducting prosecution. For instance, prosecution can be speeded up by requesting PACE or slowed down by taking advantage of procedural steps already available (requesting extensions, further processing, requesting oral proceedings). If applicants are provided with another option, they will use it to their advantage and to their competitors disadvantage.

Question 5: In your view. would such a system benefit the public at large? No
Comments/reasons/examples: The basic bargain underlying the patent system is that an applicant discloses an invention to the public in return for which the granting authority gives the applicant a limited monopoly for any invention which meets the requirements for grant. If examination is deferred, the applicant has a de facto monopoly for everything covered by the application, even if it is not patentable. This breaks the bargain. If the application is examined promptly, then the harm is small. If the examination is deferred, the harm becomes greater.

Question 6: Would such a system have an impact on competitors' behaviour?: Yes
Comments/reasons/examples: A competitor will want legal certainty. If such legal certainty cannot be obtained because examination has been deferred, the competitor can either take action, for instance by filing TPOs, or can decide not to compete. In the former case. the competitor has to incur expense to do the work the EPO is paid to do. This has an adverse financial effect on the third party. In the latter case, there is no competition and so the general public is likely to be adversely affected by higher prices. The answers to questions 2 to 6 support **epi**'s view that NO system of deferred examination should be introduced.

Question 7: Should all European and Euro-PCT applications be eligible for postponed examination? If so, why? If not, please indicate what limitations on eligibility could be envisaged.: No
Comments/reasons/examples: **epi** considers that there should be no deferred examination system. However, **epi** also considers that, during examination, there should be no discrimination between applications on the basis of the route taken to reach the EPO. It is considered that examination of all applications should, as far as practical, start at the same time relative to the earliest claimed priority date. In other IP5 offices, the latest that examination can start is 3 years from the filing date. In the EPO, substantive examination should start at the latest at 4 years from the earliest claimed priority date. It could be considered whether the opportunity to request deferment of examination should be afforded ONLY to small entities. It is considered that there should be no opportunity to request deferment of any divisional application.

Question 8: Which postponement option would you consider the most suitable?: Other (e.g. postponed search, postponed decision to grant; please specify)
Comments/reasons/examples: **epi** considers that no option of deferment should be adopted. There should be no postponement of search. The EPO is providing a very useful service to the system by providing its search reports within, generally, 6 months. This provides everyone in the system with very valuable information regarding possible outcomes of the examination process. However, it does not provide complete certainty because there is no indication of the arguments or amendments that an applicant might submit. Any deferment of search would be adverse. Deferment of examination is not favoured for the reasons set forth above. Deferment of grant might be an option as, although it would increase legal certainty to a certain extent, it would not require the applicant to go through the expansive grant procedure until later. However, even such an option would need safeguards for third parties and would need careful examination.

Question 9: How should the postponement of examination be activated?: By filing a request
Comments/reasons/examples: **epi** still considers that no system of deferred examination should be introduced. However, assuming that one were to be introduced and assuming that the applicant has paid all the necessary fees, including the examination fee, before making a request for deferment, then it would seem that; merely filing a request should be sufficient. However, a fee could be required as long as the fee were to be set at a level such that its administration does not place a financial burden on the EPO.

Question 10: Depending on your reply to the previous question, when should a request for postponed examination be filed? Other (please specify)

For Euro-PCT applications: Other (please specify)
Comment/reasons/examples: For Euro-direct applications. any request for deferment of examination should be filed after the applicant has taken all the required steps and paid all the fees necessary for examination to commence. Thus, the applicant must have filed a substantive response to the European Search Opinion and paid the examination fee. At this stage, the applicant could abandon the application and should have considered the value of the application. Thus, at this stage, the applicant should be in a good position to determine whether deferred examination is required. For Euro-PCT applications, most of which enter the EPO at 31 months, there has, mainly, already been a search and an IPRP. The applicant should therefore be in a position to decide on whether deferred examination is required at that stage. Thus, any request for deferment should be filed at the end of the 31 months period.

Question 11: What would be the appropriate starting point for a postponement period?: Priority date
Comments/reasons/examples: This could also be the date of filing. However, the earliest claimed priority date seems most appropriate as then all applications are treated identically. If there are different starting points for different types of application, then inequalities will exist. Such inequalities already exist as Euro-direct applications are examined on average earlier that Euro-PCT applications. Such inequalities should be eliminated.

Question 12: What should be the maximum length of the postponement period?: Other (please specify)
Comments/reasons/examples: This question cannot be answered sensibly as set because the starting point is not specified. If, as in our answer to question 11, the starting point is the earliest claimed priority date, then the period should be a maximum of 4 years. This should allow the EPO to complete its further search and preliminary examination of Euro-PCT applications for which the EPO was not the ISA or IPEA and so all applications, of whatever sort, would then be on the same track.

Question 13: Should the fulfilment of any of the following requirements under the EPC be postponed until the start of examination and, if so, why? 1: Other (please specify)
Comments/reasons/examples: There should be no postponements. If there were to be a system of deferred examination, there should be no other postponements. The applicant should have to take all the steps it is presently required to take, in particular filing responses to search opinions, so as to reduce as far as possible the legal uncertainty caused by deferred examination.

Question 14: Should third parties be allowed to trigger the start of examination?: Yes
Comments/reasons/examples: Absolutely essential if, contrary to **epi**'s view, a system of deferred examination were to be introduced.

Question 15: How should a third party trigger the start of examination?: By filing an explicit request
Comments/reasons/examples: If, contrary to **epi**'s view, a system of deferred examination were to be introduced, it should be balanced, if an applicant can request deferment merely by filing a request, then a third party should be able to lift the deferment merely by filing a request. There should be no financial burden for a third party to request the EPO to do what it should be doing.

Question 16: What further requirements should be attached to the third-party activation mechanism? 1: Other (please specify)
Comments/reasons/examples: The problem here is balancing the interests of third parties, the EPO and the applicant. Clearly, the EPO should be able to prevent abuse, by applicants or third parties, but should not be burdened with a procedure which is onerous and costly to implement. On the other hand, third parties should not be burdened by extra cost to undo a privilege granted to the applicant and should NOT be obliged to identify themselves to the applicant or the general public. Thus, third parties should NOT be charged a fee and should not need to be identified on the public part of the EPO file. However, a third party could be required to identify itself ONLY to the EPO so that the EPO can properly manage the system. **epi** notes that PACE requests are not placed on the public part of the file and so a balanced system would NOT require that requests for lifting deferment should be placed on the public part of the file.

Question 17: Should the Office be able to start examination ex officio at any time?: Yes
Comments/reasons/examples: The Office should be able to manage the examination procedure for its internal purposes. This would also contribute to maintaining the anonymity of any third party requesting the lifting of the deferment.

Question 18: In which of the following situations should the Office be allowed to start examination ex
officio'? 1: Other (please specify)
Comments/reasons/examples: When a third party has requested the Office to do so or when the relevant directorate has reasonably exhausted other work.

Question 19: Do you have any other suggestions for giving applicants greater control over the speed of the examination process?: As **epi** is against any proposal for a deferred examination system, **epi** considers that applicants should NOT be given any control over the speed of the examination process. It is the duty of the EPO to grant patents and it should do this by examining at a reasonable pace while ensuring the quality of the granted patents. Giving the applicant any more opportunities to control the speed of examination is contrary to the duty of the office.

Question 20: Would you be in favour of procedural options for further reducing the pendency of a European patent application? If so. please specify: No
Comments/reasons/examples: The question is unclear. What is the comparison for "further reducing"? However, to the extent that **epi** understands the question, **epi** considers that there are already enough options available to applicants and third parties. If any other options are proposed, there should be a further consultation.

Overview of Changes in EPC Practice

M. Nollen (BE)

The following is an overview of changes in EPC practice. The changes are based on information in the Official Journal of the EPO (up to January 2019) and on the website of the EPO. Further details are to be reviewed via the OJ EPO.

Amendment to Article 2 of the Rules relating to Fees (per 1 April 2019)[1]

A new paragraph is inserted into Article 2 RFees in relation to fee changes that will not apply until a date set by the President of the Office. The applicable fees are fees relating to the use of a means of electronic communication or a document format. The background hereof is that the necessary IT developments need to be completed before the fee changes become applicable. It relates to the filing fee, the fee for grant and the transmittal fee. So, when using online filing, the amounts remain the same until further notice.

Amendment of Filing fee for non-online filings

As of 1 April 2019, the filing fee for non-online filings will be EUR 250. It will apply to payments made on or after 1 April 2019.

Grace period for wrong fee payment

A grace period of 6 months starting from 1 April 2019 is provided[2]. During this grace period, a payment in due time but only in the amount applied before 1 April 2019 will not lead to a loss of rights if the difference is made good within two months of an invitation to that effect from the Office.

Refunds of Search Fees

A revision is made on refunds of search fees, where the Search Report is based on an earlier search prepared by the EPO[3]. This can be a European Search Report, a supplementary European search report or an International Search. The earlier search can relate to a priority application, a parent application (in case that the European search report relates to a divisional) or a new application filed by an entitled person (under R17 EPC).

New form for appeal when filed on paper

As of 24 January 2019, a new form is available for filing an appeal on paper. The form is optional. It has been created to avoid typical mistakes when filing the notice of appeal and

For European Searches

Earlier type of application	With/without written opinion (WO)	Full refund	Partial refund
European (from 01.07.2005)	With WO	100%	25%
PCT (from 01.01.2004)[4]	With WO	84%	21%
National (such as BE, GB, NL, IT)	With WO	84%	21%
Any type	Without WO	70%	17.5%

For International Searches

Earlier type of application	With/without written opinion (WO)	Full refund	Partial refund
European	With WO	100%	25%
PCT	With WO	100%	25%
National (such as BE, GB, NL, IT)	With WO	100%	25%
Any type	Without WO	100%	17.5%

1 Decision of the Administrative Council of 12 December 2018, OJ EPO 2019 (January), A3, article 1 and 2. See also the notice hereon provided as A6 in the same issue

2 Id. Article 3

3 For European Searches, see OJ EPO 2019(1) A4; for International Searches, see OJ EPO 2019(1) A5

4 This applies to an international search and a supplementary international search

ensuring that the minimum requirements for the content of the notice of appeal under Rule 99(1) EPC are met. It is named EPO Form 3002 and can be downloaded as an editable PDF from the website of the EPO.[5]

Appeals may further be filed using online filing services, i.e. online filing (OLF) and EPO Case Management System (CMS, also New online filing), but not via the Web-Form filing[6]. The new form cannot be used when filing the appeal online.

Interviews and Oral Proceedings held as a video-conference[7]

Applicants and their representatives may request that an interview or oral proceedings before an examining division be held as a video-conference. Video-conferences will be conducted using IP technology (SIP, H.323, secure web-based and legacy system). The person who requested the video-conference will be provided with an electronic link allowing him to establish a connection with the EPO when the request is granted. The EPO has ceased to support video-conferencing via ISDN at the end of 2018.

The Notice in the OJ EPO further discusses how to request a video-conference. It is preferably done as early as possible. It is added therein that Oral Proceedings by video-conference are equivalent to Oral Proceedings in the traditional manner on the premises of the EPO. The examining division (or the first examiner) has discretionary power to allow a request for video-conferencing on a case-by-case basis. In case of refusal of a request for video-conferencing, this will not be an appealable decision.

Filing of priority documents

As of 1 December 2018, arrangements for electronic filing of priority documents have been amended[8]. Priority documents for European applications and international applications in the European phase may be filed both via online filing (OLF) and the EPO Case Management System (CMS), in PDF format. However, during the international phase, electronic priority documents should be filed using the ePCT-system.

A requirement is that the priority documents have been digitally signed by the issuing authority and that the signature is accepted by the EPO. This applies for instance to certified electronic priority documents with a digital signature issued by the USPTO and the Brazilian patent office.

As of 1 November 2018[9], the EPO shall include a copy of a priority application in the file of the European patent application, which copy is retrieved via the WIPO Digital Access Service (DAS) using the indicated access code. This will be done upon request of the applicant, and free of charge. This also applies to international application entering the European phase as designated or elected office. However, it does not apply to international applications under the PCT.

If the applicant has not filed a request or if the EPO is unable to retrieve a copy of the priority application via the WIPO DAS, the EPO shall include a copy of the priority application, if said priority application is:

- a European application,
- an international (PCT) application filed with the EPO as receiving office,
- a Chinese patent application or utility model application,
- a Japanese patent application or utility model application,
- a Korean patent application or utility model application,
- a United Stated provisional or non-provisional patent application.

The EPO shall inform the applicant of the inclusion, unless the priority application is a European patent application or a PCT application filed with the EPO as receiving office. If the copy cannot be included in the file, it shall not be deemed filed. The EPO shall inform the applicant in good time and give him the opportunity to file the copy subsequently (R53(1) EPC).

The applicant may request the Office of First Filing to make certified copies of priority applications available to the DAS. The applicant can thereafter request to Offices of Second Filing to retrieve the copies via DAS. Currently, there are 19 offices participating in DAS, including the patent offices of Denmark, Estonia, Finland, The Netherlands, Spain, Sweden and the UK, in addition to those of USA, Korea, China, Europe and Japan.

In view of DAS, the request for grant form (Form 1001) and the form for entry into the European phase (Form 1200) have been updated.[10]

Supplementary issues OJ EPO on the Boards of Appeal and on EQE

A first supplementary issue of the Official Journal was published[11] with information from the Boards of Appeal. In addition to the business distribution scheme, the publication includes an overview of all procedural rules as currently appli-

5 https://www.epo.org/applying/forms-fees/forms.html
6 Article 3 of the Decision of the President of the European Patent Office dated 9 May 2018 concerning the electronic filing of documents, OJ EPO 2018, A45
7 Notice from the EPO dated 15 November 2018, OJ EPO 2018, A96
8 Decision of the President dated 15 November 2018, OJ EPO 2018, A93; Notice in relation to same, A94.
9 Decision of the President dated 18 October 2018, OJ EPO, A78; Notice in relation to same, A79
10 OJ EPO 2018, A80
11 https://www.epo.org/law-practice/legal-texts/official-journal/2019/etc/se1.html

cable to the Boards, including the Rules of Procedures (for the Boards, the Enlarged Board and the Discliplinary Board) and notices relating to (a.o.) Accelerated Proceedings, conduct of Oral Proceedings, Representation, Filing of Documents.

A further supplementary issue of the Official Journal[12] was published containing the Regulation on the European Qualifying Examination, implementing provisions, instructions to candidates and a decision of the Supervisory Board from 2016. This provides the overview, there are no recent amendments.

EQE Enrolment 2020 (and withdrawal)[13]

Enrolment for the pre-examination on 16 March 2020 is open from 1 February to 30 April 2019. Enrolment will only possible for candidates who have registered commencement of their professional activity before 15 January 2019 (the "compulsory registration").

Enrolment for the main examination (EQE 2020) from 17 to 19 March 2020 can be done in the period from 1 April to 12 August 2019. Payment of the fees are to be made by credit card or bank transfer. Enrolment must be filed online via the EQE website.

Candidates may withdraw in writing from a paper or any subsequent paper at any time up to the official start of an individual paper examination. If the Examination Secretariat is informed of the withdrawal no later than 30 September 2019, the fees for sitting the respective paper(s) will be refunded. However, the enrolment fee is not refundable. Withdrawal can be done by email, fax or registered mail.

12 https://www.epo.org/law-practice/legal-texts/official-journal/2019/etc/se2.html
13 OJ EPO 2018, A99 and A108

Some Thoughts after the Conference on the New Rules of Procedure of the Boards of Appeal

D. Thomas (FR), Former Director DG1, EPO

Although this résumé aims to be as factual as possible, it should not be forgotten that it represents the personal view of the author and hence should not be taken as carved in stone.

The conference held in Munich on 5 December 2018 was interesting as one could gain some information as how the working group NRPBA[1] of the Presidium and the BOAC[2] came to its conclusions and proposals, and of the dissenting views of certain representatives, not to say lobbying groups, e.g. Business Europe, which had a strong delegation led by its President.

There were presentations by members of the working group NRPBA, mainly Chairpersons of the BoA, followed by panel discussions among some selected speakers from the user's side, see above, and the members of the BoA having given presentations. There were also Q&A session for the audience.

The whole session was moderated by Sir Colin Birss who is well known in the profession, and who has also moderated a conference at the MPI[3] a few months ago. Sir Colin Birss is member of the BOAC and Dr Bachert, judge at the BGH[4], as well member of the BOAC was present as well, and gave some comments. Mr Grossenbacher, Chairman of the BOAC opened the session.

First, something about the timing. It was pretty clear that the NRPBA will come as they appear in the second draft. According to Mr Josefsson the BOAC should adopt them at the beginning of 2019, with then approval by the AC before mid-2019, so as to ensure an entry into force on 01.01.2020. Transitional provisions are very limited and will not have a great impact.

Following the consultation earlier this year, 140 comments were filed. It was clear that some of them were taken into consideration, but others clearly not followed.

In a nutshell, the present situation with Art 12(2), 12(4), 13(1) and 13(3) RPBA will certainly not be relaxed. The contrary is to be expected, but this should not be a surprise for any reader. The thrust of the whole appeal procedure will be the judicial revision of first instance decision, not simply to continue the procedure started in first instance.

1 NRPBA = New Rules of Procedure Boards of Appeal
2 BOAC = Boards of Appeal Committee, a newly-established subsidiary body of the Administrative Council
3 MPI = Max Planck Institute
4 BGH = Bundesgerichtshof (German Federal Court of Justice)

There are also interesting developments in respect of transparency of the BoA when it comes to their workload, designation of the members of a BoA, and remittals.

An important factor which also came to light is the large discretion the Boards will have in deciding on the admission of submissions at any moment during appeal procedure. Let's hope that this discretion will be properly exercised, as there is no instance able to check whether it has been correctly exercised. In view of its case law, the EBA will most probably not help.

From the presentations and the comments made during those presentations, it appears clearly that the BOAC played an important role in the drafting of the NRPBA.

The three rings of convergence

The NRPBA provide three rings of convergence 1) when entering appeal, 2) once the appeal and the reply to the appeal have been filed, and 3) after a communication under R 110(2) or Summons to Oral Proceedings have been issued. They correspond to the existing situation, but they have been heavily strengthened.

1) When entering appeal

An important aspect is that not "everything which has been presented" at the outset of the appeal procedures will be admitted. In Art 12(4) NRPBA parts of the statement of grounds of appeal or the respondent's reply, i.e. parts of a party's appeal case, which are not directed to facts, etc. on which the decision under appeal was based are considered as an "amendment" and will only be admitted at the discretion of the Board.

This applies not only to amendments to the application or to the patent, but to any submission, i.e. requests, facts, objections, arguments and evidence which the party submitted before the department of first instance but on which that department did not base its decision!

In the case of an amendment to the patent application or the patent, the applicant or patent proprietor must explain why the amended claim overcomes the objections raised, i.e. raised in the decision under appeal, or by the opponent in its statement of grounds.

Mainly, it is only in case the first instance did not exercise its discretion correctly that submissions might be admitted, provided they have not been abandoned in first instance procedure.

2) Limitation on a party amending its appeal case after the initial stage of the proceedings

A reasoned request for admittance of any "amendment" at this stage of the appeal proceedings is mandatory. The admittance is subject to the Board's discretion alone. Where an amendment to a patent application or patent is concerned, the onus on the applicant or patent proprietor is to demonstrate both

- why the amendment overcomes the objections raised, cf. first level of the convergent approach,
- and why the amendment does not give rise to new objections.

3) After a communication under R 110(2) or Summons to Oral Proceedings have been issued

The basic principle of the third level of the convergent approach is that, at this stage of the appeal proceedings, amendments to a party's appeal case are not to be taken into consideration.

The only exception is

- when the Board expressly invites a party to file observations within a period specified by the Board, or
- if a party is able to present compelling reasons which justify clearly why the circumstances leading to the amendment are indeed exceptional.

Needless to say that the measures envisaged under this heading, met a certain resistance from the side of the audience, especially when representing the applicant/proprietor.

Transparency of the Boards of Appeal and of the designation of its members – case management

1) Advanced planning

As it happens in some national jurisdictions, e.g. the German Federal Constitutional Court (BVerG), for each Board, a list of cases will be published in which, in the coming year, the Board is likely to hold oral proceedings, issue a communication, or issue a decision in written proceedings.

The list is not binding and might change during the year, if for instance, appeals are withdrawn. No rights can be derived from the list.

The advance planning of the expected workload for the coming year is intended to increase efficiency for the Boards and the parties.

In order to draw up the list, it has been made clear that each rapporteur will have a target of decisions to achieve at the end of the year. The (unofficial) figures seems to be 22 cases/year/rapporteur, whereby at the end of the day the president of the Boards insisted upon the fact that the quality of the work done will be a more important factor than the mere production figure.

One aim of this measure seems also to achieve a better distribution of the workload of legal members.

2) Designation of the members of a given Board

The Chair of each Board will continue to determine the composition of the Board for each particular case in accordance with the business distribution scheme, but will designate the rapporteur before determining the remaining composition of the Board.

The Chair of the Board will as well designate a member of the Board or himself, to consider the admissibility of the appeal. In most cases, the Chair of the Board will designate a legally qualified member to consider the admissibility of the appeal. Where the rapporteur (i.e. in most cases a technically qualified member) has been designated before the composition of the Board has been completed, the Chair of the Board may decide to designate the legally qualified member to consider the admissibility of the appeal only once the complete composition of the Board has been determined.

3) Consolidation of appeal proceedings

The main change here is that the parties will not any longer asked to give their consent in case of consolidation of appeals.

4) Extension of periods set by the Boards

Only periods specified by the Boards can be extended following a reasoned request. In general they will be of 4 months.

The period, 4 months, for the respondent to reply to the grounds of appeal cannot be extended. This has led on the spot to strong protests from the audience, especially in the case of a proprietor confronted with a plurality of appealing opponents.

5) Acceleration of appeal proceedings

Whilst acceleration was already possible under the present RPBA. In case of acceleration at the request of a party, the other parties will be informed and may comment, but will not normally not be invited to comment.

A Board may also accelerate an appeal at its own motion. In such a case, the Board will not inform the parties.

If acceleration is decided, time lines will be set and the parties will have to abide by in a much stricter manner.

6) Summons to oral proceedings

It will become mandatory for a Board to send a communication in annex to the summons. According to the information given, the annex to the summons will represent the view of the whole board, not just that of a rapporteur. The summons will be issued in general with a time lead of four months.

7) Change of date of Oral proceedings

The reasons given in the Notice of VP3 have now been entered in the RPBA. The serious reasons for requesting a change of date must relate to the representative. Giving reasons why another representative cannot take over will not be any longer necessary. That substantive submissions have been made by several representatives of a firm will however be taken into account, i.e. like in Guidelines E-III, 7.1.1.

When requesting a change of date, the dates at which a representative is not available will have to be given. This applies as well to the other parties.

There is not, like in first instance, a set rule about days to be kept free between oral proceedings. This is left to the discretion of the Boards.

8) Remittal

In the future, the rule should be that remittals will be an exception, unless there are special reasons like a fundamental deficiency in first-instance proceedings.

The aim is to avoid ping-pong between the Boards and the departments of first instance. It has been a wish of numerous representatives that first instance divisions should decide on all possible issues, even if for instance the main problem is a problem of sufficiency or added subject-matter.

One suggestion was for the first instance divisions may be to decide on one point, but to give an opinion on all others contentious points. As the thrust of the appeal procedure is the judicial revision of first instance decisions, it might not be the judicial review of opinions.

It will have to be seen if this is at all practical, and some scepticism appears not to be misplaced. The comment fell that sufficiency and inventive step are linked, so that it might be possible to decide on both. Dr Bachert brought forward that whilst the BGH has to remit in the absence of technical members, as the Boards of Appeal have technical members remittal should not be necessary.

Since a claim suffering from added subject-matter does in principle not have an effective date, clear instructions as to which theoretical date should be taken into account when assessing novelty or inventive step should be given.

What good is it to discuss the novelty or inventive step of a non-enabled invention?

9) Abridged decisions

If the decision is announced at the end of oral proceedings, and the parties have given their consent, it may be in abridged form.

Under the condition that the provisions of Art 113(1) have been respected, and if the Board agrees with the decision of first instance and all its findings, it can, without the consent of the parties, decide in abridged form. In such a situation, it is irrelevant whether the decision has been announced orally in oral proceedings.

Reservations came from the audience in relation with abridged decisions as a Board of Appeal is not the only forum of discussion possible.

10) Issuance of decisions after oral proceedings

A time limit of three months has been set, but as there is no sanction in case the time limit is not respected, some scepticism came up from the audience.

11) Video or telephone conferences before the Boards?

Art 12(1,e) NRPBA mentions video or telephone conferences between a Board and parties, but no specific rules of procedure for such video or telephone conferences are to be found in the NRPBA. Oral proceedings in the form of video conferences are certainly not on the agenda.

Transitional provisions

The NRPBA will apply to all pending appeals with two exceptions:

- Art 12(4-6) NRPBA will not apply retrospectively to grounds of appeal or replies filed before the date of entry into force of the revised version, irrespective of whether this period expires before, on or after the date of entry into force of the revised version.
- Art 13(2) NRPBA will only apply to a submission filed after the statement of grounds of appeal or a reply thereto if, at the date of entry into force of the NRPBA, summons to oral proceedings or a communication of the Board under R 100(2), has not been notified.

Effect on the procedure of first instance

In the explanatory notes the drafting committee acknowledges that as a consequence of the convergent approach now implemented in Art 12 and 13 NRPBA, it is to be expected that more issues will be raised and dealt with in the proceedings at first instance. Hence, this should reduce the need to remit cases.

It is manifest that the number of auxiliary requests filed in first instance will increase. Even at present, not filing, or worse, withdrawing a request in first instance, means that the chances for it to be admitted during appeal are very remote. They well be even less in the future.

Whether the efficiency of the whole procedure before the EPO will be increased remains thus to be seen.

During the discussion, the President of the BA indicated that the Boards have been in discussion with DG1 when revising the RPBA, and that in any case, the President of the EPO is represented in the BOAC.

This fine report was published before in the "Blog du Droit Européen des Brevets" (https://europeanpatentcaselaw.blogspot.com).

Emerging Technologies and the EPO

L. Bosotti (IT), Member of the OCC

Luciano Bosotti

The report on "Patents and the Fourth Industrial Revolution" of December 2017[1] bears witness to the attention paid by the EPO to Information and Communication Technologies (ICTs). The 6thIndo-European ICT Conference, co-hosted by the EPO and the Indian Ministry of Electronics and Information Technology, in association with the European Business and Technology Centre, and the Centre for Development of Advanced Computing held at the EPO in Munich on 29 November 2018[2] and the one-day conference Patenting Blockchain held at the EPO in The Hague on 4 December 2018[3] further confirm the continuous interest brought by the EPO as a

1 http://documents.epo.org/projects/babylon/eponet.nsf/0/17FDB5538E87B4B9C12581EF0045762F/$File/fourth_industrial_revolution_2017__en.pdf
2 https://www.epo.org/learning-events/events/conferences/2018/global-patenting-and-emerging-technologies/programme.html
3 https://www.epo.org/learning-events/events/conferences/blockchain2018/programme.html

stakeholder in the Fourth Industrial Revolution. The presentations at both conferences are available for consultation and downloading at the website addresses indicated below.

2. A presentation given in Munich (Weibel - IP Counsel, Siemens) placed emphasis on three main points. Firstly, technologies such as 3D printing/distributed manufacturing impact the conventional understanding of infringement as occurring at a certain place. The question as to where IP is infringed may thus become difficult to answer with protecting (possibly remote) application of patented technology representing a new frontier for patent rights. Secondly, increasingly distributed activities may render proper definition of mutual contributions to certain results very important. Agile registration of rights with the purpose of documenting scope and origin of innovation is thus desirable. Also, the increased computing power of AI can remove from the camp of science fiction the concept of machine-made invention. Naming as the inventor/creator an organization/enterprise which controls the activity of AI apparatus making an invention might thus become a somewhat disquieting yet realistic perspective.

By way of comment, one may note that the learning process in a machine operating on the basis of a neural network (NN) paradigm may identify an information set (model) embodying certain concepts adapted to solve a previously unsolved technical problem underlying the (machine-made) invention.

How can such a model be described in compliance of Art. 83 EPC, that is in natural human language, and - more to the point - claimed in compliance of Art. 84 EPC by avoiding that the extent of protection should be very strictly limited? How can such a model be searched and compared with the prior art in order to ascertain compliance with Art. 52 to 56 EPC, with the prior art possibly including, in addition to earlier conventional patent documents, also earlier documents related to machine-made inventions and, more to the point, possible prior public "disclosures" of such inventions? How can one evaluate the inventive step involved in such a "machine-made" invention, which may simply derive from a very high number of repeated of trial-and-error loops largely beyond the ability of the human mind? Machine-made inventions, if possibly patented, may render the question as to if IP is infringed a – far from trivial – question deserving close scrutiny: so-called equivalents may come into play and applying, say, the function-way-result (FWR) test may be far from easy: should perhaps AI be applied for that purpose?

Plenty of food for thought for the new generations, indeed.

3. The presentation Examining Blockchain Inventions in The Hague indicates the formation of CII teams in DG1, across sectors and across DGs leading to the formation of a network of CII experts including 1 or 2 examiners in each large directorate, and a first line contact person for all CII related questions in mix divisions. This initiative should enable working level knowledge of all examiners concerning CIIs and assessing skill sets within the directorate to define a training plan. Hopefully the initiative should facilitate adoption of "real world" approach in evaluating (also) clarity issues (Art. 84 EPC) in EP proceedings.

4. The event of 4 December in The Hague focused on *patenting blockchain*, that is patenting blockchain-related inventions. With patent information and copyright mentioned as possible applications of blockchain, dynamic distributed databases that update as assets are exchanged on a digital platform (or payments are made) were also mentioned as possible applications along with registration of patents, reducing administration, cost and speed up patenting and licensing process.

Indeed, the European Register is essentially a (distributed) ledger, which is desired to be immutable and incorruptible, with associated timestamps, for which controllable access (via cryptography, for instance) prior to publication may represent a key factor. Also, the patenting process and maintenance in force involves payments, both to the office and from the office (for fee refunds, for instance) as well as automated transaction and real-time monitoring. Consequently, the issue of *blockchain patenting* (that is the possible use of blockchain technology in support of the patenting process) may deserve some consideration. Investigating possible developments towards *blockchain patenting*, also as a tool for securing a deadline (filing date, priority date, etc.) as an alternative to more conventional means, may thus represent a field of possible activity by the EPO and EPI bodies.

Artificial Intelligence – A New Challenge for Technology and Law?

Report about the Karlsruhe Institute of Technologies (KIT) annual symposium "Karlsruher Dialog Technik und Recht" in December 2018

Dr. Johannes Schmid (DE), Member of the Editorial Committee

The former judge of the German Federal Court of Justice Prof. Dr. Klaus-J. Melullis heads a research group on patent law at the Center of Applied Law of Karlsruhe Institute of Technology. Prof. Mellulis together with the German Bar Associations academy organizes an annual symposium on current topics at the interface of technology and patent law. The goal of this conference series is to foster a dialogue between the competence fields of law on the one hand and technology on the other. This year's symposium was directed at the ongoing developments in the field of artificial intelligence (AI) in general and in particular neural networks and machine learning. Among the addressed topics were inventions or creations made by autonomous systems as well as decisions of such systems that can potentially not be tracked back to humans without further consideration. The symposium was attended by about a hundred participants from research and law practice. After an introduction by Prof. Melullis, the symposium featured nine talks by high-profile researchers and practitioners. In the following, an overview of the topics is given.

1. AI in robotics (Prof. Dr. Torsten Kröger)

Prof. Kröger is a lecturer at the faculty of computer science at KIT and works in the field of robotics. He opened his talk by pointing out that it is difficult to find a single definition of AI. For this reason, he prefers the well-defined term of machine learning. He described examples of intelligent (learning) behavior of robotic systems. Further, he discussed technical concepts of machine learning algorithms and showed examples of the abilities of current systems. Still further, he presented possible new application areas of machine learning approaches. One message of Prof. Kröger was that machine learning is mainly a tool and not a magic bullet. This tool, however, has a huge potential to help, support and assist humans at work and in everyday life.

2. New concepts for responsibility in the context of AI and robotics (Prof. Dr. Susanne Beck, LL.M.)

Prof. Beck is a lecturer at the faculty of law at Leibniz-University Hannover and conducts research in the field of criminal law. In her talk she focused on challenges faced by lawmakers with the upcoming of intelligent robotic systems. In particular, she discussed civil and criminal liability of AI systems. Potentially liable entities include the producer of an intelligent system (i.e. the programmer or the vendor) and the user of the system. In addition, she described the concept of the electronic person (e-person) representing the system itself and discussed concepts for fully or partially imposing liability on this electronic person. As an example, Prof. Beck discussed whether it is appropriate to impose liability on the driver of an autonomous vehicle who has relied upon his system for a long time before an accident occurs. She concluded her talk with pointing out that the ongoing developments require an appropriate adaption of standards with respect to civil and criminal liability.

3. AI in patent applications and in the work of the German Patent and Trademark Office (GPTO, Dr. Klaus-Dieter Herrmann)

Dr. Herrmann heads one of GPTOs patent departments. In his talk, he reported on the growing number of patent applications relating to AI. In particular, he pointed out that a total of 37.100 patent applications relating to AI has been filed with the GPTO so far. This number has shown a strong increase recently. He provided a few examples for patent applications relating to applications of AI for controlling gas turbines, for medical diagnosis, for predictive maintenance and for autonomous driving. In the second part of his talk, Dr. Herrmann gave an update on the current efforts of the GPTO to enable a semantic search in patent documents based on neural networks. In the discussion following the talk, Dr. Herrmann provided insights into the GPTOs approach regarding sufficiency of disclosure of patent applications relating to AI. Further, he informed the audience that with respect to determining whether an invention relating to AI is to be considered a technical invention, the GPTOs approach is equivalent to the European Patent Offices approach.

4. Technical and economic consequences of AI (Dr. Jochen Hanisch)

Dr. Hanisch is attorney at law and heads the network development and network management Department of AUDI AG, Ingoldstadt. After a brief introduction, Dr. Hanisch provided an overview of applications of AI in the

context of autonomous driving. Then, he discussed civil, criminal and public law aspects of AI. He pointed out the various challenges faced by lawmakers with the upcoming new technologies in particular with respect to the relationship between humans and intelligent machines.

5. Copyright protection for creations of machines (Daniel Schönberger, lic. iur., LL.M.)

Daniel Schönberger is head of legal for Switzerland and Austria at Google Switzerland GmbH, Zürich. He reported on Googles AI principles and responsible practices. He lined out an argumentation why it could be beneficial to grant rights to intelligent machines. Mr. Schönberger gave an overview of the risks of upcoming AI technologies. He emphasized, however, that the fact that innovation ultimately drives prosperity and economic growth should not be neglected. As a consequence, it is required to find and create a legislative environment that allows and incentivizes developments in this field rather than closes down creativity in a misconceived effort to protect it.

6. Patentability of technological developments by AI (Prof. Dr. Andreas Wiebe, LL.M.)

Prof. Wiebe teaches law at Georg-August-University Göttingen and conducts research in the fields of competition and intellectual property law. In his talk, he discussed problems relating to inventions made by intelligent machines. If an intelligent system independently, i.e. without human guidance, can recognize patterns and derive therefrom an independent course of action to develop innovative products, it is possible that such a system invents a new concept. Prof. Wiebe raised and discussed the question whether an intelligent system could be an inventor. One resulting problem then lies in the question of ownership of the invention (user, developer or owner of the intelligent system?). Another problem could arise from intelligent systems generating patent applications or prior art (cf. approaches like www.allpriorart.com). Prof. Wiebe recognized the conflict potential with respect to the current patent system resulting from machines becoming more and more intelligent. One possible solution could be to introduce a new separate patent system for inventions made by intelligent systems.

7. Questions in the context of a conclusion of contract by intelligent systems (Dr. Torsten Kraul, LL.M.)

Dr. Kraul is attorney-at-law with Noerr LLP, Berlin and focusses on telecommunication, internet, e-commerce and IT law. In his talk he discussed advantages and disadvantages of different concepts for introducing autonomous systems into the legal framework of the conclusion of contracts. For instance, an autonomous system could either be treated as a representative or as a simple messenger for a natural person. Dr. Kraul discussed implications for contracts resulting from these different concepts. According to Dr. Kraul, there is a need for new regulations covering these upcoming issues.

8. Liability for the consequences of the use of AI (Prof. Dr. Garald Spindler)

Prof. Spindler teaches law at Georg-August-University Göttingen and conducts research in the fields of company, copyright, internet and telecommunication law. In his talk, he discussed challenges for legislation arising from non-deterministic behavior of autonomous systems. In particular, it is a challenge to determine civil and criminal liability relating to decisions involving autonomous intelligent systems. One option to solving these issues is to apply the concept of absolute liability of the person putting the system to use.

9. Digital legal persons: liability for the actions of autonomous software agents (Prof. em. Dr. Gunther Teubner)

Prof. Teubner is emeritus professor of Goethe-University Frankfurt. In his talk, he summarized and discussed risks arising from the upcoming use of autonomous software agents. In particular, these risks can be categorized into (1) an autonomy-risk relating to independent decisions made by software agents, (2) a combination risk relating to a tight cooperation of human and software agents, and (3) a network risk arising from interactions of computers with one another. All three different categories present different challenges for lawmakers and require different approaches. Prof. Teubner provided arguments why the concept of an electronic person might not yet be applicable to current systems.

National Laws on the Patentability of Plants

(update 25 January 2019)

Summary

Art 53(b) EPC excludes from patentability plants or animal varieties or essentially biological processes for the production of plants or animals. Some national laws contain a provision excluding from patentability, besides essentially biological processes, the products derived thereof.

Question (Q)

Is there a specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process?

No	**33**
Yes	**5**

MS	National Law / EN translation	Remarks	Q
AL	Law No. 9947 of 7 July 2008 **Art 6.2** **EN Translation** *Exceptions to patentability* *Patents shall not be granted in respect of:* *2. Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.*	**Art 5.5 (c)** *Art 5 Patentable Inventions* *5. Biotechnological inventions shall also be patentable if they concern:* *c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.*	No
AT	Patentgesetz 1970 BGBl. 1970/259 idF BGBl. I 37/2018 (Patentgesetz) **§ 2(2) Patentgesetz** *§ 2.* *(2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen oder Tiere. (…)* **EN Translation** *Patents shall not be granted for plant and animal varieties and for essentially biological processes for producing plants and animals and plants or animals that are exclusively obtained by such processes. […]*	§2(2) of the Austrian Patent Law in full reads: *"(2) Patente werden nicht erteilt für Pflanzensorten oder Tierrassen sowie für im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen oder Tiere. Der Begriff der Pflanzensorte wird durch Artikel 5 der Verordnung (EG) Nr. 2100/94 über den gemeinschaftlichen Sortenschutz, ABl. Nr. L 227 vom 1. September 1994 S. 1, in der Fassung der Verordnung (EG) Nr. 2506/95, ABl. Nr. L 258 vom 28. Oktober 1995 S. 3, definiert. Ein Verfahren zur Züchtung von Pflanzen oder Tieren ist im wesentlichen biologisch, wenn es vollständig auf natürlichen Phänomenen wie Kreuzung oder Selektion beruht. Erfindungen, deren Gegenstand Pflanzen oder Tiere sind, können patentiert werden, wenn die Ausführung der Erfindung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist. Satz 1 Teil 2, wonach Patente nicht für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren erteilt werden, berührt nicht die Patentierbarkeit von Erfindungen, die ein mikrobiologisches oder sonstiges technisches Verfahren oder ein durch diese Verfahren gewonnenes Erzeugnis zum Gegenstand haben, wobei ein mikrobiologisches Verfahren jedes Verfahren ist, bei dem mikrobiologisches Material verwendet, ein Eingriff in mikrobiologisches Material durchgeführt oder mikrobiologisches Material hervorgebracht wird."*	Yes

MS	National Law / EN translation	Remarks	Q
BE	The Belgian Code of Economic law provides: **Art. XI.5.** § 1 Ne sont pas brevetables : 1° les variétés végétales et les races animales ; 2° les procédés essentiellement biologiques pour l'obtention de végétaux ou d'animaux. § 2. Les inventions portant sur des végétaux ou des animaux sont brevetables si la faisabilité technique de l'invention n'est pas limitée à une variété végétale ou à une race animale déterminée. § 3. Le paragraphe 1er, 2°, n'affecte pas la brevetabilité d'inventions ayant pour objet un procédé microbiologique, ou d'autres procédés techniques, ou un produit obtenu par ces procédés. **EN Translation** Art. XI.5. *§ 1. Shall be excluded from patentability:* *(1) plant and animal varieties;* *(2) essentially biological processes for the production of plants or animals.* *§ 2.The inventions relating to plants and animals are patentable if the technical feasibility is not limited to a particular plant or animal variety.* *§ 3. The paragraph 1, (2)shall not apply to microbiological processes or to the products obtained by such processes.*	The patentability of plants is discussed in Art. XI.5. of the new Belgian Code of Economic law of which book XI entered into force on 1 January 2015.	No
BG	Bulgarian Patent Law **Art 7 (1)** **EN Translation** *Exceptions to Patentability* *(1) Patents shall not be granted for:* *(...)* *3. plant varieties or animal varieties;* *4. essentially biological processes for obtaining plants and animals.*	Patentability of biotechnological inventions is set in Art 7a (3): *Inventions relating to plants or animals shall be considered patentable, if the technical realisation of the invention is not reduced to a certain plant or animal variety.*	No
CH	Bundesgesetz über die Erfindungspatente (Patentgesetz, PatG) vom 25. Juni 1954 Art 2(2)b **Art 2(2)b PatG** Von der Patentierung sind ferner ausgeschlossen: […] b. Pflanzensorten und Tierrassen und im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren; unter Vorbehalt von Absatz 1 **patentierbar sind jedoch** mikrobiologische oder sonstige technische Verfahren und die damit gewonnenen Erzeugnisse sowie **Erfindungen, deren Gegenstand Pflanzen oder Tiere sind und deren Ausführung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist.** **EN Translation** [Excluded from patentability are:] b. Plant varieties and animal varieties or essentially biological processes for the production of plants and animals; however, subject to the reservation of paragraph 1, microbiological or other technical processes and the products obtained thereby as well as inventions that concern plants or animals are **patentable provided that their application is not technically confined to a single plant or animal variety.**	An essentially biological process that comprises at least one non-biological, technical step that is required for arriving at the desired solution (e.g. irradiation, temperature shock), will be patentable and so will be the products obtained by that process. Swiss patent law is clear as to the non-patentability of essentially biological processes but is somewhat silent as to the patentability of products obtained by essentially biological processes. From the wording of Art.2 (2)b PatG, last half-sentence (emphasized in bold letters), it may be inferred, however, that it was not the legislator's intention to exclude novel and inventive products from protection solely because they have been obtained by essentially biological processes. This view seems to be confirmed by the federal court decision BGE 121 III 125 (1995), Asta Medica vs Lendi, which also emphasizes patentability of plant product inventions as long as they are not confined to specific plant varieties. This understanding is also mirrored by the examination guidelines wherein patentability of products obtained by essentially biological processes is not excluded although not explicitly stated either. In essence, the goal of the Swiss legislator is to avoid double protection of plant inventions by both the plant varieties protection act and the patent law.	No

MS	National Law / EN translation	Remarks	Q
CY	Patent Act of 1998 (Law 16(I)/98, as amended by Laws 21(I)/99, 153(I)/2000, 163(I)/2002 and 163(I)/2002). Article 5a EN Translation Essentially biological processes for the production of plants or animals are not patentable. (…) It is understood that the foregoing restriction shall not affect the patentability of patents having as an object a microbiological method or other technical methods or a product that is a result of such methods.	The Biotech Directive (98/44) has been implemented in Cyprus law, as an amendment to the Patent Act of 1998.	No
CZ	Law No. 527/1990 Coll. on Inventions and Rationalisation Proposals (Patent Law) Section 4.b EN Translation Exclusions from patentability Patents shall not be granted in respect of: (…) b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes and the products thereof.	In two relevant Czech Laws (Nos. 527/1990 and 206/2000), there is no provision that explicitly excludes patentability of plants (or animals) obtained by essentially biological process. Consequently, the patentability of plant, wherein the plant is produced by essentially biological processes, would be an issue of official/judicial interpretation of the existing legal provisions. Unfortunately, up to now there is no relevant case law in the Czech Republic. Plant or animal varieties or essentially biological processes for the production of plants or animals are excluded from patentability by the Patent Law (Law No. 527/1990), nevertheless, the Law No. 206/2000, on the Protection of Biotechnological Inventions (which is an implementation of Biotech Directive 98/44/EC) in Section 2.b classifies plants and animals among the patentable inventions, "if the technical feasibility of the invention is not confined to a particular plant or animal variety".	No
DE	Patentgesetz in der Fassung der Bekanntmachung vom 16. Dezember 1980 (BGBl. 1981 I S. 1), das zuletzt durch Artikel 1 des Gesetzes vom 19. Oktober 2013 (BGBl. I S. 3830) geändert worden ist **§ 2a (1)1 Patentgesetz** *Patente werden nicht erteilt für* *1. Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere;* **EN Translation** *Patents shall not be granted for* *1. plant or animal varieties or for essentially biological processes* *for the production of plants or animals and plants and animals exclusively obtained by such processes;* (The underlined part has recently been added to the German provision. The amendment entered into force on 25 October 2013)	*Bundestagsdrucksache 17/14222 regarding No. 1 (Amendment of Section 2a of the Patent Act – PatG):* *With this supplementation to Section 2a Subsection 1 Number 1 PatG, it will be clarified that, with regard to essentially biological processes for the production of plants and animals, not only the processes but also plants and animals produced by such processes are not patentable, even if they are no plant or animal varieties which are anyhow excluded from patentability under Section 2a Subsection 1 Number 1 PatG. The current version of this stipulation literally adopted Article 4 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ([…] – Biopatent Directive). In this respect, the Enlarged Board of Appeal of the European Patent Office determined in its decision concerning patent cases "broccoli" and "tomato" (G2/07 and G1/08) of December 9, 2010 that the mere use of technical process steps for performing or supporting essentially biological processes do not render the processes patentable. However, in its decision, the Enlarged Board of Appeal does not deal with the question of the patentability of products in the form of animal and plants produced by such animal- or plant related processes. The Federal Government is of the opinion that, according to the object and purpose of Article 4 of the Biopatent Directive, the patentability exclusion should mandatorily also apply to such animals and plants. The non-patentability of conventional breeding processes could otherwise be easily circumvented. In the interest of breeders and farmers, it shall therefore be clarified that plants and animals which immediately arise from their conventional breeding should not be covered by patents of third parties having generic product claims. The potential to obtain patent protection by the German industry – especially the chemical and*	Yes

MS	National Law / EN translation	Remarks	Q
		pharmaceutical industry – should, however, not come restricted by anything going beyond the intention of this clarification. Products derived from biologically bred animals or plants, such as plant oils, should remain patentable provided they comply with the other patentability requirements. Only with a formulation which clearly relates the patentability exclusion of processes and products to the same matter, i.e. "plants and animals", it will be possible to comply with the available scope for national regulations defined by the EU-Biopatent Directive which is particularly restricted to clarifications. In this context, the terms "plants and animals" do not only cover the produced animals and plants, but also material, such as seed, or in connection with animals, sperm, ovules and embryos, which is obtained by conventional biological processes and is useful for the production of plants and animals. The use of the term "exclusively" shall safeguard that undisputable patentable, especially genetically modified plants and animals will not be covered by the patentability prohibition because of the fact that they additionally underwent an essentially biological crossing and selection process.	
DK	Patents Act, cf. Consolidate Act No. 91 of 28 January 2009 LBK nr 91 af 28/01/2009 Gældende (Patentloven) **Section 1(4)-1(6)** **EN Translation** *(4) Patents shall not be granted in respect of plant or animal varieties. Patents may, however, be granted for inventions, the subject-matter of which is plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety. In this Act a "plant variety" means a plant variety as defined in Article 5 of Council Regulation (EC) No. 2100/94 on Community plant variety rights.* *(5) Patents shall not be granted in respect of essentially biological processes for the production of plants or animals. In this Act an "essentially biological process" means a process consisting entirely of natural phenomena such as crossing or selection. Patents may, however, be granted for microbiological processes or other technical processes or products obtained by such processes. In this Act a "microbiological process" means any process involving microbiological material, performed on microbiological material or resulting in microbiological material.* *(6) Inventions may be patentable even if they relate to a product consisting of or containing biological material or to a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject-matter of an invention even if it previously occurred in nature. In this Act "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.*	The Danish patent law seems to be more "liberal" than the German law, and also slightly more than the Dutch law. This section was amended in the implementation of the Biotech Directive.	No

MS	National Law / EN translation	Remarks	Q
EE	Estonian Patent Act of March 16, 1994 **Art 7** **EN Translation** *Non patentable inventions* *(…)* *(2) The following biotechnological inventions shall not be protected by a patent:* *(…)* *5) essentially biological processes for the derivation of biological materials, plants or animals, except microbiological processes for the derivation of micro-organisms;* *6) inventions the application of which is confined to a single plant or animal variety.* *(3) For the purposes of this Act, "essentially biological process for the derivation of a biological material, plant or animal" means a process which consists entirely of natural phenomena such as crossing and selection.*		No
ES	Law No. 24/2015 of 24 July on Patents **Art 5.3** **EN Translation** *Non-patentable subject matter are:* *2. Plant and animal varieties. However, inventions having as an object plants or animals are patentable if the technical feasibility of the invention is not limited to a particular plant or animal variety.* *3. Essentially biological processes for the production of plants or animals. For these purposes essentially biological processes means processes which consist entirely of natural phenomena such as crossing and selection.* *The previous paragraph will not affect the patentability of inventions related to a microbiological method, or to any other technical method, or to a product obtained by such methods.*	Art 5.3 of the Spanish Patent Law excludes essentially biological processes but not the products. The Guidelines for examination (July 2016) mention the exclusion of the essentially biological processes but are silent about the products (plant and animals) obtained by an essentially biological process.	No
FI	Finnish Patents Act, No. 550 of December 15, 1967 **Chapter 1, Section 1** as amended 30.6.2000/650 and 18.11.2005/896 **EN Translation** *Anyone who has, in any field of technology, made an invention which is susceptible of industrial application, or his or her successor in title, is entitled, on application, to a patent and thereby to the exclusive right to exploit the invention commercially, in accordance with this Act (18.11.2005/896).* *(…)* *Patents shall not be granted for plant or animal varieties. Inventions which concern plants or animals shall nevertheless be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. The concept of plant variety within the meaning of this Act is defined by Article 5 of Council Regulation (EC) No 2100/94 on Community plant variety rights.* *Patents shall not be granted for essentially biological processes for the production of plants or animals. For the purposes of this Act a process for the production of plants or animals shall be considered essentially biological if it consists entirely of natural phenomena such as crossing or selection. What is said*	Finnish Patents Act excludes from patentability plant or animal varieties and essentially biological processes for the production of plants or animals. There is no legal provision excluding the products derived from essentially biological processes from patentability. The Biotech Directive was implemented to Finnish Patents Act by amendment which entered into force on 30th June 2000. The implementation was done in cooperation with other Nordic countries. Therefore the legislation regulating the patenting of biotechnological inventions is very similar in different Nordic countries.	No

MS	National Law / EN translation	Remarks	Q
	above shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process. For the purposes of this Act 'microbiological process' means any process involving or performed upon or resulting in microbiological material. *Inventions shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. For the purposes of this Act 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.*		
FR	French Intellectual Property Code (CPI) **Art L611-19** **EN Translation** *The following shall not be patentable:* *1° animal varieties;* *2° plant varieties as defined in Article 5 of Regulation (EC) No. 873/2004 introducing new rules governing intellectual property ownership of Community plant variety rights;* *3° essentially biological processes for the production of plants and animals. A process that consists entirely of natural phenomena such as crossing or selection shall be regarded as biological process.* *3° bis Products exclusively obtained by the essentially biological processes defined in 3°, including the elements constituting these products and the genetic information they contain;* *4° Processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit to man or animal, as well as animals resulting from such processes.* *II – Notwithstanding the provisions of I (3°), inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.* *III – The provisions of I (3°) shall be without prejudice to the patentability of inventions which concern a technical process, in particular a microbiological one, or a product obtained by means of such a process; any process involving or resulting in or performed upon a microbiological material shall be regarded as a microbiological process.*	Following the EU Directive N°98/44 of July 6, 1998 on biotech inventions, the French Parliament enacted a law on bioethics on August 6, 2004 (J.O n° 182 of August 7, 2004, which deals with the human body (Article L.611-18 of the French Intellectual Property Code)) and another law on the protection of biotechnological inventions on December 8, 2004 (J.O n° 286 of December 9, 2004, which deals with plants and animals (Article L.611-19 of the French Intellectual Property Code)). The new provisions recognize that biological material (i.e., any material containing genetic information and capable of reproducing itself or being reproduced in a biological system) may be involved in a patentable invention, provided that it can be isolated from its natural environment or produced by means of a technical process and that it complies with the traditional patentability requirements (the invention must be new, involve an inventive step, and be susceptible of industrial applications). **The Biodiversity Law of August 2016** (Law for the recovery of biodiversity, nature and landscape dated August 8, 2016, which entered into force on August 9, 2016) has introduced two amendments into the Code de la propriété intellectuelle (CPI) by **excluding from patentability products exclusively obtained by essentially biological processes** (Article L611-19 3°bis). According to parliamentary discussions during the lawmaking process, this amendment was essentially triggered by decisions G 2/12 (Tomatoes II) and G 2/13 (Broccoli II) of the Enlarged board of appeal of the EPO.	Yes

MS	National Law / EN translation	Remarks	Q
GB	UK Patents Act 1977 **Section 76A and Schedule A2** *76A Biotechnological inventions* *(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.* *(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.* *SCHEDULE A2 BIOTECHNOLOGICAL INVENTIONS* *(…)* *3 The following are not patentable inventions—* *(…)* *(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.* *4 Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.* *11 In this Schedule:* *"essentially biological process" means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;* *(…)*	Section 76A and Schedule A2 of the UK Patent Act excludes from patentability any essential biological process for the production of animals or plants. The UK has no legal provision excluding the products derived from essentially biological processes from patentability.	No
GR	Law No. 1733/87 (FEK 171 A' of 22.09.1987) "Technology transfer, inventions, and technological innovation" as amended by Art 18, of Law No. 1739/1987 (FEK 201, A' of 20.11.1987) **Article 5.8.b** **EN Translation** *Patents shall not be granted in the following cases:* *b. plant or animal varieties or biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.*	The Greek national law "Technology transfer, inventions, technological innovation and establishment of the Commission of Atomic Energy" (number 1733/1987 as in force) contains a provision excluding the varieties of plants and animals from patentability, besides essentially biological and microbiological processes and the products derived therefrom. The products derived from essentially biological processes for the production of plants or animals are not excluded from patentability. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection. Inventions relating to plant (or animal) varieties have patentability, only if the technical feasibility of the invention is not confined to a particular plant (or animal) variety. See presidential Decree 321/2001, the implementation of the EU Directive 98/44 on the legal protection of biotechnological inventions (relevant Art 2 -3).	No
HR	Croatian Patent Act **Art 6.1** **EN Translation** *Excluded from patent protection shall be:* *1. inventions which concern animal breeds, plant varieties and essentially biological processes for the production of plants or animals, with the exception of inventions which concern non-biological and microbiological processes and products resulting from such processes, as provided for in Article 5, paragraph (4) of this Act; a microbiological process shall imply, under this Act, any process involving or performed upon or resulting in micro-biological material.*	*Art 5.4) (…) An invention which concerns plants or animals shall be considered patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety and if the process for carrying out the invention is not essentially biological.*	No

MS	National Law / EN translation	Remarks	Q
HU	Hungarian Patent Act (Act XXXIII of 1995 on the protection of inventions by patents) **Art 6.4.b** **EN Translation** *4. The following shall not be patentable:* *(a) plant varieties [Article 105(a)] and animal breeds;* *(b) essentially biological processes for the production of plants or animals.* *5. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety or animal breed.* *(…)*	Art 6 of the Hungarian Patent Act excludes from patentability only essentially biological processes for the production of plants and animals. Hungary has no legal provision excluding the products derived from essentially biological processes from patentability.	No
IE	Irish Patents Act 1992 **Section 10b** *A patent shall not be granted in respect of (…)* *b) a plant or animal variety or an essentially biological process for the production of plants or animals other than a micro-biological process or the products thereof.*	The Irish Patents Act 1992 at present does not contain provisions which exclude plants and animals exclusively obtained by such processes.	No
IS	Icelandic Patents Act No 17/1991 **Art 1** **EN Translation** *(…) A patent shall not be granted for plant or animal varieties. It is however possible to grant patents for inventions pertaining to plants and animals if the implementation of the patent is not confined for technical reasons to a particular plant or animal variety. In this Act, plant variety refers to a plant variety as it is defined in the Act on Plant Variety Rights, No. 58/2000.* *A patent shall not be granted on an essentially biological process for producing plants or animals. By an essentially biological process, this Act refers to a method that on the whole is based on natural phenomena such as crossing and selection […]"*	The relevant provisions are almost identical to the Danish Patent Act.	No
IT	Italian Industrial Property Code (IIPC) *Decreto Legislativo 10 febbraio 2005, n. 30 Codice della proprieta' industriale, a norma dell'articolo 15 della legge 12 dicembre 2002, n. 273 and further amendments* **Art 45.4.b** **EN Translation** *Patentable subject matter* *(…)* *4. It cannot be a patentable subject-matter* *(…)* *b) plant varieties and animal breeds and essentially biological processes for production of animals or plants, including new plant varieties with respect to which the invention consists only of the genetic modification of another plant variety, even if such modification results from a process of genetic engineering.* *5. The provision of paragraph 4 shall not apply to microbiological processes and products obtained by these processes.* *As to plants or group of plants, Art 81 IIPC recites:* *Art 81-quater Patentability* *1. It can be patentable, subject to fulfilment of novelty, inventive step and industrial applicability requirements:* *(…)*	Plant varieties are clearly excluded from patent protection. Then exclusion of patentability of plants is limited to plants univocally used for the production of plant varieties and obtained solely through essentially biologically processes.	No

MS	National Law / EN translation	Remarks	Q
	e) an invention relating to plants or animals or a plant grouping characterized by the expression of a specific gene and not by its whole genome, provided that their application is not limited, from a technical standpoint, to the obtainment of a particular plant variety or animal species and that they are not obtained by means of essentially biological processes only, (…)		
LI	See under "CH"		No
LT	Lithuanian Patent Law (Law on Patents of 18 January 1994, No. I-372 as changed on: 08 November 1994; 09 and 23 December 1997; 15 June 2000; 21 December 2000; 30 October 2001; 30 June 2005; 08 June 2006; 10 May 2007; 23 December 2010) **Art 5.1 paragraph 2)** **EN Translation** *Patents should not be granted for* *(…)* *2) plant or animal varieties or essentially biological methods for obtaining thereof.* *This provision does not apply to microbiological production methods of plants or animals and to the products obtained by such methods,* ***in case the technical implementation of the invention is not limited to a particular plant or animal variety.***	What is emphasized in bold appeared as from 30/06/2005.	
LU	Loi du 20 juillet 1992 portant modification du régime de brevets d'invention telle que modifiée par la loi du 24 mai 1998 et par la loi du 11 août 2001 et par la loi du 7 avril 2006 et la loi du 25 avril 2008 **Art 5bis** **EN Translation** *1. Not patentable are:* *a) Plant and animal varieties* *b) Essentially biological methods for obtaining plants or animals.* *2. Inventions concerning plants or animals are patentable if the technical implementation of the invention is not limited to a particular plant or animal variety.* *3. Paragraph 1, item b), does not affect the patentability of inventions related to a microbiological method, or to other technical methods, or to a product obtained by such methods.*		No
LV	Patent Law of the Republic of Latvia (in force since 01.03.2007) **Art. 10 (Biotechnological Inventions)** **EN Translation** *1. A patent shall be granted to biotechnological inventions:* *1.1. containing biological material isolated from its natural environment or acquired with the help of a technical method, even if it has been previously met in nature;* *1.2.. pertaining to plants or animals if the technical nature of the invention does not confine itself to some specific plant or animal variety; and* *1.3. pertaining to microbiological or other technical method or a product acquired with such a method if it is not a plant or animal variety.* *2. A patent shall not be granted to plant or animal varieties or to the basically biological methods for the acquisition of plant or animal varieties.*		No

MS	National Law / EN translation	Remarks	Q
MC	Patent law in Monaco N°606 of June 20, 1955	There is no specific provision in the national law that excludes from patentability the plant products directly obtained by using an essentially biological process.	No
MK	Macedonian Law on Industrial Property **Art 26.1** **EN Translation** *A patent may not protect an invention:* *1) which relates to new animal and plant varieties and essentially biological processes for the production of animals or plants, with the exception of biotechnological inventions, for which the technical feasibility is not restricted to a certain type, and microbiological processes and products generated from such processes;* *(…)*		No
MT	Maltese Patents and Designs Act (Cap. 417 Laws of Malta) **Art 4.5** *A patent shall not be granted in respect of: (…)* *e) plant and animal varieties:* *Provided that patents shall not be granted for plant varieties only after a new form of plant variety protection is introduced in such form as may be prescribed:* *Provided further that a patent may still be granted for a plant variety in respect of which a patent application is still pending on the date that a new form of plant variety protection is prescribed;* *(f) essentially biological process of the production of plants or animals:* *Provided that this is without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;* *6. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.* *(…)*		No
NL	Dutch Patent Act 2010 (Rijksoctrooiwet 2010) **Art 3.1.d** **EN Translation** *No patents shall be issued for:* *(…)* *(c) plant or animal varieties,* *(d) essentially biological processes, entirely consisting of natural phenomena such as crossings and selections, for the production of plants or animals as well as the products obtained as a result thereby (…)*	Unlike the EPC and in conflict with the Biotech Directive (98/44 EC), the Dutch Patent Act 2010 excludes from patentability plants or animals produced by essentially biological processes, even if the technical feasibility of the invention is not confined to a particular plant or animal variety	Yes

MS	National Law / EN translation	Remarks	Q
NO	The Norwegian Patents Act, no 9 of December 15, 1967 (last amending Act on July 1, 2013) **Section 1** **EN Translation** *Within any technical field, any person who has made an invention which is susceptible of industrial application, or his successor in title, shall, in accordance with this Act, have the right on application to be granted a patent for the invention and thereby obtain the exclusive right to exploit the invention commercially or operationally.* *Subject matters not regarded as inventions include anything which merely consists of:* *1. discoveries, scientific theories and mathematical methods;* *2. aesthetic creations;* *3. schemes, rules or methods for performing mental acts, playing games or doing business, or programs for computers;* *4. presentations of information.* *Inventions may also constitute patentable inventions when they concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used. Biological material, which is isolated from its natural environment or produced by means of a technical process, may be the subject of an invention even if it already occurs in nature. Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.* *A patent cannot be granted in respect of plant or animal varieties. Inventions that concern plants or animals may, however, be patentable if usage of the patent is not technically limited to one particular plant or animal variety. The King may, by regulation, determine what should be considered a plant or an animal variety.* *A patent cannot be granted for what are essentially biological processes to produce plants or animals. An essentially biological process means, for the purpose of this legal text, a process, which consists entirely of natural phenomena such as crossing or selection. A patent may, on the other hand, be granted for microbiological or other technical processes or for a product produced by such processes. A microbiological process means, for the purpose of this legal text, any process involving, performed upon or resulting in the production of microbiological material.* *A patent shall not be granted for methods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals. This provision shall not prevent the grant of patents for products, including substances and compositions of substances, for use in such methods.*	Products obtained by microbiological or other technical processes are patentable, but the law does not say anything of products obtained by essentially biological processes. Also relevant is the patent regulation's definition of "plant variety"; **Section 88 Definition of plant variety** Under the patent act and regulation a plant variety is understood to be a stock of plant within a single botanical taxon of the lowest rank, which 1. Can be defined on the basis of the characteristics resulting from a given genotype or combination of genotypes, 2. can be distinguished from any other population of plants on the basis of the occurrence of at least one of the said characteristics, and 3. can be considered as a unit with regard to the ability to reproduce unchanged. The existence of characteristics as mentioned in first paragraph no. 1, can be invariable or variable between variety constituent parts of the same kind, provided that the variation level is due to the genotype or combination of genotypes.	No

MS	National Law / EN translation	Remarks	Q
PL	Industrial Property Law (IPL), Act of 30 June 2000 (as amended) **EN Translation** **Art. 29** 1. Patents shall not be granted for: (…) (ii) plant varieties or animal breeds and purely biological processes for the production of plants or animals; this provision does not apply to microbiological production processes or the products obtained by the processes, 2. The process for the production of plants or animals, referred to in Art. 29.1, item ii) is purely biological if it consists entirely of natural phenomena such as crossing or selection.	While essentially (in Polish purely) biological processes for the production of plants varieties or animal breeds are excluded from patentability, there is no explicit exclusion of patentability of products derived from such biological processes. Furtheremore, it is not possible to obtain a patent for a new plant variety or animal breed, irrespective of their production process, i.e. even produced by a microbiological process. According to Article 93[1] of the IPL "microbiological process" means any process involving or performed upon or resulting in microbiological material. As plant varieties or animal breeds are excluded from the patent protection, the processes for production of plant varieties or animal breeds do not protect indirectly products obtained directly by the processes according to Art. 64 of the IPL: **Article 64** A patent granted for a process of manufacture shall also cover products directly obtained by means of that process. However, in accordance with Art. 932 of the IPL biotechnological inventions directed to plants or animals not restricted to a single plant variety or animal breed are patentable: **Art. 93[2]. 1** The following, in particular, shall be considered as biotechnological inventions eligible for granting a patent protection: (…) 3) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety. However, the law does not exclude a possibility of obtaining a patent for processes for the production of new plant varieties or animal breeds (not purely biological), despite the fact that they lead to production of new varieties or breeds.	No
PT	**[Until 30.06.2019]** Portuguese Industrial Property Code (IPC) - (approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April) Art 53.3.b EN Translation Art 53. Limitations regarding patents 3. The following shall also not be the subject matter of a patent: (…) b) Plant or animal varieties, as well as essentially biological processes for the production of plants or animals; (…) Art 54 Special cases of patentability 1.The following shall be patentable: (…) d) An invention concerning plants or animals, if its technical feasibility is not confined to a particular plant or animal variety;	(*)The wording excluding plants and animals exclusively obtained by such processes is present in the new PT law that will entry in force on 01.07.2019. The "*Guide to Procedures concerning Technological Rights*", published by INPI-PT, has not yet been updated to reflect this change in law.	Yes*

MS	National Law / EN translation	Remarks	Q
	e) A biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature; f) An invention concerning a microbiological process or other technical processes, or products obtained by means of such processes. 2. An essentially biological process for the production of plants or animals means any process consisting entirely of natural phenomena such as crossing or selection. (…) **[From 01.07.2019]** Portuguese Industrial Property Code (IPC) - Decree-Law 110/2018 of 10 December 2018) The new Portuguese IP code entering in force on 01.07.2019 will explicitly prohibit the protection for plants or animals exclusively obtained by means of an essentially biological process. Art 52 Limitations regarding patents (…) 3. The following shall also not be the subject matter of a patent: (…) c) Plant and animal varieties and essentially biological processes for obtaining plants or animals, **and plants or animals exclusively obtained by such processes**. (…) Art 53 Special cases of patentability 1.The following shall be patentable: (…) (…) **d) Without prejudice to paragraph b) of paragraph 3** of the preceding article, an invention having as its object vegetable or animal, if its technical feasibility is not confined to a particular plant or animal variety; e) A biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature; f) An invention having as its object a microbiological process or other technical processes, or products obtained by such processes. 2. It is understood by essentially biological process of obtaining plants or animals, any process which consists entirely of natural phenomena, such as crossing or selection.	.	
RO	Romanian Patent Law 64/1991 **Art 9.b** **EN Translation** *Patents shall not be granted under this Law in respect of:* *(…)* *b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or products obtained thereby;* *(…)*	**Art 7.b-c** *Art 7 - A patent shall be granted for any invention having as a subject-matter a product or a process, in all technological fields, provided that it is new, involves an inventive step and is susceptible of industrial application.* *Inventions in the field of biotechnology shall be patentable if they relate to:* *(...)* *b) plants or animals, if the technical feasibility of the invention is not limited to a particular plant variety or animal breed;* *c) a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process.*	No

MS	National Law / EN translation	Remarks	Q
RS	Serbian Patent Law (Issued in "Official Gazette of the Republic of Serbia", no. 99/11, dated December 27th 2011); in force since January 4th, 2012 **Art 9.3** **EN Translation** *Exceptions to Patentability* *A patent shall not be granted in respect of:* *(...)* *3. a plant or animal variety or an essentially biological process for the production of a plant or animal, provided that this provision shall not apply to microbiological processes or the products obtained by means of such process.* *(…)* *Essentially biological process referred to in item 3) of this Article for the production of plants or animals is a process consisting entirely of natural phenomena such as crossing or selection.*		No
SE	The Patents Act (Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014) **Article 1 a** **EN Translation** *Patents are not granted in respect of plant varieties or animal breeds. A patent may, however, be granted in respect of an invention that relates to plants or animals if the technical feasibility of the invention is not confined to a particular plant variety or animal breed. The concept of a plant variety is defined in Chapter 1, Article 3, of the Act on the Protection of Plant Varieties Rights (Act 1997:306).* *Patents shall not be granted in respect of essentially biological processes for the production of plants or animals.* *(…)* *A patent may, however, be granted for an invention that concerns a microbiological process or another technical process or a product obtained by means of such a process.* *(…)* *An invention may be patentable even if it concerns a product consisting of or containing biological material or a process through which biological material is being produced, processed or used. A biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurs in nature.* *(…)* *(Act 2004:159).*	Under Swedish law, there is no provision excluding products derived from essentially biological processes.	No
SI	Intellectual Property Act **Art 16** **EN Translation** *Subject-matter of short-term patent protection* *(1) With the exception of processes, plant varieties and animal breeds, a short-term patent may be granted for inventions which are new, susceptible of industrial application and are the result of a creative effort.*		No

MS	National Law / EN translation	Remarks	Q
SK	Slovak Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act) **Art 6.1** **EN Translation** *Exceptions to patentability* *1. Patents shall not be granted to* *a) plant and animal varieties,* *b) essentially biological processes for creation plants or animals,* *(…)*	*Art 3 Definition of terms* *For purposes of this Act* *(...)* *c) essentially biological process for creation plants or animals shall mean a process based exclusively on natural phenomena such as breeding or selection,* *(...)* *Article 5* *Patentability of inventions* *1. Patents shall be granted for inventions from all fields of technology, which are new, involve inventive activity and are industrially applicable.* *2. Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to (…)* *b) a plant or an animal, if a technical feasibility of an invention is not reduced to a* *particular plant or animal variety (Act No 132/1989 Coll. on Protection of Rights to New Plant and Animal Variety),* *(...)*	No
SM	Industrial Property Consolidation Act of the Republic of San Marino, Law n. 79 of 25 May 2005 **Art 2.4** **EN Translation** *(Subject-matter of the patent and exclusions from patentability)* *4. The following inventions are not patentable:* *(…)* *c) inventions concerning animal varieties or essentially biological processes for the production of animals varieties; this provision shall not apply to microbiological processes and the products thereof;* *(…)* *5. An essentially biological process means a process, which consists entirely of natural phenomena such as crossing or selection.*	The wording excluding plants and animals exclusively obtained by such processes present in DE and NL law is not present in San Marino Act	No
TR	**Industrial Property Law 6769 (Enactment Date:22.12.2016; in force since 10.01.2017)** **Patentable inventions and exceptions to patentability** **Article 82-** (…) (3) Patent shall not be granted for the following inventions: a) Inventions against public order or morality. b) Plant or animal varieties or essentially biological processes for the production of plants or animals, excluding microbiological processes or the products thereof; (…) (5) Microbiological process mentioned in subparagraph (b) of paragraph three means any process involving or performed upon or resulting in microbiological material; essentially biological process means the production of plants or animals consisting entirely of natural phenomena such as crossing or selection. (…)	Articles 82(3)(b-d) and (5) of the new IP Code includes non-patentable biotechnological inventions to bring the law in line with the provisions of the EPC. Concerning the plant varieties, previous law was also excluding the patentability of plant varieties therefore nothing has changed in that matter. Currently there is no National Court decision regarding the patentability of plant varieties.	No

Assessment of Assertions of Synergy as a Basis for Inventive Step in Compositions Comprising Mixtures

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Abstract

Patent claims for inventions predicated on the existence of synergistic action of mixtures are common, yet often the evidence provided on which the assertion of synergy is based is not as compelling as it may first appear. Here we provide guidance to both the professional representative and the patent examiner on points to consider when submitting or assessing evidence for synergy, and make recommendations as to how the credibility of the process could be improved.

Introduction

"Plausibility" has made a firm entry into the patent law vocabulary. Although it seems common sense that a patent applicant needs to show in a credible manner that the invention actually works over the claimed range, the patent examiner seems to be faced with a (legal) problem to translate his doubts about the plausibility of the invention into a substantiated reason to refuse certain claims. Especially in the field of so-called synergistic mixtures, there often seems to be a disproportionality between what has been credibly demonstrated and the extent of the exclusivity granted to the patent applicant. Although case law seems to be shifting towards a more plausible position, some perspectives on data analysis could be of use to patent examiners.

This led to the authors making a presentation to European patent examiners in November 2016 on issues pertinent to the assessment of patent claims for inventions predicated on the existence of synergistic action. This article is essentially a transcript of what was presented.

Many scientific papers have been published on methods for determining the presence of synergistic action. However, this article does not seek to explore the different methodologies in detail. Instead, the intention is to provide guidance to both the professional representative and the patent examiner on points to consider when submitting or assessing evidence for synergy. Although the article has been assembled in the context of mixtures of agrochemicals, the content has broader applicability.

Definition of Synergy

There is some debate as to the precise definition of synergy. A common definition, to be found, for example in the Collins English Dictionary and adopted either explicitly or implicitly in a number of patent cases, is that synergy occurs when the combined action of two or more agents is greater than the sum of their individual effects. (In the context of agrochemical research, the term "agent" would normally refer to a particular substance at a particular dose.) But use of the word "sum" is too rigid and leads to obvious problems e.g. if agent A alone has 60% effect and agent B alone has 70% effect then according to this definition the predicted effect of A+B would be 130%, which is clearly nonsense in most situations. Moreover, while the idea that the predicted effect of a mixture should be equal to the sum of the individual effects might seem intuitively reasonable, the reality is that this would only be the case under a very particular set of circumstances that would rarely, if ever, occur in practice.

A more realistic and scientifically justifiable definition is as follows: synergy is said to occur when the combined action of two or more agents is greater than could have been predicted based on the performance of the agents when used alone.

Demonstrating Synergy

In our opinion, synergy will have been demonstrated if it has been convincingly shown that the performance of a mixture is indeed better than could justifiably have been predicted. This gives rise to two challenges: (i) how to calculate the predicted response, and (ii) how to interpret the difference between observed and predicted responses in the knowledge that both are subject to the effects of random variation.

Deciding How the Predicted Response should be Calculated

There is no single method of deriving predicted responses that is appropriate in all cases. Strictly, the choice of method should be dictated by the researcher's understanding of how the agents in question would be expected to act together in the absence of any synergistic effect. In practice, however, the choice of method often appears to be somewhat arbitrary, with no reference to mode of action (MOA). In fact, many interested parties appear to be unaware that there is a choice at all or appear not to understand the circumstances under which each method is appropriate.

Different methods of calculating predicted responses can sometimes result in very different outcomes. This point is crucial because it means that the interpretation as to whether a particular mixture is synergistic can change depending on

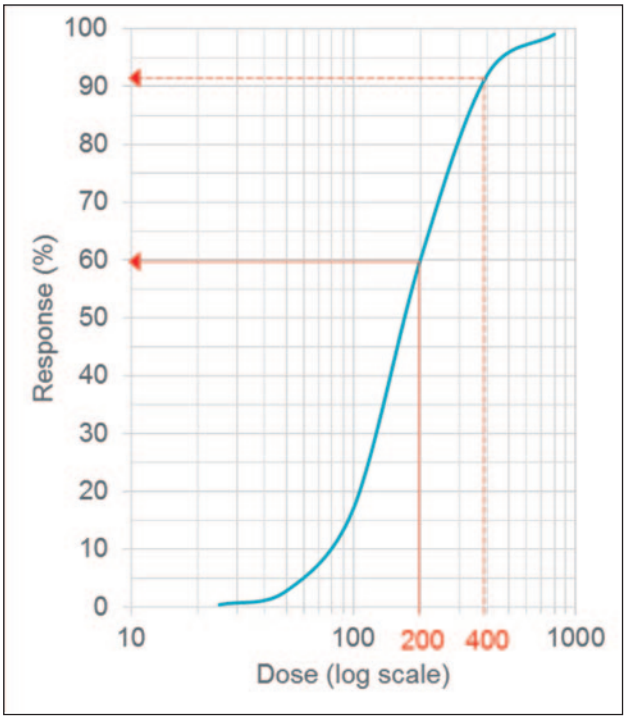
which method is used. The fact that the issues surrounding the choice of method are not widely understood no doubt means that patent applications are sometimes filed in which the observed response to a particular mixture looks somewhat better than the predicted response for no other reason than the latter has been calculated using an inappropriate method. Consider a hypothetical case involving substance S1 at 200g, substance S2 at 200g, and the combination of these two agents, in which both agents alone gave an observed response of 60%. Based on the well-known "Colby"[1] method, the predicted response for a mixture of two agents each giving 60% response is 60 + 60 - 60×60/100 = 84%. But suppose S1 and S2 were actually the same substance; under this scenario, S1 at 200g + S2 at 200g is nothing other than the same substance at 400g, and the likely response to this "mixture" is entirely dependent on the slope of the dose response relationship for the substance in question. With a fairly steep slope as shown in Figure 1a, the likely response to the mixture would be around 92%, which is somewhat bigger than the response predicted using the Colby method and thus implies that the substance in question is synergistic with itself. Conversely, with a fairly shallow slope as shown in Figure 1b, the likely response to the mixture would be around 75%, which is somewhat less than the response predicted using the Colby method and thus implies that the substance in question is antagonistic with itself.

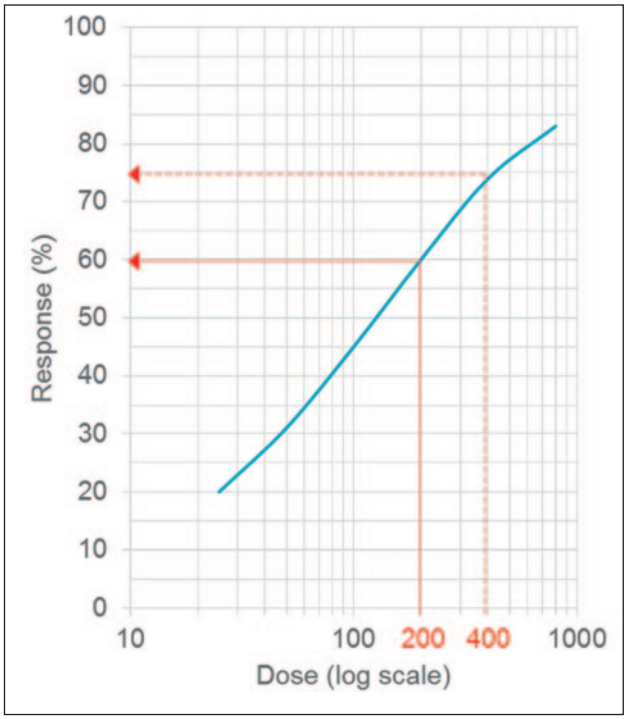
1 Colby, S. R. 1967. Calculating synergistic and antagonistic responses of herbicide combinations. Weeds 15:20–22.
2 Wadley, F.M. (1945). The evidence required to show synergistic action of insecticides and a short cut in analysis. Circ. U.S. Dep Agric. 223.

While this concept is most easily demonstrated by assuming S1 and S2 are the same substance, exactly the same principle applies to any mixture in which one substance essentially behaves like a serial dilution of the other, such that either can be substituted for the other in fixed proportion depending on the relative activities of the substances in question. This might be the case when mixing substances which have the same, or similar, MOA's for example.

To be clear, this is not a criticism of the Colby method per se. The Colby method (which is also variously attributed to Abbott, Bliss, Limpel and others) is, in fact, entirely appropriate in cases where, in the absence of any synergistic effect, the agents are expected to act independently. The problem is that this method is simply not appropriate in other circumstances. In cases where it is reasonable to assume that the MOA of the agents in question are so similar that, in the absence of any synergistic effect, one agent will behave exactly like a simple dilution of the other, an entirely different approach to calculating predicted responses is called for – one that is based on dose response modelling using, for example, methodology advocated by Wadley[2].

The problem of choosing an appropriate method of calculating predicted responses is further exacerbated by the fact that, often, mixture studies are conducted at a time when the researcher may be unaware of the respective MOA of each agent. In these circumstances it might be impossible to identify which method of calculating predicted responses is most appropriate.





Figures 1a and 1b. Likely response at 400g for a substance that gives a response of 60% at 200g, assuming either a steep dose response slope (Figure 1a, left) or a shallow dose response slope (Figure 1b, right).

Taking Into Account the Impact of Random Variation

All biological experiments are impacted by the effects of natural variation. A key consequence of this is that, even if a mixture was neither synergistic nor antagonistic, the observed response would not be expected to be identical to the corresponding (appropriately derived) predicted response. Instead, observed and predicted responses would be expected to differ to some extent, according to the laws of random variation. In practice, this means that there is a 50% chance that the observed response to any given mixture will be numerically greater than its predicted response simply due to random variation alone. Of course, in such cases the magnitude of the difference between observed and predicted responses may be relatively small but this does not necessarily preclude an assertion of synergy from being made, or a patent predicated on such an assertion from being granted.

Disclosures of synergy rarely include enough detail of the experimental design and levels of underlying variation to allow the reader (even one with high level statistical expertise) to estimate what size of deviation between observed and predicted responses could be expected simply due to random variation alone. Moreover, given all of the factors that can vary between one dataset and another such as the nature of the recorded response and the level of replication, it is impossible to come up with a "rule of thumb" in this respect. But having said this, in the absence of convincing evidence to the contrary, it is reasonable to assume that the size of deviation attributable to random variation alone could be quite large, and assertions of synergy based on relatively small differences between observed and predicted responses should be interpreted with this in mind. This concern applies regardless of the method of estimating predicted responses.

It could be argued that any assertions of synergy should be backed up with an appropriate statistical test – one that assesses the probability of obtaining a difference between observed and predicted responses of an equal or greater magnitude to that presented simply due to random variation alone. In practice, however, standard statistical tests are rarely appropriate for synergy studies, and deriving a bespoke test that takes proper account of all relevant sources of random variation is in most cases far from straightforward. Also, the structure of the statistical test itself would need to vary from one case to another depending on issues such as the precise experimental design and the nature of the response. While some scientific papers relating to synergy include statistical tests, no particular test is widely accepted by the scientific community. Moreover, at least some of the tests discussed in the published literature have subsequently been shown to be flawed. There are exceptions. For example, if two agents are to be mixed and it is known that only one shows activity when used alone, the question can be simplified to "is A+B better than A alone", in which case it is possible to design a study in such a way that the resulting data can be analysed using standard statistical methodology. (Although some would argue that the concept of synergy does not apply in cases where only one agent shows activity when used alone.) But in general, reliance on a statistical test does not seem to be a viable way forward.

Cherry Picking of Results

Often, the design of a synergy study will include an entire matrix of different treatments (e.g. five doses of substance X and four doses of substance Y plus all possible combinations). Under this scenario, if there was in reality no synergy and no antagonism whatsoever, we would expect around half the mixtures to have an observed response that is numerically greater than their respective predicted response, and half to have an observed response that is numerically less. If this were indeed the case then by looking at the entire set of results it should be apparent that the deviations between observed and predicted responses are no different to what we might reasonably expect by chance. But if the applicant chose to submit only those results which showed the biggest deviation in the positive direction, the evidence for there being a synergistic response would appear more compelling than was actually the case. Such "cherry-picking" of results is therefore misleading and disclosure of all relevant results should be encouraged.

Mixture	Observed Response	Predicted Response	Observed - Predicted
X at 100ppm + Y at 10ppm	76.0	45.2	30.8
X at 200ppm + Y at 20ppm	73.2	61.1	12.1
X at 400ppm + Y at 10ppm	84.3	74.1	10.2

Table 1a. Results as might be submitted in support of a synergy claim

Substance Y	Substance X					
	0	25ppm	50ppm	100ppm	200ppm	400ppm
0		20.0	31.0	45.0	60.0	74.0
10ppm	0.4	18.0, *20.3* -2.3	29.1, *31.3* -2.2	**76.0, *45.2* 30.8**	63.2, *60.2* 3.0	**84.3, *74.1* 10.2**
20ppm	2.8	30.8, *22.2* 8.6	39.2, *32.9* 6.3	16.7, *46.5* -29.8	**73.2, *61.1* 12.1**	65.7, *74.7* -9.0
40ppm	17.0	23.3, *33.6* -10.3	47.0, *42.7* 4.3	41.1, *54.4* -13.3	54.0, *66.8* -12.8	81.8, *78.4* 3.4
80ppm	60.0	74.4, *68.0* 6.4	74.6, *72.4* 2.2	73.2, *78.0* -4.8	87.9, *84.0* 3.9	87.5, *89.6* -2.1

Table 1b. Full Results. Responses are in percentages. For mixture treatments, table shows observed response, predicted response (in italics) and difference between observed and predicted. Cherry-picked results corresponding to Table 1a shown in bold font.

How Independent are the Results?

In cases where multiple results have been submitted, it is important to take into account the extent to which different results are truly independent from one another. In many synergy studies, the data generated for any given agent when used alone contributes to the calculation of predicted responses for a number of different mixtures, and so if the response to a particular agent happens to be somewhat lower than expected this could result in all of the corresponding mixtures appearing to be better than predicted. An example of this is shown in Table 2.

Substance Y	Substance X				
	0	25ppm	50ppm	100ppm	200ppm
0		20.3	31.0	44.9	61.2
10ppm	19.5	30.4, *35.8* -5.4	42.0, *44.5* -2.5	68.5, *55.6* 12.9	68.2, *68.8* -0.6
20ppm	40.8	61.5, *52.8* 8.7	64.4, *59.2* 5.2	48.3, *67.4* -19.1	83.7, *77.0* 6.7
40ppm	**33.5**	65.2, *47.0* 18.2	74.2, *54.1* 20.1	74.9, *63.4* 11.5	84.9, *74.2* 10.7
80ppm	81.2	87.8, *85.0* 2.8	85.7, *87.0* -1.3	87.2, *89.6* -2.4	94.0, *92.7* 1.3

Table 2. Responses are in percentages. For mixture treatments, table shows observed response, predicted response (in italics) and difference between observed and predicted. Note response for substance Y alone at 40ppm is much lower than would be expected based on the results of the other three doses, resulting in inaccurate predicted responses which in turn leads to the false impression that all four mixtures involving substance Y at 40ppm are synergistic.

Generality

If synergy between two (or more) substances does indeed exist, then it is probable that the synergistic relationship is specific to certain doses or, more likely, to certain ratios of doses. So, if synergy has been convincingly demonstrated for a single mixture (e.g. substance X at 50g + substance Y at 10g), it is not clear how broad a claim this one result should allow. In order to substantiate an assertion that an entire specific ratio of doses, say 5:1, of the substances in question is synergistic it does not seem unreasonable to expect the applicant to submit data demonstrating a consistent synergistic effect at several different dose combinations in the same 5:1 ratio. Similarly, to justify a claim covering a range of ratios, it does not seem unreasonable to expect the applicant to submit data demonstrating synergistic effects at or across those different ratios. Extending a patent claim to cover doses and/or ratios far outside the range for which synergy has been demonstrated is difficult to justify.

Synergy Factors

Often, results of synergy studies are presented in terms of "synergy factors", calculated as the ratio of observed response to predicted response. If, for a given mixture, the observed response is identical to the predicted response this would result in a synergy factor of 1, while any factor greater than one would typically be presented as evidence of synergy. There are two concerns here. Firstly, factors close to 1 might deviate from 1 simply due to the effects of random variation (as explained earlier). Secondly, such ratios inadvertently give more emphasis to results at the low end of the response range than at the high end. For example, if the observed response = 30% and the predicted response = 20% then the difference of 10% equates to a synergy factor of 1.5, whereas if the observed response = 90% and the predicted response = 80% then the difference of 10% equates to a synergy factor of 1.125. Moreover, such factors can become very unstable when the predicted response is very low, and of course they make no sense at all if the predicted response is zero.

Conclusions

Currently, the standard of patent claims which cover an invention predicated on the synergistic action of mixtures of agrochemicals is of variable scientific quality, which in itself is not surprising given there are no guidelines in this respect. Moreover, the complexities of the science are such that it can be difficult for the examiner to critically assess the data and arguments provided by the applicant in support of those claims. Together, these factors undermine the credibility of the process. Although the complexities will not go away, the credibility of the process could be improved if the following three recommendations were adhered to:

1. the method of calculating predicted responses should be justified and should be based on the applicant's understanding of how the agents in question would be expected to act together in the absence of any synergistic effect;

2. observed and predicted responses are expected to deviate to some extent simply due to the effects of random variation, and synergy-based inventions should be assessed with this in mind, especially in cases where differences are small and/or inconsistent;

3. the practice of "cherry-picking" of results should be discouraged and, instead, disclosure of all relevant results should be seen as the norm.

Monoclonal Antibodies and Sequence Identity: what's the EPO's Practice?

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Abstract

Since the first marketing authorization for a monoclonal antibody (Mab) in the 1980s, the patent system has never stopped adding the fuel of interest to the fire of ingenuity in the field of monoclonal antibodies (Mabs).
In view of the ever-increasing pace of technological progress in this highly competitive environment, patent applications are often filed at the stage of Mab "prototypes", before any product is available that could be further developed. Patent claims have naturally adapted to this practice in order to attempt to protect not only the Mab « prototypes » but also downstream developments, and in particular the lead antibody that will ultimately be put on the market, as well as Mabs inspired by and unreasonably close to the lead Mab.
In this context, claims based on sequence identity are often sought after by applicants although they may not be accepted by the European Patent Office (EPO). EPO practice concerning Mab sequence identity cases appears rather variable, all the more so given that there is no official guideline in this area. A journey through Board of Appeal decisions and examination files nonetheless enables certain conclusions to be drawn in order for Applicants to be in a better position to handle examination proceedings.

Introduction

The commercial development of monoclonal antibodies (Mabs) began in the 1980s, with the marketing authorization in 1986 of the first monoclonal antibody (Mab): Muromonab. It was only at the end of the 1990s, with the arrival of chimeric Mabs, such as the famous Rituximab in 1997, that the Mab market really took off, and in 2017 it was worth more than 100 billion dollars[1].
The success of Mab development is closely linked to the patent system because of the many innovations in this feld and the high expenditure on Research and Development (R&D) necessary to obtain marketing authorization for a Mab. Spending on R&D usually exceeds one billion dollars for each new Mab[2,3]. Patents play their full role in this context by stimulating funding in the field of Mabs and by providing investors with a return on their investment.

When the question of filing a patent application arises for a Mab, it is therefore important to know when to file, what is the best scope of protection and how to anticipate the evolution of the Mab (planned or not). The consequences of haphazard drafting can be catastrophic, to the point of deterring investors in the event that the claims no longer cover the product under development or if they cannot prevent a third party from developing a Mab unreasonably close or similar to the developed Mab.

How can we patent a Mab in Europe?

The European Patent Office (EPO) accepts two main ways to patent a Mab.

The first way consists in protecting the Mab via so-called « functional » claims. There claims are usually focused on the target and its interaction with the Mab. The scope of functional claims can be very broad since it extends to all Mabs having the claimed functional features. These claims are commonly sought and usually accepted by the EPO when a new target is identified (T735/00), or when the target is already known but the Mab was difficult to obtain (T0187/04) or when the Mab has an unexpected property.
Unexpected properties that can be found in the functional claims are often supported by a characterization of the target, such as the epitope recognized, or by the nature of the interaction between the Mab and its target, such as affinity (e.g. Kd/Ka) or the effect of the Mab on its target (e.g. agonistic/antagonistic effect). Functional claims can also be based on the property of a Mab to compete with a reference Mab, which amounts to indirectly characterizing the epitope recognized and affinity thereto.
Functional claims can be in the following forms:

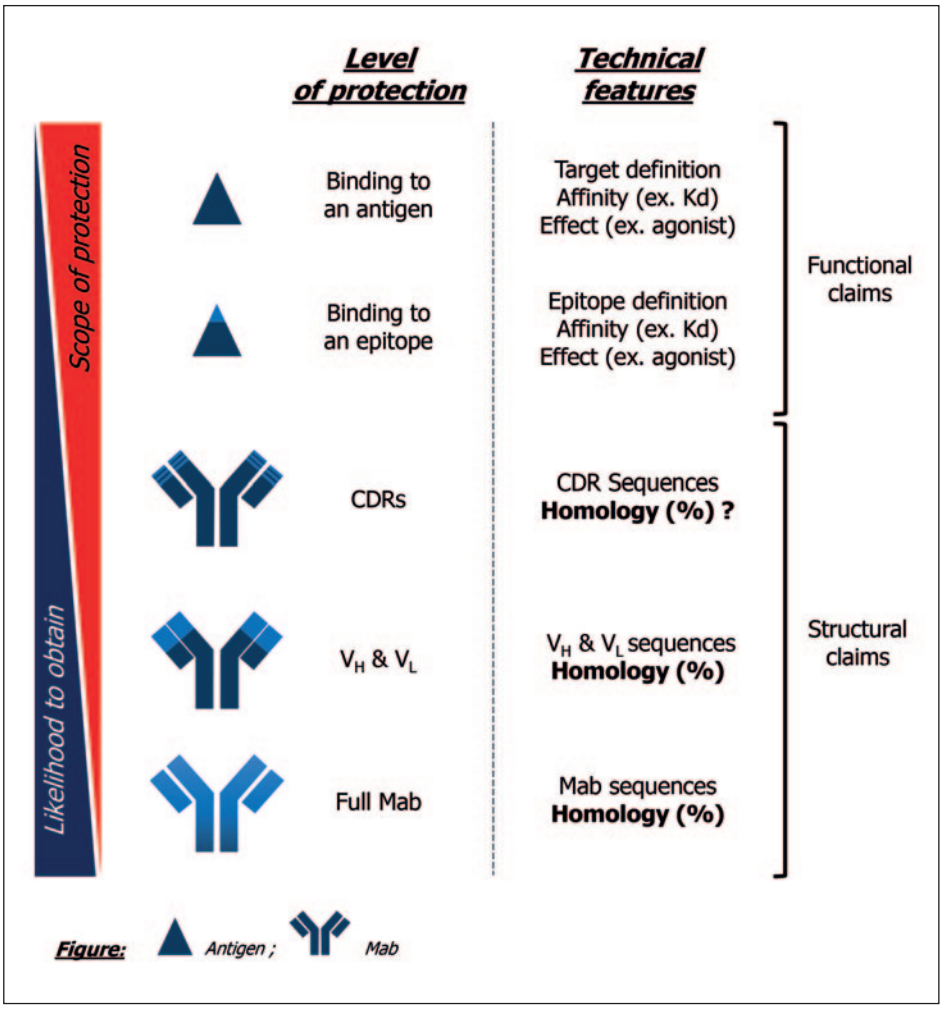
"Antibody that binds specifically to antigen X"
"Antibody that binds specifically to peptide Y within antigen X"
"Antibody that binds specifically to antigen X with a Kd < Z"

The second way to patent a Mab is based on so-called "structural" claims that seek to define the Mab as such, usually via its sequences. The EPO considers that the sequence claims must at least specify the sequence of the 6 CDRs (Complementarity-Determining Regions) involved in the interaction with the target. According to

1 Global Monoclonal Antibodies Market Hit $100 Billion in 2017: Report - https://www.prnewswire.com/news-releases/global-monoclonal-antibodies-market-hit-100-billion-in-2017-report-300599684.html
2 DiMasi et al., Innovation in the pharmaceutical industry : new estimated of R&D costs, Journal of Health Economics, 2016
3 DiMasi et al., The cost of biopharmaceutical R&D: is biotech different?, Manage. Decis. Econ., 2007

the EPO, the 6 CDRs are necessary to obtain the claimed technical effect for the entire Mab and so to meet the requirements of inventive step (Article 56 EPC). However, there are exceptions such as single domain antibodies "sdAb" for which inventive step can be acknowledged if experimental data are provided (T0617/07).
The scope of sequence claims is usually narrower than functional claims because they are limited to one Mab having specific sequences. Structural claims can be in the following forms:

"Antibody that binds specifically to antigen X comprising a heavy chain of SEQ ID NO : 1 and a light chain of SEQ ID NO : 2"



The Figure summarizes the main ways to patent a Mab in Europe.

The choice of the type of claims and the drafting thereof are of great importance.

It is essential to clearly delineate the scope of protection in order to strike the right balance between overly restrictive structural claims and overly broad functional claims. In this context, it may be wise to opt for claims based on sequence identities. However, this seemingly simple strategy is not infallible before the EPO.

Sequence identity

Although regularly used in claims by Applicants for decades, sequence identities are, in a growing number of cases, not accepted by the EPO as the appropriate defining feature of the claims. The reasons for refusing the application may be multiple but are usually based on Article 83 EPC (disclosure of the invention) or Article 56 EPC (inventive step). The Examiners can for example consider that any modification of the Mab sequences can change the specificity, and consequently that Mabs having homologous sequences may lose all recognition capability for the target.
Nevertheless, European examination files appear very heterogeneous and Mabs patents claiming sequence identity are regularly granted. It is sometimes difficult to explain this heterogeneity as the EPO has not published any official guideline on this subject. A journey through Board of Appeal decisions and examination files nonetheless enables us to have some ideas on how to proceed to protect Mabs with claims based on sequence identity.

Sequence identity *stricto sensu*

In general, the CDRs are intangible for the EPO, which considers that the slightest modification of the CDRs can affect the recognition of the target. Thus, a claim directed only at sequence identity of CDRs is usually not allowed in Europe. However, claims mentioning a degree of identity applied to a region broader than the CDRs, such as the variable region or the heavy/light chain, and specifying that the degree of identity does not apply to CDR sequences, are usually allowed by the EPO. Such claims may be drafted as follows:

"Antibody that binds specifically to antigen X comprising a heavy chain having at least 90% amino acid identity to SEQ ID NO : 1 and a light chain having at least 90% amino acid identity to SEQ ID NO : 2, wherein CDR1 of the heavy chain consisting of the amino acid sequence of SEQ ID NO : 3, CDR2 of the heavy chain consisting of the amino acid sequence of SEQ ID NO : 4, CDR3 of the heavy chain consisting of the amino acid sequence of SEQ ID NO : 5, CDR1 of the light chain consisting of the

amino acid sequence of SEQ ID NO : 6, CDR2 of the light chain consisting of the amino acid sequence of SEQ ID NO : 7 and CDR3 of the light chain consisting of the amino acid sequence of SEQ ID NO : 8."

This type of claim has been accepted in several examination files (ex. EP2630160, granted in 2016) but also by the Board of Appeal in the decision T 0516/11.

It is interesting to note that some Examiners have agreed to issue claims based on a sequence identity applied to a larger region than the CDRs without specifying that the identity does not apply to CDRs. This is the case, for example, of patent EP2320940 issued in 2015, drafted in the following form:

"Antibody that binds to antigen X, wherein the antibody comprises a heavy chain variable region sequence having at least 95% amino acid sequence identity to SEQ ID NO: 1 and a light chain variable region sequence having at least 95% amino acid sequence identity to SEQ ID NO: 2."

However, patents granted with this type of claim are uncommon because the Examiners have a tendency to challenge inventive step by considering that it is not guaranteed that Mabs presenting a CDR sequence homology are indeed able to bind to the target.

Sequence identity and functional features

In decision T2101/09, the Board of Appeal recognized that it might be necessary to further limit the scope of a claim referring to a functional feature.

Thus, many patents are granted with claims associating a certain degree of sequence identity with a Kd value (EP1639092, granted in 2016), epitope recognized (EP2219672, granted in 2016) and/or the effect of the Mab on its target (EP2418220 and EP2486941, granted in 2017).

This strategy is particularly relevant because the EPO requires that claimed Mabs have an "*unexpected property*" in order to recognize inventive step. Functional features that are linked to a degree of identity can therefore also be useful to defend inventive step. It should nevertheless be ensured that the application satisfies the requirements of Article 83 EPC so that the skilled person may achieve Mabs with the desired function on the basis of a particular known antibody and also weed out non-functional variants without undue burden (T617/07).

What degree of identity can be expected?

There is no guideline from the EPO regarding the acceptable degree of identity. In the decision T2101/09, the Board of Appeal observes that it is sometimes necessary to further limit the scope of a claim by increasing the degree of identity, but without specifying the criteria that must be taken into account in determining this degree of identity.

Thus, the degree of homology/identity accepted depends on the relevant prior art and the particular circumstances of each individual case (a general principle recalled in T2101/09). The lower the degree of identity claimed, the more likely it is that the EPO considers that the claim does not address the technical problem (Article 56 EPC) or that the skilled person cannot perform the invention over the whole area claimed without undue burden (Article 83 EPC).
In general, the sequence identity that is commonly observed in granted claims is at least equal to 90%.

Conclusion

The history of Mabs, which are the most fruitful medicinal products of the last decade for the biotech industry, is closely linked to the patent system since their emergence in the 1980s.

In the field of Mabs, the use of sequence identity is widespread when it comes to claiming Mab sequences. However, European practice for issuing sequence identity claims appears to be very heterogeneous and it is sometimes difficult to know what is acceptable or not for the EPO. A journey through Board of Appeal decisions and examination files provides some lessons in the practice of the EPO.

Firstly, CDRs are intangible for the EPO: a claim focused on a degree of identity of CDR sequences is generally not allowed in Europe. However, two main forms of claims seem to be accepted by the EPO. The first form consists in applying the degree of identity to a region broader than the CDRs while specifying that said degree of identity does not apply to CDR sequences. The second form consists in associating the degree of identity with a functional feature. This strategy can be particularly useful when the functional characteristic is a reflection of an "unexpected property" that justifies inventive step.

Thus, it is recommended to define the degree of identity in different ways and to provide fallback positions to combine degree of identity with functional features. It is nevertheless necessary to ensure that all the combinations contemplated have direct and unambiguous support in the original application to satisfy the requirements of Article 123(2) EPC.

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FICPI Position on Patent Law Harmonisation

M. Caine, J. Collin, P. Mendes da Costa, J. Modin

FICPI was invited to a recent B+ Sub-Group meeting on 26 September 2018 to present its position on the three main patent law harmonisation topics currently under consideration: grace period, prior user rights, and conflicting applications. The presentation given by FICPI at this meeting can be found at https://www.ficpi.org.

In June, 2018 FICPI passed a resolution on conflicting applications and adopted an extensive position paper on these key harmonisation topics.

This article provides a brief background to FICPI's consideration of these topics and summarises the positions reached.

Background

A constructive dialogue between patent law practitioners and users from various jurisdictions is of great importance to the international IP system. Such discussions facilitate an understanding of various national or regional systems and can be of great assistance in finding common ground for harmonisation. The Patent Law Treaty (PLT) made significant progress on harmonising procedural aspects encountered in securing patent protection. While WIPO carried out work for a number of years on harmonising substantial patent law after the signing of the PLT, these efforts failed to achieve any harmonised positions. Group B+ is now taking steps to move forward with substantive patent law harmonisation within the dedicated B+ Sub-Group.

Grace period, prior user rights and conflicting applications have been identified as key topics that are linked together. These topics have been discussed for some years now within Group B+. Within this forum it has been recognised that by balancing the metes and bounds of a grace period, prior user rights and conflicting applications, a potential "harmonisation package" could be developed. This would be a substantial step forward on the road to substantive patent law harmonisation.

FICPI, one of the major international IP organisations, has studied key aspects of substantive patent law harmonisation for many years. With practitioners representing 86 countries and regions around the world, FICPI members represent a diverse range of experiences and possess deep knowledge of the business needs of the IP system (both users of the system as well as intellectual property offices which effectively administer the system). FICPI members represent clients ranging from individuals and SMEs to multi-national industries, as well as universities, governmental and non-governmental organisations and other institutions. By drawing on the learning of this broad range of professionals, FICPI is able to speak in support of an IP system that is fair and balanced for all who are affected by IP rights, including IP owners and third parties.

Over the years, FICPI has carried out an ongoing analysis of the grace period and related harmonisation topics. More recently, a FICPI working group was assembled to study the harmonisation issues raised by the B+ Sub-Group. A core working group was established consisting of members from eleven countries (Australia, Brazil, Canada, China, France, Germany, Israel, Japan, Sweden, the United Kingdom and the United States). Beyond this core group, extensive discussions within FICPI led to consensus at the last Executive Committee in Toronto in June 2018, and adoption of a comprehensive position paper (see FICPI Position on Patent Law Harmonisation).

Guiding principles

In reaching its position, FICPI considered that a well-balanced harmonisation package should:

- be relatively simple and easy to understand;
- be based on well-established principles of patent law; and,
- strike an appropriate balance between the interests of different kinds of users of the patent system (large and small entities, as well as individuals, all of whom can in different situations be applicants, third parties or the general public).

FICPI's work was guided by the following principles:

- A first applicant and a second applicant, claiming similar subject matter and facing the same prior art, should both be entitled to patent protection as long as they do not claim exactly the same subject matter (double patenting should be avoided) – the second applicant should not lose out completely just because he filed second.

- For a reasonable period of time, applicants who disclose their invention before filing a patent application still deserve a patent as long as their invention is patentable in relation to the rest of the prior art (i.e. except for the their own pre-filing disclosure) and nobody else has independently disclosed the invention before the priority or filing date.

- Prior user rights should be recognised for third parties who have started commercial use, or have made significant preparations for such use, before the filing date of the patent application, even if such use originates from the applicant's pre-filing disclosure.

- Inventors should be encouraged to file a patent application as soon as possible after making a patentable invention in the interest of third parties and the public at large.

- Consistent with a first-to-file system, prior art that is used for an assessment of novelty and inventive step should only include information that has been made available to the public prior to the filing or priority date of a patent application, i.e. there should be no "secret prior art".

- A "first-to-disclose" system should be avoided.

With these principles in mind, FICPI developed its position on the three components of a possible harmonisation package: grace period, prior user rights and conflicting applications.

Grace period

FICPI has repeated its long-standing support for a well-balanced grace period. The most recent and comprehensive statement of FICPI's position on grace periods can be found in 2013's White Paper on Grace period, and this is further discussed in a 2016 Briefing Paper on Grace Period.

In short, FICPI considers that key features of a grace period should be:

- a term of 12 months running up to the priority date or filing date (FICPI recognises good arguments for both alternatives);

- disclosures to be "graced" may take any mode of disclosure by the inventor or derived from the inventor's disclosure by a third party. (Independent disclosures by third parties before the filing date of a patent application should not be graced);

- a pre-filing disclosure made by an inventor should not constitute a quasi-priority right in relation to third party disclosures;

- third parties may acquire prior user rights irrespective of a disclosure made by the inventor before the filing date but within the grace period, provided that all other criteria for obtaining prior user rights are met. This should contribute to limiting the effect of the grace period to a "safety net" and incentivise those who disclose an invention to file a patent application as soon as possible thereafter;

- any declaration or statement to invoke a grace period should not be mandatory at the time of filing a patent application. On the other hand, FICPI would not be opposed to a system that affords applicants an opportunity to make a voluntary statement giving details of pre-filing disclosures to obtain certain advantages. For example, after the filing of a voluntary statement, there could be a presumption that a pre-filing disclosure mentioned in the statement is to be excluded from the prior art when assessing novelty and inventive step unless and until a third party proves otherwise;

- in order to afford further transparency, FICPI also proposes that Patent Offices should give notice of new patent applications to the public ("public filing notice") no later than, say, 6 months after the filing date. Such notice would provide bibliographic data of the application including details of any priority claim and any voluntary statement concerning a pre-filing disclosure.

Prior user rights

Prior user rights are seen by FICPI as an important component for balancing the effect of a grace period according to the concept that the grace period is a "safety net" for applicants and nothing more.

According to FICPI's position, prior user rights should be acknowledged for a party ("prior user") despite the existence of a patent or patent application owned by another party (a patentee/applicant) if:

1) the prior user legitimately started commercial use or had made significant preparations for such use before the priority date of the other party's patent application, even where the other party, relying on the grace period , had already publicly disclosed the invention before the priority date, provided that at least one of the conditions

2a, 2b or 2c below is also met:

2a) the prior user conceived the invention independently of the patentee/applicant;

2b) the prior user exploited the invention based on knowledge that was in the public domain at the time the prior user started commercial use or had completed significant preparations for such use;
2c) the prior user had obtained knowledge of the invention from the patentee/applicant and begun the prior use with the explicit or implicit consent of the patentee/applicant ("implied licence"), there being no abuse in relation to the latter, and in particular no contractual or implicit requirement for the prior user to refrain from using the invention or from disclosing it to third parties or to the public. (Conversely, prior user rights should not be recognised in situations where a prior user began exploitation of an invention on the basis of information derived from the applicant that was not in the public domain and without the applicant's consent.)

Other details of FICPI's position on Prior user rights are described in a 2015 FICPI White Paper on Prior user rights.

Conflicting applications

In its resolution of June 2018 FICPI supported a "Whole of Contents Novelty" (WCN) approach for determining the relationship between an earlier and later filed applications, where the later application is filed before the earlier one has been published.

In situations where an earlier filed patent application is unpublished at the time of filing of a later patent application, there is a possible conflict between the two applications. Resolving such a conflict is critical not only in determining which applicant has the better right to a patent for the invention, but also is in the public interest in avoiding double-patenting, i.e. two different patents protecting exactly the same subject matter. This type of conflict has been treated differently over the years by various the patent systems and a brief recap of the historical development of patent law on this issue might be of assistance in appreciating how FICPI reached its position.

In the UK, before 1883, patents were awarded to first person to achieve grant. Once a first patent had been granted, another patent for the same invention could not be granted, even to an applicant who had filed his application earlier. A system of "Prior Claiming" was thus devised to avoid this inequitable situation. Prior Claiming acknowledged that both first and second applicants had made inventions over the prior art and were equally entitled to a patent, subject to the need to avoid double patenting. Prior Claiming efficiently avoided double patenting by giving precedence to the earlier filed application thereby preventing the later applicant from securing claims to subject matter claimed in the patent granted on the earlier filed application. However, an intrinsic problem with the Prior Claiming approach was that examination of the later application could not be concluded until the fate of the claims of the earlier application was known.

To overcome this problem, the WCN approach was adopted in the European Patent Convention (EPC) in 1977 (which started to operate in 1978). WCN effectively required the later claims to exclude all subject matter that could potentially be claimed in the earlier application. This is achieved by **deeming** all of the contents of the earlier application to form part of the state of the art in relation to an application that is filed later but before the first is published, and applying the novelty test.

It is important to appreciate that under this approach, the contents of the earlier application are not actually part of the state of the art for the purpose of novelty or inventive step, but they are "considered" to be comprised within the state of the art to avoid double patenting. This is reflected in the wording of Article 54(3) EPC. It is also confirmed by the Travaux Préparatoires of the EPC Diplomatic Conference:

"The problem which Article 52 [54], paragraph 3, sets out to cover does not relate to the assessment of novelty but to a conflict between two applications; it is as such that it should be dealt with".[1]

WCN is therefore a test to identify subject matter that should be "subtracted" from the claims of the later application in order to avoid double patenting. WCN is not a true novelty test over traditional "prior art". The earlier, unpublished application is not true prior art in the sense that it has been made available to the public – it is considered to be part of the state of the art purely for the purposes of applying the subtraction called for by WCN.

When considering the problem of conflicting applications, the notion of "distance" between an earlier unpublished application and the claims of a later application has been discussed within the B+ Sub-Group. Such "distance" would arguably define a standard applicable for determining the patentability of the claims of a later filed application in view of the contents of an earlier filed application that is unpublished at the time of the later filing. FICPI notes however that any definition of such "distance" would encounter serious difficulties: what "distance" should be used? How should it be defined? Should this "distance" be a new standard?

FICPI also notes that with WCN there is no need for any "distance" or gap (beyond novelty) between an earlier

1 See Comments on the preparatory documents to the Travaux réparatoires to the EPC, Art. 54

and later applications. By applying WCN, double patenting is successfully avoided without the need for additional "distance" between the disclosure of the earlier application and the claims of the later one.

FICPI views WCN favourably as a simple yet efficient solution for avoiding double patenting, which moreover provides:

- equal rights to early and later filers when assessing novelty and inventive step over the state of the art;
- no need for anti-self-collision provisions;
- no need for terminal disclaimers;
- a solid predictable system that has been tested in practice (EPC) for some 40 years.

FICPI's position is explained in detail in its 2018 Resolution on Conflicting applications, and a full explanation with a historical perspective of "secret" prior art can be found in an article by Michael Caine : "The problem with secret prior art".

Conclusions : FICPI's proposal for a package solution for substantive patent law harmonisation

FICPI proposes a straightforward package solution which fairly balances the interests of different stakeholders in the patent system as follows:

- A Grace period which is a safety-net for applicants, as detailed in FICPI's 2013 White Paper on Grace period and 2016's Briefing Paper on Grace Period, that gives applicants the possibility of filing a voluntary statement of pre-filing disclosures and involves Patent Offices publishing basic details of new patent applications within 6 months of their filing date. Such a regime would strike an appropriate balance between the competing interests of different stakeholders and will provide an incentive for inventors to file patent applications promptly after a pre-filing disclosure, thereby limiting the period of uncertainty for third parties to an acceptable level. A pre-filing disclosure should not give rise to any priority-type rights in relation to disclosures made by others.
- Prior user rights as described in FICPI's 2015 White Paper on Prior user rights. Prior user rights should be available to third parties who have independently made an invention or acquired knowledge of an invention in a legitimate way from the inventor within a qualifying period running up the filing date or priority date of the patent application.
- A whole of contents approach to the treatment of conflicting applications as described in FICPI's 2018 Resolution on Conflicting applications and summarised above.

FICPI looks forward to a continued participation and related discussions in the process of developing a harmonised, well-balanced global patent system.

Patenting Emerging Computing Technologies before the EPO – 20 Decisions You Should Have Heard Of

M. M. Fischer (DE)

Emerging computing technologies, such as Artificial Intelligence[1] (AI), Machine Learning (ML), Blockchain Technology, Big Data, Self-Driving Vehicles (SDV) have become a "hot topic" within – but of course also well beyond – the patent community. The EPO with its well-established and stable jurisdiction regarding computer-implemented inventions (CII) and its ambition to be the worldwide benchmark in patenting CII has placed special emphasis on patenting emerging computing technologies by, for example, organizing conferences on patenting AI and Blockchain Technology. It updated its Guidelines for Examination to provide more guidance on the patentability of CII in general and inventions in the field of AI, Machine Learning, Big Data, etc. in particular (see sections F-IV, 3.9.3; G-II, 3.3, 3.3.1, 3.3.2 etc.) and has published a study on Self-Driving Vehicles. The following article explicitly does not want to dwell on the basics of patenting CII, such as the COMVIK approach, but intends to shed light on a compilation of decisions that may be helpful in arguing why an invention is patentable or not before the EPO. Although some of the emerging

1 The term "Artificial Intelligence" was coined in 1956 by John McCarthy at the Dartmouth Conference which is considered by many as the birth of AI as a research field. The field did not grow organically and had to cope with setbacks. Since AI could not hold the enthusiastic promises it initially made, the field entered into a depression at least twice (called "AI winters") – periods during which AI research did not get a lot of funding and research facilities were closed down. Possibly, the current boom period should therefore also be regarded in a realistic manner against this backdrop.

computing technologies mentioned above are not entirely new, their large-scale industrial application and thus their relevance for the field of Intellectual Property has only recently become the focus of attention[2]. While there are not so many decisions by the Boards of Appeal in these fields yet, the principles set out in the following decisions may be applied or extrapolated thereto and may thus assist in drafting, prosecuting and opposing future patent applications/patents before the EPO.

The Decisions

In the first section, I will discuss decisions that give guidance on how to deal with mathematical/algorithmic features in the claims. In the second section, I will present a selection of decisions relating to inventions from different technical fields some of which are patentable and some of which are not. The third section deals with user interaction and user interfaces, while the fourth section deals with decisions that rely upon the concept of a notional business person and make a rigorous distinction which features may be used in the statement of the problem. All 20 decisions are discussed within a context/network of related decisions.

a) Mathematical/Algorithmic Features in the Claims

1. **T297/86** of 29.09.1989:
Automatic Control of Printing Press

The patent underlying this decision deals with the use of linear regression analysis to correlate subjective and objective harmonic analysis data related to print quality and obtain regression parameters. These parameters, once learnt, can be used to predict the subjective data based on objective data obtained.

The Board held that the use of linear regression and harmonic analysis data was indeed inventive when applied to the specific problem. The inventive step appears to lie in the mathematical step: "It is the merit of the present invention that it has been recognized that the harmonic analysis approximates most closely the actions of the machine operator."

An early important decision applicable to AI, Machine Learning and Big Data inventions where the inventive step relies on mathematical steps for a technical purpose.

2. **T1227/05** of 13.12.2006:
Simulation of a circuit subject to 1/f noise

Mathematical/algorithmic features can be regarded as technical features if they serve an adequately defined technical purpose. Another important aspect of the decision is that an enhanced speed of the algorithm, when compared to other algorithms, cannot be sufficient to establish a technical character of the algorithm. ("Algorithmic efficiency is not a technical effect.", cf. **T2418/12**, **T1784/06**, **T42/10** and **T1370/11**). If enhanced speed (or better use of resources) is obtained within a technical process, such as image compression, then this effect can be considered to be a technical effect.

It is recommendable to describe this adequately defined technical purpose associated with the mathematical/algorithmic features at least in the description so that it can be included in the claims, if necessary. In **T953/94**, the Board found allowable a method of controlling a "physical" process using a mathematical model, although a reference to an unspecified "physical process" might, according to **T1227/05** be rejected as a "meta-specification".

Albeit not explicitly confirmed by the Boards of Appeal, it appears that simulation of a technical or physical process or product is considered to be technical, while simulation of non-technical subject-matter is not. For example, in **T1265/09**, which also involved simulation, the subject-matter of determining an efficient schedule for a plurality of scheduled agents in a telephone call center was not deemed technical. Incidentally, in **T489/14** ("Modelling Pedestrian Crowd Movement"), the Board is currently (February 2019) considering to submit a set of questions relating to the field of simulation to the Enlarged Board of Appeal. The Applicant suggested the following questions[3]:

I. *Can a computer-implemented method of simulation based on laws of physics or calculating values which represent physical quantities for aiding the design of technical aspects of a physical system or technical product or for aiding the technical operation of a physical system or technical product be considered to be or to serve a technical purpose provided the technical purpose is adequately defined?*
II. *If the answer to question I is "No", in a claim directed to a method of designing, making or operating the physical system or technical product and which recites steps in a method of simulation for aiding the design of technical aspects of the physical system or technical product or for aiding technical operation of the physical system or technical product, would the simulation method steps be considered as contributing to the technical character of the claim and, thus, be considered in an assessment of inventive step?*
III. *Can a computer-implemented method of simulation involving values which represent physical quantities which can be influenced by or driven by non-physical factor(s) (such as aggregated human behavior) and yet still be accurately simulated and be technically relevant such that the simulation is still able to aid the design of technical aspects of the physical system or*

2 https://www.wired.com/story/despite-pledging-openness-companies-rush-to-patent-ai-tech

3 Moufang, R., «Zur Patentierung von Entwurfs- und Simulationsverfahren in der EPA-Rechtsprechung», GRUR Int. 2018, Heft 12, 1146-1152

technical product or the technical operation of the physical system or technical product still be considered to be or to serve a technical purpose provided the technical purpose is adequately defined.

T1227/05 is certainly a landmark decision and is, for example, highly relevant for the field of "Big Data", in which data from (known) sensors are analysed by novel and inventive algorithms and used to control a (known) technical device.

3. **T625/11** of 19.01.2017:
Determining a threshold of a parameter for operation of a nuclear reactor

The Board discussed whether a technical use of the output of a computer process can be a factor in determining technical character of the claim. In the present case, the Board stated that recognition of a technical character connected with the use of the threshold value resulting from the simulation for proper operation of a nuclear reactor would lead to a significantly more specific redefinition of the objective technical problem solved by the invention, namely determining at least one threshold value of a nuclear reactor operating parameter in order to allow better use of the reactor. Since the claimed solution was not disclosed in any of the cited prior art documents, the Board held that the claimed method did involve an inventive step.

The Board concluded that the determination of the value, being a threshold value of an operating parameter for a nuclear reactor, conferred a technical character on the claim and, further, that the technical character went beyond the mere interaction between the simulation algorithm and the computer system.

The claimed method itself does not bring about a technical effect. It was sufficient that only the use of a parameter determined by the method brings about a technical effect.

By contrast, in **T471/05**, the Board confirmed the refusal of a patent application which related to the mere design of an optical system, which can be carried out as a purely mental act or as a purely mathematical design algorithm and, consequently, encompasses embodiments falling within the category of methods for performing mental acts as such and within the category of mathematical methods as such both expressly excluded from patent protection under Art. 52(2)(a) and (c) in conjunction with Art. 52(3) EPC.

4. **T914/02** of 12.07.2005:
Designing a core loading arrangement for loading nuclear reactor fuel bundles into a reactor core

The whole method may be performed mentally, based on the appropriate, available data pertaining to the geometry of the core, the number of fuel bundles, the respective reactivities of the bundles, the reactor design rules etc. Moreover, as a result, the claimed method provides a design of a core loading arrangement which may be a purely mental, abstract scheme of how bundles could be arranged in an actual, real-world nuclear reactor core, rather than a concrete, physical reactor core loading.

The involvement of technical considerations is not sufficient for a method which may exclusively be carried out mentally to have technical character. One of the few cases where an application has been refused under Art. 52(2)(c) EPC because it did not exclude that it could be performed purely mentally. Inserting language such "using a computing device" in the claim could have overcome at least this objection.[4]

b) Tour d`horizon through different technical fields

5. **T598/07** of 19.05.2010:
Heartbeat monitoring method based on a neural network

The patent application underlying this decision refers to the use of a neural network in a heart monitoring apparatus to identify irregular heartbeats, which was considered to be technical. The decision deals with a nice example of a technical application of a neural network, in particular a Kohonen neural network.[5]

The decision is relevant for all sorts of technical applications of neural networks. In recent times, Deep Learning algorithms, e.g. convolutional neural networks (CNN), which are special types of neural networks, have gained a lot of attention since they were able to reduce the error rate in computer vision speech recognition applications. CNN are often efficiently trained using GPUs (graphics processing units) which by itself may be a basis for a technical effect.

Many AI applications involve a training phase and an operating phase. Although not explicitly stated in the updated version of the Guidelines for Examination, it is recommended to direct an independent claim to each phase.

4 Do not confuse this decision with **T625/11** since both deal with nuclear reactor technology.

5 AI techniques, such as neural networks, deep learning, clustering, support vector machines, etc., are different from other, let us call them "conventional", algorithms in that they typically involve a training phase in which they are presented some samples (e.g. images) by means of which the AI algorithm learns to classify the image. In an operating phase, once the algorithm has been trained, it can be shown new samples that it has not seen before and it can classify them. However, the classification it makes depends on the training samples and unlike conventional algorithms it is not well understood why the AI technique comes to a certain decision ("black box") and cannot be mathematically proven that it works correctly in all cases which may lead to safety problems e.g. in the case of self-driving vehicles. There is a similarity with pharmaceutical inventions in which studies/tests can show that a drug is able to cure a disease but it is not fully understood why this is the case, whether the drug helps persons suffering also from other diseases and whether there are any side-effects. For obtaining a patent for AI inventions, this means that, like for pharmaceutical inventions, it may be advisable to file test results that show that an AI technique indeed achieves a technical effect.

6. **T1784/06** of 21.09.2012:
Classifying a set of data records

The application deals with the problem of classifying a set of data records. The Board held that the problem was non-technical since the automatic classification of data records serves only the purpose of classifying the data records, without implying any technical use of the classification.

In some cases, a method which relates to an algorithm which is per se considered non-technical may be considered technical if it refers to a special architecture, e.g. adapting a machine learning algorithm to a GPU (graphics processing unit), cf. EP Patent EP 1 569 128 B1.

7. **T1358/09** of 21.11.2014:
Document classification

In this decision, the Board held that the classification of documents based on their textual content is non-technical. As a consequence, in **T22/12**, it has been decided that classifying an e-mail as spam is also non-technical.

8. **T2418/12** of 14.07.2017:
Suggesting a related term

The algorithm underlying claim 1 serves the overall purpose of suggesting query terms that are semantically related to the various "senses" of a particular input term. This is not a technical problem, for whether terms are "related" to each other is a cognitive or linguistic matter and not a technical issue (cf. **T1358/09**, **T2230/10** and **T2439/11**). Subject-matter relating to linguistic and/or semantic aspects of texts is often considered to be non-technical.

9. **T1316/09** of 18.12.2012:
Analysing content of an incoming electronic message

Methods of text classification per se do not produce a relevant technical effect or provide a technical solution to any technical problem.

Critical voices may argue that semantic analysis of texts is conceptually similar to object recognition in images. (Following **T208/84**, object recognition in images as a sub-discipline of digital image processing is considered to be technicaly). Therefore, it is not understandable why the first is not considered to be technical in contrast to the latter.

10. **T208/84** "VICOM" of 15.07.1986:
Image Processing

The underlying patent application relates to a method of digitally processing images in the form of a two-dimensional data array.

The Board held that a basic difference between a mathematical method and a technical process can be seen, however, in the fact that a mathematical method or a mathematical algorithm is carried out on numbers (whatever these numbers may represent) and provides a result also in numerical form, the mathematical method or algorithm being only an abstract concept prescribing how to operate on the numbers. No direct technical result is produced by the method as such. In contrast thereto, if a mathematical method is used in a technical process, that process is carried out on a physical entity (which may be a material object but equally an image stored as an electric signal) by some technical means implementing the method and provides as its result a certain change in that entity. The technical means might include a computer comprising suitable hardware or an appropriately programmed general purpose computer.

In this landmark decision, an image (although its representation could be seen to be nothing more than a two-dimensional array of numbers) has been considered as a physical entity[6]. This decision is applicable to all sorts of image, video and audio processing processes and in particular to the fields of image, video and audio compression and analysis (e.g. objection recognition, face recognition, speech recognition), cf. **T1586/09** (Quality of transmitted digital audio signals).

The decision, albeit old, is still highly relevant and may, for example, be important for self-driving vehicles relying on analysis of camera images.

11. **T1286/09** of 11.06.2015:
Image classification of a digital image

The gist of the present invention consists essentially in increasing the diversity of exemplar images used to train a semantic classifier by systematically altering an exemplar colour image to generate an expanded set of images with the same salient characteristics as the initial exemplar image. More specifically, an exemplar image may be altered by means of "spatial recomposition", i.e. by cropping its edges or by horizontally mirroring it.

The present application relates generally to the field of digital image processing and, in particular, to a method for improving image classification by training a semantic classifier with a set of exemplar colour images, which represent "recomposed versions" of an exemplar image, in order to increase the diversity of training exemplars. All features are considered to be technical. Image classification can be assumed to be technical. Image classification is one big field of application of AI (e.g. Neural Networks, etc.)

T1148/05 also deals with image classification and thus similar technical subject-matter but was considered to lack an inventive step.

6 Analogy: In the digital world, image processing allows for example to sharpen the contrast of an image. In the real-world, an image restorer who restores old paintings can achieve the same effect using mechanical and/or chemical methods. Therefore, both processes, the digital image processing and the methods applied by the image restorer, should be considered to be technical.

12. **T1285/10** of 23.05.2014:
Diagnosing and recommending treatment for a physiological condition using AI routines

The decision does not discuss whether claim 1 involves any non-technical steps. At least step (i) includes a physical/technical analysis step ("optical reader or scanner"). The decision appears to suggest that there are no problems regarding technicality with patenting medical diagnosis systems based on AI.[7] As a general rule, to render a claim technical, it is advisable to include "sensors" or any steps relating to a technical (physical/chemical/physiological, etc.) measurement.

13. **T2050/07** of 19.03.2013: Providing a genotype estimate based on an analysis of DNA samples

The mathematical features have been considered to contribute to the technical character of the claims.

The question arose whether non-technical features can establish novelty vis-à-vis an earlier application according to Art. 54 (3) EPC. The question was left unanswered since the features in question were considered as contributing to the technical character of the claim.

The decision opened up the field of bioinformatics for patent protection before the EPO. Not many decisions by the Boards of Appeal in this field have followed so far.

14. **T1326/06** of 30.11.2010:
Encryption/Decryption/Authentication

Methods for encrypting/decrypting of electronic messages must be considered as technical even if they essentially rely on mathematical methods.

Cryptography (encrypting, decrypting or signing) is technical, cf. **T27/97**, **T556/04**.

Making the system more secure/more reliable is generally accepted as a technical effect. The decision may unfold relevance in the field of Blockchain technology.

15. **T1842/10** of 30.04.2014:
Computer-aided modelling method for the behavior of steel volume

The claim is not only directed to a modelling method but also comprises a control method for a means that influences a steel volume.

Control of an external device (X-ray apparatus, etc.) or the operation of the computer itself (memory management, load distribution **T318/10**, etc.) is normally considered to be technical.

c) User interaction/User interfaces

16. **T1670/07** "Broken technical chain fallacy" of 11.07.2013: Facilitating shopping with a mobile wireless communications device

The decision says that a technical effect may arise from either the provision of data about a technical process, regardless of the presence of a user or its subsequent use, or from the provision of data (including data that on its own is excluded, e.g. produced by means of an algorithm) that is applied directly in a technical process. In the case at issue, the data was produced by means of an algorithm and was not applied directly in a technical process, so that neither possibility applied.

The Appellant argued that a reduction in use of resources would be achieved. The Board countered that this was only caused by the way the brain of the user perceives and processes the visual information given by a particular way of presenting information. This was considered as a "broken chain" of technical effects and not accepted. It is not advisable to argue that a technical effect is achieved if this effect is only achieved if the user reacts in a certain way to the information presented. The following two decisions show exceptions:

17. **T528/07** of 27.04.2010:
Providing a business-to-business relationship portal

If the cognitive content of the information presented to the user relates to an internal state prevailing in a technical system and enables the user to properly operate this technical system, it has a technical effect. An internal state prevailing in a technical system is an operating mode, a technical condition or an event which is related to the internal functioning of the system, may dynamically change and is automatically detected. Its presentation typically prompts the user to interact with the system, for example to avoid technical malfunctions.

This decision refers to an exception of how to escape from the "broken technical chain fallacy". While psychological factors may not contribute to the technical character, cf. e.g. T862/10, physiological effects (such as physical properties of the human visual perception, T509/07) may be considered to make a technical contribution.

18. **T2035/11** of 25.07.2014: Navigation System

The Board distinguished between

- a navigation system (broader interpretation) which calculates the route with the cheapest cost by using

7 Is the situation different, in other words is the system still technical, if there is no physical/chemical analysis step but only a user answering questions via e.g. a computer-based questionary based on which a medical diagnosis is made? In T1153/02, it was not discussed whether some features were non-technical. The application was refused based on a lack of inventive step in view of the prior art.

a Travelling-Salesman-Algorithm without any position-determining device (This is a purely mathematical pencil & paper problem) and

- a navigation system (narrower interpretation) with a position determining device and being configured to provide route-guidance information in dependence on the actual real-world position of the system.

"In the Board's view, providing real-time route-guidance information to a user in dependence on the user's real-world position is a technical task. It involves an interaction between the user and the navigation system, wherein the navigation system continuously measures the user's position using technical means and, on the basis of these measurements, provides the user with information aimed at enabling the user to manage the technical task of moving a vehicle to a desired destination.

Although the completion of this technical task depends on the user acting upon the provided route-guidance information and hence on an intervention by the user, it does not rely on subjective considerations by the user or on psychological effects. The user may still decide to ignore the route-guidance information, but that does not detract from the technical character of the navigation system as a technical tool to be used interactively in a technical process and not merely in a preparatory phase as a substitution of what could also be done using pencil and paper."

The decision seems to be another way of escaping from the broken technical chain fallacy, cf. **T2172/03**.

Even if the technical effect of reducing costs is only brought about by the user driving the car as recommended, the system as a whole is considered to be technical.

Cf. Guidelines G-II, 3.3: "Defining the nature of the data input to a mathematical method does not necessarily imply that the mathematical method contributes to the technical character of the invention (**T2035/11**, **T1029/06**, **T1161/04**). Whether a technical purpose is served by the mathematical method is primarily determined by the direct technical relevance of the results it provides."

This decision may unfold relevance in the technical field of self-driving vehicles.

d) Notional Business Person and Requirement Specification

19. **T1463/11** of 29.11.2016:
"Cardinal Commerce" – Notional Business Person

The patent application deals with authentication of a consumer via a computer at a centralized merchant authentication processing system.

The Board held that the notional business person (more generally, the non-technical person) cannot normally require even notorious technical means. The reason was that the inventor may have obtained a technical effect using technical means, even notorious means, in a way that would not have been obvious to the skilled person. That was what a patent was meant to reward. To allow the notional business person to prescribe technical means would be to foreclose any discussion of whether they were used in a technically non-obvious way. This should not lead to a proliferation of patents for technically trivial inventions; they would be obvious to the skilled person.

Following the COMVIK approach, this decision introduces the "notional business man" in addition to the "person skilled in the art". The notional business man gives a requirements specification to the person skilled in the art which has to be free from all (even notorious) technical requirements.

The decision was confirmed in **T630/11** and further developed in **T144/11** in which the Board stated as a headnote that a problem of the type "implement [the business requirement]" will normally never lead to an allowable claim. Either the implementation will be obvious or have no technical effect, or if not, the implementation will have a technical effect that can be used to reformulate the problem essentially to "achieve [the effect of the implementation]". However, the implementation-type problem is just a starting point that might have to be modified when the implementation is considered. It helps when a technical problem is not apparent at the outset. Examining the business requirements carefully and correctly establishing what is to be implemented ensures that all technical matter arising from the idea of the invention and its implementation is taken into account for inventive step.

This decision may be important for the technical field of Blockchain in which technical problems occur in a business/administrative context.

20. **T2079/10** of 19.04.2018:
Control of cellular, geographically distributed alarm systems

The patent application underlying this decision relates to electronic control of cellular, geographically distributed alarm systems.

The Board considered claim 1 to include technical features, in particular the feature that a control unit is triggered by physical measurement parameters. Hence, claim 1 is not purely a business method.

The Board expounds that the feature of physical parameters cannot be taken as part of the problem statement under the COMVIK approach. Moreover, it cannot be assumed

that the technically skilled person chooses a physical parameter, on the basis of which the technically skilled person gets from the business person a purely abstract business model as a concept for implementation.

The decision may be considered to be a consequence of **T1463/11**.

This decision could be important for AI inventions. In particular for e.g. neural networks suitable for processing real world data such as video.

Outlook – Enforcement of Patents

The initiatives by the EPO in the fields of emerging computing technologies and its stable jurisdiction contribute to an ideal framework for obtaining patents in these fields. However, let us have look at the situation regarding the enforcement of patents in the field of emerging computing technologies. What is the nicest (or better: broadest) patent worth if it cannot be reasonably enforced – either because the courts do not have the technical expertise or even more importantly the infringement of such patents is intrinsically difficult to detect? The first problem could be solved by the Unified Patent Court which offers the possibility to recruit technical judges who have technical expertise in the emerging computing technologies mentioned above. The second problem is more difficult to tackle. Rachel Free and Loretta Pugh have shown in their article "Implications of the General Data Protection Regulation for Detecting Infringement of AI Patents" in EPI Information 3/2018 that the GDPR may be helpful in detecting patent infringement.

Another approach that I would like to add is the standardization process that has just started in the field of AI. "ISO/IEC JTC 1/SC 42" is a committee that was newly established that deals with the standardization of AI[8]. Moreover, if one thinks about safety relevant fields, such as algorithms that are applied in self-driving vehicles, it is clear that such algorithms will have to be examined carefully by a technical authority[9] (e.g. TÜV in Germany, MOT in the UK) and that they will underlie some standardization. It is also thinkable that manufacturers of self-driving vehicles will be forced to openly disclose the algorithms that they employ. The highest number of patents within CII that are enforced are standard essential patents (SEP) in the field of telecommunications because one can easily determine whether someone infringes a patent. If AI is also governed by standards, then enforcing patents in this field will also be possible without undue burden such as reverse engineering.

If you have any questions or comments, please contact the author: michaelfischer1978@web.de

The author runs a newsletter on computer-implemented inventions. Please write to the same e-mail address if you wish to subscribe.

8 https://www.iso.org/news/ref2336.html
9 Like the European Medicines Agency (EMA) examines the admission of medicinal products based on tests, clinical studies, etc.

epi Amicus Curiae Brief Regarding G1/18

Position Paper

Dear Mr Josefsson,

epi files the present amicus curiae brief in order to assist the Enlarged Board in its deliberations.

Admissibility

epi considers that the reference to the Enlarged Board is admissible. There are clearly diverging decisions from different Boards of Appeal (T1897/17 on the one side and T1325/15 and T2406/16 on the other side), as explained in the President of the EPO's reference. It is an important point of law as it will have effects on the practice within the EPO. Moreover, it is an important question for the users of the EPC system as it could have wide ranging effects on users' practices. **epi** therefore considers that the Enlarged Board should admit the reference and issue an opinion on it.

Interpretation of Article 108

epi notes that Article 108(1) refers to the conditions which must be met if an appeal is to be deemed to be "filed". This word occurs in both the relevant sentences of Article 108(1) in English. (In the German text, the relevant words are "einzulegen" and "eingelegt". In the French text, the relevant word is "formé" in both sentences.) This contrasts with the wording in Rule 101, where the word used is "inadmissible" ("unzulässig" in German and "irrecevable" in French). It is therefore clear that Article 108 and Rule 101 are addressing different situations. Article 108 sets the conditions which must be met before an appeal is considered to have been filed at all. In contrast, Rule 101 is dealing with situations where an appeal is considered to have been filed, because the conditions of Article 108 have been

met, but where the appeal has deficiencies which mean that, although it is deemed to be filed, it is inadmissible[1].

It is logical that there should be a difference between filing and admissibility. In order to determine whether an appeal has been filed, all that needs to be done is to determine whether a document purporting to be a notice of appeal has been filed and whether the appeal fee has been paid. This is merely a clerical action and does not need any involvement of a Board. On the other hand, deciding whether the appeal is admissible cannot be a clerical action but must involve the Board. It is logical that a determination as to whether an appeal has been properly filed should be made before a Board gets involved in determining admissibility[2].

Therefore, in **epi**'s view, the meaning of Article 108 is clear in that it sets the conditions which must be met before an appeal can be considered to be properly filed.

Article 51 EPC

epi considers that it is also useful to look at Article 51(2) EPC. This reads as follows:

> "(2) Time limits for the payment of fees other than those fixed by this Convention shall be laid down in the Implementing Regulations."

It is clear from this that there are two types of time limits for paying fees to the EPO. The first type consists of the time limits set in the EPC itself. The second type consists of the time limits set in the Implementing Regulations. The Implementing Regulations do not set a time limit for paying the appeal fee. Therefore, the time limit for paying the appeal fee must be set in the EPC itself. It can be seen that Article 108 itself is headed "Time limit and form". It is therefore abundantly clear that Article 108 must be setting the time limit not only for filing the notice but also for paying the appeal fee[3]. Certainly, this has been the accepted reading of Article 108 ever since the inception of the EPC[4].

It is therefore **epi**'s view that Article 108, when read in the context of Article 51, clearly means that the two month time limit applies to both the filing of a notice of appeal and the payment of the appeal fee. Therefore, if either a notice of appeal is not filed or the appeal fee is not paid within the two months, the appeal is deemed to be not filed and so it can never have come into existence.

The consequence of this is that, if the appeal fee is paid after the expiry of the two month time limit, there is no appeal for it to be applied to and so it is to be refunded.

epi considers that the Enlarged Board should answer the question posed by the President of the EPO in line with the comments made above.

Yours sincerely,

Francis Leyder
epi President

1 epi can see that there is a slight problem in that Rule 101 does refer to Article 108. However, this seems a minor problem in that a Rule cannot over-ride the provisions of an Article. Article 108 is clear in that it relates to the filing of an appeal and so its provisions in this respect must over-ride any provision in Rule 101 to the contrary. In any event, any perceived conflict could easily be overcome by amending Rule 101 so that it does not refer to Article 108.

2 This also applies to the other instances referred to by the President of the EPO, for instance for filing an opposition. Again, it needs to be checked whether something purporting to be an opposition has been filed and whether the opposition fee has been paid before involving an opposition division to determine whether the opposition is admissible.

3 If this is not the case, then there is no provision in the EPC or the Implementing Regulations setting the time limit for paying the appeal fee. If there is no time limit for paying the appeal fee, then this leads to absurd consequences in that a party could file an admissible notice of appeal but not pay the appeal fee and the Board would have to point out this deficiency, which could then be remedied by paying the appeal fee at any time the appellant chooses. This is clearly not what was intended by the drafters of the EPC in 1973 or 2000. Similar absurd consequences would apply in all the analogous situations identified by the President of the EPO.

4 This also applies to the other instances referred to by the President of the EPO, for instance for filing an opposition. Again, it needs to be checked whether something purporting to be an opposition has been filed and

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Report of the Committee of Biotechnological Inventions (Biotech)

A. De Clercq (BE), Chair

Ann De Clercq

1. Patentability of plants and animals – T1063/18

T 1063/18 concerns the appeal by the applicant against the decision of the Examining Division to refuse European patent application no. 12 756 468.0 (publication no. EP 2 753 168 A1) for the sole reason that the claimed subject-matter was "found to be within the exception to patentability according to Article 53(b) EPC and Rule 28(2)" (here: plants exclusively obtained by means of an essentially biological process).

At the oral proceedings in T 1063/18, which took place on 5 December 2018, Technical Board of Appeal 3.3.04, in an enlarged composition consisting of three technically and two legally qualified members, held that Rule 28(2) EPC (see OJ 2017, A56) is in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. In these decisions, the Enlarged Board of Appeal had concluded that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC did not have a negative effect on the allowability of a product claim directed to plants or plant material.

In the reasoned decision dated 5 February 2019, the Board stated that Rule 28(2) EPC could not be interpreted in such a way that it was not in conflict with Art. 53(b) EPC as interpreted by the Enlarged Board of Appeal, i.e. the conflict could not be resolved by way of interpretation. The Board also saw no reason to deviate from the interpretation of the Enlarged Board. The Board concluded that, in view of Article 164(2) EPC, the provisions of the Convention prevailed and decided to set aside the decision under appeal and to remit the case to the Examining Division for further prosecution.

Our committee agrees with the well-founded decision in T 1063/18 and believes that it is actually the only one that could reasonably be reached. Given this decision our committee submits that the need to remove subject-matter as referred to in Rule 28(2) EPC - by disclaimer or otherwise – de facto no longer has any legal basis and should be removed from the Guidelines for Examination. This decision should be mentioned in the Guidelines and we are of the opinion that it should be applied consistently by the examining divisions as soon as possible.

The Biotech Committee is of the opinion that in particular one aspect is made clear by decision T 1063/18. The exclusion of product claims directed to plants or plant material directly obtained and/or defined by an essentially biological process in the sense of Article 53(b) EPC cannot be achieved by amending the Regulations to the Convention. Such an exclusion could only be the consequence of a further development in the jurisprudence of the Enlarged Board of Appeal or of a revision of the European Patent Convention, e.g. Article 53(b) EPC.

The Biotech Committee will present its analysis to the **epi** members attending the CPL meeting on 19-20 February 2019.

2. Overview of patentability of plants in the Member States

Already before the decisions of the Enlarged Board of Appeal, a few countries had adapted their legislation in order to exclude from patentability product claims where the claimed products have been generated by an essentially biological process for the production of plants. Our committee has in the past published an overview of the national laws of the EPC Contracting States based on input of its members. This overview has now been updated and is published in this issue of **epi** Information.

3. Guidelines for Examination – biotech issues

The Biotech Committee has offered a proposal for discussion of the Guidelines for Examination at the SACEPO Working Party on Guidelines on 22 February 2019 (delegates of the Biotech Committee will be present at said meeting). Amongst these are also comments to the Rule 28(2) EPC disclaimer parts of the Guidelines.

4. Next meeting

The Biotech Committee will continue to deal with all questions relating to biotech and related life sciences inventions. The Biotech Committee will also be involved in any other topics that come up for discussion related to biotech or referred to it by EPPC or other channels.

The next meeting date of our committee is still to be scheduled in 2019. A meeting with the EPO Biotech Directors will also be scheduled for this or next year.

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