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Information

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

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Women and IP – the long road to equality

Cover:
Florale Impression 17
This picture painted by
Markus Böckhorst
(European Patent Attorney, DE)
was part of the
epi Artists Exhibition 2021

Markus Böckhorst

After having successfully completed the professional training and high school graduation, graduation as Diploma Engineer (TU Munich). Then worked as a European Patent Attorney and Patent Assessor. Meanwhile additional qualification as Diplom Litigator. Alongside work since 1975 occupation with sculpture and concrete and abstract painting. Several studies by Hansjörg Gartner, Peter Casagrande and Egon Stöckle, among others, as well as repeated longer stays at the European Art Academy in Trier studying under Joe Allen, Claude Mancini and Christine Henn. Accompanying numerous group and individual Artists exhibitions. Member of the Professional Association of fine artist.
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Nach Berufsausbildung und Abitur, Abschluss an der TU-München zum Dipl. Ing.(Univ). Danach tätig als European Patentattorney bzw. Patentassessor. Zwischenzeitlich Zusatzabschluss zum Diplom Litigator. Berufsbegleitend seit 1975 Beschäftigung mit der Bildhauerei sowie der konkreten und abstrakten Malerei. Studienaufenthalte bei Hansjörg Gartner, Peter Casagrande und Egon Stöckle, sowie wiederholt längere Aufenthalte an der Europäischen Kunstakademie Trier unter anderem bei den Dozenten Joe Allen, Claude Mancini und Christine Henn. Begleitend dazu zahlreiche Gruppen- und Einzelausstellungen. Mitglied im Berufsverband der Bildenden Künstler.
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Après une formation professionnelle et un baccalauréat, il optient un diplôme d'ingénieur à l'université technique de Munich. Puis travaille comme mandataire en brevets européens ou assesseur en brevets. Entretemps il optient un diplôme supplémentaire de « litigator ». Depuis 1975, parallèlement à son travail, il s'intéresse à la sculpture et à la peinture concrète et abstraite. Il a fait des séjours d'études auprès de Hansjörg Gartner, Peter Casagrande et Egon Stöckle, ainsi que des séjours répétés et prolongés à l'Académie européenne des arts de Trèves, entre autres auprès des professeurs Joe Allen, Claude Mancini et Christine Henn. Il a exposé dans de nombreuses expositions collectives et individuelles. Il est membre de l'association professionnelle des artistes plasticiens.
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epi Anniversary

M. Nevant (FR), Editorial Committee

The first issue of **epi** Information was published 40 years ago! The editorial of this first issue, along with the foreword of the then **epi** President, are reproduced below[1].

Marc Nevant

Both documents are more topical than ever: this journal is your journal, and we are delighted with past, present and future contributions which have (will) fuel(ed) discussion and debate within our membership. We are also thankful to all previous members of the Editorial Committee who have made our journal what it is now.

The format of the journal has certainly evolved over the past 40 years (from a black & white paper version with a yellow cover in the beginning, then a light blue cover until 2015, and finally a digital version with colour photographs since 2016), but the spirit has remained the same.

What will **epi** Information look like in 40 years? Will there still be an Editorial Committee? It is hard to tell how the information will be disseminated, and our profession promoted, in two generations. However, we have no reason to doubt that the best use will be made of the technology, and that the human contribution will always be decisive in deciding the editorial line.

epi Anniversary to our journal, and long life to it!

EDITORIAL

Here is the first issue of EPI Information. In future issues your Editorial Board would like to publish letters from members particularly on controversial matters and matters where you wish to comment or criticize actions or decisions taken on your behalf by our Council or where you think the Council ought to act.

This is your publication. Use it.

Jean Brullé · Ernst J. Schönhöfer · Ken Veryard

epi

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Le Président

My Dear Colleagues,

It is with great pleasure that I write these few lines to introduce the first edition of the Information Bulletin of our Institute.

For a long time, your representatives on the Council have wished for an informal means of communication with other members of the Institute to show that the Institute is not just a kind of monster devouring your membership fees but a living organism in constant evolution.

Before realising this wish, the Council had to resolve a number of organisational problems and functions inherent in setting up so complex a multinational body. These problems are now practically resolved thanks to the efforts and understanding of all and your Council can concentrate on the essential work of improving the conditions of your professional work in the field of the European Patent Convention.

Thanks to the efforts of our former President K. Veryard, our Vice-President E.J. Schönhöfer and of our French member of Council J. Brullé, our Information Bulletin can now appear and I thank them especially for devoting their efforts and their time to this work of common interest.

I am sure that you will welcome our Bulletin and that you will contribute and collaborate with it for the good of all of us.

That is why I wish with high confidence, long life and success to the Institute's Bulletin.

G. BRESSAND

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1 The foreword was actually written in all three official languages, see https://patentepi.org/r/info-2401-06

Introduction

Note from the CEC
By-elections epi committees

epi members wishing to contribute to the work of **epi** can be a member of one or more **epi** Committees. At the 97th Council meeting, there will be By-elections to fill vacant positions in several Committees.

epi members wishing to stand for election must submit their completed nomination form before the 97th Council meeting scheduled for 27 April 2024. If a member wishes to stand as a candidate for more than one Committee, they must submit a completed nomination form for each Committee.

Link to nomination page:
https://epi.patentepi.org/elections
(By-Elections are available for **epi** members after login)

epi Mitglieder, die einen Beitrag zur Arbeit des **epi** leisten möchten, können Mitglied in einem oder mehreren **epi** Ausschüssen werden. Auf der 97. Ratssitzung wird es Nachwahlen geben, um freie Positionen in mehreren Ausschüssen zu besetzen.

epi Mitglieder, die sich zur Wahl stellen möchten, müssen ihr ausgefülltes Nominierungsformular vor der 97. Ratstagung am 27. April 2024 einreichen. Wenn ein Mitglied für mehr als einen Ausschuss kandidieren möchte, muss es für jeden Ausschuss ein ausgefülltes Nominierungsformular einreichen.

Link zur Nominierungsseite:
https://epi.patentepi.org/elections
(Die Nachwahlen sind für **epi** Mitglieder nach Login verfügbar)

Les membres de l'**epi** qui souhaitent contribuer au travail de l'**epi** peuvent être membres d'un ou de plusieurs commissions de l'**epi**. Lors de la 97ème réunion du Conseil, des élections intermédiaires seront organisées afin de pourvoir les postes vacants au sein de plusieurs commissions.

Les membres de l'**epi** qui souhaitent se présenter aux élections doivent soumettre leur formulaire de candidature dûment rempli avant la 97e réunion du Conseil prévue le 27 avril 2024. Si un membre souhaite se porter candidat pour plus d'une commission, il doit soumettre un formulaire de candidature complété pour chaque commission.

Lien vers la page de nomination
https://epi.patentepi.org/elections
(Les élections intermédiaires sont disponibles pour les membres de l'**epi** après connexion)

epi Artists Exhibition 2024

Launch on 27 May 2024
Deadline for registration on 6 May 2024

The **epi** Artists Exhibition has become a cherished tradition within the cultural life of **epi**. Opened for the first time in 1991, it was followed by further events in 1994, 1996, 1998, 2000, 2003, 2006, 2009, 2012, 2015, 2018 and 2021 and is repeated every three years.

European patent attorneys who apart from their professional job also are artists showing their creative works. The interesting works on display have ranged from paintings to graphical and fine art works, such as ceramics, sophisticated watches and jewellery, and artistic textile creations.

Throughout the years, the Exhibition has taken place in the foyer of the EPO which offered the possibility to present the artworks to a wide audience.

2021 was the Exhibition's 30th anniversary and Covid 19 restrictions required us to organize the Exhibition in a virtual manner on the **epi** website.

A special website for the presentation of all **epi** Artists and their artworks was launched on the **epi** website to present their artwork to an even wider audience.

To duly honour the 31 participating **epi** artists and their artworks, **epi** organised a virtual "Get Together" and gave the artists the opportunity to present themselves to the audience, introduce their artworks, and to exchange experiences and thoughts.

As the virtual exhibition was a great success, we have decided to hold the next exhibition in virtual form in 2024 as well.

A prerequisite for each Exhibition is a large number of participating artists wishing to present their skills and artworks. Therefore, we hope that the virtual platform will encourage even more participants from all the contracting member states.

Our intention is to present the artworks and the artists also for a longer period to enable all **epi** members to appreciate their artistic creativity on the dedicated website.

epi invites all creative **epi** members warmly to participate by submitting the application form which can be found here:

https://patentepi.org/r/epi-artists-exhibition-registration

In addition, please submit your brief biography and a photograph together with some background information outlining your inspiration; history of the artwork; and/or the techniques used.

Kindly note that the deadline for registration is 6 May 2024.

The launch of the virtual **epi** Artists Exhibition will be on 27 May 2024. The opening of the exhibition will be enriched by a "**epi** Artists Get Together" where the participating artists will have the opportunity to present their artworks to the **epi** audience.

The invitation to the virtual opening and a virtual tour through the exhibition will be sent to all epi members closer to the event.

We are looking forward to receiving numerous applications to enable us to prepare the virtual **epi** Artists Exhibition in 2024.

For further inquiries, please contact us at the **epi** Secretariat at info@patentepi.org

Women and IP – the long road to equality

Nina Ferara (DE), *with thanks to Fatema Sardharwala, Katerina Hartvichova, Sally Bannan, John Gray, Jonna Sahlin, Olga Sirakova for great discussions and suggestions for the article.*

We have made great strides when it comes to women's rights in the last few decades. This year marks 40 years since the last European country granted women the right to vote – which seems both shockingly recent and impossibly long ago in terms of all the changes in the world since then.

On February 11 each year, we celebrate the International Day of Women and Girls in Science, and March 8 is widely celebrated as the International Day of Women. The month of March is known as Women's History Month in some countries. To acknowledge these events, let us look at gender equality as it relates to our IP profession – both for inventors as well as for professional representatives. To add some more general context, data on women scientists and engineers in high-tech fields is also provided.

The goal of this article is to inform **epi** members of the current state of affairs – where we stand in terms of participation of women in IP. A stretch goal would be to start a conversation about how we as **epi** members can contribute to increasing gender diversity in our profession and beyond by removing various existing barriers. This conversation is vital for the continuing success of our profession: it is a well-established fact that diverse teams perform better in the workplace[1], the conversation will facilitate us to tap into a wider pool of talent, and it is simply the right thing to do to work towards a just and egalitarian society.

The data on inventors has been provided by the European Patent Office in 2022[2]. The data on the gender ratio among our ranks has been provided by the **epi** (statistics as of December 2023). The data on percentage of women scientists and engineers in high-technology sectors has been sourced from Eurostat[3].

Let us dive right in!

Figure 1 shows the percentage of women among scientists and engineers[4] working in high-technology sectors[5] (high-technology manufacturing and knowledge-intensive high technology services) in 2019. The data is sourced from Eurostat and includes several other countries as well as EU member states. Overall, the percentages of women are between 13% and 34%, with a variance of over 20 percentage points with a ceiling far below parity (i.e. 50%).

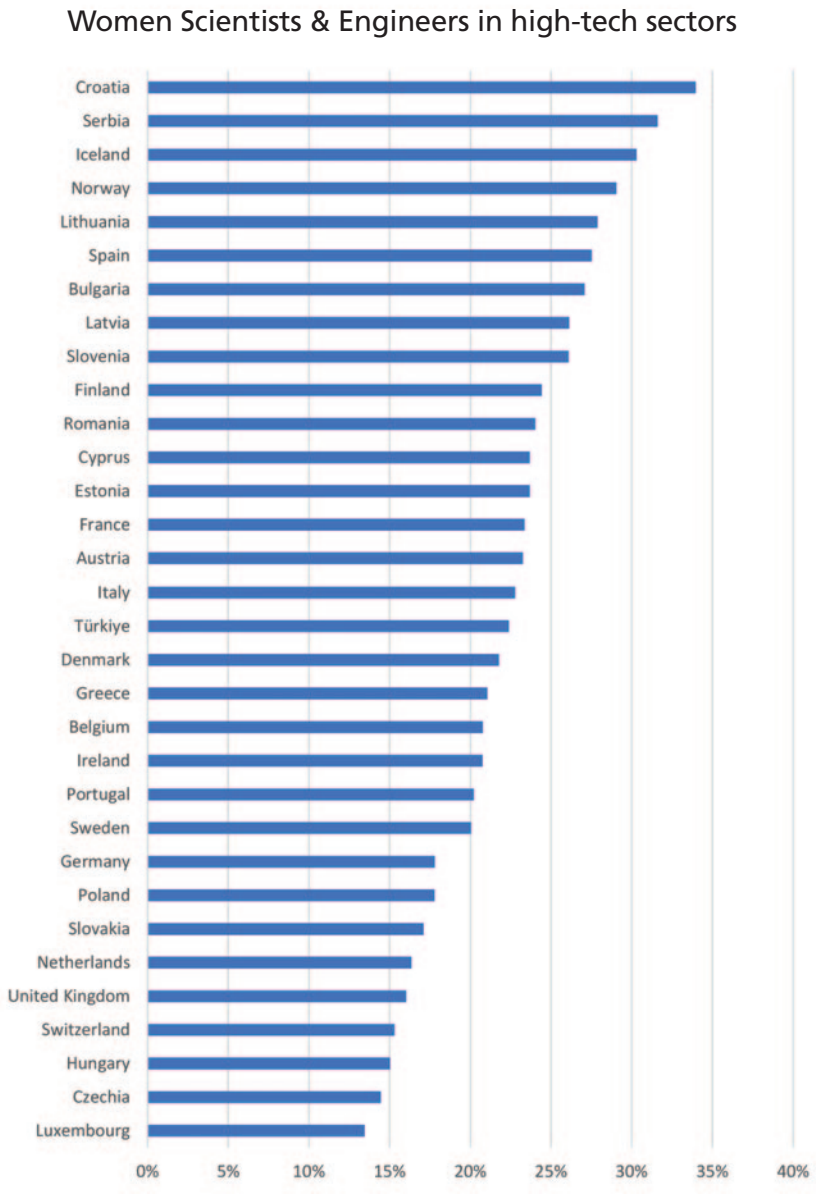

Figure 1: Women scientists and engineers in high-tech sectors in 2019, Eurostat.

1 https://hbr.org/2016/11/why-diverse-teams-are-smarter
2 https://www.epo.org/en/news-events/press-centre/press-release/2022/452251
3 Source dataset: hrst_st_nsecsex2, https://ec.europa.eu/eurostat/databrowser/view/hrst_st_nsecsex2
4 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Scientists_and_engineers
5 https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:High-tech

Note that the data for scientists and engineers overall (as opposed to in high-tech fields) looks much more equal. Among the top 10 countries with the highest percentage of women are a few Balkan states and Baltic states, Nordic countries and Spain. These countries are established champions of greater gender equality in STEM – there is a lot of research on this topic[6] (outside of the scope of this article). Some common theories as to the reasons include: overall more egalitarian societies, historical circumstances and greater access to childcare. Among the bottom 10 are most DACH countries (DACH stands for Germany (D), Austria (A) and Switzerland (CH)), as well as a few of their neighbours. The UK and Sweden also make the bottom 10. The DACH countries commonly rate on the lower end among gender equality in the STEM area (but typically not in terms of the overall gender equality index[7,8]). The average for the European Union as a whole (excluding the UK) is 21%. This appears to be on a slow upward trend – in 2022, this number was 22% (presumably, the trend would be more positive were it not for the Covid-19 pandemic, which disproportionately affected women[9].)

Nina Ferara

Figure 2 is reproduced from the Women's participation in inventive activity report provided by the EPO in 2022. It shows the women inventor rate (WIR) among the EPC member states. The percentages of women inventors are between 8% and 31%, which is strikingly similar to the variance from Figure 1 above. Among the top 10 are the Baltic countries, Balkan countries, and Spain together with a couple of others. While there is some intersection between the top countries with women inventors and the top 10 countries of women scientists and engineers in high-tech sectors, there is also some divergence. The bottom 10 countries show a lot more similarity: the DACH countries score low again, as well as Czechia and the Netherlands. Overall, the average percentage of women inventors for EPC member states is 13%, which is quite a bit lower than that in high-tech STEM positions. When we talk about the gender disparity among inventors, it is important to remember that it cannot be explained solely by the so-called „leaky pipeline" problem – i.e. the fact that women are more likely than men to leave the STEM field at each educational and career level. While this is certainly a factor, the difference between the average percentages of women in high-tech STEM fields and women inventors indicates that there are additional barriers preventing women that are already in STEM from inventing or from formalizing their inventions via patenting. There are some ongoing efforts to uncover and remove these as yet hidden barriers[10,11], but more work is needed in this area. Increasing the participation of women in patenting activities would boost the overall innovation potential in Europe. This is why this work must be urgently done, especially by members of our profession.

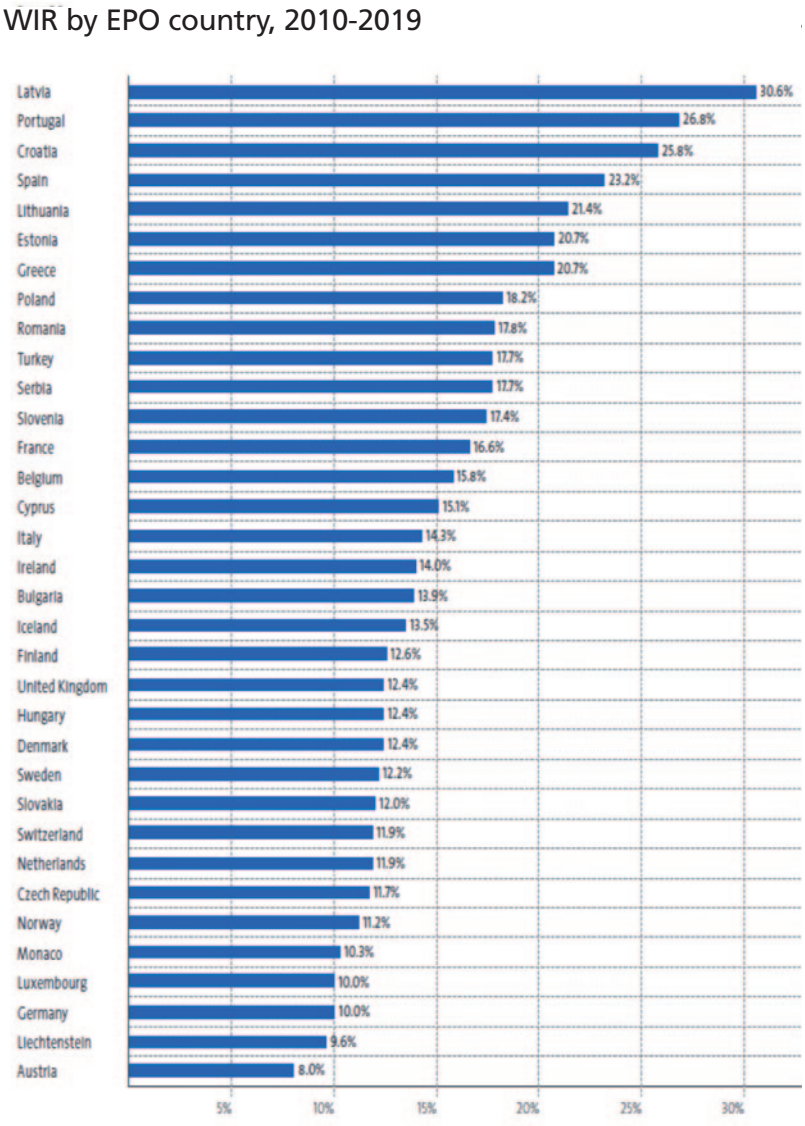

Figure 2: Women inventors rate 2010-2019, EPO

6 https://esthinktank.com/2022/03/24/women-in-stem-in-the-european-union-facts-and-figures
7 https://eige.europa.eu/gender-equality-index/2023/compare-countries
8 https://www.economist.com/graphic-detail/glass-ceiling-index
9 https://eige.europa.eu/gender-statistics/dgs/browse/eige/eige_covid
10 https://ipo.org/index.php/diversity-in-innovation-toolkit
11 https://www.cisco.com/c/en/us/about/legal/win.html

Women EPAs

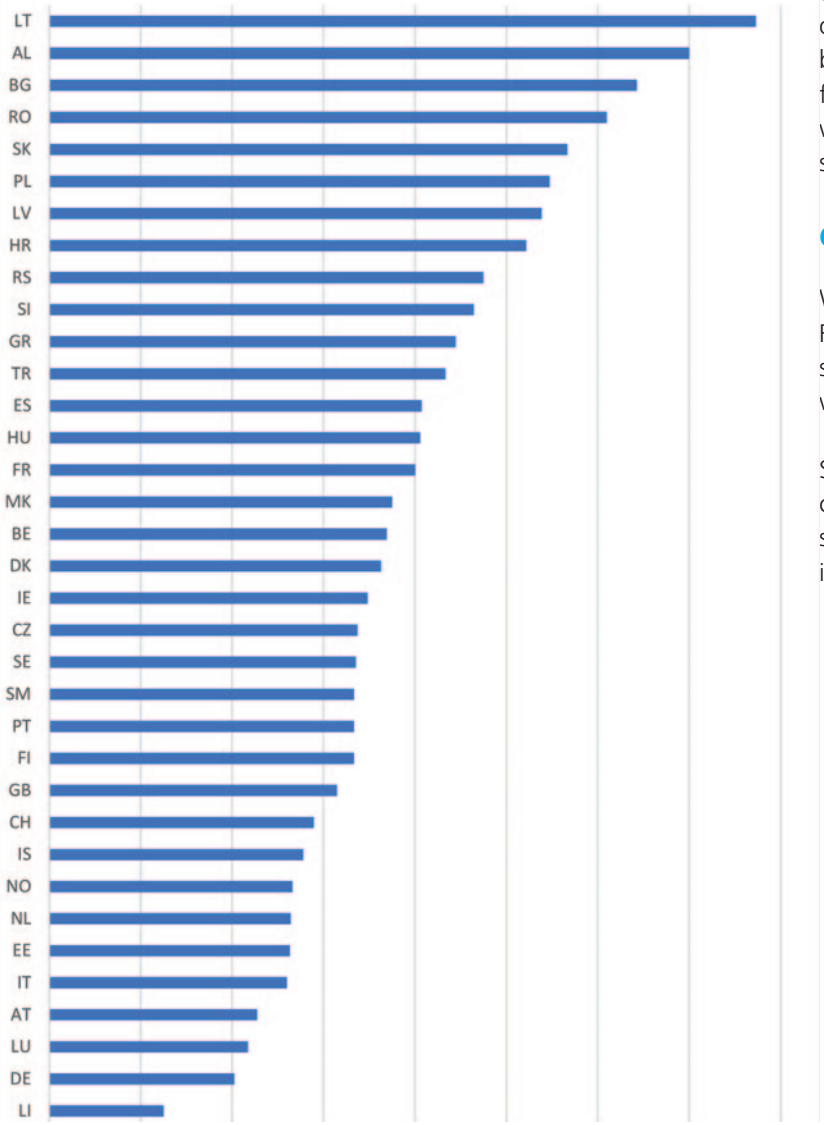

Figure 3: Percentage of women among European Patent Attorneys, 2023

Finally, let's take a look at the gender ratios by country for European Patent Attorneys (EPAs) in 2023, shown in Figure 3. The data excludes member states with fewer than 10 **epi** members. The percentages of women range from 13% to 77% in this case – a major variance as compared with the previous two figures. Overall, 29% of European Patent Attorneys are women. The top 8 countries have more than 50% women among their EPA ranks. The top 10 includes the Baltic countries, Balkan countries and Eastern European countries. Among the bottom 10 are DACH countries, Estonia (as an outlier among the Baltic countries), Italy, Netherlands and Iceland. Generally, it is important to acknowledge that the percentages of women among European Patent Attorneys are slightly higher than those among scientists and engineers in high-tech STEM fields according to Eurostat. A possible further area of investigation would be to look at the gender breakdown of EPAs according to the technical field in which they practice, and compare it with the corresponding gender statistics among scientists and engineers.

Conclusion

What are some key takeaways from this data? First, that there is a lot more work to do to strive for equality of women inventors and women in IP.

Second, that we should all consider how we can contribute to improve the rather abysmal statistics on women inventors. Here are some ideas:

- You can start by taking a look at the resources on the **epi** page of the Diversity & Inclusion Working Group[12]. There are a lot of great resources elsewhere as well[13,14,15].
- Consider contributing to the initiatives of patent offices[16,17] and professional organisations[18].
- Highlight women inventors for awards that can increase their visibility and allow them to serve as role models[19] for others.
- If you are working in-house, think about how you can help remove any 'hidden' barriers for women inventors and launch internal initiatives aimed at increasing their numbers[10,11]. This will allow your company to benefit from the brilliant inventions by the women in your R&D departments.
- If you are in private practice, aim to provide diverse teams to your clients and try to proactively approach women in R&D who may become inventors with the right encouragement and resources.

12 https://patentepi.org/en/diversity-and-inclusion/resources.html
13 https://ipo.org/index.php/diversity-inclusion/
14 https://ipinclusive.org.uk/
15 https://www.women-in-ip.com/
16 https://www.dpma.de/dpma/veroeffentlichungen/patentefrauen/index.html
17 https://www.wipo.int/women-and-ip/en/
18 https://www.cipa.org.uk/diversity-type/women-in-ip/
19 https://www.epo.org/en/news-events/european-inventor-award
20 https://eismea.ec.europa.eu/programmes/european-innovation-ecosystems/women-techeu_en

- If you work with individual inventors or startups, inform them about funding or mentorship schemes aimed at women[20]. Consider pro bono work with inventors from public institutions or micro entities.

When it comes to our profession as a whole, consider establishing inclusive hiring practices, making sure that your retention rates for men and women look similar (remember the leaky pipeline!), and evaluating the gender split among the leadership roles in your firm. Offer internal mentorship programs or empower your employees to participate in external ones. Consider outreach to universities or professional networks and keep in mind that there are likely additional hurdles out there for women who may wish to become patent attorneys.

Finally, looking at participation of women in IP is, of course, only one aspect of the diversity and inclusion conversation. It is one that may be less relevant in some countries (especially the top 8 of Figure 3 above!), but remains an important topic in others. We should strive to continue discussing and influencing this aspect of D&I, whilst also looking at other diversity aspects and continuing to exchange best practices and knowledge.

Next deadline for **epi** Information	Nächster Redaktionsschluss für **epi** Information	Prochaine date limite pour **epi** Information
The Editorial Committee invites contributions for publication in the next issue of **epi** Information. Documents for publication or any enquiry should be sent by eMail to (editorialcommittee@patentepi.org) no later than **13 May 2024**. Further information can be found in our "Guidelines for Authors" here: https://patentepi.org/r/guidelines-epi-info	Bitte senden Sie Ihre Beiträge zur Veröffentlichung in der nächsten Ausgabe der **epi** Information an den Redaktionsausschuss. Alle Artikel oder Anfragen schicken Sie bitte an folgende Email Adresse editorialcommittee@patentepi.org bis spätestens **13. Mai 2024**. Weitere Informationen finden Sie in unseren „Guidelines for Authors" auf der **epi** Webseite: https://patentepi.org/r/guidelines-epi-info	La Commission de Rédaction vous invite à lui faire parvenir vos contributions pour publication dans le prochain numéro d'**epi** Information. Les documents pour publication ou toute demande d'information doivent être envoyés par courriel (editorialcommittee@patentepi.org) au plus tard le **13 mai 2024**. De plus amples informations sont disponibles dans nos « Directives pour les auteurs » à l'adresse : https:// patentepi.org/r/guidelines-epi-info

Case Law

One year after G 2/21: where do we stand today?

Dr. T. Exner (DE), Michalski Hüttermann & Parter mbB

Since the publication of decision G 2/21, there have been eleven decisions by Technical Boards of Appeal in which post-filing data were considered admissible and in which it was decided whether the technical effect of these data could be taken into account in assessing the requirements of Art. 56 EPC. One case does not seem to be comparable to the other decisions, apparently involving aspects of Art. 83. In the remaining 10 decisions, the "encompassed by the technical teaching" criterion of G 2/21 is applied consistently. There seems to be a consensus that the original application does not need to explicitly state the technical effect relied on. The criterion "embodied by the same originally disclosed invention" appears to have been of less relevance in deciding the case. However, there appears to have been less consistency in the interpretation of this criterion.

It is now a year since the Enlarged Board of Appeal had to decide on the reliability of a technical effect shown only by post-filing data in the assessment of inventive step. The wording of the answer is reminiscent of answers usually given by the CJEU. It was not much of a surprise that the Enlarged Board held that post-filing data cannot be disregarded simply because they are filed after the filing date. The first referral question had, however, asked whether a technical effect that was shown *exclusively* by post-filing data should be disregarded under the principle of free evaluation of evidence. The word "exclusively" did not appear in the Enlarged Board's answer, but the phrase "*evidence, on which the effect rests*" implied that such evidence was meant.

The standard set by G 2/21

In reviewing case law of the Boards of Appeal, the Enlarged Board identified a core issue which it considered to be common ground to all decisions: What does the skilled person, with the common general knowledge in mind, understand at the filing date from the application as originally filed to be the technical teaching of the claimed invention?[1] The technical effect shown by post-filing data had to be derivable by the person skilled in the art from the technical teaching of the application as filed.[2]

At the end of the decision, the Enlarge Board summarised two aspects of "the relevant standard for the reliance on a purported technical effect",[3] i.e. a technical effect demonstrated by post-filing data: **(i)** the effect must be encompassed by the technical teaching of the original application, and **(ii)** it must be embodied by the same originally disclosed invention. As stated above, the assessment is of course to be made from the point of view of the person skilled in the art.

The main question that arises in the light of the reasons of the decision is what standards the words "encompassed" and "embodied" set for the disclosure of the application as filed. The Enlarged Board gave no guidance in this respect. It will be of interest to applicants what follows from the fact that the Enlarged Board said that it has identified the above first criterion as common ground after reviewing the case law of the last two decades: Will Technical Boards of Appeal take this as confirmation to continue as before, or will they change their approach in the light of G 2/21 when considering post-filing data?

Examples of evidence considered/ not considered prior to G 2/21

Two decisions in which Boards took rather contradictory approaches illustrate where the shoe really pinched prior to the decision G 2/21.

In decision **T 939/92** (AgrEvo), the claim at issue covered a large number of compounds in a product claim, and the Board did not consider it credible that all compounds had the purported technical effect. The applicant had "*been given ample opportunity … to provide further evidence, either by test results or by other means*" to prove the technical effect.[4] The Board would therefore have accepted additional data, which was, however, not submitted.

A similar situation arose in decision **T 488/16**: a group of chemical compounds, defined in a product claim, was ascertained to have a technical effect, but the application as filed lacked data for any of the compounds covered by the claims. The Board disregarded the post-filing data, because it did not consider it plausible to the person skilled in the art that every compound disclosed in the application as filed would have the purported technical effect.[5]

In applying criterion **(i)** of G 2/21, the effect shown by the post-filing data submitted in T 488/16 was apparently encompassed by the general teaching of the application as filed. However, in both T 939/92 and T 488/16, the Boards had taken the view that the person skilled in the art would not consider the purported effect to be clearly applicable to all disclosed compounds. It was only in T 488/16 that the Board held that there was a need for appropriate teaching in the original application. In T 939/92, the Board was apparently prepared to accept and take into account post-filing data whenever filed.

As regards the second criterion of G 2/21, it seems difficult to dissect the claims in either of the two decisions to the effect that for some compounds the purported effect was not embodied by the same invention.

The case of G 2/21 finalised and interpreted

The case underlying decision G 2/21, namely **T 116/18**, has in the meantime been decided in favour of the patentee. Claim 1 at issue was a product claim, namely an insecticidal composition comprising a specific compound and a further compound defined by a Markush formula. This effect had already been disclosed in the application as filed. Data in the application as filed showed a synergistic effect on two insect species. During opposition proceedings, the patentee had submitted further data showing a synergistic effect for a third insect species. The opponent had filed data with the grounds of appeal showing that the synergistic effect did not occur over the whole range claimed for the first two insect species, i.e. the insect species for which the opposed patent contained data. Here, the problem to be solved could be limited to the third insect species.

The referring Board concluded that the patentee's post-filing data should be taken into account, and that on this basis an inventive step could be acknowledged.

In its reasoning, the Board found that the two criteria for considering the technical effect, namely in **(i)** the "technical teaching", and in **(ii)** the "same originally disclosed invention", were in fact one and the same issue.[6] The Board was of the view that "G 2/21 seeks to prevent speculative inventions."[7] Therefore, the assessment had to be made on the basis of the broadest technical teaching of the

1 See point 71 of the reasons of G 2/21
2 See point 72 of the reasons of G 2/21
3 See points 93 and 94 of the reasons
4 See point 2.6.7 of the reasons of T 939/92
5 See point 4.9 of the reasons of T 488/16
6 See point 11.9 of the reasons of T 116/18
7 Often termed armchair inventions, see point 11.8 of the reasons of T 116/18

application as filed.[8] For criterion **(i)** above, this meant that the technical effect relied on did not have to be disclosed literally.[9] For criterion **(ii)** above, this meant that there was no requirement for the application as filed to contain experimental data.[10] Moreover, for criterion (ii) above, the test would be whether the skilled person would have legitimate reason to doubt that the purported technical effect could be achieved with the claimed subject-matter.[11]

Further interpretation

A further decision that provided a general interpretation regarding a new technical effect was **T 2465/19**, although it did not deal with the submission of additional data. Similarly to T 116/18, the Board quoted the second answer of decision G 2/21 to the effect that the technical effect relied on did not have to be explicitly stated in the application. It only had to be derivable from the original application.[12]

In this respect, therefore, both decisions read G 2/21 as applying a reality-based approach, which is consistent with the Board's observation in pre-G 2/21 decision T 2371/13 that it would be common to rely on a technical effect that was not explicitly mentioned in the application as filed.[13]

Irrespective of whether the Enlarged Board intended its second criterion to have this meaning, the following overview shows that all Boards seem to have adopted this approach. It is only at first glance that one of the Boards appears to be out of line.[14]

The Boards on post-filing data

In addition to T 116/18, a total of 12 post-G 2/21 decisions were issued in 2023, in which post-filing data had been submitted to be used for the assessment of inventive step. In two decisions, T 2911/19 and T 573/21, such data were not admitted as late filed in the absence of exceptional circumstances. These two decisions will not be discussed further here. Of the remaining 10 decisions, 8 cited the Enlarged Board in G 2/21. In three of these 10 decisions, the Board did not consider post-filing data. As explained below, one of these three cases appears to involve sufficiency aspects, and is therefore best left out of the overall picture. In one of the 10 decisions, T 364/20, the patentee relied on post-filing data for more than one technical effect. The Board took an interesting approach: the post-filing data were taken into account only to the extent that the purported technical effect was found to be derivable from the application as filed.

The remaining 6 decisions where post-filing data were successfully filed will be briefly discussed first.

Decisions where post-filing data were taken into account

In **T 873/21**, claim 1 related to a composition comprising two active ingredients for the treatment of a metabolic disorder in a horse. The application as filed disclosed an improved effect compared to monotherapy with one of the two active ingredients.[15] Post-filing data showing a synergistic effect were taken into account by the Board. The effect was regarded as derivable from the original application. As for the above criterion **(ii)**, the effect was embodied by an originally disclosed combination, as this was the preferred combination in the original application.[16]

Claim 1 as assessed in **T 2735/19** defined cancer treatment in the form of a second medical use claim, limited to a dosage regimen. While the description as filed referred to a "cancer therapeutic drug", data in the application as filed only showed an effect on breast cancer. Post-filing data showed an effect on further cancer types. The Board concurred with the patentee that, based on the common general knowledge of the mode of action of the active ingredient, the skilled person would expect a general effect on tumours, and not just on breast cancer.[17] Criteria (i) and (ii) of G 2/21 were therefore found to be met, and the data were considered.[18] The purported technical effect was regarded as credible for the scope of "cancer".[19]

Dr. Torsten Exner

T 885/21 concerned a claim 1 that defined a first medical use of an antibody-cytotoxin conjugate. The description disclosed an advantageous homogenicity in terms of site specificity and stoichiometry, as well as improved stability. Pharmacological effects were shown in examples of the patent as filed. Post-filing data related to features identified as different from the prior art. They showed improved homogenicity and pharmacological effects as disclosed in

8 See points 11.8 and 11.9 of the reasons
9 See point 11.10 of the reasons
10 See point 11.12 of the reasons, referring to points 93 and 60 of the reasons of G 2/21; see also point 11.14 of the reasons
11 See points 11.11 and 11.14 of the reasons
12 See point 5.3.1 of the reasons of T 2465/19
13 See point 6.1.2 of the reasons of T 2371/13
14 See decision T 258/21. A closer look at the circumstances tells a different story, see below
15 See point 3.3.2 of the reasons of T 873/21
16 See points 3.3.2 and 3.3.3 of the reasons of T 2735/19
17 See points 5.2 and 7.2.3 of the reasons of T 2735/19
18 See points 11.11 and 11.14 of the reasons
19 See point 5.2 of the reasons of T 2735/19

the application. The effect shown by these data was thus regarded as encompassed by the technical teaching and embodied by the disclosed invention.[20]

In **T 1329/21**, claim 1 related to a cosmetic formulation comprising, inter alia, cellulose particles of a certain size. The application as filed had given a reduced stickiness of formulations as a purpose of the invention. Inter alia an improved absorption capacity and better spreadability were described. Post-filing data in the form of a table showed, under the item "sensory properties", evaluations of properties, such as oiliness and absorption. The original application had provided similar evaluations. The Board found that the technical effect shown was clearly encompassed by the technical teaching of the original application.[21]

Claim 1 at issue in **T 728/21** defined a medical use of a tablet formulation for cystic fibrosis in certain patients. Post-filing data included a diagram of the dissolution properties of the components of the formulation, from which it could be concluded that the tablet formulation as claimed had an improved dissolution compared to the prior art. The original application had already in the summary section several times named dissolution values and contained a figure showing dissolution profiles. The Board therefore found that the application as filed "*addressed dissolution of tablets … as an aspect of the disclosed invention … and specifically described the claimed tablet composition as an embodiment of the disclosed invention*".[22] The data could therefore be considered.

T 591/21 concerned a dishwashing composition. Data in the application as filed showed better cleaning properties compared to the closest prior art. The Opposition Division had, however, questioned that the conditions used for obtaining the data were comparable.[23] In response, the patentee had filed new data. Since the technical effect was unchanged, the conditions of G 2/21 were apparently not an issue, and the decision does not even cite G 2/21.

Noteworthy, in none of these 6 decisions did a Board express doubts about the plausibility of the technical effect for which post-filing data had been submitted. Any general conclusion based on these 6 decisions is therefore somewhat limited.

Decisions where post-filing data were not taken into account

The decision referred to above, in which an effect shown in post-filing data was only partially taken into account, is **T 364/20**. Claim 1 at issue related to a composition comprising different paraffins. The patentee had included two tables of data into a letter filed during opposition proceedings. These tables apparently resembled tables included in the application as filed, and related to further compositions falling within the claimed subject matter. The property to be relied upon was the presence of less volatile organic compounds, thereby inter alia imposing a reduced health impact. The Board held that the presence of less volatile organic compounds was not a technical effect, but that the purported effect on health was. However, there was no mention of a positive impact on health in the application as filed.[24] Although the Board did study the post-filing data, this technical effect was not taken into account.

Although T 364/20 does not mention decision G 2/21, the Board de facto found that criterion (i) established by the Enlarged Board was not met. While the outcome was thus not in favour of the patentee, the approach taken appears to seamlessly join the approach of the above decisions.

The decisions in which the Boards did not take post-filing data into account at all are T 887/21, T 258/21 and T 681/21.

T 887/21 concerned a second medical use of a nutritional composition. Claim 1 defined the use as the prevention of secondary infections following a viral infection characterised by a certain enzyme activity. It may be helpful to know that the second auxiliary request limited the secondary infections to infections of the respiratory tract by pathogenic bacteria. The background section of the application as filed began with the words "Infections of the respiratory tract", and the end of the summary section referred to influenza as the viral infection. The Board found that there was one single instance where the application as filed named infections of the gastrointestinal tract as a secondary infection. For the sake of fairness, it should be added that this paragraph seems to be the definition of the secondary infections to be prevented. No data were provided in the application as filed. The patentee filed post-filing data, in which a strain of *Salmonella typhimurium* was used at various concentrations, and referred to the generic claim wording. The Board found that the cells used in these data were not the cells on which the application had based a concept of action. Most of all, *Salmonella typhimurium* is known to cause gastroenteritis, and was not mentioned in the application as filed. The post-filing data would therefore provide entirely new information.[25] The skilled person would thus not find the technical effect of the post-filing data "*as being encompassed by the technical teaching and embodied by the same originally disclosed invention*".[26]

20 See point 6.4.1 of the reasons of T 885/21
21 See point 3.2.4 of the reasons of T 1329/21
22 See point 2.2 of the reasons of T 728/21
23 See point 3.3.1 of the reasons of T 591/21
24 See point 11.5.3 of the reasons of T 364/20
25 See point 2.15.3 of the reasons of T 887/21
26 See point 2.15.4 of the reasons of T 887/21

After all, decision T 887/21 therefore appears to be largely in line with the above decisions that were in favour of the applicant/proprietor. The negative outcome in this case was based on the interpretation of the scope of the invention vis-à-vis the disclosure of the original application as a whole, and the conclusion that the effect shown by the post-filing data was beyond the underlying technical teaching.

Claim 1 at issue in **T 258/21** again related to a second medical use, namely reducing ischemic stroke damage. The application as filed did not provide any data or scientific explanation of the medical use. In essence, the information provided seemed to be a statement at the beginning of the section 'Detailed Description': "*The present invention is based on the discovery that … is effective in reducing stroke damage …*". This was followed by a paragraph with explanations on stroke, and a subsequent paragraph provided embodiments of the cause of the stroke. Two post-published abstracts were submitted as annexes, purporting to demonstrate improvements in the treatment over two cited documents, including a higher activity and reduced side effects.[27] The description of the application as filed named the ability to rapidly reduce blood pressure, as well as safety, including the absence of side effects, as characteristics of the active ingredient used.[28] However, according to the Board, improved activity and reduced side-effects were "*neither contemplated nor even suggested in the original application*".[27] Nevertheless, the Board then provided an assessment of the content of the annexes, beginning with the words "*Moreover, even if said technical effect would have been derivable from the original application …*".

At first glance, the approach taken in T 258/21 appears to be at odds with the approach taken in T 728/21 or T 1329/21. Compared to these other two decisions, the original application in T 258/21 may have had very limited disclosure relating to the technical effect subsequently relied on. However, the purported technical effect does not seem to be a completely new effect, as in T 887/21.

What may have played an important role in T 258/21 is, firstly, that the claim defined a second medical use. Secondly, the technical effect discussed in terms of inventive step appears to be identical to the definition of the medical use in the claim at issue. Thus, it appears that the Board was actually confronted with a sufficiency issue.[29] As the Enlarged Board held in G 2/21[30], "*it is necessary that the patent at the date of its filing renders it credible that the … therapeutic agent … is suitable for the claimed therapeutic application.*" However, in T 258/21 the application at issue did not contain any data. This aspect of sufficiency seems to take decision T 258/21 out of a pure inventive step assessment. Therefore, it seems advisable to exclude this decision from a comparison that is intended to be limited to circumstances where a purported technical effect is relied upon when defining the problem to be solved.

Finally, **T 681/21** concerned a laundry detergent; claim 1 defined a fabric treatment composition which differed from the closest prior art in that it contained a specific cationic polymer. The patentee argued in favour of improved softness, in particular a synergy resulting from the presence of the polymer and another component of the composition, silicone.[31] The question arose as to whether this effect could be relied upon. A document in the form of a technical report was available as post-filing data. The first paragraph of the application as filed already named improved softening, and two paragraphs later improved softening was named as the problem to be solved. The paragraph between these passages acknowledged that silicone is conventionally added to provide softness to fabrics. In one further instance the description referred to "fabric softening silicone". The Board concluded that the formulation of the technical effect relied on by the patentee was different from that identified in the patent.[32] A synergistic effect of the cationic polymer and silicone was neither disclosed nor suggested in the original application. The technical effect would therefore not have been considered by the skilled person as being encompassed by the technical teaching of the application as filed.[33]

Again, at first glance, the approach taken in T 681/21 does not seem consistent with that taken in T 728/21 or T 1329/21. It is also striking that in T 873/21 it was found that a synergistic effect was derivable from the application as filed, whereas this was not the case in T 681/21.

However, two aspects of the case of T 681/21 should be noted: (a) silicone is obviously a commonly used softener, and (b) the skilled person apparently also knows the cationic polymer as a softener.[34] The technical effect therefore boils down to the alleged synergistic effect, of which, indeed, there does not appear to be any suggestion in the application as filed. In the application underlying T 873/21 statements such as the following taught an improvement when using a combination: "*The combination therapy … advantageously leads to improved insulin sensitivity where monotherapy with one or more dopamine receptor agonist is insufficient*".[35] In contrast, the application underlying

27 See point 1.3.2 of the reasons of T 258/21
28 See page 9, second paragraph, of PCT application WO 2012/135617
29 See the frequently cited distinction under point 2.5.2 of the reasons of G 1/03. See also point 74 of the reasons of G 2/21
30 See point 74 of the reasons of G 2/21
31 See point 1.2.1 of the reasons of T 681/21
32 See point 1.2.2 of the reasons of T 681/21
33 See point 1.2.3 of the reasons of G 2/21
34 See point 1.2.4 of the reasons of G 2/21
35 See the third paragraph on page 4 of WO 2016/046150

T 681/21 taught: "*We have now found that if instead of addition as part of the laundry detergent, the silicone is provided as part of a separate composition, then the softening performance is improved*".[36] What is and what is not a new effect ultimately depends on the circumstances of each case.

Conclusion

The EBA has distilled the real problem on the basis of the keywords and additional questions provided to it. It has provided the Boards and applicants with two criteria as an answer. On the whole, an almost homogeneous approach can be deduced from the above 11 decisions. As soon as post-filing data did more than confirm data in the application, G 2/21 was consulted and at least the Enlarged Board's criterion **(i)** – is the effect encompassed by the technical teaching of the original application – was assessed through the eyes of the skilled person. The Boards have breathed life into this criterion and appear to have applied it consistently. In general, the first criterion seems to be sufficient to decide whether a technical effect shown by post-filing data can be used for the assessment of inventive step or not.

As regards criterion **(ii)** – is the effect embodied by the same originally disclosed invention – it appears that the Boards may not have a uniform interpretation. T 116/18 even seems to provide a through ball for a further referral to the Enlarged Board. In two decisions post-filing data failed condition (i) of G 2/21 because patentees tried to rely on a completely new technical effect.

36 See paragraph [0006] of EP 3 221 438

Decision	Appeal from	Facts and conclusion	data
T 873/21 (20 June 2023)	Examination	Combination preparation for the treatment of metabolic disorders in horses – post-filing data show a synergistic effect, the application teaches an improved effect over monotherapy with a dopamine receptor agonist	considered
T 887/21 (13 July 2023)	Opposition	Use of a nutritional composition against a second infection – no data in the application, post-filing data show an effect regarded as beyond the teaching of the application; different disease, different mechanism	not considered
T 2735/19 (19 July 2023)	Opposition	Cancer therapy – post-filing data show a generalisation of the technical effect, which the skilled person would have expected	considered
T 258/21 (24 July 2023)	Examination	Reduction of ischemic stroke damage – no data in the application, post-filing data show an effect regarded as not suggested in the application	not considered
T 116/18 (28 July 2023)	Opposition	Synergistic effect of compounds in an insecticide composition – data in the application questioned and not considered, post-filing data relate to other insects	considered
T 885/21 (14 September 2023)	Opposition	First medical use of antibody conjugates – data show effects already disclosed in the original application	considered
T 1329/21 (19 September 2023)	Opposition	Cosmetic formulation comprising cellulose microparticles – post-filing data show properties falling withing the purpose of the invention according to the application	considered
T 364/20 (04 October 2023)	Opposition	Paraffin composition – positive effect on health argued, no such effect mentioned in the application	not considered
T 681/21 (30 October 2023)	Opposition	Fabric treatment composition – synergistic effect of 2 components in terms of softening argued, softening is denoted the problem to be solved in the application, however, no synergistic effect mentioned	not considered
T 728/21 (16 November 2023)	Opposition	Tablet formulation – data show improved dissolution, dissolution an aspect of the invention according to the application	considered
T 591/21 (23 November 2023)	Opposition	Dishwashing detergent composition – filed data confirm effect of data in the application	considered

Which case has now prevailed, T 939/92 (AgrEvo) or T 488/16? In other words, is it possible to overcome the "we don't buy it" objection with post-filing data? Firstly, it seems that G 2/21 has led to a more precise wording: instead of a problem being solved, all decisions assess the technical effect. Furthermore, the bar is obviously set too high in T 488/16 by requiring that "the asserted activity has been made sufficiently plausible" by the application as filed.[37] If this were the standard, even in T 591/21 post-filing data could not have been submitted to address the Opposition Division's doubts about comparability of conditions with those of a cited document. Consequently, neither T 939/92 nor T 488/16 appear to be fully in line with the G 2/21 standard. As acknowledged in T 116/18[38], "*any rationale developed in the previous plausibility case law*" is no longer decisive.

According to decision T 116/18, a "we don't buy it" objection can now be raised under the above criterion **(ii)**. Be that as it may, situations where the person skilled in the art does not consider a purported effect for part of the claimed subject matter to be credible in the light of the application as filed will not disappear[39]. It is fairly safe to say that this situation directly translates into criterion **(i)** of G 2/21: the effect would not be encompassed by the technical teaching of the original application for that subject matter. The result would therefore in all likelihood be the same as in T 488/16, and not as in T 939/92.

37 See point 4.2 of the reasons of T 488/16
38 See point 11.3.2 of the reasons of T 116/18
39 See the situation of T 258/21, which can be viewed in the same light

Reliance on a purported technical effect for inventive step – Quo vadis "plausibility" after G 2/21?

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In the context of the effect-driven assessment of inventive step under the European Patent Convention (EPC) it is usually crucial for the outcome whether an Applicant/Patentee can rely on a specific technical effect corresponding to an improvement over the prior art. In the absence of such improvement, the claimed subject-matter is often found to be obvious. From the perspective of the Applicant/Patentee, flexibility is required to adapt an initially disclosed technical effect in case new evidence such as new prior art or new experiments comes up during examination or opposition proceedings. In a first-to-file system like the EPC, however, the Applicant/Patentee should also not be able to later invoke any effect at will to exclude purely speculative filings and corresponding unwarranted advantages for such Applicants/Patentees. In G 2/21, the Enlarged Board of Appeal (EBA) is concerned with providing guidelines on how a proper balance can be achieved. The provisions of G 2/21 have meanwhile been applied in several decisions.

Background

In order to assess inventive step (Article 56 EPC) in an objective and predictable manner, Technical Boards of Appeal of the European Patent Office (EPO) developed the so-called "**problem-solution approach**". The Boards identified three main stages: **(i)** determining the "closest prior art", **(ii)** establishing the "objective technical problem" to be solved, and **(iii)** considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person. The objective technical problem is formulated based on the **technical effect** resulting from the distinguishing feature(s) of a claim and the disclosure in the closest prior art. Depending on the technical effect, the corresponding problem may be the provision of an improvement or simply an alternative over the closest prior art. Alternative solutions are frequently rejected for being obvious. For this reason, Applicants/Patentees primarily attempt at relying on an improvement, which often can be argued

to be unexpected and therefore nonobvious. The purported effect is therefore very often crucial in the evaluation of patentability.

Such an effect needs to be established **i)** per se and **ii)** over the whole breadth of the claim in order to be accepted, and a challenge very often concerns one or both aspects. During the lifetime of a patent application or patent, an originally disclosed effect may therefore be successfully challenged through evidence not yet considered by the EPO, such as new prior art or new experiments. If the Applicant/Patentee should not be limited to a less ambitious effect or even only an alternative in such a situation, the Applicant/Patentee should be able to adapt the originally disclosed technical effect. Consideration of "post-published" evidence, i.e. evidence not forming part of the original application, might become necessary to establish the adapted effect both per se and over the whole breadth of the claims. As an Applicant/Patentee may not at the time of filing the application be aware of prior art or other evidence that might come to light only later during prosecution/post-grant proceedings, some flexibility is needed to allow the Applicant/Patentee to defend its case in such situations. However, as the EPC is based on the first-to-file principle, an Applicant/Patentee is generally not allowed to invoke any technical effect at will after the application has been filed, in particular in situations where the application as filed does not disclose any kind of solution and subsequently produced evidence is the first material going beyond mere speculation. The invention in essence must be disclosed in the application as originally filed.

There is no straightforward answer to the question of under which circumstances an Applicant/Patentee may or may not rely on post-published evidence to establish a technical effect which will be taken into account for the assessment of inventive step and which often will be essential for establishing patentability. On the one hand, care must be taken that no unfair advantage is given to the Applicant/Patentee, and on the other hand, the Applicant's/Patentee's ability to defend its case should not be unduly restricted when circumstances change unforeseeably. The catchword "plausibility" has been used in the past to encapsulate the problem of when to allow or disallow post-published evidence.

On March 23, 2023, the Enlarged Board of Appeal (EBA) issued its much-awaited decision on this topic, **G 2/21**.

Below, the facts underlying G 2/21 will first be summarized. The EBA's guidelines in G 2/21 will then be reviewed. Following that, the reasoning of the Technical Board 3.3.02 for admitting post-published evidence in the underlying case **T 0116/18** and following the guidelines in G 2/21 will be outlined. Finally, an overview of currently available decisions applying G 2/21 in the context of Art. 56 EPC will be provided.

The facts underlying G 2/21 – a short recap

Claim 1 in the underlying case T 0116/18 was directed to an insecticide composition comprising thiamethoxam and a compound represented by formula Ia.[1] The claimed subject-matter differed from the closest prior art in that both thiamethoxam and the compound according to formula Ia had to be selected from a respective broader disclosure in the closest prior art.[2] The finally adapted relevant purported technical effect was an improvement due to a synergistic activity between thiamethoxam and a compound according to claim 1 against the insect *Chilo suppressalis*.[3]

According to the application as filed, a synergistic effect between the more general formulae I (comprising subset Ia as claimed) and II (comprising thiamethoxam as claimed) against insects in general can be achieved.[4] The application contained five test examples evaluating the presence/absence of synergy between two insecticides.[5] Test example 3 related to *Chilo suppressalis*, but the tested insecticide compositions were not according to granted claim 1.[6]

In the course of the opposition proceedings, the Patentee filed post-published evidence which in the referring Board's view was sufficient proof of a synergistic effect against *Chilo suppressalis* across the entire breadth of claim 1 as granted.[7] According to the referring Board, the problem to be solved consisted therefore in the provision of an improved insecticide composition and the solution to this problem would be considered unobvious if the post-published evidence showing synergy for the claimed combination were to be accepted, while the claimed subject-matter would be only an obvious alternative insecticide composition if not.[8] Patentability hinged solely on the post-published evidence.

The referring Board discussed three purportedly diverging lines of earlier case law from the Boards of Appeal regarding the circumstances under which post-published evidence can be taken into account on substantive grounds:

(i) Type I case law: post-published evidence can be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved, or, in other words, if the effect is already "credible" from the application as filed

1 Reason 1.1 of T 0116/18 (decision of July 28, 2023, published November 2023)
2 Reason 6 of T 0116/18
3 Reason 13 of T 0116/18
4 Reason 17.1 of T 0116/18
5 Reason 3 of T 0116/18
6 Reason 17.1 of T 0116/18
7 Reasons 4 and 6 of T 0116/18
8 Reasons 6 and 22.1 of T 0116/18

("***ab initio* plausibility**"). A representative example is T 1329/04. The burden of proof for *ab initio* plausibility usually rests with the Applicant/Patentee;[9]

(ii) Type II case law: post-published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent in suit ("***ab initio* implausibility**"). A representative example is T 0919/15 which, like the referral case, concerned a synergistic effect. The burden of proof for *ab initio* implausibility usually rests with the opponent;[10] and

(iii) Type III case law: rejecting the concept of plausibility altogether ("**no plausibility**"). An example is T 0031/18, in which the Board held that a technical effect must either be explicitly mentioned in the application as filed or at least be derivable therefrom, but without requiring a specific level of plausibility.[11]

The guidelines of the EBA

The EBA explained that, according to established jurisprudence of the Boards of Appeal, inventive step is to be assessed at the effective date of the patent on the basis of the information in the patent together with the common general knowledge then available to the skilled person.[12] An effect cannot be validly used in the formulation of the technical problem if the effect required additional information not at the disposal of the skilled person even after taking into account the content of the application in question.[13]

Having analyzed a selection of jurisprudence in the context of the three different approaches use by the referring Board (type I, II, and III case law, *supra*),[14] the EBA found that the core issue common to all decisions rests with the question of what the skilled person, with the common general knowledge in mind, understands at the filing date from the application as originally filed as the technical teaching of the claimed invention.[15] According to the EBA:[16]

> *"Applying this understanding to the aforementioned decisions, not in reviewing them but in an attempt to test the Enlarged Board's understanding,* ***the Enlarged Board is satisfied that the outcome in each particular case would not have been different from the actual finding of the respective board of appeal****. Irrespective of the use of the terminological notion of plausibility, the cited decisions appear to show that the particular board of appeal* ***focused on the question whether or not the technical effect relied upon by the patent applicant or proprietor was derivable for the person skilled in the art from the technical teaching of the application documents****." (emphasis added)*

On this basis and without rejecting the reasoning of any cited decision in its substance, the EBA stated in order no. 2:

> *"A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention."*

In its concluding remarks, the EBA emphasized:[17]

> *"The Enlarged Board is aware of the abstractness of some of the aforementioned criteria. However, apart from the fact that the Enlarged Board, in its function assigned to it under Article 112(1) EPC, is not called to decide on a specific case, it is* ***the pertinent circumstances of each case*** *which provide the basis on which a board of appeal or other deciding body is required to judge, and the actual outcome may well to some extent* ***be influenced by the technical field of the claimed invention****." (emphasis added)*

Although the referring questions did not require an answer on the issue of sufficiency of disclosure under Art. 83 EPC, the EBA accepted the appropriateness of a comparative analysis and comparative considerations in this regard.[18] The corresponding statements are also interesting for a better understanding of its guidance under Art. 56 EPC. The EBA stated that the notion of "plausibility" has been used in particular in the context of second medical use claims. According to the EBA, a technical effect, which in the case of second medical use claims is usually a therapeutic effect, is a feature of the claim, so that the issue of whether it has been shown that this effect is achieved is a question of sufficiency of disclosure. Hence, according to the EBA, because the subject-matter of second medical use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, **it is necessary that the patent at the date of its filing renders**

9 Reasons 13.4 and 15 of T 0116/18 referral (interlocutory decision of October 11, 2021)
10 Reasons 13.5. and 15 of T 0116/18 referral
11 Reason 13.6 of T 0116/18 referral and reason 65 of G 2/21
12 Reason 23 of G 2/21
13 Reason 25 of G 2/21
14 Reasons 65 to 69 of G 2/21
15 Reason 71 of G 2/21
16 Reason 72 of G 2/21
17 Reason 95 of G 2/21
18 Reason 73 of G 2/21

it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application.[19] It added that the scope of reliance on post-published evidence is much narrower under sufficiency of disclosure (Art. 83 EPC) compared to the situation under inventive step (Art. 56 EPC).[20] The EBA also stated:[21]

> *"In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published data."*

The more limited scope and very different wording provided for second medical use claims under Article 83 EPC emphasizes the broader scope under Art. 56 EPC.

The main conclusions that can be drawn from G 2/21

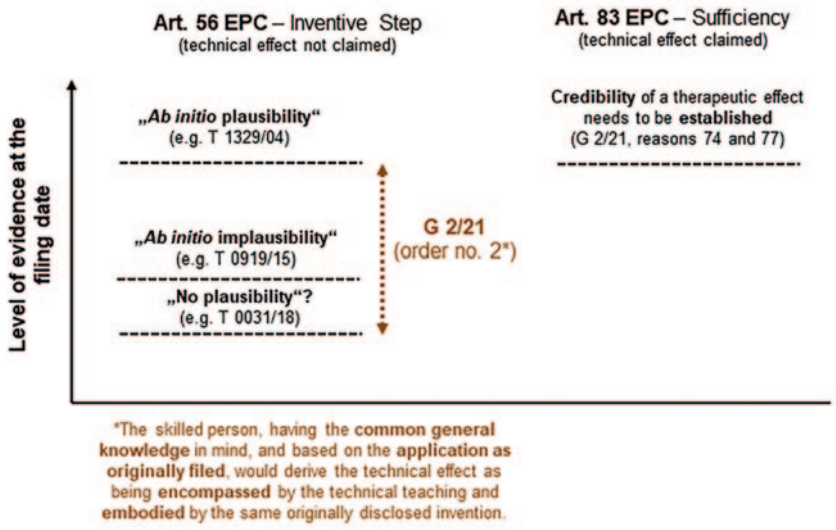
There is no indication that the EBA wished to create an altogether new standard for evaluating whether an Applicant/a Patentee can rely on post-published evidence to back up a technical effect under inventive step considerations. Rather, it formulated a test which it considered common across the existing jurisprudence. This test therefore can be seen to encompass the previous standards, and at least the decisions analyzed in G 2/21 appear to retain their validity as references.

The EBA focused on the application as filed and the understanding of the skilled person as at the filing date, emphasising that an invention cannot be solely based on knowledge made available only after the filing date. It did not give *carte blanche* to reliance on any technical effect and to using post-published evidence in all instances.

The criteria in order no. 2 remain rather abstract and there is consequently no clearly defined common standard. The decision must rest on the specific facts of the particular case and may also depend on the technical field of the claimed invention. Consequently, G 2/21 allows great flexibility for the Boards to reach decisions on a case-by-case basis. While existing case law can continue to apply, new case law can also be developed in different technical fields.

By way of comparing the much narrower guidelines of the EBA as regards sufficiency of disclosure (Article 83 EPC) for medical use claims and the requirements under order no. 2 for inventive step (Article 56 EPC) it can be concluded that a credible disclosure in the application as filed for a purported effect is not always a mandatory requirement under inventive step but will depend on the facts of each case.

The above main conclusions can be schematically summarized as follows:



The application of the EBA guidelines in T 0116/18

The referring Board relied on order no. 2 of G 2/21 and applied the two-fold test, namely whether the skilled person having the common general knowledge in mind, and based on the application as originally filed, would consider the effect as being

(i) encompassed by the technical teaching, and

(ii) embodied by the same originally disclosed invention.[22]

The Board first provided a general interpretation of order no. 2 and then applied its interpretation to the facts of the case.

In its general analysis the Board firstly noted that G 2/21 seeks to prevent speculative inventions and that there is no "carte blanche" for patent applicants or patentees:[23]

19 Reason 74 of G 2/21
20 Reason 77 of G 2/21
21 Reason 77 of G 2/21
22 Reason 11.3 of T 0116/18
23 Reason 11.1 of T 0116/18

> *"The Enlarged Board did not hold that a patent applicant or proprietor can **always** rely on a purported technical effect. On the contrary, the Enlarged Board, by way of order no. 2, established requirement(s) that must be met. The Enlarged Board thus **did not give patent applicants and proprietors "carte blanche"** to be able to rely on a purported technical effect at any stage of the proceedings. Therefore, it can be concluded from order no. 2 that patent applicants and proprietors should not be able to invoke any technical effect **at will**. Instead, the focus on the application as filed and the filing date (G 2/21, point 93 of the Reasons) is intended **to prevent the filing of applications directed purely to speculative (armchair) inventions made only after the filing date**." (emphasis added)*

The Board considered whether order no. 2 provides a new standard or is a summary of the old standards in the existing case law. The Board found that it would not matter since it is now the requirements of order no. 2 that have to be followed rather than simply using any rationale developed in the previous so-called plausibility case law.[24]

The Board reasoned that **both** requirements of order no. 2 are **separate** requirements which must be met **cumulatively**. [25] It concluded that

- for requirement (i) to be met, the purported technical effect together with the claimed subject-matter need only be conceptually comprised by the broadest technical teaching of the application as filed, which in turn means that said effect need not be literally disclosed by way of a positive verbal statement[26], and

- for requirement (ii) to be met, the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, must not have legitimate reason to doubt that the purported technical effect can be achieved with the claimed subject matter. Experimental proof of the purported technical effect or a positive verbal statement is not necessarily required in the application as filed.[27]

It is noteworthy that when defining the conditions under ii) the Board used the same wording as it used for summarizing the "ab *initio* implausibility" standard in its referral decision, i.e. "***would have legitimate reason to doubt** that the purported technical effect can be achieved with the claimed subject matter*" (supra).

The Board then applied the general interpretation of order no. 2 to the facts of the case:

- The Board found that the broadest technical teaching of the application as filed can be considered to be that a combination of a compound of general formula I with a compound represented by general formula II can result in a synergistic effect against insects. Regarding (i), the Board thus reasoned that the purported technical effect (i.e. the synergistic activity against *Chilo suppressalis*) is encompassed by the broadest technical teaching of the application as filed, because the compounds of formula Ia of claim 1 as granted are a subset of those of formula I, thiamethoxam as referred to in claim 1 as granted falls within the definition of formula II and *Chilo suppressalis* is a specific insect species and therefore falls under the corresponding broader term "insects".[28]

Dr. Anja Fux

Dr. Eva Ehlich

- Regarding (ii), the Board found that the application contains examples demonstrating a synergistic effect against *Chilo suppressalis*, although not for an insecticide combination in accordance with claim 1 as granted, but rather for a combination of clothianidin or dinotefuran (and not thiamethoxam as claimed) with a compound of formula Ia.[29] The Board considered clothianidin and thiamethoxam to be structurally very similar and therefore concluded that the skilled person would have no legitimate reason to doubt that the synergistic effect against *Chilo suppressalis* would be maintained when replacing clothianidin with thiamethoxam (as in the claimed insecticide combination).[30] In particular no concrete evidence was provided, derived from the common general knowledge, as to why the skilled person would have legitimate reason to doubt that the specific purported technical effect can be achieved.[31] In order to specify such legitimate reasons to doubt, the Board indicated that it would

24 Reason 11.3.2 of T 0116/18
25 Reason 11.4 of T 0116/18
26 Reason 11.10 of T 0116/18
27 Reasons 11.11 to 11.14 of T 0116/18
28 Reasons 15 and 16 of T 0116/1
29 Reason 17.2 of T 0116/18
30 Reason 17.4.1 of T 0116/18
31 Reason 17.4.2 of T 0116/18

need to see evidence showing that the purported effect is irreconcilable with the common general knowledge. In this context, it emphasized that the unpredictable and surprising nature of a synergistic effect in general was not sufficient to generate such doubts.[32]

The main conclusions that can be drawn from T 0116/18

The Board interpreted the guidelines given by the EBA in order no. 2 as a new test.

Post-published evidence cannot always be taken into account; rather the two conditions provided in order no. 2 need to be cumulatively fulfilled.
Post-published evidence cannot be disregarded solely because there is no verbal statement or no experimental proof in the application as filed.
This Board interpreted the purported new test condition ii) in order no. 2 still very much in line with the previous "*ab initio* implausibility" standard in its referral decision. The Board nevertheless placed much emphasis on the experimental evidence in the application as filed and its supportive nature for the purported effect.

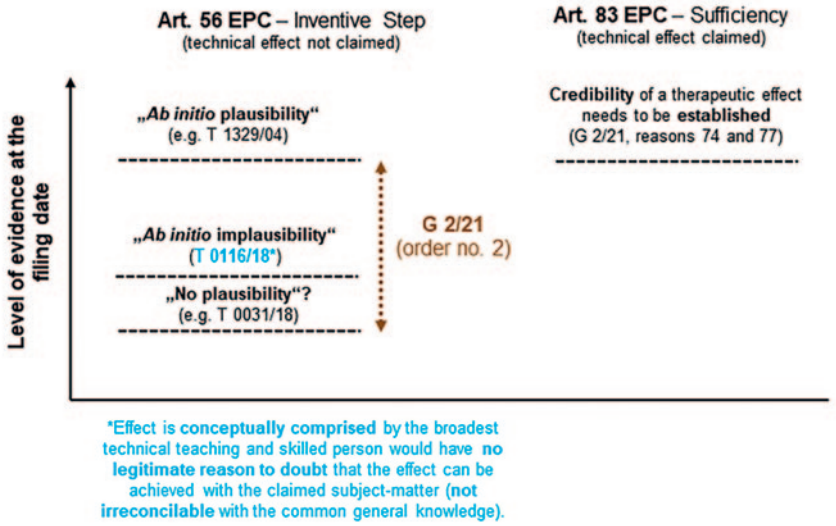
With the existing experimental evidence in the background, the Patentee in this case had the benefit of the doubt regarding remaining uncertainties while the burden of proof rested mainly on the Opponent.

In our opinion, the Board in T 0116/18 applied a standard falling within the range of order no. 2 of G 2/21, this standard (as outlined above) being very much in line with what this Board considered the "*ab initio* implausibility" standard in its referral (see figure).

Other decisions applying order no. 2 of G 2/21

As of February 2024, we are aware of 14 decisions concerned with reliance on a purported technical effect in the context of inventive step which applied the test stipulated in G 2/21. Only decision T 1989/19 (also from Board 3.3.02) seems to have used a very similar approach as in T 0116/18. However, the other decisions did not apply the very same interpretation as provided in T0116/18 (*supra*). In summary, only about one third of the decisions rejected a purported technical effect and corresponding post-filed evidence while the majority of the decisions accepted it. Two decisions (T 1891/21 and T 0681/21) differentiated between main requests (MR) and auxiliary requests (AR). The decisions are summarized in the following timeline:

32 Reasons 17.4.2. and 17.4.3 of T 0116/18



Summary

It would appear from current developments that there is a trend towards a lower standard for reliance on a purported technical effect (and post-published evidence) and higher burden on the Opponent to disqualify such effect and evidence. However, this may merely be due to the specific circumstances of the cases considered so far. As emphasized by the EBA, the deciding body is required to base its judgment on the particular circumstances of each specific case.

In any event, it seems to be not a foregone conclusion that the existing case law regarding the higher standard, i.e. more like the former "*ab initio* plausibility" standard, no longer applies. The EBA appears to have left this open.

Finally, T 0116/18 has also not yet been conclusively settled, since the Opponent filed a petition for review under Art. 112a(1) EPC on January 17, 2024 (*see* case number R 04/24). According to the Opponent, the requirements established by the Board under which criterion (ii) of order no. 2 of G 2/21 can be considered fulfilled (*supra*) constitute a new test that was not discussed at the hearing and therefore violated the Opponent's fundamental right to be heard.

Patent practice

Note from the Committee on Biotechnological Inventions

The **epi** Biotech Committee continues to provide legal analysis and opinion sharing and stakeholder engagement. At beginning of this year, urgent attention was needed on a sudden and unexpected new regulation proposed by the European commission regarding New Genomic Techniques (NGTs) plants. The aim was to divide plants by their major (or minor) variations and whether they would fall under restrictive GMO legislation concerning release and use (or not). However, in a major a major surprise to the industry, an additional provision banning patents on NGT plants was, at the last moment, inserted into the legislation. This was worryingly passed by the EU Parliament in a vacuum, without proper legal analysis or consultation of stakeholders. The **epi** reacted rapidly, and was able to draft, with little time, a position paper that we are delighted to share with you today. A big thank you to the members of the Biotech committee and to our Presidium and in particular to Jan Desomer for their contribution, which was much appreciated and made it possible to complete this work in a very short time. That such draft legislation can be passed by the EU Parliament in such a manner, with such speed and without proper consultation, is rather worrying for us. The **epi** and BC however intend to react to this sudden development. There will be an **epi** podcast (**epi**'s very first!) about this topic soon.

epi Position Paper on New Genomic Technique (NGT) Plant Patenting Proposal of the European Parliament

P. R. Thomsen (CH), **epi** President

About epi

The Institute of Professional Representatives before the European Patent Office (**epi**) is the professional body representing all European Patent Attorneys. Currently the Institute has about 14,000 European Patent Attorneys as members coming from all the 39 Contracting States of the European Patent Convention and who work either in industry or in private practice. European Patent Attorneys help their clients and employers, which include multinational corporations, SMEs and private inventors, to create value from their inventive ideas, thus providing jobs and strengthening the European economy.

epi as an organisation deals primarily with the development and implications of patent law. **epi** is at the forefront of patent law developments and regularly serves public policy leaders by issuing legal opinions and highly specialised advice.

Executive Summary

The Court of Justice of the EU (CJEU) clarified that plants derived from new mutagenesis techniques such as gene editing fall within the scope of the current EU GMO legislation[1]. To address and change that situation and as part of its "farm-to-fork" strategy, the European Commission has now proposed a regulation on plants obtained by certain new genomic techniques (NGTs) with the aim to create a special class of plants which can be released and used in farming within the EU under less strict conditions than the GMO legislation[2]. On 7 February 2024, the Members of the European Parliament (MEPs) adopted a proposal[3] of the Committee on Environment, Public Health and Food Safety (ENVI) to amend the draft Regulation from the European Commission that had been intended to foster the development of plants obtained by New Genomic Techniques[4] (NGT Plants) in Europe.

The amendments include a broad new exclusion from patentability for such NGT plants and also plants obtained through classical mutagenesis or cell fusion, as well as "*plant material, parts thereof, genetic information and process features they contain*".

epi would recommend **to not include any patentability exclusion in the proposed regulation on NGT plants** and has the following remarks on this proposal:

- The impact of a patent ban on innovation in this highly innovative sector cannot be underestimated as the patent system ensures the disclosure of innovations to the public and allows a return on investment in development of new products.

- The Plant Variety Protection (PVP) system[5] is not a proper substitute for patent protection of NGT traits.

1 C-528/16 of 25. July 2018

2 Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625, COM(2023) 411 final

3 P9_TA(2024)0067

4 Plants obtained through targeted mutagenesis and cisg

5 E.g. by Council Regulation (EC) 2100/94 of 27July 1994 or under corresponding national law

- A broad ban on plant patents will be counterproductive and lead to a lack of innovation in the development of much needed plant traits that can counter some of the issues Europe is facing now and will be facing in the future regarding productivity, sustainability and climate change.

- The extent of proposed patent ban is both disproportionate (in view of existing legislation and industry initiatives) and vague concerning the extent of what is to be excluded from patentability or restricted in scope of protection.

- The proposed patent ban would also impact on non-EU member states of the EPC which are not part of the current legislative process.

- **epi** furthermore questions whether the proposed patent ban is compatible with the obligations of WTO members under the TRIPS Agreement.

- **epi** is very concerned that a broad patenting exclusion is proposed without any systematic impact assessment and a detailed discussion with stakeholders.

- **epi** expressly endorses the proposal by the Commission to compile a much-needed fact-based study into NGTs and the potential impact of patent protection before any legislative steps are taken that will significantly curtail intellectual property rights in this field.

Background

On 7 February 2024, the Members of the European Parliament (MEPs), in a first plenary reading, adopted a proposal[6] of the Committee on Environment, Public Health and Food Safety (ENVI) to amend the draft Regulation from the European Commission that had been intended to foster the development of plants obtained by New Genomic Techniques (NGT Plants) in Europe[7].

Several of the proposed amendments are aimed at excluding from patentability all NGT plants (i.e. plants obtained by targeted mutagenesis and cisgenesis), but also plants obtained by classical mutagenesis or cell fusion, as well as "*plant parts and plant material thereof, genetic information and process features such plants contain*".

Furthermore, amendments are proposed that would limit the scope of protection (including for existing patents covering plant-related subject matter) afforded by patents on products containing or consisting of genetic information or by patents on technical processes that enable the production of a product containing or consisting of genetic material. Currently, such protection extends to material in which the product is incorporated and in which the genetic information is contained and performs its function, as well as to biological material obtained through propagation or multiplication. The amendments would exclude from protection "*plant material which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process*".

The patentability ban and restriction of scope of protection would be achieved by including in the proposed Regulation two Articles (Article 4a[8] and Art 33a[9]) amending Articles 4, 8 and 9 of Biotech Patent Directive 98/44/EC. The patentability exclusion in these proposed amended articles would apply from the date of entry into force of the proposed NGT Plant Regulation (amendment 70[10]).

As justification for the proposed ban on patenting plants and further restrictions on the scope of protection for plant-related patents, the document refers to the risk that "*allowing for new genomic techniques and their results to be patented risks [gives] multinational seed companies even more power over farmers' access to seeds*" and would "*deprive farmers of all freedom of action by making them dependent on private companies*"[11] and that "*it should be ensured that breeders have full access to the genetic material of NGT plants*"[12]. To secure the full breeder's exemption "*NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption … For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited*"[13] .

Following the 7 February 2024 vote on the draft legislation, the matter was referred back for inter-institutional negotiations and the European Parliament now has to start the trilogue with EU member states in the Council and the European Commission on the final law.

Position

As **epi**, we are particularly concerned about these developments.

Biotechnology has been identified as a key technology with significant potential to boost Europe's competitiveness with innovative solutions that also contribute to the EU's

6 P9_TA(2024)0067
7 COM(2023) 411 final

8 Amendment 33 - Proposal for a New Article 4a Exclusion from patentability
9 Amendment 69 - Proposal for a New Article 33a Amendments to Directive 98/44/EC1a
10 Amendment 70 to Art 34 -paragraph 2- subparagraph 1
11 Amendment 167 - Proposal for a New Recital 1a
12 Amendment 23 - Proposal for a New Recital 45a
13 Amendment 23 - Proposal for a New Recital 45a

sustainability ambitions. NGTs have the potential to contribute to the innovation and sustainability goals of the European Green Deal and of the 'Farm to Fork', Biodiversity and Adaptation to Climate Change, Strategies to global food security, the Bioeconomy Strategy and to the Union's strategic autonomy.

Europe has always been a pioneer in biotechnology, particularly agriculture-related biotechnology, and the protection of inventions through intellectual property is essential for the survival of many Europe-based innovative companies, spin-offs, SMEs and research institutes active in this sector in a highly competitive global setting.

The impact of a patent ban in this highly innovative sector at this stage cannot be estimated and has in our view the potential to seriously damage Europe's innovation power in this crucial area.

The patent system ensures the disclosure of innovations to the public and allows a return on investment in development of new products

New technologies such as gene editing and NGTs offer new opportunities. However, they require significant investments. Conditions for commercial access to the foundational patents related to these technologies (often in the hands of academic institutions) include payment of substantial fees on the path towards commercialization. Furthermore, the creation of NGT based traits will require considerable investments in R&D, regulatory compliance and market acceptance. The ability to adequately protect newly created traits with patents is therefoin our view an essential component to secure sustainable investments in the breeding of innovative crops.

Contrary to the common misconception, also expressed in the adopted proposal, that patents are only used by large multinationals to create monopolies to the detriment of SMEs, farmers and the public, patent protection plays an essential role in the cycle of innovation and investment, especially for the smaller players such as spin-offs, SMEs and research institutes. In exchange for a complete disclosure of technical contributions, the innovator is awarded a time-limited period of exclusivity, after which those contributions enter the public domain and are then free for all to be used. The patent system encourages full and early public disclosure of innovations that could otherwise be kept secret. Patents thus fundamentally allow for important technologies to be made available for the public, in the form of both innovative products brought to market and the contribution to public knowledge that persists in public domain once the respective patents expire. Many inventions may have never been developed in the first place, nor brought to market, had it not been for the temporary exclusivity granted to the original innovators. In other words, in exchange for a brief period of exclusivity, society is granted access to essential technology that may never have existed had it not been for the possibility of temporary patent protection.

PVP is not a proper substitute for patent protection of NGT traits

The proposal, as adopted by the EU Parliament, boldly states that "*NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption*" (new recital 45a).

PVP rights, however, only protect specific plant varieties, i.e. a given specific assembly of genetic make-up, including traits, in a single species. A PVP certificate grants the right to exclusively commercialize the protected variety. But PVP rights do not separately protect the genomic modifications leading to the traits within the protected varieties. Through the breeder's exemption associated with the PVP legislation, breeders can use any commercial variety comprising one or more genomic modifications brought to the market (even when protected by a PVP certificate) for further crossing with their own varieties to introduce these genomic modifications and develop new varieties that contain the NGT-based traits of the original PVP protected variety. The breeder's exemption allows free commercialization of the newly developed variety without any consideration for the holder of the PVP on the originator variety (save a few exceptions). Once a variety containing a newly developed NGT-trait is marketed, this trait would become available through straightforward introgression breeding for anyone, without compensation for the innovator. PVP rights also do not provide protection against copying innovations on traits by independently recreating mutations linked to a desirable trait. Therefore, NGT-based plant traits (that can be used in many different plant varieties) cannot be effectively protected by the PVP system. Only a generic protection of the newly developed genomic modification leading to a given trait through invention patents, independent from the variety protection, can ensure adequate return on investment.

Peter R. Thomsen

A ban on plant patents will be counterproductive

A patentability ban would hamper further developments specific to agricultural conditions in Europe, as there would be no adequate compensation for the efforts and investments made. Plant breeding is a highly regional business.

For example, seeds produced in the mid-west of the US are often not well-suited for Europe or Latin America. Should there be no adequate patent protection, it is hard to see who would develop and work on specific regional solutions for Europe using these new techniques. This will lead to a lack of innovation in much-needed traits that can counter some of the issues Europe is now and will in the future be facing regarding productivity, sustainability and climate change. The objectives of the European Green Deal and "Farm to Fork" Strategy that are in part relying on the development of new (NGT) traits hence risk being totally missed.

The extent of proposed patent ban is both disproportionate and vague

The proposal as amended by the EU Parliament refers to exclusion from patentability not only for the NGT plants themselves but also to "*plant parts and plant material thereof, genetic information and process features such plants contain*".

The term "*genetic information … such plants contain*" could potentially encompass the complete genomic information of the envisaged plants, which obviously goes well beyond the intended scope of the NGT regulation as well as the gist of the current EU Biotech Directive 98/44/EC.

Also the term "*process features such plants contain*" is totally unclear and lacks any definition in the proposal. Is it intended to exclude from patentability the methods and tools used, such as CRISPR/Cas proteins or TALENs and the like when applied to plants? This potentially endangers the patentability of a whole field of genome editing technology and goes well beyond the ambit and the original objective of a Regulation on NGT plants. A clarification is thus urgently suggested by **epi** to avoid misinterpretations when applying the ultimate Regulation as part of European Union's secondary law.

Furthermore, the proposal additionally suggests amending Articles 8 and 9 of the EU Biotech Directive 98/44/EC. Article 8 is proposed to be amended to exclude from the scope of protection all "*biological material*" (i.e. not limited to plants, but also eukaryotic cells, viruses, micro-organisms, etc.) "*obtained independently of the patented biological material and from essentially biological processes*". The proposed amendment to Article 9 aims at limiting the scope of protection afforded by the EU Biotech Directive 98/44/EC to a patent on a biological material containing genetic information or to a patent on a process for such product to be produced as extending to biological material derived therefrom through propagation or multiplication, by excluding from such protection plant material obtained or which can be obtained by an essentially biological process.

It should be noted that, contrary to Rule 28(2) of the European Patent Convention, these exclusions do not refer to "**exclusively** obtained by essentially biological processes". As such, it can be questioned whether these exclusions from the scope of protection would also apply to the progeny of plant material which would remain patentable (e.g. transgenic plants) obtained through crossing and selection.

Finally, the ban on patentability is disproportionately broad in that it would ban patents not only for NGT plants but also for plants obtained through (classical) mutagenesis and cell fusion, whose regulation is not at all affected by the current draft NGT plant regulation.

The proposed patent ban seems disproportionate to the perceived concerns of farmers and breeders organisations, which are already largely addressed by existing mechanisms that have been carefully crafted in view of those concerns and with proper consultation with the full range of stakeholders.

Specifically, farmers and breeders enjoy a general research exemption in EU patent law. In addition, breeders' exemptions are implemented by many EU Member States and the recently implemented Unified Patent Court Agreement introduced a breeder's exemption for patents[14].

Furthermore, under the current EU Biotech Directive 98/44/EC, farmers are already entitled to save seeds under the same conditions as for plant variety protection.

It should also be noted that the EPC already excludes from patentability plants or plant material if the claimed product is exclusively obtained by means of an "essentially biological process", as well as excluding from patentability essentially biological processes as such[15].

Apart from these legislative measures, several voluntary initiatives have been launched over the last years across the crop sector, intending to address concerns raised by some stakeholders with regards to access to genetic material, particularly by small market participants, and to facilitate access to patented materials.

Impact on non-EU member states of the EPC

Since the EU Biotech Directive 98/44/EC is explicitly referred to in the European Patent Convention (EPC), these changes could also affect non-EU member states of the EPC which are not party to the current EU legislative proceedings.

An amendment of the EU Biotech Directive 98/44/EC would require EU Member States to amend their national patent systems accordingly to appropriately implement the amend-

14 See Art. 27 lit. c) And i) UPCA
15 See e.g. Enlarged Board of Appeal opinion G 3/19 of 14. May 2020

ments. However, a majority of the patents in Europe are granted under the European Patent Convention, and any amendment of the EU Biotech Directive 98/44/EC through this regulation would not automatically apply to the EPC, as it is an intergovernmental agreement, but would require an amendment of the EPC itself.

epi warns against hasty adaptation of the EPC since it would hamper the rights of non-EU members states as well.

Further, **epi** warns against hasty parallel amendment of the EU Biotech Directive 98/44/EC in the context of the legislative process primarily aiming at arriving at a Regulation of NGT plants.

Is the proposed patent ban in line with obligations of WTO member states under the TRIPS Agreement?

Article 27.3b TRIPS allows member states to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". However, when looking at the proposed amendments to the Biotech Directive, the exclusions on patentability would extend to genetic information, process features and even to all "biological material" obtained by essentially biological processes, which seems to be in conflict with the TRIPS agreement.

Would the legislative process for amending the Biotech Patent Directive withstand scrutiny?

epi questions whether amending the Biotech Directive through a regulation on environmental safety of NGT plants is appropriate. Indeed, the NGT regulatory framework aims to regulate and protect human and animal health and the environment, and therefore provides no legal basis for regulating IP rights, let alone installing a complete broad patent ban on NGT plants.

Even the rapporteur of the ENVI committee suggested that, although she acknowledges the concerns of breeders and farmers, the issue of patents for plants obtained through NGTs should be addressed in a separate piece of legislation to prevent the proposal from exceeding its scope[16].

In addition, amendments to the Biotech Directive in this way pose a genuine risk for other technological sectors, as similar legislation or amendments to the Biotech Directive could be simply introduced without re-opening profound discussions on the Biotech Directive. In this context, it is important to point towards the final report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973) of 17 May 2016, commissioned by DG Grow of the European Commission, wherein none of the Experts recommended amending the Biotech Directive.

epi agrees with the need for a thorough study on any potential IP issue as proposed by the European Commission and the EU Parliament

The original proposal of the NGT regulation by the European Commission of July 2023 included a suggestion to carry out a study on the potential impact of Intellectual Property Rights around NGT plants.

The proposal amended by the European Parliament contains the following paragraph 5a to be added to Article 30 of the proposed Regulation: "*By June 2025 the Commission shall submit a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and, in particular, on opportunities for SMEs. The report shall assess whether further legal provisions are necessary in addition to those provided for in Article 4a and Article 33a of this Regulation. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, the report shall be accompanied by a legislative proposal to address further necessary adjustments in the intellectual property rights framework.*"

This seems to imply that even more severe restrictions on plant IP rights are to be envisaged than the ones already proposed. **epi** notes that again here, the reference to "*opportunities for SMEs*" is important since it seems to imply that SMEs would lack opportunities due to the existence of patent rights on plants. This should probably be changed into "*missing opportunities for SMEs in absence of effective IP protection*".

epi endorses the proposal by the Commission to timely initiate and compile a much-needed fact-based impact study into NGTs and the potential impact of patent protection before any legislative steps are taken that will significantly curtail intellectual property rights in this field, to avoid a negative effect on the European market.

In any case, any impact study should additionally engage with representatives from the full breadth of industry stakeholders, including the many Europe-based start-ups, SMEs, and research organizations active in the plant- and agricultural-biotechnology fields as well as experts in the field of Intellectual Property, in particular patents, to reach a reasonable and balanced consensus between all stakeholders. **epi** would be happy to provide corresponding expertise in the field of plant patents and their effect on innovation in the plant and breeding sector.

16 A9-0014/2024, page 46

Fee-related support measures for small entities

J. Boff (GB)

A new regime of "fee-related support measures for small entities" has been introduced. Some of these entities are not small, just politically favoured, and all may be better supported by government measures than from European Patent Office (EPO) resources. However, the following summarises these support measures and the effect they may have on applicants and practice.

Jim Boff

Background

Fee reductions for specified classes of applicant are not new to the EPO. From the beginning, reductions in certain fees were available in some circumstances to applicants who had appropriate language/nationality qualification [Article 14, Rule 6].

In 2014[1], the scope of the Rule 6 reduction was limited to reductions in filing and examination fees, and applicability limited to applicants in one of the categories:

(a) small and medium-sized enterprises;
(b) natural persons; or
(c) non-profit organisations, universities or public research organisations.

In 2018[2], a reduced (or rather not increased) appeal fee was introduced for applicants falling in these categories, regardless of language/residency.

Now in 2024 a decision (the Decision) and accompanying notice[3] (the Notice) will become operational 1st April 2024. The Decision makes changes to the Rules and Rules Relating to Fees (RRF) which alter the scope and applicability of fee reductions. The Notice supplies some explanatory remarks but is not totally clear.

Under the Decision former Rules 6(3)-6(7) are deleted and replaced by two Rules 7a and 7b (why not 6a and 6b is just one of those mysteries). Rule 7a prescribes reductions available, and Rule 7b prescribes the requirement for a declaration of entitlement under Rule 7a and the consequences of an incorrect declaration.

In addition, Articles 11 and 14 of the Rules Relating to Fees (RRF) are amended as discussed below where relevant.

Entitlement to, and scope of fee reductions

Rules 7a(1)-(2) relate to Article 14 EPC related fee reductions and preserve the scope (filing fee and examination fee) and applicability of the current language related fee reductions.

Rule 7a(3) introduces a new general fee reduction for applicants in the categories

(a) microenterprises;
(b) natural persons; or
(c) non-profit organisations, universities or public research organisations

and is applicable to such applicants regardless of language and location.

The fees eligible for reduction are:

(a) filing fee;
(b) fee for a European or supplementary European search;
(c) examination fee, and in addition the previously paid international search fee where the European Patent Office acted as International Searching Authority;
(d) designation fee;
(e) fee for grant;
(f) renewal fees for the European patent application.

Rule 7a(4) excludes the availability of the Rule 7a(3) reductions where the same person has filed five or more European patent applications or Euro-PCT applications within a period of five years preceding:

- the date of filing of the European patent application concerned or
- the date of entry into the European phase of the Euro-PCT application concerned

1 CA/D 19/13 OJ EPO 2014, A4 - and Notice OJ EPO 2014, A23
2 CA/D 17/17 OJ EPO 2018, A4 - and Notice OJ EPO 2018, A5
3 CA/D16/23 OJ EPO 2024, A3 - and Notice OJ EPO 2024, A8

Rule 7a(5) indicates that where there are multiple applicants, each applicant has to be eligible for a fee reduction of whatever sort to apply.

Rule 7a(6) confirms that the eligibility criteria must be met by the day of payment of a fee for the reduction to apply.

Amended **Article 11 RRF** states that a reduced appeal fee is available for applicants who meet the conditions of Rules 7a(2)(a)-(d).

Amended **Article 14(1) RRF** states that the reduction laid down in Rules 7a(1)&(3) shall be 30% of the relevant fee.

New **Article 14(3) RRF** states that if more than one reduction applies to the same fee for the same application, the reductions shall be calculated sequentially.

Effect of changes in scope and applicability

SMEs who are not microenterprises ***lose the current fee reduction on appeal fee***, but are otherwise not directly affected.

Applicants previously eligible for language related fee reductions ***retain that eligibility***, and this is not limited if they have filed 5 or more applications in the previous five years.

Those who are eligible for the Rule 7a(3) reductions get ***a significant reduction*** which can be cumulative with any language related fee reduction [e.g. filing fee would be reduced by 30% under language regime and then a further 30% reduction would be applied to the reduced fee – a 51% reduction in total].

Regardless of language, those who are eligible for the Rule 7a(3) reductions who go via the PCT route with ISA=EP could see a reduction of near 50% in official fees on entering the European regional phase, since the PCT search fee will be subject to a retrospective fee reduction applied at time of entering the European regional phase.

Comment on eligibility

Unlike US provisions for claiming micro entity reductions, the EP provisions contain no income limit for eligibility. [*Insert billionaire's name here*] could claim the fee reduction.

Under the current Rule 6, small and medium-sized enterprises were defined by reference to Commission recommendation 2003/361/EC of 6 May 2003. That recommendation is complex, particularly concerning related enterprises, and although previous notices from the EPO concerning this only discussed size, some wondered whether this was correct.

The new provisions deals with this issue by comprising ***no definition of these terms***. The Notice from the EPO indicates how the EPO will interpret these terms, and in particular points to Article 2 of the Commission recommendation, perhaps limiting any scope for doubt[4]. However, the absence of definitions explicitly in the rules is perhaps unfortunate.

The Notice indicates that the reduction in fees will apply to fee payments made on or after 1st April for European patent applications and Euro-PCT applications which have entered the European phase, irrespective of their filing date.

Eligibility is required at the point of filing the European patent application or entering the regional phase.

Requirement for a declaration

Rule 7b(1) provides that applicants wishing to benefit from a reduction of fees under Rule 7a shall declare themselves to be a person within the meaning of Rule 7a(2) or (3), at the latest when the first reduced payment is made.

Rule 7b(2) requires applicants to inform the European Patent Office of any change of status affecting eligibility for a reduction of fees at the latest when the fee concerned is paid.

Rule 7b(3) gives the EPO power to ask for evidence of status in the event of reasonable doubt as to the veracity of the declaration or, subsequently, as to the applicant's eligibility for a reduction of fees

Rule 7b(4) Indicates that if it becomes apparent that an incorrect declaration has been filed, or the EPO has not been informed of a change of status and a reduced payment is made, the fee shall be deemed not to have been paid and the application shall be deemed to be withdrawn.

Comment on declarations and incorrect declarations

Although the Notice indicates that declarations may be made on Form 1001/1200 when filing, or if made separately on Form 1011, the latter at least will not be available until 1st April 2024. This is unfortunate for those who want to pay a fee 1st April and may want the applicant to sign the form rather than sign as representative.

4 Article 2(3) of the recommendation states *"…, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million"*

The Notice states that if a patent application is transferred, fee reductions will continue to apply only if the new applicant is also eligible for fee reductions and that the new applicant must file a new declaration. The Notice indicates that "transfer" in this context means the date of legal effect of registration of the transfer. This is a useful safeguard against the risk that an unrecorded transfer (of which the representative may be unaware) might cause problems.

The penalty for an incorrect declaration (fee deemed not paid and application deemed to be withdrawn) is severe. Although the Notice indicates normal remedies of further processing or re-establishment of rights apply extreme care would appear appropriate to check each time a fee is paid that eligibility remains. For example, a microenterprise may have 9 employees and turnover/balance sheet meeting the definition when it enters the European regional phase. If it then recruits one person it would fall outside the definition. If this only becomes evident several years on, the consequences could be fatal, because the legal remedies would no longer be available.

Commentary on practice overall

The fee reductions may be helpful to the smallest applicants or least active clients, but **the greatest ongoing care is required**, particularly with microenterprises, where it would be easy to drift out of eligibility.

The limitation to eligibility by requiring less than 5 applications filed in the previous 5 years would appear intended to limit scope to those with little involvement in the patent system: but one application a year is not what some would consider little involvement.

It will be interesting to see whether there is an increase in the number of applications filed by individual inventors who happen to be employed by enterprises not eligible for fee reductions.

Those of a devious disposition might consider whether there will be an increase in the number of applications filed by microenterprises whose sole purpose is to prosecute one or more (but less than 5) applications to grant.

Summary

The fee reduction package means well but may not be the best targeted application of EPO funds (which come from applicant fees).

As well as perhaps encouraging new entities to file patent applications, the package may promote new behaviours aimed at obtaining reduced fees.

Time will tell whether tighter targeting of the support will be required for sustainable financing of the system.

Some thoughts on the Disciplinary System of the European Patent Organisation

Dr. W. Fröhling (DE), Vice Chair, P. Rosenich (LI), Chair

1. General Comment

The basic concept of the disciplinary system of the European Patent Organisation is working well and fulfills the needs of the Organisation.

There are deficiencies in its daily operation in that in certain cases it takes too long to issue a decision. But these deficiencies are mainly of procedural nature and can be solved by amending the additional rules of procedure of the three disciplinary bodies (DC, DB and DBoA) of the Organisation.

For amendments of the additional rules of procedure, the disciplinary bodies themselves are in charge. Once the disciplinary bodies have reached an agreement on such amendments, the DBoA will submit this proposal for amendments to the Administrative Council for the Council's approval.

The three disciplinary bodies of the Organisation have started to review these rules and will meet for a first meeting soon in order to discuss what needs to be done and how to proceed.

2. The Disciplinary Committee and its work

The DC is the 1st half of the 1st instance of the disciplinary system of the Organisation. Every Member State of the Organisation has the right to be represented by an **epi** member (preferably from that State) in the DC. There are no substitutes for the members of the DC.

As part of the disciplinary system of the European Patent Organisation, the DC is independent in its work (deciding on compliance of members of the institute with the Rules of Professional Conduct) and how it organizes its work (in accordance with the Additional Rules of Procedure of the DC). The term of the DC is coincident with the term of the **epi** Council. At the inaugural meeting of the new Council the members of the new DC are appointed by the Council. Further, the Council decides on the budget of the DC.

The DC is not one of the "committees" of the **epi** Council or the **epi** Board which are supposed to support with their work the **epi** President, the **epi** Board and the **epi** Council, ie the executive and legislature. The DC is part of the judiciary as also expressed for instance in the name of the DC in the German version of the Rules of Professional Conduct: "Disziplinarrat" (plain translation: Disciplinary Council).

The Chair of the DC creates, at the beginning of the term of the new DC, a number of fixed chambers (consisting of a chair, a rapporteur, a member and a substitute member) whereby the Chair takes into consideration amongst other things the experience of the members of such a chamber in disciplinary matters and the language skills of the members.

All incoming complaints against **epi** Members are handled by the DC. After an initial formal check (and a check in case of complaints of **epi** members against other members of the **epi** if the complainant has tried to settle the dispute according to Art. 5(a) of the **epi** Code of Conduct before filing the complaint), the Chair assigns the incoming complaint to one of the chambers.

The chamber's main tasks are (i) to study the details of the complaint and any comments of the President of the EPO and President of the **epi** and, if necessary, conduct on its own motion further investigations and, if necessary or requested by the defendant, conduct oral proceedings, and (ii) eventually issue a decision which could be:

a. To dismiss the case, or
b. To issue a warning, or
c. To issue a reprimand, or
d. To refer the case to the Disciplinary Board.

All this has to be done within 9 months after having received the complaint. On request of the chamber this term can be extended by the Chair of the Disciplinary Board by a maximum of 6 additional months. If the chamber has not issued a decision after 9 months or, if an extension has been granted, at the end of this extension, the case would be taken over by the Disciplinary Board.

The chambers of the DC are issuing their decisions within the applicable 9 months or 15 months term. Within the last 25 years none of the DC cases have been taken over by the DB because of time overdue. The Registrar of the DC watches the 9 month term carefully and remind the chamber. The DB also watches that term.

3. The roles of the Disciplinary Committee with the disciplinary system of the Organisation

a. The DC has a filtering role within the disciplinary system of the Organisation with the effect that the DB and/or DBoA is in most cases involved only in important or severe cases:

i. All incoming complaints are checked regarding formalities and the severeness of the case. Simple cases between **epi** members (eg unpaid bills) can often be settled by a phone call.

ii. Once a complaint has been assigned to a chamber of the DC, that chamber investigates the details of the complaint and collects all evidence in order to prepare the case for decision. If the chamber decides to refer the case to the DB the case has been inve stigated, if necessary, oral proceedings have been conducted and the relevant evidence is stored in a structured and ordered way in the file, ie the DB receives the case (in most cases) in a state "ready for decision".

The effect of this role of the DC on the efficiency of the disciplinary system of the Organisation should not be underestimated:

i. The initial check reduces in many cases the overall number of cases to be dealt with.

ii. The preparational work by the chamber involved saves a lot of time and efforts for the DB and/or the DBoA in cases which the DC is referring to the DC or which are appealed by the defendant and/or the Presidents of EPO and **epi**.

iii. Due to the composition of the DC and its chambers, local habits and languages can be equally considered in order to provide a fair procedure in an international environment. Not only complainers but also defendants may feel secure in that respect.

b. The work of the DC helps to maintain the high reputation of the profession enjoys in the public, but in particular within the European Patent Organisation:

i. Simple cases of non-compliance with the Rules of Professional Conduct, in particular in connection with disputes between **epi** members about non severe subject matters (like unpaid bills), should be decided by the DC, ie. by a disciplinary body of the Organisation comprising only **epi** members and no members from the EPO. Only severe cases should be decided by the DB, a disciplinary body with members of the **epi** and the EPO and chaired by a legally trained Chair coming from the EPO,

Dr. Werner Fröhling

ii. This setup is, by the way, a strong indication that the Member States and the Administrative Council of the European Patent Organisation gave a lot of trust in the **epi** and the DC/**epi** and its Members should be proud of it.

Paul Rosenich

The trust is demonstrated by the fact that the DC (comprising only **epi** members) has been entrusted by the Administrative Council to serve as the 1st half of the 1st instance of the disciplinary system. The DC has the following tasks

- of initially checking all incoming complaints,
- of conducting all necessary preparations to make the case ready for decision,
- and eventually also of deciding the case on the base of the findings of the DC as described above, without any involvement from the outside, in particular from the EPO (except the right of the Presidents of **epi** and EPO to submit their comments on the cases to the chambers involved and their right to file an appeal).

But also the concept of having, at the level of the DB and DBoA, disciplinary bodies which are composed of members coming from the **epi** and the EPO with the Chair coming from the EPO and the majority of members coming from the EPO is convincing and corresponds to international standards of disciplinary systems since severe cases and/or cases that have been appealed are decided by court like disciplinary Bodies within the legal frame of the European Patent Organisation (an independent organisation *sui generis*). Similar disciplinary systems for national patent attorneys and advocates can be found for instance Germany, Poland and many other Member States of the European Patent Organisation.

c. The fact that all the Member States of the Organisation have the right to be represented by an **epi** member in the DC without substitutes reflects the importance of the DC as a body of the **epi** aside of and independent in its work from the **epi** Council and **epi** Management. As a matter of practice, the DC is always composed of basically senior, experienced **epi** Members, many of them with legal education in addition to the patent attorneys profession and many of them also involved in national Disciplinary Bodies. This in turn secures a proper international view on matters of Discipline and also gives trust to all Members of the **epi** and the Public, that also local habits on national level are considered when dealing with disciplinary cases.

d. Further, by having representatives of all Member States in the DC, the chambers of the DC have also via its members direct access to the national disciplinary systems of said states, which might be an important source of information in the work of the chambers of the DC.

Educational events

epi Educational trainings and events

We are pleased to announce our upcoming educational trainings and events for 2024! Stay up to date and check our training overview, which is updated constantly.

Session Calendar[1]

Webinar series on Patent Litigation

With the start of the UPC patentees will have the choice to litigate their European patents either before the UPC or before a national court. In this series of webinars, the specifics of patent litigation before the national courts will be considered per country.

- 24 April 2024: United Kingdom
- 8 May 2024: Italy
- 19 June 2024: Scandinavian Countries

Further webinars for continuing professional education:

- 22 May 2024: US submarines and UFOs: Useful, little-known patent and design strategies only available in the US

Planned Seminars with Livestream

- 4 June 2024: Infringement by Equivalence (Eindhoven tbc)
- 11 June 2024: A fresh look on procedural aspects of appeal proceedings (Bologna tbc)
- 9 October 2024: A fresh look on procedural aspects of appeal proceedings (Munich tbc)
- 28 November 2024: Freedom to operate (FTO) (Munich tbc)

Life of a Patent – Distance Learning Course

This distance learning course is intended for beginners in the profession but also for any patent practitioners/ patent engineers that would like to refresh their EPC knowledge and skills

.

- 2 April 2024 – 14 June 2024

Participants find out about the main steps of pre-drafting and drafting a European patent application, together with the formal and substantive aspects of prosecution. Further information and registration can be found on our website[2].

You can find all events and trainings in our overview[3].

1 https://patentepi.org/r/training-2024
2 https://patentepi.org/r/info-2401-01
3 https://patentepi.org/r/training-2024

In addition, **epi** members and **epi** students have access to relevant online courses, online lessons and other resources, such as webinar recordings, via epi-learning[4].

Sounds interesting?

epi students are automatically registered on this platform and can take advantage of support and training offers specifically designed for **epi** students.

In order to gain access to the platform, we require consent from **epi** members. This will be presumed when you fill in the survey link[5] the required data.

4 https://www.epi-learning.org
5 https://www.surveymonkey.de/r/epi-learning_platform

Navigating the EQE format changes[1]

Attention to all EQE candidates and supervisors!

epi has got you covered with comprehensive information about the new EQE format and navigating the change. We have now added detailed summaries for each paper, accessible via click-through links! To access regulations and notices relating to EQE, please visit the official website www.eqe.org

1 https://patentepi.org/r/info-2401-07

epi Student membership

epi student members have access to additional information on the **epi** learning website, including the student forum described below. Other benefits of student membership include receiving alerts about **epi** training courses, priority access to our educational events, and reductions on course fees for **epi** educational events, such as tutorials, seminars and webinars. Candidates for **epi** student membership may apply, at any stage of their training, to the **epi** Secretariat (epi.student@patentepi.org), simply by filling in the online application tool[1], providing the necessary documents[2] and paying the fee.

1 https://patentepi.org/r/student-membership-01
2 https://patentepi.org/r/student-membership-02

https://patentepi.org/r/linkedin

Follow us on LinkedIn for **epi** educational news!

epi Equivalence Seminar

B. van Wezenbeek (NL), PEC Member

On 18 October 2023, about 100 **epi** members from all over Europe gathered in Munich for a seminar titled 'Infringement by Equivalence in Major EPC Jurisdictions'. At this seminar, Olaf Ungerer, Sylvain Thivillier, Paolo Rambelli, Claude Quintelier and undersigned highlighted the peculiarities in case law on infringement by equivalency in Germany, France, Italy, Belgium, and the Netherlands, respectively. Moderation of the event was provided by Thomas Pott.

Although infringement by equivalence is covered by Art. 69 EPC and the Protocol to Art. 69, it appeared from the presentations of the speakers that there was little harmonization between these five jurisdictions. This was made more prominent when, in the afternoon, the audience was involved in a discussion of a mock case in which, for a granted patent, 5 different embodiments were shown not to be literally infringing. When the presenters tried to predict how each of their national courts would decide on the infringement by the 5 different embodiments, it appeared that there was no agreement between them. On the contrary, in all of these 5 embodiments, it was found that, in some countries, an embodiment would be deemed to be equivalent, whereas in the other countries this would not be the case.

It was concluded that this outcome meant that there would be a challenging task, in the future, for the UPC to ensure an actual harmonization. It will, however, still take time before such a harmonization will be established. In the meantime, **epi** is planning to hold further seminars on this topic to keep its members up to date on this subject, possibly including other jurisdictions (and the UPC). If you are interested to attend a follow-up seminar on infringement-by-equivalency, please look out for our seminar/webinar listings and our email notifications.

Report from epi Tutors' Meeting

M. Mackett (GB), Chair Professional Education Committee Subcommittee **epi** Students and EQE Candidates
B. Atalay (TR), Chair Professional Education Committee Subcommittee Tutors and Coaches

The first **epi** Tutors' Meeting of 2024 was held on February 15, 2024. The meeting was in online format moderated by Margaret Mackett. It featured two segments with different speakers and topics.

In the first segment, Margaret Mackett and Kateřina Hartvichova discussed changes to the examination system, including a fast track option available for candidates who wish to wait 3 years before sitting the main modules. They also discussed phasing in the new examination format from 2025 to 2027. As a result of the introduction of the foundation module in 2025, there will be no pre-examination but the existing papers A to D will form the main examination. The need for more detailed materials for those new to the profession was also discussed, along with the structure. The importance of a methodology for passing an exam and the challenges faced by candidates in dealing with condensed exam information were also highlighted.

Kateřina Hartvichova discussed the expected similarity between M4 and today's D2, with preparation for the forthcoming year on the agenda. Margaret Mackett then outlined the upcoming academic year's tutorial and workshop plans, and the introduction of mock papers. She also mentioned plans to provide additional tutorials and papers for M1 and M2, and discussed the fact that candidates will need to pass all parts of the M3 paper in one sitting due to the changes to the testing of legal issues relating to unity, etc. only once over the three parts of M3.

While the REE for the new examination format has already been published, we are still awaiting the publication of the IPREE which should fill in the gaps and provide candidates and tutors with more information relating to the new examination papers.

Margaret Mackett mentioned that a Working Group has already been set up for preparing training material for the new examination format and asked if there were any other tutors who would like to join the Working Group. Seven more tutors expressed interest in joining the Working Group.
In the second segment, Francis Leyder discussed the requirements for a European patent to have unitary effect and the reasons for requests being rejected. Francis Leyder also explained the necessity for translations, particularly, human translations of text in the drawings, when filing requests. He demonstrated the use of the EPO's interactive dashboard, which provides insights on the status of requests, technology fields, languages used, and geographical origin.

EQE Main examination training courses
in Maastricht

Since 2014, Maastricht University has been preparing candidates for the European Qualifying Examination (EQE). This training is for candidates who already have a basic understanding of European patent law. One of the cornerstones of our courses is the interactivity and personalized approach: two tutors and group sizes limited to 16 participants stimulate the exchange of ideas and learning from each other. This training consists of an on-site training in Maastricht, followed by an online learning period via Zoom up to the EQE examination dates.

At the basis of each of the courses are specially developed methodologies to solve the current main examination papers using a pragmatic and efficient approach. After providing some background and theory, the most important aspects of the methodologies are illustrated by solving cases. Some cases are based on old exam papers, others are specially made for the Maastricht courses. Materials are provided electronically during the course to reduce the books needed and to facilitate electronic notetaking.
Of course, the tutors closely follow all developments in the EQE. The methodologies are continuously adapted to accommodate for such developments, including the e-EQE and the exam format in which the papers are split up into multiple parts. But also, more subtle changes in the structure of the exams and/or the desired answering structure are considered.

The on-site training for each of the papers starts with three days of workshops (A and B combined), given at the Faculty of Law at the University of Maastricht. After the course, you'll have access to Maastricht University's electronic learning environment, which will provide you with online support from fellow students and the tutors as well as additional exercises so you can practise your exam skills.
The online learning period involves monthly follow-up coaching sessions via Zoom to discuss the assignments. Close to the EQE examination dates a separate Q&A session is organized for more practical questions relating to the methodology and/or online examination environment.
All course material and teaching will be in English. The courses are given by a team of renowned teachers.

Training for EQE Papers A and B

In Paper A, a set of claims and the introductory portion of a European patent application have to be drafted. In Paper B, a response to a communication from the examining division has to be drafted, while taking account of the cited prior art and the instructions from the client. The training covers the skills needed to tackle both electricity-mechanic and chemical aspects of the current combined-technology papers. The methodologies borrow from real-life skills and approaches to drafting applications and answering office actions to provide an intuitive approach. We apply them step-by-step as a group to A and B papers and cases covering combined-technologies, focusing on the parts of the answer where most of the marks can be gained.

Workshop duration:
On-site training: 3-days:
Monday 4 - Wednesday 6 November 2024
Online learning trajectory: from November 2024 to March 2025: several cases/full papers will be provided, both chemistry and electricity-mechanics; one of the assignments will be marked by the tutors.

Training for EQE Paper C

In Paper C, a notice of opposition has to be drafted following the grant of a European patent. In the course, a newly developed, simple and efficient methodology for tackling Paper C will be taught, which has been successfully applied by many of our previous candidates. The methodology will be put into practice with various example cases.

Workshop duration:
On-site training: 3-days:
Monday 21 - Wednesday 23 October 2024
Online learning trajectory: from October 2024 to March 2025: several cases/full papers will be provided; one of the assignments will be marked by the tutors.
Training for EQE Paper D

In Part I of Paper D, a set of legal questions have to be answered. In Part II, a legal opinion must be drafted following an inquiry from a client. An intuitive methodology will be taught for answering Part I questions and for analyzing and preparing a response to the inquiry in Part II. The methodology will be put into practice with example questions and cases.

Workshop duration:
On-site training: 3-days:
Monday 7 - Wednesday 9 October 2024
Online learning trajectory: from October 2024 to March 2025: several cases/full papers will be provided; one of the assignments will be marked by the tutors.

For detailed information of and registration for the Main Examination training courses, see:
https://curriculum.maastrichtuniversity.nl/education/course/eqe-exam-training

Maastricht University Leading in Learning!

CEIPI preparation courses for the European Qualifying Examination 2025

A complete range of high-quality courses using proprietary high-quality training material

Preparation for the EQE Foundation Paper F 2025

Preparatory seminar for the new EQE Foundation Paper F 2025 from 21 to 25 October 2024 in Strasbourg or online
Fee: 1 900 €*. Closing date for receipt of applications: 27 September 2024.

"Mock exam" course for the Foundation Paper F on 6 and 7 February 2025 online
Candidates take a mock exam according to the format of the e-EQE and discuss the paper with the tutors in plenary sessions.
Fee: 800 €*. Closing date: 10 January 2025.

Preparation for the EQE main examination 2025

Introductory "Methodology" courses on papers A+B, C and D in Paris or online
Papers A+B: 13 September 2024
Paper C: 14 September 2024
Paper D: 11 – 12 September 2024
Each part (A+B, C, D) can be attended separately. Fee: papers A+B or C: 650 €, paper D: 975 €*.
Closing date: 9 August 2024.

Preparatory seminars for papers A+B, C and D in Strasbourg or online
Papers A+B and C: 18 to 22 November 2024
Paper D: 13 to 17 January 2025 in Strasbourg
Fee: 1 900 € for each five-day seminar (ABC or D), 975 € for the A+B or C part, respectively*.
Closing date: 11 October 2024.

"Mock exam" courses for papers A+B, C and D online
Candidates take mock exams according to the format of the e-EQE and discuss the papers with the tutors in plenary sessions.
Papers A+B: 4 February 2025
Paper C: 5 February 2025
Paper D: 12 February 2025
Courses A+B, C or D can be attended separately. Fee per course: 800 €*.
Closing date: 10 January 2025.

"Correction of paper" module for papers A+B, C and D
Candidates write a former mock exam paper and receive a personalized correction by an experienced tutor. Four possible dates of submission before taking the EQE 2025.
Each paper can be chosen separately.
Fee: 300€ per paper.

*The CEIPI offers reduced package prices for candidates enrolling simultaneously for the complete range of courses preparing for one or more papers of the EQE. Further information about the courses and enrolment is available in OJ EPO 4/2024

Training preparing for the European Patent Administration Certificate (EPAC) 2024 online

6 half-day sessions on 29 May, 5, 12 and 19 June, 4 and 11 September 2024 and one full-day session on 25 September 2024.
Fee: 1 500 €. Closing date: 17 May 2024.

Contact CEIPI International Section: Christiane Melz, tel. +33 (0)368 85 83 13, email: christiane.melz@ceipi.edu

For further information on the above trainings and more, please scan the following QR code

Committee Reports

Report of the Litigation Committee

K. Finnilä (FI), Chair, T. Walshe (IE) Secretary

Kim Finnilä

Triona Walshe

The first meeting of the newly elected Litigation Committee was held virtually on 29th November 2023. The following officers were elected for the forthcoming term.

Chair: Kim Finnilä (FI)
Vice Chair: Tilman Pfrang (DE)
Secretary: Triona Walshe (IE)

During the virtual meeting, it was agreed that election of the sub-committees would be deferred until the next in-person meeting (now planned for April 2024). It was further agreed that the structure of the sub-committees would be reviewed together with the list of open topics at the next in-person meeting. In the interim, the newly elected executive committee have met to commence preparations for the April in-person meeting.

Updates on the UPC

On the 23rd January 2024, the Irish Government approved the proposal to hold the necessary constitutional referendum in June 2024 on Ireland's participation in the Unified Patent Court. Should the referendum pass, Ireland will become the 18th member state in the UPC system. The Irish Government have also indicated that they will host a local division of the UPC.

UPC Administrative Committee (AC) and UPC IT Team & Registrar

The meetings with the **UPC IT Team & Registrar** and as observers before the **UPC Administrative Committee** are ongoing.

The 9th meeting with the **UPC IT Team & Registrar** was held on 11th December 2023 with all observer

groups, BusinessEurope, EPLAW, EPLIT and **epi**, participating in the meeting. Discussions centred around issues regarding access and searchability of UPC documentation together with procedural issues arising from the CMS, including the important topic of third party intervention.

The 9th meeting of the **UPC AC** was held on 24th November 2023. The EPLC accreditation requests by CEIPI and Fernuniversität in Hagen were approved. The search for a Director and Expert Committee (responsible of the rules of mediation and arbitration and for drawing up a list of mediators and arbitrators) for the Patent Mediation and Arbitration Centre (PMAC) was also launched.

The UPC has published details of the case load of the UPC for since the start of operations on 1st June 2023 which was most recently updated on 31st January 2024. A brief summary of the data in the report follows:

As of 31st January, the Court of First Instance (CoFI) has received a total of 217 cases, of which there are 83 infringement actions, 26 of the infringement actions have led to 86 counterclaims for revocation.

The CoFI has also received 22 applications for provisional measures, preserving evidence and orders for inspection. The Paris and Munich central divisions have received 21 and 4 revocation actions respectively.

As of 31st January 2024, the Court of Appeal (CoA) has received 11 appeals under RoP 220.1 (litera a/b or c) and 13 appeals under RoP 220.2, 1 request for discretionary review, 2 applications for suspensive effect and 3 applications for an order for expedition of an appeal.

The next 10th meeting with the **UPC IT Team & Registrar** is due to take place on Monday 26th February 2024. The date for the next meeting of the UPC AC has yet to be announced.

Report of the Committee on Biotechnological Inventions

S. Wright (GB), Chair and B. Taravella (FR), Secretary

Below is a summary of discussion points in our Biotechnology Committee (BC) since the last Q4_2003 report:

1. NGT Plants

New Genomic Techniques (NGTs) are a variety of techniques that alter the genetic material of an organism and are subject to the same rules as GMOs[1]. The European Food Safety Authority has evaluated potential safety issues[2] of NGTs and on January 24 adopted a position on the Commission proposal[3] on NGTs. The proposal to have two different categories and two sets of rules for NGT plants. NGT plants considered equivalent to conventional ones (NGT 1 plants) would be exempted from the requirements of the GMO legislation[4], whereas for NGT 2 plants this legislation adapts the GMO framework to those NGT plants. All NGT plants should remain prohibited in organic production as their compatibility requires further consideration. That is a quite extreme position that the European Parliament (i.e. the Committee on Environment, Public Health and Food Safety (ENVI)) has taken for plant patents. Following the proposal from the ENVI Committee the European Parliament is scheduled to vote on the draft legislation during the upcoming 5-8 February 2024 plenary session, after which a trilogue negotiations will be take place with EU Commission and EU member states in the Council before the Regulation could be finally adopted. **epi**, together with other associations and companies has called on February 2 upon Members of the EU-Parliament to reconsider the proposed amendment to ban patents on NGT plants to encourage innovation and to foster competitiveness in Europe. Following the **epi** Board meeting of February 8, BC was requested to draft a position paper. Starting from February 28, the position paper has been distributed

Simon Wright

Brigitte Taravalla

1 https://patentepi.org/r/info-2401-02
2 https://patentepi.org/r/info-2401-03
3 https://patentepi.org/r/info-2401-04
4 https://patentepi.org/r/info-2401-05

to the EPO Council and the EPO Working Party and also at national level with the strong support of the BC's members in their respective countries. Finally, the BC's Chair and Secretary have been invited to participate in an exciting new project **epi** is launching – an **epi** podcast discussing the proposed amendment to ban patents on NGT (New Genetic Technologies) plants. The recording is planned on March 22. Our aim with this podcast is to provide a platform for in-depth discussions on the potential effects of such an amendment, exploring its scientific, ethical, and socio-economic dimensions.

2. Special Biotech Committee meetings with the EPO / DG1

A meeting has been arranged with DG1 by EPPC's chair, Chris Mercer on 27-29 February 2024 in The Hague. The meeting took place in hybrid format and BC has been invited to join the meeting. BC's members attended in person were Kosti Vasiliki (FM), Thea van der Wijk (FM), Koen Vanhalst (FM) and Adraian George Tombling (associate member). BC proposed specific Biotech topics to be added at the agenda such as NGT plants and SEQ listings. The idea of producing a position paper by BC on the SEQ listing topic has been discussed as a support for any discussion between **epi** Presidium and EPO President in the next future.

3. Biotech Committees

An in-person BC is organised on 16 April, 2024 in Barcelona. Another meeting will be planned for 2024 only by Videoconference to respect the established 2024 BC's budget.

4. Associate members

Following the first BC of the new mandate of Dec 6, 2023, a call has been sent for requesting associate members to join the BC. We received a lot of positive answers. Past associate members applied again and well as new associate members.

Report of the Harmonisation Committee

J. Brown (GB), Chair

The EPO last year actively pursued Substantive Patent Law Harmonisation ("SPLH"). The baton has now been picked up by Mr Julian Elbro of the UKIPO in his capacity as Chair of the Group B+ Working Group on SPLH.

Mr Elbro and his team are organising two virtual meetings with European user groups, the first one will be on19th March 2024 and the second meeting could be just before or just after the next **epi** Council Meeting (due to be held on 26th April 2024). The **epi** President has appointed myself (as leader of the delegation) and Filippo Santi (Secretary of **epi** Harmonisation Committee) to represent **epi** at the first meeting. It is expected that Mr Elbro will issue a questionnaire after the first meeting. The second meeting will consider the replies of the various European interested parties to the questionnaire.

The **epi** representatives at the first meeting will be bound by the previous decisions of the **epi** Council. If the second meeting is held before the next **epi** Council Meeting, the **epi** representatives at the second meeting will be in the same position as they were at the first meeting. However, if the second meeting is held after the next **epi** Council Meeting, then the **epi** Harmonisation Committee may need to put draft decision(s) to the next **epi** Council Meeting, depending of course on the papers made available for the second meeting and the views of the **epi** Harmonisation Committee on any proposals for SPLH made in the papers from the Chair of the Group B+ Working Group.

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Next Board and Council Meetings

Board Meetings
130th Board Meeting in Alicante (ES) on 3 June 2024
131st Board Meeting in Munich (DE) 13 September 2024 (hybrid)

Council Meetings
97th Council Meeting in Sofia (BG) on 26 and 27 April 2024
98th Council Meeting in Budapest (HU) on 16 November 2024
99th Council Meeting in Vilnius (LT) on 16 and 17 May 2025

Disciplinary Bodies, Committees and Audit

Disziplinarorgane, Ausschüsse und Rechnungsprüfung · Organes de discipline, Commissions et Vérification des comptes

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Update of the searchable database of professional representatives on the EPO website

P notify the Legal Division of the EPO of any changes to your contact details, ensuring that the list of professional representatives remains up to date. The list of professional representatives maintained by the EPO is also the one used by **epi**. To ensure that you receive **epi** mailings and email correspondence at the correct address, kindly inform the Legal Division of the EPO (Dept. 5.3.2.1).

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

European Patent Office
Dept. 5.3.2.1
Legal Division
80298 Munich
Germany

Tel.: +49 (0)89 2399-5231
legaldivision@epo.org
www.epo.org

The relevant form(s) to be submitted in the case of changes can be downloaded from the new EPOwebsite:
https://patentepi.org/r/epo-legal-division

At the button of the options for professional representatives you will find a link to consult your details in the searchable database of professional representatives. As from 1 November 2023, professional representatives can use the representative area in MyEPO Portfolio to request changes to their entry on the list and to manage their telecommunication details, including the publication of these details in the searchable database on the EPO website as a self-service. Deletion from the list of professional representatives can then also be requested via the Representative area. For more information about the Representative area, you may consult the announcement in the September edition of **epi** information. Additionally, the EPO will be publishing a feature guide and dedicated FAQs to provide further details.

Further information and forms relating to the list of professional representatives can be found on the EPO website and in the FAQ section of the **epi** website (https://patentepi.org/en/faq).

IPRISK Intellectual property

LLOYD'S

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European patent attorneys handle National, European and Foreign patent applications and patents. Those patent applications and patents may have a high commercial value and the loss of those patents might cause their proprietor serious damages for which the patent attorney might be liable. In particular for those working in private practice it is thus highly recommended to have a professional liability insurance.

At **epi** we realized that it was not always easy, and in particular not cheap, for our members to subscribe an appropriate professional liability insurance, so we decided to help our members in offering them a product tailormade for them.

What?

In line with the **epi** Council decisions, **epi** negotiated and agreed a framework contract for a professional liability insurance setting out general principles and conditions applicable in all 39 EPC Contracting States. The framework contract was signed with RMS, a Coverholder at Lloyd's, and placed by certain Underwriters at Lloyd's of London.

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