



Results of the Election to the 21st Council

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Cover:

The Water Lily

Digital photography, 2024
by Anna Helena Nilsson Öman
(European Patent Attorney, SE)
was part of the **epi** Artists
Exhibition 2024



Anna Helena Nilsson Öman

Anna Helena was born in Karlstad, Sweden in 1968. She completed her MSc. in Chemical Engineering at the Royal Institute of Technology, Stockholm, Sweden in 1995. Further to this she studied Art at the Kyrkerud Art School, Årjäng, Sweden in 1996 and did studies in digital photography, Brobygrafiska, Sunne, Sweden from 2007-2008.

Anna Helena passed the EQE 2019. Art, music, science and spending time in the nature are very important parts of her life. They are sources of great inspiration and joy. Her art is mostly photo-based, often with added elements. Many of the photos are taken with a photographic technique commonly referred to as Intentional Camera Movement, ICM, wherein the camera is not held still but is rather moved during the moment of exposure. Visit @hnostudios at Instagram.

Anna Helena wurde 1968 in Karlstad, Schweden, geboren. 1995 schloss sie ihr Masterstudium in Chemieingenieurwesen am Königlichen Technischen Institut in Stockholm, Schweden, ab. Darüber hinaus studierte sie 1996 Kunst an der Kyrkerud Kunsthochschule in Årjäng, Schweden, und absolvierte von 2007 bis 2008 ein Studium der digitalen Fotografie an der Brobygrafiska in Sunne, Schweden.

Anna Helena hat 2019 die EQE-Prüfung bestanden. Kunst, Musik, Wissenschaft und Zeit in der Natur sind sehr wichtige Bestandteile ihres Lebens. Sie sind Quellen großer Inspiration und Freude. Ihre Kunst basiert hauptsächlich auf Fotografie, oft mit zusätzlichen Elementen. Viele der Fotos werden mit einer Fototechnik aufgenommen, die gemeinhin als Intentional Camera Movement (ICM) bezeichnet wird, bei der die Kamera nicht still gehalten, sondern während der Belichtung bewegt wird. Besuchen Sie @hnostudios auf Instagram.

Anna Helena est née à Karlstad, en Suède, en 1968. Elle a obtenu son master en génie chimique à l'Institut royal de technologie de Stockholm, en Suède, en 1995. Elle a ensuite étudié l'art à l'école d'art Kyrkerud, à Årjäng, en Suède, en 1996, puis la photographie numérique à Brobygrafiska, à Sunne, en Suède, de 2007 à 2008.

Anna Helena a réussi l'EEQ en 2019. L'art, la musique, la science et les moments passés dans la nature occupent une place très importante dans sa vie. Ils sont pour elle une source d'inspiration et de joie. Son art est principalement basé sur la photographie, souvent agrémentée d'éléments supplémentaires. La plupart de ses photos sont prises à l'aide d'une technique photographique communément appelée « mouvement intentionnel de l'appareil photo » (ICM), qui consiste à ne pas maintenir l'appareil photo immobile, mais à le déplacer pendant l'exposition. Visitez @hnostudios sur Instagram.

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Editorial

A Decade of Progress: Digital Evolution and Institutional Adaptability

M. Thesen (DE), Chair, Editorial Committee



Michael Thesen

As we begin 2026, **epi** Information marks a quiet but significant milestone: ten years of electronic publication. This transition, which began in 2016, represents more than just a change in format – it reflects our profession’s ongoing adaptation to an increasingly digital world while maintaining our commitment to quality content and professional discourse.

This anniversary coincides with another significant achievement: the successful adoption of comprehensive disciplinary system reforms by the **epi** Council at meeting C101. After extensive deliberation spanning two sessions in January and February, the Council approved fundamental changes to our disciplinary framework. These reforms streamline proceedings, enhance transparency, and strengthen the profession’s

capacity for self-governance. The disciplinary system reform represents years of collaborative effort involving multiple stakeholders, expert consultations, and careful consideration of best practices. Most significantly, it demonstrates our profession’s commitment to continuous improvement and institutional excellence.

Looking ahead, new challenges await. Artificial intelligence continues to transform patent practice, requiring updated skills and approaches. The Unified Patent Court system matures, creating new opportunities and considerations for practitioners. International patent harmonization efforts advance, demanding continued engagement and expertise.

epi Information remains committed to chronicling these developments and providing the analysis our community needs to navigate change effectively.

The path forward requires continued collaboration, open dialogue, and shared commitment to excellence. **epi** Information will remain your partner in this journey.

Introduction

Results of the Election to the 21st Council

Notice

Members of the Institute wishing to object against the election results must submit their written objection duly signed to reach the Secretariat of the Institute by 30 March 2026 at the latest. Any objections reaching the Institute after this date will not be taken into consideration.

Special thanks to the members of the Electoral Committee, Margaret Mackett, Markus. A. Müller and Arni Vilhjálmsson, who secured the successful process of election to Council. A big Thank you to the team of the **epi** Secretariat for the excellent support and commitment.

Ergebnisse der Wahl zum 21.Rat

Hinweis

Mitglieder des Instituts, die gegen das Wahlergebnis Einwände erheben möchten, müssen ihre schriftlichen Einwände rechtsgültig unterzeichnet bis spätestens 30. März 2026 beim Sekretariat des Instituts einreichen. Später eingehende Einwände werden nicht berücksichtigt.

Besonderer Dank gilt den Mitgliedern des Wahlausschusses, Margaret Mackett, Markus. A. Müller und Arni Vilhjálmsson, die den erfolgreichen Ablauf der Wahl zum Rat sichergestellt haben. Ein großes Dankeschön an das Team des **epi** Sekretariats für die hervorragende Unterstützung und Engagement.

Résultats de l'élection au 21. Conseil

Note

Les membres de l'Institut désirant contester les résultats de l'élection doivent faire parvenir leurs objections écrites dûment signées au Secrétariat de l'Institut avant le 30 mars 2026 au plus tard. Toute objection parvenant à l'Institut après cette date ne sera plus prise en considération.

Nous remercions tout particulièrement les membres de la Commission Electorale, Margaret Mackett, Markus. A. Müller und Arni Vilhjálmsson, qui ont assuré la réussite du processus d'élection au Conseil. Un grand merci à l'équipe du secrétariat de l'**epi** pour son excellent soutien et son engagement.

Magdalena Augustyniak
Generalsekretär / Secretary General / Secrétaire Général

Erläuterung	Legend	Légende
* als stellvertretendes Mitglied zur Wahl	* stood as substitute only	* éligible comme suppléant uniquement
** Losentscheid bei gleicher Stimmenzahl	** tie vote position decided by lot	** classement par tirage au sort à égalité de voix
+ nominiert im wieder eröffneten Nominationsverfahren	+ nominated in reopened nomination procedure	+ nommé dans la procedure de nomination re-ouverte

Please note that the term of office of these Council members will start after confirmation of the validity of the election at the 102 Council meeting on 11 May 2026 of the newly elected Council duly constituted under Article 2.3 of the By-Laws of the Institute.

AL - Albania

Sent ballots: 10		Participation: 70%		Received ballots: 7	
Candidates					
DODBIBA, Eno		2	PANIDHA, Ela		4
NIKA, Melina *		5	SHOMO, Vjollca *		5
NIKA, Vladimir		6			
Allotment of seats					
Full Member			Substitute		
NIKA, Vladimir		6	NIKA, Melina *, **		5
PANIDHA, Ela		4	SHOMO, Vjollca *, **		5

AT - Austria

Sent ballots: 209		Participation: 37%		Received ballots: 77	
Other capacity					
Received valid ballots: 21					
Candidates					
HANEMANN, Otto *		16	PREHOFER, Boris André		17
HEDENETZ, Alexander Gernot		18	WOLFRAM, Markus *		17
Allotment of seats					
Full Member			Substitute		
HEDENETZ, Alexander Gernot		18	WOLFRAM, Markus *		17
PREHOFER, Boris André		17	HANEMANN, Otto *		16
Private practice					
Received valid ballots: 56					
Candidates					
HARRER-REDL, Dagmar		49	SCHWEINZER, Friedrich		19
POTH, Wolfgang		36	WEINZINGER, Philipp *		35
Allotment of seats					
Full Member			Substitute		
HARRER-REDL, Dagmar		49	WEINZINGER, Philipp *		35
POTH, Wolfgang		36	SCHWEINZER, Friedrich		19

BE - Belgium

Sent ballots: 328		Participation: 40%		Received ballots: 131	
Candidates					
CLERIX, André		69	RENES, Suzanne Paula		34
DE CLERCQ, Ann G. Y.		79	VAN DEN BOECK, Wim		41
LEYDER, Francis		51	VAN MINNEBRUGGEN, Ewan Benito Agnes		58
QUINTELIER, Claude *		43	VANHALST, Koen *		72

Allotment of seats			
Full Member		Substitute	
DE CLERCQ, Ann G. Y.	79	VANHALST, Koen *	72
CLERIX, André	69	QUINTELIER, Claude *	43
VAN MINNEBRUGGEN, Ewan Benito Agnes	58	VAN DEN BOECK, Wim	41
LEYDER, Francis	51	RENES, Suzanne Paula	34

BG - Bulgaria

Sent ballots: 42

Participation: 38%

Received ballots: 16

Candidates			
BENATOV, Samuil Gabriel	8	NIKOLOV, Vladislav Zdravkov *	6
GEORGIEVA, Mariya Georgieva	6	SIRAKOVA, Olga Rousseva	10
GEORGIEVA-TABAKOVA, Milena Lubenova *	10	TAHTADJIEV, Konstantin	13
IVANOV, Ivan Nikolov	4	TSVETKOV, Atanas Lyubomirov	8

Allotment of seats

Full Member		Substitute	
TAHTADJIEV, Konstantin	13	GEORGIEVA-TABAKOVA, Milena Lubenova *	10
SIRAKOVA, Olga Rousseva	10	GEORGIEVA, Mariya Georgieva	6
BENATOV, Samuil Gabriel	8	NIKOLOV, Vladislav Zdravkov *	6
TSVETKOV, Atanas Lyubomirov	8	IVANOV, Ivan Nikolov	4

CH - Switzerland

Sent ballots: 678

Participation: 31%

Received ballots: 212

Other capacity

Received valid ballots: 110

Candidates			
BLÖCHLE, Hans	61	GIANNINI, Reto *	60
CORIC, Dragan	54	HOFFMANN, Jürgen Gerhard	68
FAVRE, Nicolas	82	WIRTH, Christian Martin *	56
FINALE, Christian Thierry	44		

Allotment of seats

Full Member		Substitute	
FAVRE, Nicolas	82	GIANNINI, Reto *	60
HOFFMANN, Jürgen Gerhard	68	WIRTH, Christian Martin *	56
BLÖCHLE, Hans	61	CORIC, Dragan	54

Private practice

Received valid ballots: 102

Candidates			
BÖCKMANN GENANNT DALLMEYER, Georg Nikolaus +	11	ROSENICH, Paul +	19
HENTSCHEL, Sarah *	67	SCHNEITER, Sorin +	31
KAPIC, Tarik	76	THOMSEN, Peter René	79
KÖRNER, Thomas Ottmar	34	WERNER, André *, +	48
LIEBETANZ, Michael	75		

Allotment of seats

Full Member		Substitute	
THOMSEN, Peter René	79	HENTSCHEL, Sarah *	67
KAPIC, Tarik	76	KÖRNER, Thomas Ottmar	34
LIEBETANZ, Michael	75	WERNER, André *, +	48

CY - Cyprus

Sent ballots: 7

Participation: 100%

Received ballots: 7

Candidates

CURLEY, Donnacha John	3	ROUSOUNIDOU, Vasiliki A.	6
GOLSER, Adrian Victor	1		

Allotment of seats

Full Member		Substitute	
ROUSOUNIDOU, Vasiliki A.	6	GOLSER, Adrian Victor	1
CURLEY, Donnacha John	3		

CZ - Czech Republic

Sent ballots: 80

Participation: 29%

Received ballots: 23

Candidates

FISCHER, Michael *	5	HOLASOVA, Hana	17
FOUSKOVÁ, Petra	19	MALUSEK, Jiri	12
GUTTMANN, Michal *	11	OSMEROVA, Sona *	7
HARTVICOVA, Katerina	19	VONDRAS, Jan +	13

Allotment of seats

Full Member		Substitute	
FOUSKOVÁ, Petra	19	GUTTMANN, Michal *	11
HARTVICOVA, Katerina	19	OSMEROVA, Sona *	7
HOLASOVA, Hana	17	FISCHER, Michael *	5
MALUSEK, Jiri	12	VONDRAS, Jan +	13

DE - Germany

Sent ballots: 5408

Participation: 21%

Received ballots: 1155

Other capacity

Received valid ballots: 438

Candidates

HERING, Stefanie Alexandra	188	SUNDERMANN, Corinna	259
HUMMEL, Thorsten Markus	154	TÜNGLER, Eberhard	194
KREMER, Véronique Marie Joséphine	254	WILHELM, Wolfgang	119
MARX, Thomas	194	WINTER, Andreas	314

Allotment of seats

Full Member		Substitute	
WINTER, Andreas	314	TÜNGLER, Eberhard **	194
SUNDERMANN, Corinna	259	MARX, Thomas **	194
KREMER, Véronique Marie Joséphine	254	HERING, Stefanie Alexandra	188

Private practice

Received valid ballots: 717

Candidates			
BAPTISTA DE ALMEIDA SOUZA, Maria Claudia	208	STEPHAN, Henrik Hans Wilhelm	74
CIRL, Christine	289	STORK, Martina	413
HARTIG, Michael *	218	VOGELSANG-WENKE, Heike	456
KÖRFER, Thomas	111	WEISS, Robin Sebastian	147
MOHR, Christian A.	241	ZHANG, Lu	118
SCHOBER, Christoph D.	345	NOMINATION WITHDRAWN	233

Allotment of seats			
Full Member		Substitute	
VOGELSANG-WENKE, Heike	456	CIRL, Christine	289
STORK, Martina	413	MOHR, Christian A.	241
SCHOBER, Christoph D.	345	HARTIG, Michael *	218

DK - Denmark

Sent ballots: 332

Participation: 46%

Received ballots: 154

Candidates			
CARLSSON, Eva	51	KOEFOED, Peter	95
CHEN, Sangzi Sandra +	35	MARKVARDSEN, Peter *	22
FEVRE, Anna-Kathrine +	37	STRUVE, Casper	47
HEGNER, Anette *	41	ZAKHAROVA, Natalia +	26
KANVED, Nicolai	40		

Allotment of seats			
Full Member		Substitute	
KOEFOED, Peter	95	HEGNER, Anette *	41
CARLSSON, Eva	51	MARKVARDSEN, Peter *	22
STRUVE, Casper	47	FEVRE, Anna-Kathrine +	37
KANVED, Nicolai	40	CHEN, Sangzi Sandra +	35

EE - Estonia

Sent ballots: 15

Participation: 73%

Received ballots: 11

Candidates			
KAULER, Urmas	6	SARAP, Margus	8
KOPPEL, Mart Enn	9	TOOME, Jürgen	8

Allotment of seats			
Full Member		Substitute	
KOPPEL, Mart Enn	9	SARAP, Margus **	8
TOOME, Jürgen **	8	KAULER, Urmas	6

ES - Spain

Sent ballots: 284

Participation: 37%

Received ballots: 105

Candidates

APRAIZ, Idoia	36	URIZAR ANASGASTI, José Antonio	5
DRIAU MOLL, Christian Gabriel	26	VÁZQUEZ VÁZQUEZ, Nieves *	31
PEREZ SANCHEZ, Manuel Jesus	29	VEGA ROCHA, Susana	42
ROQUÉ ROSELL, Núria	41	VILALTA JUVANTENY, Luis	53
SÁNCHEZ, Ruth	54		

Allotment of seats

Full Member		Substitute	
SÁNCHEZ, Ruth	54	APRAIZ, Idoia	36
VILALTA JUVANTENY, Luis	53	VÁZQUEZ VÁZQUEZ, Nieves *	31
VEGA ROCHA, Susana	42	PEREZ SANCHEZ, Manuel Jesus	29
ROQUÉ ROSELL, Núria	41	DRIAU MOLL, Christian Gabriel	26

FI - Finland

Sent ballots: 209

Participation: 45%

Received ballots: 94

Candidates

BANKS, Peter *, +	21	SAHLIN, Jonna Elisabeth	52
HÄYRINEN, Ville Tapani	34	TIILIKAINEN, Jarkko Tapio	46
KALLIOLA, Sanna Marketta *, +	32	VATTULAINEN ERKKILÄ, Anniina	43
KONKONEN, Tomi-Matti Juhani	40	VIROLAINEN, Nina Erika *	31

Allotment of seats

Full Member		Substitute	
SAHLIN, Jonna Elisabeth	52	HÄYRINEN, Ville Tapani	34
TIILIKAINEN, Jarkko Tapio	46	VIROLAINEN, Nina Erika *	31
VATTULAINEN ERKKILÄ, Anniina	43	KALLIOLA, Sanna Marketta *, +	32
KONKONEN, Tomi-Matti Juhani	40	BANKS, Peter *, +	21

FR - France

Sent ballots: 1414

Participation: 32%

Received ballots: 452

Other capacity

Received valid ballots: 164

Candidates

AJDARI, Emmanuel	126	GUÉRY-JACQUES, Géraldine *, +	142
AUDUREAU, Jean-François Stéphane Patrick +	117	SENNINGER, Thierry	128
GENDRAUD, Pierre	99	TARAVELLA, Brigitte	146

Allotment of seats

Full Member		Substitute	
TARAVELLA, Brigitte	146	GENDRAUD, Pierre	99
SENNINGER, Thierry	128	GUÉRY-JACQUES, Géraldine *, +	142
AJDARI, Emmanuel	126	AUDUREAU, Jean-François Stéphane Patrick +	117

Private practice

Received valid ballots: 288

Candidates			
LEBKIRI, Alexandre	202	MOUTARD, Pascal Jean	194
MAROLLÉ, Patrick Pierre Pascal	235	NEVANT, Marc *	219
MARTIN-CHARBONNEAU, Virginie	236	ROUSSEAU, Pierick Edouard	201

Allotment of seats			
Full Member		Substitute	
MARTIN-CHARBONNEAU, Virginie	236	NEVANT, Marc *	219
MAROLLÉ, Patrick Pierre Pascal	235	ROUSSEAU, Pierick Edouard	201
LEBKIRI, Alexandre	202	MOUTARD, Pascal Jean	194

GB - United Kingdom

Sent ballots: 2989

Participation: 13%

Received ballots: 394

Candidates			
BOFF, James Charles	182	INSTONE, Alicia Claire	246
BOFF, Arthur James *	144	MERCER, Christopher Paul	251
BROWN, John D.	139	MUTTOCK, Henry Paul Jones	132
FERARA, Nina	237	ROBERTS, Gwilym Vaughan	271
GRAY, John James	197	SARDHARWALA, Fatema Elyasali	235
GWILT, Julia Louise	244	WRIGHT, Simon Mark	219

Allotment of seats			
Full Member		Substitute	
ROBERTS, Gwilym Vaughan	271	WRIGHT, Simon Mark	219
MERCER, Christopher Paul	251	GRAY, John James	197
INSTONE, Alicia Claire	246	BOFF, James Charles	182
GWILT, Julia Louise	244	BOFF, Arthur James *	144
FERARA, Nina	237	BROWN, John D.	139
SARDHARWALA, Fatema Elyasali	235	MUTTOCK, Henry Paul Jones	132

GR - Greece

Sent ballots: 23

Participation: 70%

Received ballots: 16

Candidates			
BAKATSELOU, Vassiliki	4	SAMOUILIDIS, Emmanouil	3
KOUZELIS, Dimitrios	5	VAVEKIS, Konstantinos	2
LIOUMBIS, Alexandros	8	ZOGRAFOS, Georgios	5

Allotment of seats			
Full Member		Substitute	
LIOUMBIS, Alexandros	8	ZOGRAFOS, Georgios **	5
KOUZELIS, Dimitrios **	5	BAKATSELOU, Vassiliki	4

HR - Croatia

Sent ballots: 20

Participation: 40%

Received ballots: 8

Candidates

HADZIJA, Tomislav	7	TOMSIC SKODA, Slavica *	5
SOSIC, Ivona *	6	VUKINA, Sanja	8

Allotment of seats

Full Member		Substitute	
VUKINA, Sanja	8	SOSIC, Ivona *	6
HADZIJA, Tomislav	7	TOMSIC SKODA, Slavica *	5

HU - Hungary

Sent ballots: 64

Participation: 44%

Received ballots: 28

Candidates

GROF, Palma	25	LENGYEL, Zsolt	26
HORVÁTH, Bertalan *	23	LEZSÁK, Gábor	26
KERESZTY, Marcell *	26	SZENTPÉTERI, Zsolt	25
KOMPAGNE, Hajnalka *	25	TÖRÖK, Ferenc *	27

Allotment of seats

Full Member		Substitute	
LENGYEL, Zsolt	26	TÖRÖK, Ferenc *	27
LEZSÁK, Gábor	26	KERESZTY, Marcell *	26
GROF, Palma	25	KOMPAGNE, Hajnalka *	25
SZENTPÉTERI, Zsolt	25	HORVÁTH, Bertalan *	23

IE - Ireland

Sent ballots: 91

Participation: 40%

Received ballots: 36

Candidates

BOYCE, Conor	25	MCCARTHY, Denis Alexis	27
CASEY, Lindsay Joseph *	25	MURPHY, Stephen Samuel *	16
HARTE, Seán Paul	9	SKRBA, Sinéad	28
KELLY, Donal Morgan *	19	WALSHE, Triona Mary	24

Allotment of seats

Full Member		Substitute	
SKRBA, Sinéad	28	CASEY, Lindsay Joseph *	25
MCCARTHY, Denis Alexis	27	KELLY, Donal Morgan *	19
BOYCE, Conor	25	MURPHY, Stephen Samuel *	16
WALSHE, Triona Mary	24	HARTE, Seán Paul	9

IS - Iceland

Sent ballots: 16

Participation: 88%

Received ballots: 14

Candidates

FRIDRIKSSON, Einar Karl	7	INGVARSSON, Sigurdur *	7
GUDMUNDSDÓTTIR, Anna Valborg	8	JONSSON, Thorlakur	6
HARDARSON, Gunnar Örn	7		

Allotment of seats

Full Member		Substitute	
GUDMUNDSDÓTTIR, Anna Valborg	8	HARDARSON, Gunnar Örn **	7
FRIDRIKSSON, Einar Karl **	7	INGVARSSON, Sigurdur *	7

IT - Italy

Sent ballots: 626

Participation: 39%

Received ballots: 243

Other capacity

Received valid ballots: 43

Candidates

BARACCO, Stefano	20	PAGLIA, Pietro	30
BAST, Tim	16	ROSSETTI, Elena	20
MACCHETTA, Francesco	28	SULCIS, Roberta	25

Allotment of seats

Full Member		Substitute	
PAGLIA, Pietro	30	BARACCO, Stefano **	20
MACCHETTA, Francesco	28	ROSSETTI, Elena **	20
SULCIS, Roberta	25	BAST, Tim	16

Private practice

Received valid ballots: 200

Candidates

CHECCACCI, Giorgio	121	MODIANO, Micaela Nadia	144
MASCIOPINTO, Gian Giuseppe	50	PES, Matteo	73
MAURO, Marina Eliana	90	RAMBELLI, Paolo	109

Allotment of seats

Full Member		Substitute	
MODIANO, Micaela Nadia	144	MAURO, Marina Eliana	90
CHECCACCI, Giorgio	121	PES, Matteo	73
RAMBELLI, Paolo	109	MASCIOPINTO, Gian Giuseppe	50

LI - Liechtenstein

Sent ballots: 20

Participation: 70%

Received ballots: 14

Candidates

HARMANN, Bernd-Günther	11	PISCHETSRIEDER, Tobias M.	14
HOLZHEU, Christian *	13	SCHWAB, Robert *	10

Allotment of seats

Full Member		Substitute	
PISCHETSRIEDER, Tobias M.	14	HOLZHEU, Christian *	13
HARMANN, Bernd-Günther	11	SCHWAB, Robert *	10

LT - Lithuania

Sent ballots: 20

Participation: 50%

Received ballots: 10

Candidates

ARMALYTE, Elena	9	PAKENIENE, Ausra *	6
JACKUNE, Indre *	8	PETNIUNAITE, Jurga	9

Allotment of seats

Full Member		Substitute	
ARMALYTE, Elena	9	JACKUNE, Indre *	8
PETNIUNAITE, Jurga	9	PAKENIENE, Ausra *	6

LU - Luxembourg

Sent ballots: 27

Participation: 74%

Received ballots: 20

Other capacity

Received valid ballots: 5

Candidates

LAMPE, Sigmar *	4	PIRIOU, Soazig Marie Yvonne *	2
LECOMTE, Didier	4	VAN TROOST, Pascal Rudolf Dymphena	3

Allotment of seats

Full Member		Substitute	
LECOMTE, Didier	4	LAMPE, Sigmar *	4
VAN TROOST, Pascal Rudolf Dymphena	3	PIRIOU, Soazig Marie Yvonne *	2

Private practice

Received valid ballots: 15

Candidates

BRUCK, Mathis	12	MELLET, Valérie Martine	9
LEAL, Tiago +	3		

Allotment of seats

Full Member		Substitute	
BRUCK, Mathis	12	LEAL, Tiago +	3
MELLET, Valérie Martine	9		

LV - Latvia

Sent ballots: 13

Participation: 54%

Received ballots: 7

Candidates

FORTUNA, Jevgenijs	6	OSMANS, Voldemars	6
JONANE-OSA, Indra	1		

Allotment of seats

Full Member		Substitute	
FORTUNA, Jevgenijs	6	JONANE-OSA, Indra	1
OSMANS, Voldemars	6		

MC - Monaco

Sent ballots: 7

Participation: 57%

Received ballots: 4

Candidates

AMIRA, Sami	3	SCHMALZ, Günther	4
HAUTIER, Nicolas *	3	THACH, Tum *	4

Allotment of seats

Full Member		Substitute	
SCHMALZ, Günther	4	THACH, Tum *	4
AMIRA, Sami	3	HAUTIER, Nicolas *	3

ME - Montenegro

Sent ballots: 1

Participation: 100%

Received ballots: 1

Candidates

LUTOVAC, Vuk	1
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Allotment of seats

Full Member		Substitute	
LUTOVAC, Vuk	1		

MK - North Macedonia

Sent ballots: 14

Participation: 79%

Received ballots: 11

Candidates

DAMJANSKI, Vanco	4	KJOESKA, Marija	7
FILIPOV, Gjorgji	4	KOSTOVSKA-STOJKOVSKA, Zivka	3
JOANIDIS, Biljana	4	PEPELJUGOSKI, Valentin	2

Allotment of seats

Full Member		Substitute	
KJOESKA, Marija	7	JOANIDIS, Biljana **	4
FILIPOV, Gjorgji **	4	DAMJANSKI, Vanco **	4

MT - Malta

Sent ballots: 6

Participation: 33%

Received ballots: 2

Candidates

FINKE, Steffi	2	SANSONE, Luigi	2
GERBINO, Angelo *	1		

Allotment of seats

Full Member		Substitute	
FINKE, Steffi	2	GERBINO, Angelo *	1
SANSONE, Luigi	2		

NL - Netherlands

Sent ballots: 593

Participation: 38%

Received ballots: 224

Candidates

AALBERS, Arnt Reinier	81	SCHOONEVELDT, Gerben	59
BLOKLAND, Arie *	71	TANGENA, Antonius Gerardus	82
CROMSIGT, Jenny	112	VAN BUUL, Bastiaan Richard Marinus	49
LAND, Addick Adrianus Gosling	29	VAN KALKEREN, Hendrik Antonius *	66
LOUWAARD, Jan-Willem Paul	59	VAN VELZEN, Maaïke Mathilde	113
MAAS, Huub Pieter André	87	VAN WEZENBEEK, Lambertus A.C.M.	66
NIESING, Willem	75	VERMEULEN, Martijn	74
REIJNS, Tiemen Geert Pieter	122		

Allotment of seats

Full Member		Substitute	
REIJNS, Tiemen Geert Pieter	122	NIESING, Willem	75
VAN VELZEN, Maaïke Mathilde	113	VERMEULEN, Martijn	74
CROMSIGT, Jenny	112	BLOKLAND, Arie *	71
MAAS, Huub Pieter André	87	VAN WEZENBEEK, Lambertus A.C.M.	66
TANGENA, Antonius Gerardus	82	VAN KALKEREN, Hendrik Antonius *	66
AALBERS, Arnt Reinier	81	LOUWAARD, Jan-Willem Paul **	59

NO - Norway

Sent ballots: 106

Participation: 35%

Received ballots: 37

Candidates

HJELSVOLD, Bodil Merete Sollie	24	TAFJORD, Harald	9
NIKOLOV, Nikolay Dontchev	6	THORVALDSEN, Knut *	4
REITAN, Katja	33	THRANE, Dag *	13
REKDAL, Kristine	21	TRONBØL, Turid Helene	21
SINGH, Tajeshwar	8	VAN DIJK, Victor Emmanuel Stephanus	13

Allotment of seats

Full Member		Substitute	
REITAN, Katja	33	VAN DIJK, Victor Emmanuel Stephanus	13
HJELSVOLD, Bodil Merete Sollie	24	THRANE, Dag *	13
REKDAL, Kristine	21	TAFJORD, Harald	9
TRONBØL, Turid Helene	21	SINGH, Tajeshwar	8

PL - Poland

Sent ballots: 222

Participation: 31%

Received ballots: 69

Candidates

AUGUSTYNIAK, Magdalena Anna	37	MALEWSKA, Ewa	8
BURY, Marek	36	PAWLOWSKI, Adam	32
CZARNIK, Maciej	32	PRZYLUCKI, Michal Wiktor	11
KAWCZYNSKA, Marta Joanna	33	ROGOZINSKA, Alicja	19
KREKORA, Magdalena	26	SIELEWIESIUK, Jakub *	23
LEWICKA, Katarzyna Dorota	8		

Allotment of seats

Full Member		Substitute	
AUGUSTYNIAK, Magdalena Anna	37	CZARNIK, Maciej **	32
BURY, Marek	36	KREKORA, Magdalena	26
KAWCZYNSKA, Marta Joanna	33	SIELEWIESIUK, Jakub *	23
PAWLOWSKI, Adam **	32	ROGOZINSKA, Alicja	19

PT - Portugal

Sent ballots: 43

Participation: 60%

Received ballots: 26

Candidates

ALVES MOREIRA, Pedro	17	DO NASCIMENTO GOMES, Rui *	21
CARVALHO FRANCO, Isabel	21	FERREIRA MAGNO, Fernando Antonio	15
CORTE-REAL CRUZ, António *	20	PEREIRA DA CRUZ, Joao	21
CRUZ, Nuno *	20	SILVESTRE DE ALMEIDA FERREIRA, Luís Humberto *	15

Allotment of seats

Full Member		Substitute	
CARVALHO FRANCO, Isabel	21	DO NASCIMENTO GOMES, Rui *	21
PEREIRA DA CRUZ, Joao	21	CORTE-REAL CRUZ, António *, **	20
ALVES MOREIRA, Pedro	17	CRUZ, Nuno *, **	20
FERREIRA MAGNO, Fernando Antonio	15	SILVESTRE DE ALMEIDA FERREIRA, Luís Humberto *	15

RO - Romania

Sent ballots: 34

Participation: 44%

Received ballots: 15

Candidates

BONCEA, Oana-Laura	13	MUNTEANU, Manuela-Cornelia	9
ENESCU, Miruna	11	TEODORESCU, Mihaela	8
FIERASCU, Cosmina-Catrinel	11	TULUCA, F. Doina	4
GEORGESCU, Cristina	2	VASILESCU, Raluca *	4

Allotment of seats

Full Member		Substitute	
BONCEA, Oana-Laura	13	TEODORESCU, Mihaela	8
ENESCU, Miruna	11	TULUCA, F. Doina	4
FIERASCU, Cosmina-Catrinel	11	VASILESCU, Raluca *	4
MUNTEANU, Manuela-Cornelia	9	GEORGESCU, Cristina	2

RS - Serbia

Sent ballots: 39

Participation: 59%

Received ballots: 23

Candidates

BOGDANOVIC, Dejan	12	SUNDERIC, Bojan *	3
BRKIC, Zeljka	5	TOMIC, Marija	13
HERAK, Nada	6	TRAVICA, Katarina	10
JANKOVIC, Mara	12	ZATEZALO, Mihajlo	6
PLAVSA, Uros	6		

Allotment of seats

Full Member		Substitute	
TOMIC, Marija	13	ZATEZALO, Mihajlo **	6
BOGDANOVIC, Dejan	12	PLAVSA, Uros **	6
JANKOVIC, Mara	12	HERAK, Nada **	6
TRAVICA, Katarina	10	BRKIC, Zeljka	5

SE - Sweden

Sent ballots: 503

Participation: 32%

Received ballots: 161

Candidates

BJERNDSELL, Per Ingvar	35	LINDROTH, Anders	74
BLUROCK, Maryna	27	MARTINSSON, Peter	68
FRANKS, Barry Gerard	26	NORGREN, Magnus	16
GUSTAFSSON, Tomas	26	SJÖGREN PAULSSON, Stina	73
GYNNERSTEDT, Erik Carl Magnus	42	THÖRNBORG, Anders Uno	34
HANSON, Maria Elisabeth Mimmi *	39	WIKLUND, Ronney	24
ISAKSSON, Anders	26	YDRESKOG, Margareta	52

Allotment of seats

Full Member		Substitute	
LINDROTH, Anders	74	HANSON, Maria Elisabeth Mimmi *	39
SJÖGREN PAULSSON, Stina	73	THÖRNBORG, Anders Uno	34
MARTINSSON, Peter	68	BLUROCK, Maryna	27
YDRESKOG, Margareta	52	GUSTAFSSON, Tomas **	26
GYNNERSTEDT, Erik Carl Magnus	42	FRANKS, Barry Gerard **	26
BJERNDSELL, Per Ingvar	35	ISAKSSON, Anders **	26

SI - Slovenia

Sent ballots: 27

Participation: 78%

Received ballots: 21

Candidates

BENCINA, Mojca *	7	KUNIC, Barbara	10
BORIC VEZJAK, Maja	10	MACEK, Gregor	17
BORSTAR, Dusan	8	OSOLNIK, Renata	16
GOLMAJER ZIMA, Marjanca	9		

Allotment of seats

Full Member		Substitute	
MACEK, Gregor	17	GOLMAJER ZIMA, Marjanca	9
OSOLNIK, Renata	16	BORSTAR, Dusan	8
BORIC VEZJAK, Maja	10	BENCINA, Mojca *	7
KUNIC, Barbara	10		

SK - Slovakia

Sent ballots: 25

Participation: 52%

Received ballots: 13

Candidates

BAD'UROVÁ, Katarina	11	MESKOVA, Viera *	4
CECHVALA, Radovan	7	NEUSCHL, Vladimir	10
MAJLINGOVA, Marta *	8		

Allotment of seats

Full Member		Substitute	
BAD'UROVÁ, Katarina	11	MAJLINGOVA, Marta *	8
NEUSCHL, Vladimir	10	CECHVALA, Radovan	7

SM - San Marino

Sent ballots: 14

Participation: 93%

Received ballots: 13

Candidates

AGAZZANI, Giampaolo	11	PETRAZ, Davide Luigi *, +	9
MAROSCIA, Antonio	10	TIBURZI, Andrea	4

Allotment of seats

Full Member		Substitute	
AGAZZANI, Giampaolo	11	TIBURZI, Andrea	4
MAROSCIA, Antonio	10	PETRAZ, Davide Luigi *, +	9

TR - Türkiye

Sent ballots: 88

Participation: 58%

Received ballots: 51

Candidates

ARKAN, Selda Mine *	10	ISIKLI, Irfan Can	3
ATALAY, Baris	24	KAYAHAN, Senem	8
AYGÖR, Kemal Rifat	10	MUTLU, Onur	10
AYYILDIZ DALMA, Güler	19	MUTLU, Aydin	12
BAKIRCI, Utkan Bahri	20	TAS, Emrah	10
CAYLI, Hülya	15	YALVAÇ, Oya	9
HAMAMCIOGLU, Volkan	18	YILDIRIM, Kemal Baran	17

Allotment of seats

Full Member		Substitute	
ATALAY, Baris	24	YILDIRIM, Kemal Baran	17
BAKIRCI, Utkan Bahri	20	CAYLI, Hülya	15
AYYILDIZ DALMA, Güler	19	MUTLU, Aydin	12
HAMAMCIOGLU, Volkan	18	MUTLU, Onur **	10

Report on epi Council Meeting C101

Meeting Structure and Timeline

The 101st epi Council meeting was conducted online in two separate sessions. The first session took place on January 30, 2026, and was interrupted at 18:22. The meeting resumed on February 10, 2026, from 14:00-16:00 CET to complete the remaining agenda items.

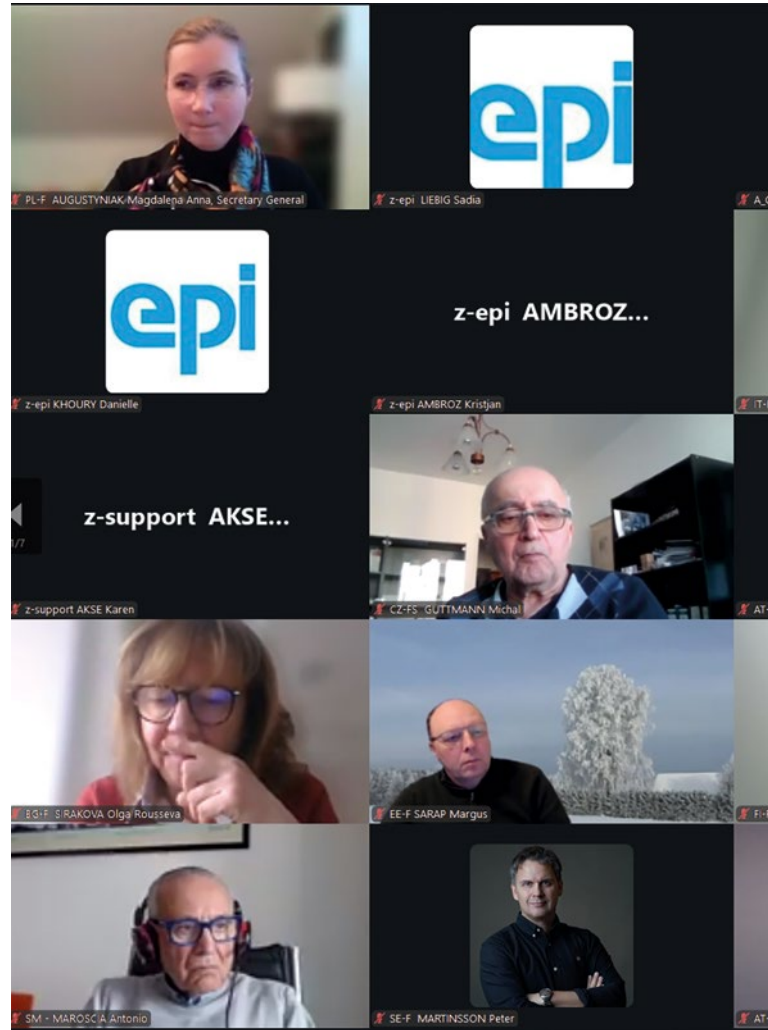
Primary Focus

The meeting addressed the fundamental reform of the disciplinary system for European Patent Attorneys. The Council reviewed proposed amendments to the Regulation on Discipline for Professional Representatives (RDR), the Founding Regulation of the Institute, the Regulation on the European Qualifying Examination (REE), and related procedural rules.

First Session Outcomes

During the initial session, Council members engaged in extensive discussions regarding various aspects of the proposed disciplinary system reform. The debates covered topics including the composition of disciplinary bodies, procedures for handling anonymous complaints, qualification requirements for committee members, and the overall structure of the new system.

The session culminated in a vote on the comprehensive reform package. Despite receiving support from 82% of participating members (90 votes in favor), the proposal did



not achieve the required absolute majority of 93 votes (i.e., two thirds) from all 139 elected Council members. Only 110 Council members participated in the vote, which took place after the scheduled end time of the meeting.

Following this outcome, the participating Council members voted to interrupt the meeting and continue at a later date to reconsider the final vote on the proposed reforms with a higher number of Council members present during the voting.

Continuation and Final Results

The February 10th session saw a high participation, with more than 130 Council members registering to attend.

Upon reconsideration, the Council approved the amendments to the RDR and Founding Regulation with 104 votes in favor, 22 against, and 5 abstentions. The Council also





supported the proposed amendments to the REE and adopted the Additional Rules for Elections and Appointment to the future Disciplinary Board.

Key Structural Changes

The reformed disciplinary system represents a significant restructuring of existing procedures. The new framework eliminates the middle-tier Disciplinary Board of the European Patent Office and expands the role of the Disciplinary Committee, which will be renamed the “Disciplinary Board of the Institute of Professional Representatives before the European Patent Office” (**epi** Disciplinary Board).

The Council retained flexibility in determining the composition of the **epi** Disciplinary Board, i.e., the numbers of professional representatives and legally qualified members, rather than fixing specific numbers in the regulations. The minimum experience require-

ment for candidates was reduced from fifteen to eight years to make positions more accessible while maintaining professional standards.

The handling of anonymous complaints was clarified, with such matters to be forwarded to the **epi** Board for consideration of formal action. The Council also established clear procedures for various aspects of the new system while maintaining the authority to adapt these procedures based on evolving needs.

Administrative Considerations

Several administrative matters were addressed during the meeting. Article 16 of the By-Laws was temporarily reverted to its previous wording until the Autumn 2026 Council meeting because the implementation double-signature requirement met technical difficulties with certain banks.





The By-Laws Committee was tasked with preparing necessary adaptations to accommodate the new disciplinary framework for the next Council meeting.

Implementation Timeline

The approved reforms will proceed to the Administrative Council of the European Patent Organisation for final approval. Implementation is anticipated for early 2027, providing time for the necessary preparatory work and transitional arrangements. The new system will require the Council to elect a new **epi** Disciplinary Board during the autumn 2026 meeting in Bratislava.

Conclusion

The C101 meeting demonstrated the Council's commitment to reforming the disciplinary system and to finalizing the process before the newly elected Council takes over. At the same time, broad participation in the decision-making process was ensured. The two-session format, though unusual, ultimately facilitated more comprehensive involvement from Council members and strengthened the legitimacy of the final decisions through enhanced participation.





Patent Practice

The Ghost in the Patent: Why AI Can Draft Documents but Cannot Make Judgement Calls

B. Best (DE), European Patent Attorney

Artificial intelligence now produces patent documents with striking fluency, but this does not mean it can replace patent attorneys. This article argues that the true value of patent practice lies not in text production, but in navigating the friction between four risk dimensions – legal validity, technical accuracy, commercial utility, and psychological impact. It demonstrates why AI cannot make the value judgments required to navigate these competing interests. Finally, it proposes four operational guardrails as a framework for patent attorneys to use AI as a tool for thought rather than a substitute for judgment.

The Category Error: Fluent Intelligence and the Illusion of Understanding

Generative AI can now draft patent documents with striking fluency. Descriptions, embodiments, even claims can be produced in seconds. This surface-level linguistic competence has encouraged

a dangerous inference: that patent practice is fundamentally a drafting task, and therefore largely automatable.

That inference is a category error. It confuses the *what* of patent practice (the production of text) with its *why* (the strategic intent that gives the text meaning). The true risk to the profession is not the emergence of a superior artificial intelligence, but the gradual displacement of human judgment. When practitioners use AI to replace thinking rather than to support it, they begin to treat strategy – the core professional skill – as a cognitive burden to be outsourced. Drafting is automated; judgment quietly follows.

AI fails at the core of patent strategy in two fundamental ways:

First, AI is not capable of situated decision-making. Patent strategy is never a purely abstract optimization problem. It is embedded in a concrete situation: a specific inventor

and applicant, a specific competitive landscape, an examiner culture, a litigation horizon, a client's risk tolerance, budget constraints, and long-term commercial intent. Human practitioners continuously integrate weak signals, tacit knowledge, and contextual cues that are not fully articulable and often not even consciously formalized. AI, by contrast, operates on representations detached from lived context. It can recombine patterns and propose plausible options, but it cannot *inhabit* the situation in which a strategic choice must be made. Its "judgment" is statistical, not situated.

Imagine it is 10:00 on a Monday morning. You receive an International Search Report (ISR) on a client's flagship PCT application. The examiner has rejected claim 1 for lack of novelty but indicates that dependent claim 9 is allowable. An AI views this as a logic gate. Optimizing for "Grant," it calculates the statistical success of various responses and offers a menu of binary options: fight the rejection with arguments, or accept claim 9 for a quick win.

The human practitioner sees a different landscape. They recall the difficult phone call with the client last week: the company's Series B funding is contingent on a positive signal from the patent office *immediately*. They analyze the examiner's objection to claim 1 and see that while it is based on a flawed interpretation that *could* be rebutted, this specific examiner is notoriously difficult to turn around in the international phase. The decision, therefore, is not a calculation but a maneuver. The attorney recommends limiting the international phase to claim 9 to secure a positive International Preliminary Report on Patentability (IPRP) to satisfy the investors, while quietly planning to fight for the broader claim 1 later, maybe via divisional applications in only the most critical target markets.

This is situated decision-making. The AI sees a probability of success; the human sees a conflict of values.

Second, AI cannot take responsibility for a decision.

Strategy is not merely the generation of options; it is the commitment to one path over others, with full awareness that alternatives are being foreclosed. Every patent filing embodies such a commitment: claims not pursued, jurisdictions not entered, disclosures not made. These are normative decisions with legal and commercial consequences. AI cannot bear those consequences. It cannot answer for a lost enforcement opportunity, a fatal admission, or a misaligned filing strategy. Responsibility always attaches to a human agent – and that fact is not a temporary technological gap, but a structural feature of professional and legal practice.

When the human practitioner is reduced to validating machine output, they surrender what German philosophy aptly calls *Geist* (mind, spirit): the situated understanding, purposive intention, and willingness to stand behind a decision. This *Geist* is the true "ghost" in the patent. Like a mountain guide who turns back despite favorable forecasts because the snow "feels wrong," the patent attorney's irreplaceable role lies

not in producing information, but in exercising judgment under uncertainty, and accepting professional accountability for the chosen course.

Functional Intelligence and the Trap of Satisficing

Patent practice is often taught and practiced as a form of expert analysis in a legal-technical "*data space*". The patent attorney is trained to identify relevant facts, survey the legal terrain, enumerate risks, and present structured options. This was the model in which the author himself was trained almost two decades ago. The professional posture is analytical and technically rigorous, but deliberately non-directive: "*Here are the examiner's objections and three possible claim amendments. How would you like to proceed?*"

This mode of practice reduces professional value to the ability to synthesize information and enumerate possibilities. Strategy becomes a menu. The attorney functions as an intermediary between complex systems – law, technology, procedure – organizing them into intelligible choice sets.

The problem is that this is precisely the domain in which AI excels. As Markus Gabriel observes in *The Meaning of Thought*¹, *artificial systems possess functional intelligence*: the ability to process data, detect patterns, and generate coherent outputs, without possessing *Geist* – situated understanding, intention, or meaning. In this sense, AI is not a deficient analyst; it is the ultimate data-space analyst.

When attorneys rely on AI in this purely analytical mode, they risk falling into what Advait Sarkar calls "outsourced reason" in *Artificial Intelligence as a Tool for Thought (Microsoft Research)*²: the gradual substitution of human judgment with machine-generated plausibility. The cognitive danger is not merely efficiency-seeking, but the phenomenon Sarkar identifies as **satisficing**. Because AI outputs meet a threshold of apparent correctness, they dampen critical engagement. The draft looks like a patent claim; it reads like a patent claim; therefore, it is treated as *good enough*. The traditional "blank page problem" is replaced by a more insidious "filled page problem", in which the attorney shifts from active strategic construction to passive evaluation; reviewing, trimming, and approving a statistically probable draft rather than deliberately engineering a legally and commercially optimal one.

This is the quiet trap of functional intelligence. When professional value is defined as mapping the option space rather than choosing a path through it, the human practitioner becomes replaceable. The attorney has been acting as a **cartographer** – skilled, informed, and precise, yet ultimately detached from the responsibility of navigation itself.

1 <https://patentepi.org/r/info-2601-1>

2 <https://patentepi.org/r/info-2601-2>

The Mountain Guide: Identity and Accountability

The **cartographer** is obsessed with the document. Like a technician using a high-precision **GPS**, they use AI to generate technically accurate text and valid claims. When the GPS (AI) suggests a route – “*Narrow claim 1 to overcome D1*” – the Cartographer accepts it because the map is clean and the file is legally tidy.

A **mountain guide** knows that the map is not the territory. They do not merely display the map; they recommend the route. A hiker has little use for a guide who pauses at every junction to ask, “*Which way would you like to go?*” Guidance, by definition, entails direction. Patent strategy is no different. It is not a single calculation or optimization problem, but an act of navigation across what Markus Gabriel calls distinct *fields of sense* (*Sinnfelder*); irreducible domains of meaning.

To the mountain-guide patent attorney, these fields of sense present themselves as **four winds** that often blow in opposite directions:

1. **Legal Validity** (The Rules)
2. **Technical Accuracy** (The Facts)
3. **Commercial Utility** (The Money)
4. **Psychology/Ethics** (The Human Element)

Strategic decisions arise precisely at the intersections of these fields, where no dataset yields a uniquely correct answer. A broader claim may increase commercial leverage while heightening validity risk; a narrower claim may be easier to grant but commercially of limited value. Additional disclosure in the patent description may strengthen enablement but may map out a workaround path. These trade-offs cannot be resolved by factual analysis alone. They are **judgment calls made under uncertainty**, where gains in one dimension imply losses in another.

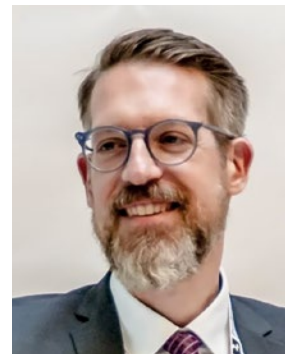
The mountain guide’s task is to synthesize these competing considerations and move from the neutral *data space* into what might be called the *consequence space*: the domain in which choices have irreversible legal and commercial effects. This is where AI cannot follow. While AI can model possibilities and rank alternatives, it cannot inhabit the future in which those alternatives will be tested – by examiners, competitors, courts, or markets.

This role is grounded in the concept of **skin in the game** articulated by Nassim Nicholas Taleb in *Skin in the Game* (Random House, 2018)³. Taleb argues that bureaucracy is a construction by which a person is separated from the consequences of their actions. AI is the ultimate bureaucrat.

3 <https://patentepi.org/r/info-2601-3>

It produces text but bears no risk. The patent attorney, unlike an AI system, is a legally accountable and professionally insured actor who bears the consequences when a strategy succeeds or fails. Responsibility is not an administrative detail to be minimized; it is the source of professional legitimacy.

Recent empirical research supports this view. In *Product Manager Practices for Delegating Work to Generative AI* (2025)⁴, Mara Ulloa et al. introduce a “Selective Delegation Framework,” showing that professionals systematically refuse to delegate tasks where failure would impose personal or professional cost. Their conclusion is explicit: accountability must not be delegated to non-human actors. This finding aligns with Cristina DiGiacomo’s first commandment of human–AI coexistence⁵: humans must own the outcomes of AI-assisted decisions. AI may generate content, but responsibility for its impact remains irreducibly human.



Bastian Best

This distinction exposes a further limitation of AI in patent practice. Drafting competence is not strategic judgment. An AI does not experience a claim as a legal boundary that will be attacked, defended, or enforced. It does not experience uncertainty as risk. The mountain guide does. Like a guide who senses a subtle change in weather despite favorable forecasts, the patent attorney relies on situated judgment to decide when to proceed, and when to turn back.

This demands a shift in professional identity. Historically, the identity of the patent attorney was tied to the craft of drafting. As AI commoditizes that craft, professional value must migrate elsewhere – to the one element that cannot be automated or delegated: accountability. The future of the profession lies not in competing with machines at producing text, but in embracing the non-delegable burden of judgment and responsibility that machines, by their nature, cannot assume.

Four Guardrails for the Mountain Guide

Before proposing concrete guardrails, it is worth observing how professional authorities have begun to respond to generative AI in patent practice. The European Patent Institute (**epi**) has published *Guidelines for the Use of Generative AI in the Work of Patent Attorneys*⁶, emphasizing essential duties: maintain client confidentiality, understand model limitations, verify outputs, and ensure that AI use never excuses errors or

4 <https://patentepi.org/r/info-2601-4>

5 <https://patentepi.org/r/info-2601-5>

6 <https://patentepi.org/r/info-2601-6>

omissions. These guidelines rightly situate responsibility with the practitioner and warn against professional misconduct and data leakage.

However, their focus is largely *preventive*. They excel at identifying risks to professional conduct – confidentiality, quality assurance, client consent – but do not offer substantive guidance on how AI can be deployed to *improve strategic outcomes* for clients. They tell us what not to do, but not much about *what good looks like* when AI is used to elevate strategy rather than displace it.

The four guardrails below are offered to fill that void. They are not mere constraints on risk; they are disciplines that enable the attorney to engage AI as a *tool for thought* – preserving purposive human intention (*Geist*) and strengthening strategic value for clients.

Guardrail 1: Defining the Route (Metacognition)

Advait Sarkar warns in *Artificial Intelligence as a Tool for Thought* (Microsoft Research, 2025)⁷ against skipping *metacognitive reasoning*: high-level planning and mental decomposition that precedes execution. In patent practice, this means that the attorney must define the route **before** the machine writes the first word.

A common cartographer's error occurs when strategic intent is silently delegated to the machine – for example, asking an AI to “write the claims” and then evaluating the result without first determining the optimal hierarchy of distinguishing features and fallback positions. In such cases, the attorney is no longer guiding the process; they are auditing it after the fact.

The mountain guide does the opposite. They perform the metacognitive work themselves: constructing the invention narrative, deciding which technical features carry commercial value, and determining how scope should be allocated across the main claims and dependent claims. Only then is AI engaged – to execute a human-defined plan, not to hallucinate one of its own. AI may assist in exploring alternatives, but it must not be allowed to decide what strategy *is*.

Guardrail 2: Feeling the Terrain (Material Engagement)

Fully outsourcing drafting risks the loss of what Sarkar calls *material engagement*: the hands-on cognitive interaction with the “clay” of one's work. Without this engagement, the attorney becomes a “middle manager of their own thinking” – reviewing text they did not author and cannot deeply defend.

⁷ <https://patentepi.org/r/info-2601-7>

A cartographer may allow AI to generate dependent claims without ever inhabiting the reasoning that underlies them, only to find themselves unable – perhaps during oral proceedings – to explain why a particular fallback exists or what strategic function it serves. The words are present; ownership is not.

The mountain guide, by contrast, insists on touching the clay. They personally shape the protection hierarchy and scope boundaries before linguistic drafting begins. In the author's own patent drafting workflow⁸, this principle is enforced through a mandatory “Claim Strategy” step: a functional, high-level outline where the human manually refines the protection logic before any claim language is generated by AI. Text follows thought, not the other way around.

Guardrail 3: Forging the Non-Obvious Path (Combating Convergence)

Large language models are subject to what Sarkar calls *mechanized convergence*: a gravitational pull toward statistically average, widely represented solutions. This is not a defect; it is a structural feature of probabilistic systems.

In patent practice, however, this tendency is dangerous. In the author's experience, state-of-the-art LLMs do not meaningfully distinguish between granted patents and published applications. A dominant signal in their training data therefore seems to be the *surviving*, narrowed version of an invention in a granted patent – the compromise that passed examination. This may help explain why claims generated by AI tools tend to drift toward a “safe” center: easily grantable, but commercially thin and readily designed around.

The cartographer accepts this comfort as prudence. The mountain guide recognizes it as a strategic failure. Valuable positions are often non-obvious, uncomfortable, and defensible only through skill. To counter convergence, the attorney must actively push the AI away from the statistical average, directing it toward maximum-scope positions that require human judgment to justify and human accountability to defend. To achieve this, the mountain-guide patent attorney can use the **protocol of extremes**. Do not ask for “the best claim.” Ask for the boundaries:

- *Prompt A*: “Draft a claim that is extremely broad and aggressive. Ignore validity risks.”
- *Prompt B*: “Draft a claim that is extremely narrow and virtually guaranteed to be granted.”

By forcing the AI to generate the boundaries, the attorney can navigate the space between them.

⁸ <https://patentepi.org/r/info-2601-8>

Guardrail 4: Sensing the Warning Signs (Productive Resistance)

Sarkar argues that AI should not function as an obedient servant, but as a *provocateur*—a source of productive resistance that prevents the user from moving uncritically through a task. Agreement is easy; challenge is valuable.

The cartographer treats a confident AI draft as a favorable weather forecast and proceeds accordingly. The mountain guide, by contrast, uses AI to surface warnings rather than reassurance. This can be implemented through a series of mandatory claim checks that act as critiques, not corrections. These provocations do not “fix” the draft; they force the attorney to confront weaknesses, trade-offs, and unresolved strategic questions.

In doing so, AI becomes a mirror for judgment rather than a substitute for it. The attorney is compelled to re-enter the *consequence space* – to engage in the legal reasoning, risk assessment, and responsibility-taking that no machine can assume.

Conclusion: Only the Ghost Can Decide the “Why”

The rise of generative AI exposes a fault line within the patent profession. Those who reduce their role to purely neu-

tral facilitation – mapping options, summarizing objections, and asking clients “which way?” – are increasingly replaceable. These are the cartographers. By contrast, the mountain guides – those who synthesize technical, legal, commercial, and psychological realities into a recommended course of action – operate in a domain AI cannot enter.

Machines excel at producing the *what*: the text, the variants, the enumerated possibilities. They can even generate the *what else*: alternative claims, fallback positions, and plausible amendments. What they cannot do is decide the *why*. They cannot commit to a strategic boundary, inhabit the consequences of that commitment, or bear responsibility when the strategy is tested by examiners, competitors, or courts.

The “ghost” in the patent – the *Geist* of situated understanding, purposive intention, and accountability – remains irreducibly human. AI can assist judgment, challenge assumptions, and expand the space of possibilities. But it cannot assume authorship of strategy, because strategy is inseparable from responsibility.

AI will not replace the patent attorney who uses machines to think better. It will replace the one who uses machines to think less.

Extending the positive impact of the European patent system through validation

L. Hynes, Regional Co-ordinator, European and International Affairs, EPO

Protecting innovation is a critical enabler for international growth, market entry and business expansion. But for many innovators, and specifically micro, small and medium-sized enterprises (MSMEs) as well as Public Research Organisations (PRO) and universities, the cost and complexity of navigating different national patent systems quickly become a barrier – often shutting down opportunities to scale beyond Europe. Multiple, often duplicative, procedural steps and requirements are not only costly to applicants but also put a strain on the scarce resources of patent offices across the globe.

Validation aligns with revived efforts at European level to strengthen multilateralism and reduce barriers to trade in a time of geopolitical fragmentation. For instance, the EU is expanding its network of Free Trade Agreements to reduce such barriers. However, disparate and unharmonised legal frameworks, as well as a potential lack of protection for innovative products,

stand out as important non-tariff barriers to trade. Thus, the validation system perfectly complements free trade initiatives as it ensures protection abroad based on the same procedures as in the exporters’ home markets. In turn, it enables European innovators to diversify their customer base and target markets without friction and with the legal certainty needed for often complex and inherently risky business operations.

Against this backdrop, the European Patent Office’s (EPO) validation system offers a unique opportunity: it allows a granted European patent to be validated in participating countries that are not party to the European Patent Convention (EPC). This gives the European patent the same effect as a national patent under those countries’ laws without having to undergo duplicative national proceedings within the respective target markets. This not only provides a cost-effective, legally sound and simpler entry in those markets for innovators, but also

frees up capacity in the validation states' national offices. This allows them to prioritise other areas such as innovation policy development, knowledge transfer or other activities that are considered of strategic relevance to those offices.

With specific regard to patent attorneys, validation also offers the possibility to expand products and services offered to clients by advising on global strategies. Additionally, it enables European patent attorneys to form strategic partnerships with local advisors and to offer their specific expertise on European patent law to a global audience.

In turn, local attorneys are uniquely positioned to support firms seeking to enter their markets, as only they possess the broader knowledge and expertise required to adequately deploy IP strategies at a national level, especially when it concerns post-grant enforcement, litigation, contract and licensing negotiations, or broader IP issues relating to trademarks, designs etc. Moreover,

only they have the relevant licenses to represent clients at national offices and courts.



Liam Hynes

In line with other international efforts under the Patent Cooperation Treaty (PCT) and the Patent Prosecution Highway (PPH), the validation system seeks to foster international cooperation and to facilitate and simplify international patent protection. EPO data shows that over 80% of the

almost 50,000 validation requests filed since 2015 have originated from PCT applications. Accession to the validation scheme has also served as a catalyst for validation states to accede to the PCT and related treaties. Validation thus complements existing international instruments by formally allowing national offices across the globe to rely on EPO search and examination results if they choose to do so. In short, validation amplifies the value of a European patent, turning what might otherwise be a Europe-only asset into a gateway to emerging markets, international collaboration, exports and licensing. And it ensures high quality search and examination, while at the same time freeing up scarce resources for national administrations.

As a scalable solution, the EPO's validation system enables the seamless extension of patent protection to new countries joining the network, ensuring that innovators can rapidly and efficiently broaden their global reach. This process unlocks potential opportunities that extend far beyond the borders of EPC states, maximising the reach and impact of innovative ideas.

Enhancing the value of the European patent

For almost 50 years, the EPO's streamlined, centralised grant procedure has delivered significant value to applicants around the world. Validation extends the benefits of the European

Key Validation Steps

1. The applicant files at the EPO, or the application enters the European phase via the PCT.
2. The EPO conducts the search.
3. The applicant pays validation fees, which are between €180 and €240 for each request per validation country.
4. If granted following EPO examination, the applicant conducts any final national requirements, such as translation, and pays the national publication fee.
5. The national office of the validation country publishes the translated claims/specification. The patent is validated.

system by offering patent holders access to additional markets without the need to file separate national applications.

- Over the past decade, the EPO has expanded the validation network to six countries:
- Morocco (2015)
- Republic of Moldova (2015)
- Tunisia (2017)
- Cambodia (2018)
- Georgia (2024)
- Lao People's Democratic Republic (2025).

As such, validation is a route to reach a combined market of 83 million people, as well as additional business partners and research collaborations – all accessed through the European patent.

Moreover, Costa Rica is set to become the first validation state in the Americas, once implementation discussions are completed. And, further agreements are under negotiation across the Americas and Africa.

The role of patent attorneys

As patent attorneys and IP advisors, you are uniquely positioned to help clients understand how validation could strengthen their broader IP and commercial strategies.

By offering validation as part of your global IP services, you can:

- Provide a streamlined "go-global" package that coordinates translations, formalities, fee payments and international representation on behalf of clients.
- Reduce the administrative burden and legal complexity for clients, particularly when navigating unfamiliar jurisdictions, languages or legal systems.
- Position your practice as a trusted strategic partner for international IP planning – from R&D and grant to global protection and enforcement.
- Enter into cooperation and strategic partnerships with local patent attorneys and lawyers, thereby expanding your own professional network and footprint.

- Export your expertise and knowledge to new markets and find new business cases abroad.
- Support local patent attorneys, who are uniquely positioned to advise on the broader aspects of patent, IP, civil, or commercial law applicable in the respective target markets, and are in possession of all relevant licenses to act as representatives locally.

The validation advantage – what it offers businesses

“The validation system represents a versatile and cost-effective way to secure and validate European patents. Uptake of the validation system as a proportion of all European patent protection activity does remain low, but this presents a strategic opportunity for early adopters to familiarise themselves with the system.”

-Robert Watson, Partner, patent attorney at Mewburn Ellis (in ‘Validating European patents outside Europe – the Validation State system’ – Nov 2023)

“As an applied research institute, it is important for us to develop co-operation beyond Europe. For us as European innovators, validation is the perfect tool for this purpose.”

-Dr Peter Ramm, Head of Strategic Projects at Fraunhofer EMFT (marking the 10th anniversary of the agreement with Morocco² – Sep 2025)

Lower barriers to international growth: Instead of managing disparate national filings, translations and local prosecution, innovators can rely on the familiar European grant process and then activate protection in selected third-country markets through validation, giving SMEs a streamlined route to export, license or form international partnerships.

Cost and time savings: Validation avoids duplicate national filings and full prosecution in each country, reducing overall costs and speeding up access to additional markets – a major advantage especially for SMEs and resource-constrained innovators.

Legal certainty and high quality: Because European patents are granted following the EPO’s rigorous search and examination process, validated patents rest on strong legal foundations, offering dependable enforceability and greater credibility in licensing or enforcement actions.

Sustained demand for validation – with room to grow

Given these benefits, demand for validation has grown steadily since 2015. In total, almost 50,000 requests have been made. These requests for validation span a wide range of technology fields.

¹ <https://patentepi.org/r/info-2601-9>

² <https://patentepi.org/r/info-2601-10>

Medical and health technologies occupy leading positions, but other strategic sectors are gaining momentum. The breadth of technology areas demonstrates how validation can support national economic priorities within validation countries. As Abdelaziz Babqiqi, Director General of the Moroccan IP office, explains: *“Validation plays a key role in positioning Morocco within the innovation landscape, contributing to the added value of Morocco’s industrial sectors, such as aeronautics, automotive and renewable energy.”*

In terms of geographic origin, France, Italy and Germany have emerged as the top European countries for validation requests, signalling strong interest among European innovators.

But like the European patent more generally, validation is in demand worldwide. Approximately half of all requests come from outside Europe, particularly from the United States. This broad adoption and continued demand highlights the value applicants place on a streamlined, cost-effective route to extend their global protection. Given the clear benefits of expanding into global markets, and as more validation agreements come into force, it is increasingly worthwhile for businesses to consider validation as part of their IP strategy.

Shaping validation success together

Although a simple idea, validation is clearly more than a procedural step. It is a valuable tool for patent holders seeking to expand their reach and open doors to new markets. In the context of the Draghi and Letta reports, validation stands as a strategic lever that can help foster European competitiveness and connect innovation to global growth. By integrating validation into their IP strategies, businesses and innovators can contribute to a stronger and more resilient landscape for European invention.

Looking ahead, the ongoing commitment and expertise of the IP community will continue to shape validation’s success and ensure its relevance in a changing world. We look forward to working with you to drive the system’s continued success.

For more information on the validation system please visit EPO webpages on validation.³

Have your say

As validation is designed to support users, we’d appreciate just 10 minutes of your time to answer a few questions⁴ and share your insights on how you and your clients interact with the system.

³ <https://patentepi.org/r/info-2601-11>

⁴ <https://patentepi.org/r/info-2601-12>

Clinical Trial Inventions in the Squeeze:

The New Transparency Rules for Clinical Trials in the EU and the Assessment of Patentability by the European Patent Office (EPO) and the Unified Patent Court (UPC)

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For this article, regulatory lawyers and patent attorneys teamed up to provide an overview of the challenges for clinical trial inventions from a regulatory and patent law perspective. The present article discusses the new transparency rules for clinical trials in the EU, relevant case law from the EPO and the UPC, and shares practical recommendations.

I. Introduction

In the course of drug development (see overview in **Figure 1**), starting from a conception, treatment effects are generally first evaluated by preclinical *in vitro* and *in vivo* testing followed by clinical trials based on preclinical results. After clinical Phase I studies usually evaluating toxicology and pharmacokinetics/pharmacodynamics in

small healthy volunteer groups,¹ initial efficacy and further safety data in small patient groups are obtained in Phase II studies. Further, Phase III studies are usually required to confirm the therapeutic benefit and gather comprehensive safety information at scale before regulatory approval.² During this process, more and more disclosure about the drug and the corresponding treatment may become available forming prior art for later filed patent applications creating obstacles for obtaining corresponding patent protection. Publication of certain documents regarding planned or ongoing clinical trials³ may form a significant part of such disclosures. Taking into account that the content and timing of such publication is governed by regulatory law, applicants/patentees need to be aware of the effects on patentability and make an effort to control and align regulatory strategies with patent filing strategies accordingly.

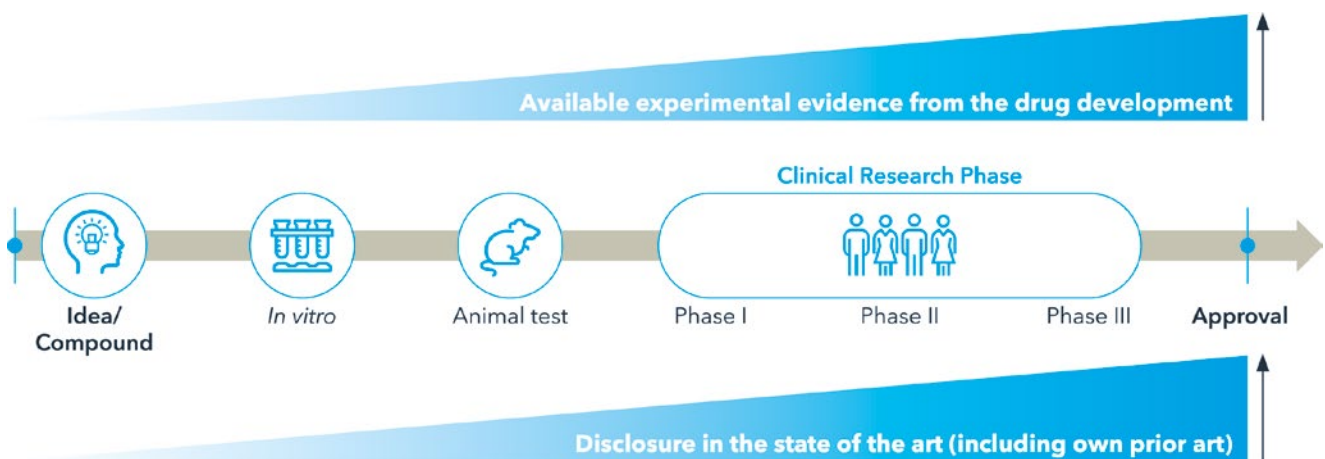


Figure 1 Overview of drug development process.

1 In certain diseases, where toxicity does not allow testing in healthy volunteers, already Phase I studies are conducted in patients.
2 For a definition of the phases see EMA, CTIS public portal: Full trial information, EMA/441147/202424, 27 January 2025, p. 3 and 4.
3 Herein also referred to as “clinical trial-related disclosures”.

4 See Art. 84 para. 4 CTR.
5 In lack of a legal definition, CCI shall mean “any information which is not in the public domain or publicly available **and** when its disclosure may undermine the legitimate economic interest or competitive position of the concerned entities, e.g., clinical trial sponsors, marketing authorisation applicants/holders or service providers”, in accordance with EMA’s understanding and CJEU, C-175/18 P and C-178/18 P.

II. Regulatory Transparency Policy

Since 31 January 2023, clinical trials of medicinal products in the EU must comply with Regulation (EU) 536/2014 (Clinical Trials Regulation – CTR), which aims at streamlining the submission and assessment of clinical information across the Member States. The cornerstone of this framework is the Clinical Trial Information System (CTIS), which not only provides a single EU portal for submissions by sponsors, but also contains an EU database for the submitted data and information. In order to increase transparency and foster innovation, this EU database is designed to be publicly accessible for patients and researchers.⁴ Confidentiality of submitted data and information is limited to a narrow set of exceptions, notably the protection of personal data and commercially confidential information (CCI).⁵ At the time CTIS was launched, this transparency concept was governed by an EMA guidance developed in 2014.⁶ These transparency rules, however, required broad publication of clinical trial application dossiers and introduced complicated deferral mechanisms, which soon proved unclear and overly complex.

Against this background, on 18 June 2024, **new EMA guidance entered into force** accompanied by a new version of CTIS.⁷ The new transparency rules aim to strike a better balance between transparency of information and protection of CCI via a more flexible approach: The total number of documents to be published in CTIS is reduced to certain key documents of interest. Deferrals have been eliminated. Instead, structured data fields are introduced for key information, which are to be filled directly by sponsors. Further, sponsors

are explicitly allowed to upload two document versions: one for use by the authorities and one for publication, which may be redacted to protect CCI. Structured data fields and documents are then published following predefined publication timelines. However, the reduced complexity comes with an increased user responsibility. For sponsors and pharmaceutical companies, it is therefore even more important to understand the challenges and **develop strategies to effectively protect CCI and maintain patentability of inventions.**

The assessment of the relevant disclosure timelines depends mainly on the classification of clinical trials under one of three applicable categories (**Table 1**).⁸

Sponsors initially select the category in the trial application, yet the Reporting Member State (RMS) may challenge that choice and issue requests for information (RFI).⁹

As part of the new EMA guidance, CTIS **introduces structured data fields** to be filled by the sponsor. These fields may allow free text entries or selections from predefined values and contain information of relevance to the public or researchers. The fields typically capture the trial title and identifiers, study design details, inclusion and exclusion criteria, primary and secondary endpoints, and information on the sponsor, investigational medicinal product (IMP) or clinical investigator sites. Depending on the trial category, and in the case of category 1, depending on the age of the trial subjects, the content of structured data fields is published according to the timelines in **Table 2**.¹⁰

Table 1 Categorization of trials under the EU transparency rules.

Category	Trial type
Category 1 Pharmaceutical development clinical trials	<ul style="list-style-type: none"> › Phase I clinical trials in healthy volunteers or patients › Phase 0 trial in healthy volunteers or patients › Bioequivalence and bioavailability trials › Similarity trials for biosimilars › Equivalence trials for combination or topical products
Category 2 Therapeutic exploratory & confirmatory clinical trials	<ul style="list-style-type: none"> › Phase I and phase II integrated clinical trials › Phase II clinical trials › Phase II and phase III integrated clinical trials › Phase III clinical trials
Category 3 Therapeutic use clinical trials	<ul style="list-style-type: none"> › Phase III and phase IV integrated clinical trials › Phase IV clinical trials and low interventional trials

6 EMA, Appendix on disclosure rules, EMA/228383/2015, 2 October 2015 (superseded).

7 EMA, Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/212507/2021, version 2.1, 7 November 2025.

8 EMA, Revised CTIS transparency rules and historical trials: quick guide for users, version 1.9, 7 November 2025, p. 5.

9 EMA, Q&A on the protection of CCI and Personal Data while using CTIS, EMA/898965/2022, version 2.2, 13 December 2024, p. 5 sec. 1.

10 EMA, Annex I: Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/194159/2023, 7 November 2025, Table I p. 2.

Table 2 Overview of publishing timelines for structured data fields.

Structured data fields	Category 1		Category 2 integrated ph1&2	Category 2 & 3 (excl. integr. ph1&2)
	Paediatrics and/or PIP	Adults		
CTIS Application fields, excluding the ones specified in the row below and in table III (Documents «for publication»: templates and personal data usually included)	First MSC ¹ decision	First MSC decision ²	First MSC decision	First MSC decision
		30 months after EU/EEA End of Trial		
CTIS Application fields: maximum duration of treatment, maximum daily dose allowed, daily dose unit of measure, maximum total dose allowed, total dose unit of measure	30 months after EU/EEA End of Trial			
MSC(s) conclusions and decision outcomes	That MSC decision			
Notifications on trial status and recruitment	As soon as submitted by sponsor			
Notifications on serious breaches, urgent safety measures, unexpected events	After MSC assessment	30 months after EU/EEA End of Trial & MSC assessment	After MSC assessment	
Corrective measures (suspension, revocation, modification request)	When applied by MSC(s)			

¹ MSC = Member State Concerned

² The following fields are disclosed at time of decision for Category 1 trials conducted solely on adult population: public title (= title in lay terms), trial identifiers in registers, protocol code, phase, medical condition, rare disease, therap. area, population age, gender, sponsor details, details of clinical investigator sites in MSC(s)

By contrast, only a limited subset of structured data fields remains generally non-public (**Table 3**).¹¹

Structured data	All categories
Sponsor legal representative details	Never
Any request for information (RFI) and RFI responses	
Validation conclusion details, assessment decision conditions (if any)	
MSC(s) assessment(s) on notifications	
3 rd country inspection details	

With the limited exceptions set out in **Table 2**, CTIS application data are already made available with the decision on the clinical trial application by the first Member State Concerned (MSC), which is before the clinical trial has even started and thus long before any results are available.¹² Additionally, **structured data fields cannot be redacted**. Sponsors should therefore exercise particular caution to avoid including any CCI in structured data fields. Only in exceptional cases, such as for dose details that are not yet in the public domain and are patentable, sponsors may enter “dummy data” (e.g. 00 digits).¹³

Considering the information provided in the structured data fields, under the new transparency rules, **only a reduced number of documents to be submitted by the sponsor is set to be published**. The EMA narrows publication to certain key documents of interest (**Table 4**).¹⁴

Table 3 Overview of non-public structured data fields.

11 EMA, Revised CTIS transparency rules and historical trials: quick guide for users, version 1.9, 7 November 2025, p. 9.

12 Art. 81 para. 5 CTR.

13 EMA, Q&A on the protection of CCI and Personal Data while using CTIS, EMA/898965/2022, version 2.2, 13 December 2024, p. 9 question 3.2.

14 EMA, Annex I: Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/194159/2023, 7 November 2025, Table II p. 3.

Documents to be submitted in two versions 'for publication' and 'not for publication'	Publication timelines		
	Category 1		Category 2 & 3 including integrated ph 1&2
	Paediatrics and/or PIP	Adults	
Protocol, including patients facing documents	Upon results' submission	30 months after EU/EEA EoT	First MSC decision
Protocol synopsis		Never	
SmPC, if available			As soon as submitted
Recruitment arrangements, including procedures for inclusion and copy of advertising material	As soon as submitted	30 months after EU/EEA EoT	
Subject information and informed consent form			As soon as submitted
Lay person summary of results	As soon as submitted		
Final summary of results	As soon as submitted		
Clinical study report, if available	As soon as submitted		

Table 4 Overview of publishing timelines for documents.

For example, subject information and informed consent form, recruitment arrangements, and the summary of product characteristics (SmPC), if applicable, are only subject to publication for category 2 and 3 trials. Other documents than those mentioned in the table above, such as the investigator brochure (IB), summary of intermediate data analysis results, if applicable, or assessment reports by the Member States, will not be published.¹⁵ Conversely, with deferrals removed, documents such as protocols may be published in some cases earlier than under the former EMA guidance, which allowed deferrals of up to seven years from the end of the trial.

However, for documents to be published, **CTIS offers redaction possibilities**. Sponsors are allowed to submit a document version "for publication" with redacted CCI parts and a document version "not for publication" that contains CCI as required for the scientific assessment by the Member State authorities. Typical examples of CCI include information related to manufacturing processes of the IMP, to future development plans for other indications not yet known to the public, new biomarkers or, in clinical trial application dossiers, dose details not in the public domain.¹⁶ In some cases, where written agreements between the sponsor and a third-party service provider expressly establish that patient facing documents (e.g. patient questionnaires or patient diaries planned to be presented to the subjects during the conduct of the clinical trial) cannot be disclosed publicly, it may be even possible to upload placeholders of those patient facing documents in the version "for publication".¹⁷ In practice,

yet quite a few potential sources of error are lurking. This is because **sponsors remain fully responsible for the level of redaction**. Member States are neither obliged to check on possible redaction errors nor to compare both submitted document versions.¹⁸ Even documents that are not required to be published, such as the IB or intermediate summaries, but are inadvertently uploaded in sections "for publication", are published nonetheless in accordance with the applicable timelines. On the other hand, each redaction - particularly in documents submitted at the end of the trial life cycle - should be carefully weighed against the transparency principles to avoid objections and RFIs from the MSC. According to the EMA guidance, it is expected that over time, information which initially was considered CCI may no longer be considered as such due to scientific advancements in that research field, and that this should translate into fewer CCI redactions in the modified documents submitted to CTIS during the trial life cycle (**Table 5**).¹⁹

III. Patent Law Background

Claims directed to therapeutic applications are drafted in the "product-for-use" format in accordance with the EPC 2000, Article 54(5).²⁰ Such claims are considered to include the therapeutic effect as a functional technical feature.²¹ Thus, for demonstrating lack of novelty, the prior art needs to expressly or implicitly make available to the public this thera-

15 For an indicative list of documents not subject to publication see EMA, Annex I: Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/194159/2023, 7 November 2025, Table VI p. 8.

16 For further examples see EMA, Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/212507/2021, version 2.1, 7 November 2025, p. 25.

17 EMA, Q&A on the protection of CCI and Personal Data while using CTIS, EMA/898965/2022, version 2.2, 13 December 2024, p. 9 question 3.3.

18 EMA, Q&A on the protection of CCI and Personal Data while using CTIS, EMA/898965/2022, version 2.2, 13 December 2024, p. 6 question 1.6 and 1.7.

19 EMA, Guidance document on how to approach the protection of personal data and CCI while using CTIS, EMA/212507/2021, version 2.1, 7 November 2025, p. 23.

20 Before EPC 2000 entered into force, such claims were drafted in the Swiss-type format, however, the different claim formats are not generally considered to differ in substance, see, e.g., G 2/08, reasons 5.10.1 to 5.10.9.

21 G 5/83, headnote II, in combination with G 2/88, headnote III, and G 6/88, headnote. See also T 158/96, reason 3.1, and T 609/02, reason 9.

	Application type	Application status	Submission date	Decision date	MSC	
Time	Initial	Authorised	15/03/2022	27/04/2022	Austria, Belgium, Czechia, France, Greece, Hungary, Ireland, Italy, Luxembourg, Portugal, Spain, Norway, Slovakia	The ██████ involves ██████
	Substantial modification	Authorised	11/10/2022	13/12/2022	Norway, Italy, Belgium, Hungary, Germany, Luxembourg, Portugal, Greece, Ireland, Spain, Czechia, France, Austria, Slovakia	The CCI Term 1 involves ██████
	Substantial modification	Authorised	24/04/2023	03/07/2023	Norway, Italy, Belgium, Hungary, Germany, Luxembourg, Portugal, Greece, Ireland, Spain, Czechia, France, Austria, Slovakia	The CCI Term 1 involves CCI Term 2

Table 5 Example of a redaction process.

peutic effect, while the “doctrine of inherency” does not apply.²² For demonstrating lack of inventive step, this therapeutic effect needs to be obvious in the sense that based on the prior art, there was a reasonable expectation of success for the skilled person to achieve this therapeutic effect.²³

In the drug development process (see again **Figure 1**), a drug may fail at any step during the development. As a consequence, confirmatory evidence for the therapeutic effect based on a regulatory standard is usually only available after the full clinical study program from Phase I to III, which, once successful, is expected to lead to an approval of the drug for this therapeutic application. It is, however, established practice that “[t]he patent system takes account of the intrinsic difficulties for a compound to be officially certified as a drug by not requiring an absolute proof that the compound is approved as a drug before it may be claimed as such. The boards of appeal have accepted that for a sufficient disclosure of a therapeutic application,²⁴ it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported.” However, “[i]t is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se. Showing a pharmaceutical effect in vitro may be sufficient if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application.²⁵” Patent applications may thus be considered

to sufficiently disclose, or “render credible”²⁶ (Art. 83 EPC), a therapeutic effect by providing evidence in the form of *in vitro* experiments, a standard which allows **certain extrapolation** and differs significantly from the standard for regulatory approval. Further, according to the case law of the EPO’s Boards of Appeal, the requirement of an enabling disclosure for a prior art document is the same as the requirement of sufficiency of disclosure for a patent application or patent. The principles developed for evaluating the requirements of Art. 83 EPC in the case of medical use claims **apply thus equally to the prior art.**²⁷ This means that a therapeutic effect in the prior art could likewise be considered enabled by *in vitro* tests, long before human results are available.

Regulatory provisions, such as the new transparency rules in the EU as discussed above, mandate the publication of certain information relating to clinical trials (such as clinical trial protocols) before the corresponding study results including, for instance, therapeutic efficacy are available. Such publications become prior art for later-filed patent applications that attempt to claim the treatment effect supported by the later-available (confirmatory) evidence from the evaluation in the corresponding clinical trial.

These clinical trial-related disclosures with predetermined publication dates form part of a highly regulated development process and therefore need to be understood in this context. Such publications often explicitly mention all features of the claims directed to the treatment (such as the indication, the

22 G 2/88, reason 10.1 and G 6/88, reason 8.1. See also T 136/24, reason 6.4, and T 2506/12, reason 2.6.

23 The “try-and-see” evaluation seems not to be used in this context, see e.g. T 293/07, reason 37.

24 As required by Art. 83 EPC.

25 T 609/02, reason 9, citing T 241/95 and T 158/96.

26 G 2/21, reason 77.

27 T 1045/21, reason 1.2.5, citing T 1437/07, reasons 25 and 26.

patient population and the dosage regimen) but lack any results and do as a rule not extrapolate by **explicitly** postulating the treatment effect. The treatment effect is, however, a limiting technical feature of the claim and may therefore by itself constitute patentable subject matter. This gives rise to the difficult question whether in the absence of an explicit disclosure, there is a corresponding **implicit disclosure** of the treatment effect (and thus lack of novelty). In case there is no such implicit disclosure, the question remains whether nevertheless there is **a reasonable expectation of success** (and thus lack of inventive step). These questions need to take into account that patent law differs from regulatory law and allows in general -despite the overall high uncertainty in this field of technology- certain extrapolations before any confirmatory evidence from, e.g. Phase III trials, is available. This makes the overall evaluation particularly difficult.

While clinical trial-related disclosures such as those published on the *clinicaltrials.gov* website may have provided already in the past certain relevant disclosure, the new transparency rules in the EU outlined above mandate very early and much more extensive disclosure of information in particular related to Phase II and III studies. As shown in **Table 4**, the disclosure requirement includes, for example, the full

clinical trial protocol that does not only provide details of the treatment (including information on patients, administration route, and dosing regimen), but often also includes a detailed scientific rationale for conducting the suggested clinical trial.²⁸ The protocol may also discuss previous pre-clinical and clinical data in this context.²⁹ The teaching of such protocols therefore goes much further than disclosures available in the past and the understanding a skilled person may gain from such documents may consequently also be much more than from previous disclosures. We will discuss in the following the existing case law at the EPO and first insights from the UPC on clinical trial-related disclosures in the prior art and venture an assessment of the expected implications of the new transparency rules for patentability of future patent applications dealing with such disclosures as prior art.

IV. Relevant Case Law at the EPO

In the last three decades, the EPO issued several decisions that discuss whether clinical trial-related disclosures anticipate or render obvious a claimed treatment effect despite such disclosures lacking the corresponding clinical trial results. **Figure 2** provides an overview of decisions ordered by their date.

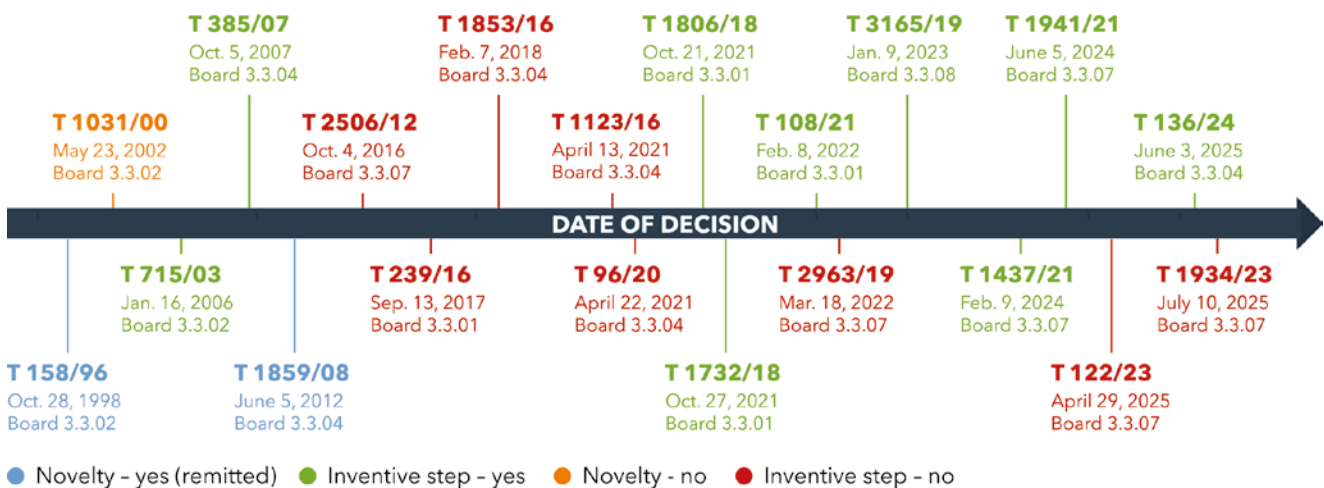


Figure 2 Overview of EPO decisions on clinical trial-related disclosures.

28 The protocol usually gives the background and rationale for the trial, but these could be also provided in other protocol referenced documents based on the view of EMA, Guideline for good clinical practice (GCP) E6(R3), EMA/CHMP/ICH/135/1995, Step 5, 23 January 2025, p. 69.
 29 See Annex I chap. D. CTR for a full listing of the required protocol contents.

a) On the question of novelty of the claimed treatment

Three early decisions discuss novelty only. In the first decision, **T 158/96**, the Board assessed whether the person skilled in the art was in a position to conclude based on the clinical trial-related disclosure **with the required certainty** that the therapeutic effect, or a pharmacological effect indisputable underlying the therapeutic application, had already been shown or proven in earlier clinical or preclinical studies that would necessarily have preceded the study disclosure in question. If that were the case, the clinical trial-related disclosure would be prejudicial to novelty.³⁰ The Board summarized in the catchword of the decision:

“The information in a citation that a medicament is undergoing a clinical phase evaluation for a specific therapeutic application is not prejudicial to the novelty of a claim directed to the same therapeutic application of the same medicament if such information is plausibly contradicted by the circumstances and if the content of said citation does not allow any conclusion to be drawn with regard to the actual existence of a therapeutic effect or any pharmacological effect which directly and unambiguously underlies the claimed therapeutic application.”

While the Board in **T 158/96** came to the conclusion that the circumstances did not allow the skilled person to conclude about the existence of the therapeutic effect with the required certainty,³¹ the standard is formulated in the catchword more as an exception to the rule that clinical trial-related information is due to **its specific context** generally prejudicial to novelty. However, despite this standard, novelty was only denied in **T 1031/00**, where the Board found that the patent does not contain any technical information concerning the claimed treatment going beyond that of the prior art (same level of disclosure) and that therefore *“the difference between that document and the application in suit resides merely in the words used but not in their technical content”*.³² In this case, the Board focused more on a comparison of the technical teachings rather than verbatim disclosures. This approach, however, seems not to be followed by later cases. The subsequent case **T 1859/08** then seems to have set a rather strict novelty standard, namely that disclosures lacking the final results of the clinical trials are generally not novelty-destroying.³³ In line with this rather strict standard, in **T 239/16**, the Board stated that implicit disclosure requires that the therapeutic effect *“would arise with certainty”* from the treatment as described in the prior art. The Board could not derive an *“explicit or implicit indication”* that effects of animal models or of other drugs in the same class as the claimed drug *“can be directly transferred”* to the treatment as disclosed in the prior art. According to the Board, there remained *“a certain*

residual doubt that the effect... is/will be achieved”. The Board concluded that the effective treatment was thus not directly and unambiguously disclosed.³⁴ Later decisions such as **T 1123/16**, **T 96/20**, **T 3165/19**, **T 1941/21**, **T 1934/23** do not even discuss novelty or only very briefly such as **T 1806/18**³⁵ and **T 122/23**.³⁶

The very recent decision **T 136/24** discusses again novelty in detail with reference to the early decision **T 158/96**. In dealing with novelty, the question of implicit disclosure had to be answered and the Board considered that the condition *“plausibly contradicted by the circumstances”* as in the catchword of **T 158/96** (*supra*) *“is not a necessary requirement”* for novelty and *“appears to have been formulated more stringently than necessary”*. The Board instead emphasized the necessary condition for novelty to be *“that the skilled person would not have been in a position to conclude with the required certainty that the relevant therapeutic efficacy had already been shown in earlier investigations.”*³⁷

The **certainty standard** for an implicit disclosure of the therapeutic effect thus seems to be established by the case law and appears much closer to the regulatory standard of confirmed evidence of a treatment effect, which is generally provided by Phase III study results. The earlier decisions could have been interpreted in that the standard for anticipation by a prior art disclosure including also implicit disclosures (Art. 54 EPC) is the same or at least similar as the standard for sufficient disclosure of a patent application or patent (Art. 83 EPC) and could thus be fulfilled by **a credible disclosure** of the treatment effect which may also be established based on preclinical and possibly earlier stage clinical experiments including Phase I results.³⁸ However, later decisions emphasize the gold standard of direct and unambiguous disclosure and apply the general definition of an implicit disclosure referring to what *“is immediately apparent to the skilled person”* and set the required level of confidence in the treatment effect at certainty.³⁹ In the very recent decision **T 136/24**, the Board considered that enablement of the prior art is a **second independent criterion** in addition to the requirement of a direct and unambiguous disclosure.⁴⁰ A prior art disclosure of a treatment effect in order to be anticipating thus appears to have to provide both **(i) a direct and unambiguous disclosure** (in line with the added subject matter standard of Article 123(2) EPC⁴¹), which, in the context of an implicit disclosure of the treatment effect, requires certainty, as well as **(ii) an enabling disclosure** requiring credibility of a treatment effect (in line with the sufficiency

30 T 158/96, reason 3.5.

31 T 158/96, reason 3.5.2.

32 T 1031/00, reason 2.1.2.

33 T 1859/08, reason 13.

34 T 239/16, reason 5.2. Similar considerations are made in T 1859/08.

35 T 1806/18, reason 6.7 regarding the treatment effect.

36 T 122/23, reason 3.

37 T 136/24, reason 6.12.5, emphasis added.

38 T 158/96, reason 3.5.2 stating that *“[i]t is indeed not exceptional that a pharmacological effect observed in an early investigation may directly and unambiguously reflect a therapeutic effect, thus underlying a therapeutic application”* and may be sufficient proof thereof. See also T 1031/00, reason 2.1.2, and T 609/02, reason 9 with reference to T 158/69.

39 T 136/24, reason 6.3.

40 T 136/24, reason 6.18. See also earlier decision T 108/21, reason 6.4.1.

41 G 2/10, reason 4.6, regarding the *“uniform concept of disclosure”*.

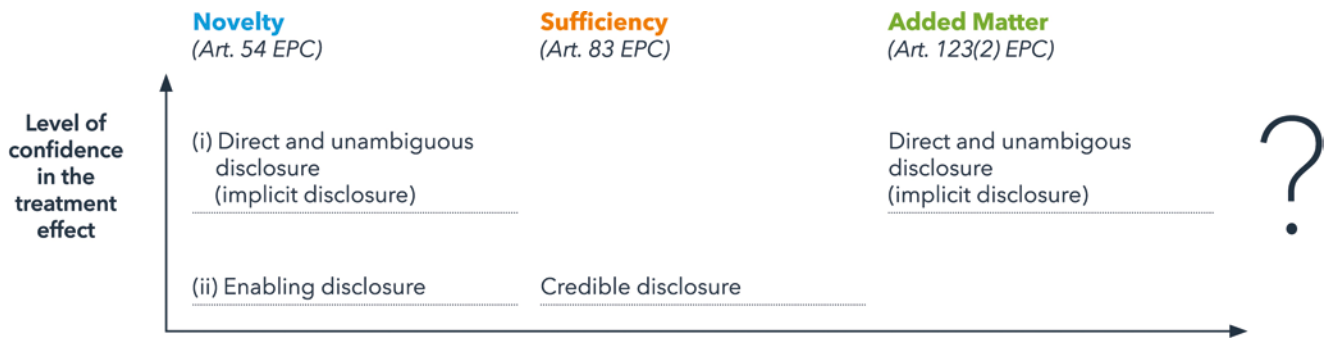


Figure 3 Suggestion for the relationship of disclosure standards for a prior art (regarding an implicit disclosure) and a patent or patent application.

standard of Article 83 EPC) (**Figure 3**).⁴² Since the “direct and unambiguous” standard requires certainty for an implicit disclosure, the second criterion of enablement with the lower “credibility” standard seems not relevant in the case of an implicit disclosure. There would, consequently, be a significant difference in the overall level of confidence in the treatment effect required when an explicit disclosure (such as a verbal statement of the treatment effect in the prior art, as is often the case in a prior patent application) is compared to an implicit disclosure (such as in clinical trial-related disclosures that do as a rule not extrapolate by explicitly postulating the treatment effect). This approach could be seen to emphasize for novelty the very strict disclosure standard of the EPO with high hurdles for implicit disclosure giving more weight to the words used rather than the overall technical content, which appears to differ from considerations in **T 1031/00**.⁴³

Taken together, the current standard for anticipation by clinical trial-related disclosures lacking trial results according to the case law of the Boards of Appeal is very high in requiring certainty for an implicit disclosure of a treatment effect. Although it remains to be seen whether a full protocol according to the new EU transparency rules including a summary of preclinical and previous clinical test results and a detailed scientific rationale may meet this very high standard for novelty, it seems that even with these additional details compared to other clinical trial protocol formats (such as those published on *clinicaltrials.gov*), the standard for an implicit disclosure might still not be fulfilled in the absence of the trial results.

During finalization of the present article in February 2026, a preview of the 2026 version of the **Guidelines for Examination in the EPO** due to enter into force on 1 April 2026 was published. Interestingly, the chapter on novelty includes now a new section directed to clinical trial-related disclosures (**Figure 4**).

Guidelines for Examination in the EPO, 2026 preview version

Part G – Patentability, Chapter VI - Novelty

6.1.2.1 Preclinical data and clinical trials in the prior art

A document is prejudicial to the novelty of a claim directed to a specific further medical use if it

- i. clearly identifies the essential conceptual features of the therapeutic treatment, i.e. the substance/composition used for treating the medical indication and any essential features of the treatment; and
- ii. plausibly establishes the underlying therapeutic effect. Plausibility may be established by way of data or scientific reasoning. It is not however necessary that the mechanism underlying the therapeutic effect be explained.

Hence if a prior art document discloses clinical trials such as phase I, II or III studies (or states that these investigations are ongoing) but fails to disclose any positive results of these studies, then such a document may not be novelty destroying because requirement (ii) may not be fulfilled. Since clinical trials fail more often than they succeed, the mere announcement of a clinical trial is in itself not enough to make the claimed invention available to the public.

Figure 4 Preview version of 2026 Guidelines, section on novelty and clinical trial-related disclosures.

The new section in the Guidelines does not refer to specific case law. It is interesting to note that “plausibility” seems to be the criterium for establishing the underlying therapeutic effect in the Guidelines while the case law seems to emphasize “certainty” as the criterium in such situations (*supra*). On the other hand, from the first reading, the Guidelines emphasize that a clinical trial disclosure without results may not in itself establish such plausibility due to the general failure rate, which may result in lack of anticipation more as a rule and lead to similar results as the case law. It remains to be seen whether a full protocol according to the new EU transparency rules including a summary of preclinical and previous clinical test results and a detailed scientific rationale may meet the plausibility requirement of prong ii) of the Guidelines and consequently may lead to lack of novelty in the future.

⁴² See also T 209/22, in particular reason 5.6, regarding the relationship of the disclosure standard for sufficiency and novelty, rendered by the same Board as in T 136/24. Reference is also made to an article by Eva Ehlich and Anja Fux on July 3, 2024, in *Managing IP* (“*Is the medical use disclosure standard different for novelty and sufficiency?*”).

⁴³ T 1031/00, reason 2.1.2.

b) Assessment of inventive step

There are several decisions which discuss inventive step.

In the very early decisions [T 715/03](#)⁴⁴ and [T 385/07](#)⁴⁵, the Boards evaluated the circumstances of the case and came to the conclusion that the clinical trial-related disclosures in the prior art did not lead to a reasonable expectation of success without providing general test criteria for such an evaluation.

In [T 2506/12](#), the Board pointed out that clinical trial designs are “based on existing favorable scientific data”.⁴⁶ It rejected “the general consideration that any clinical trial might fail” given that clinical studies “are routine tests and the fact that their outcome is uncertain does not in itself turn their results into an invention”.⁴⁷ The Board concluded that there was a



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reasonable expectation of success as “no particular reason was known which would have discouraged the person skilled in the art from carrying out an experimental evaluation to confirm the usefulness of the combination treatment.”⁴⁸ In the later decision [T 239/16](#), the Board held that the mere fact that the claimed active agent is being tested in a clinical trial for the claimed treatment “leads to an expectation of success, due to the fact that clinical studies are based on data obtained by pre-clinical testing both in vitro and in animals and require authority approval which takes ethical considerations into account.” As a consequence, the skilled person would expect all study arms to provide an effective treatment, “unless he was **dis-**

sua-ded from this by the prior art” and **expect** the study arms **to fail**.⁴⁹ According to the Board, “[f]or the assessment of inventive step, certainty as to the outcome of a clinical study is not necessary... Clinical trials in humans are planned scientific investigations. They require authority approval, which is only given after a risk/benefit evaluation. For ethical (but also economic) reasons it has to be ensured that research risks are minimised and are reason-

able in relation to any potential benefits. Ethical and economical considerations require that the “benefit” will arise with reasonable certainty and will not only “be hoped for”. This has to be taken into consideration as part of the technical circumstances when assessing the level of confidence of the skilled person in making rational predictions about achieving the envisaged treatment.”⁵⁰ Both [T 2506/12](#) and [T 239/16](#) have been cited by several decisions and several decisions seem to follow the consideration that disclosures relating to planned or ongoing clinical trials, in particular **in view of the regulatory context** of these disclosures, can provide for a reasonable expectation of success unless there is evidence in the prior art for a **dissuasion**, such as [T 1123/16](#),⁵¹ [T 96/20](#),⁵² [T 3165/19](#),⁵³ [T 108/21](#),⁵⁴ [T 1941/21](#),⁵⁵ and the very recent decision [T 1934/23](#).⁵⁶ In [T 96/20](#), for example, the Board generally held that “[c]linical trials are conventionally based on earlier preclinical studies, and the potential therapeutics tested in clinical trials are duly selected based on experimental data suggesting their success” and that therefore, “the announcement of a detailed safety and efficacy clinical trial protocol for a particular therapeutic and disease provided the skilled person with a reasonable expectation of the success of this particular therapeutic, **unless there was evidence to the contrary** in the state of the art”.⁵⁷

In [T 2963/19](#), however, the Board gave the evaluation a different nuance and acknowledged that the claimed disease “represents a particular challenge taking account of the poor prognosis and low success rates of clinical trials.” According to the Board, “the approval of a clinical study depends on the assessment of the foreseeable risks in relation to the anticipated benefit in terms of relevance of the findings, which **does not necessarily imply an expected positive outcome** and does not represent a scientific advice on the development programme of the investigational product tested.” The Board was not convinced that the mere fact that the prior art reported the testing of the claimed treatment in a Phase III clinical trial “**already by itself** provided the skilled person with a reasonable expectation that the treatment under investigation would be safe and effective”.⁵⁸ [T 1437/21](#) affirms that “[t]he approval of a clinical trial does... **not, by way of a heuristic, imply an expected positive outcome of the treatment**.”⁵⁹ [T 122/23](#) follows the rationale in [T 2963/19](#) and [T 1437/21](#).⁶⁰ These decisions thus emphasize that there is no automatic assumption of a reasonable expectation of success in case of prior art disclosing that a clinical study had been proposed or was underway and that the focus has to be on the individual technical evaluation. The considerations in the earlier decisions [T 2506/12](#), [T 239/16](#) and [T 1123/16](#)

44 T 715/03, reason 2.4.3.

45 T 385/07, reasons 13 to 18.

46 T 2506/12, reason 3.10.

47 T 2506/12, reason 3.12.2.

48 T 2506/12, reason 3.15, emphasis added.

49 T 239/16, reason 6.5, emphasis added.

50 T 239/16, reason 6.6.

51 T 1123/16, reasons 11 and 13.

52 T 96/20, reasons 8, 9 and 16 to 19.

53 T 3165/19, reasons 22 and 23.

54 T 108/21, reason 7.9.

55 T 1941/21, reasons 1.5 and 1.6.

56 T 1934/23, reasons 2.4.2 and 2.4.5.

57 T 96/20, reasons 8 and 9, emphasis added.

58 T 2963/19, reason 4.3.1, emphasis added.

59 T 1437/21, reason 4.3.1, emphasis added.

60 T 122/23, reason 4.2.1.

were held to be linked to the further circumstances of these cases.⁶¹ The very recent decision **T 136/24** emphasizes that the “*case law mainly focuses on balancing positive and negative pointers*” which are linked with the individual circumstances of the case and also rejects the idea that “*ongoing clinical studies automatically establish a legal presumption of success*”.⁶²

While it can be inferred from decisions such as **T 2506/12**, **T 239/16**, and **T 96/20** that there could be a legal presumption that clinical trial-related disclosures **due to their regulatory context automatically** provide for a reasonable expectation of success **unless there is a dissuasion**, there are several decisions such as **T 1437/21** and **T 136/24** that emphasize that there is no such automatism and that the question of whether there was a reasonable expectation of success must instead be answered on the basis of the **specific circumstances of the case** such as the nature of the active agent, how far the clinical testing had advanced, and how much was known about clinical efficacy and safety.

It will again have to be seen how a full protocol disclosure including details of the preclinical and previous clinical results and the scientific rationale for conducting the clinical trial under the new EU transparency rules will influence the evaluation. As discussed above, while the certainty standard for implicit disclosure of the treatment effect may still shield from anticipation, lack of obviousness may become difficult to argue, thus all the more calling for fling a patent application before publication of such clinical trial-related disclosures. Such an early filing will, however, also have to meet the sufficiency hurdle (Art. 83 EPC) by rendering the treatment effect credible even in the absence of the corresponding clinical trial results. As the current case law also accepts preclinical and earlier clinical data for establishing a credible disclosure, an earlier filing seems to be the less risky option but requires careful drafting to be able to argue compliance with both Art. 83 and 56 EPC. On the other hand, a later filing after the clinical trial-related disclosure is published would require

a very careful alignment of the information to be included in the regulatory documents submitted to the authorities and redaction of the clinical trial-related disclosures. In any event, the evaluation of the best strategy will be very case specific and requires cross-functional effort involving scientists, regulatory experts and patent attorneys.

V. First Insights from the UPC

The legal framework for establishing inventive step has been established by the UPC’s Court of Appeal (CoA) in the two landmark decisions *Amgen v. Sanofi and Regeneron* (UPCCoA_528/2024 and UPC_CoA_529/2024) and *Meril v. Edwards* (UPC_CoA_464/2024 et al.) that both issued on 25 November 2025. While under the UPC’s “more holistic” approach the objective problem is established first and based on the claim as a whole and the patent⁶³ rather than by looking at individual features of the claim and by comparing to a specific prior art,⁶⁴ the subsequent obviousness analysis appears to be quite similar to the obviousness evaluation under the EPO’s problem-solution approach (**Figure 5**). For instance, also in the UPC’s approach, a solution is considered obvious when there was a reasonable expectation of success.⁶⁵

It is important to note for the evaluation of second medical use claims, that the Court of Appeal for the interpretation considered that “*it is an inherent claim feature that the claimed product must be objectively suitable for the claimed use, i.e. be therapeutically effective. This requires that the claimed treatment causes a noticeable improvement of the medical condition of the patient suffering from the disease mentioned in the claim, i.e. the treatment must be meaningful. The fact that the skilled person does not derive any minimum required effect from the claim or the description does not lead to another conclusion ...*”⁶⁶

Figure 5 Overview of inventive step approaches in comparison.



⁶¹ T 1437/21, reason 4.3.1 and T 2963/19, reason 4.3.1.

⁶² T 136/24, reason 7.14. The Board in T 136/24, reason 7.14.10, expressly stated that it does not follow the rationale in T 96/20 (*supra*).

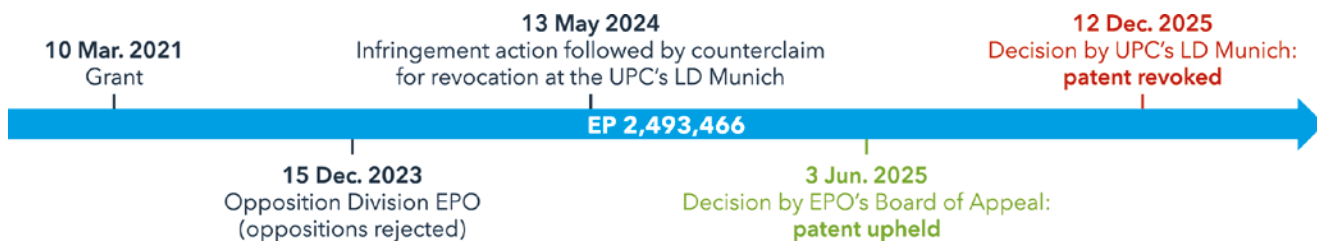
⁶³ While the CoA in *Amgen v. Sanofi and Regeneron* and *Meril v. Edwards* refers to the application (for example, Headnote 11 of *Amgen v. Sanofi and Regeneron*), the CoA in the more recent decision *VMR v. NJOY* (UPC_CoA_71/2025) of 29 December 2025 refers to the patent.

⁶⁴ For example, Headnote 11 of *Amgen v. Sanofi and Regeneron*.

⁶⁵ Headnote 17 of *Amgen v. Sanofi and Regeneron*.

⁶⁶ Headnote 2 and 3 of *Amgen v. Sanofi and Regeneron*, emphasis added.

Figure 6 Timelines regarding EPO and UPC proceedings with regard to EP 2,493,466.



A first decision with clinical trial-related disclosure was rendered by the UPC's Local Division (LD) Munich on 12 December 2025 (UPC_CFI_146/2024 et al.) on the validity of the patent underlying the decision in **T 136/24** as discussed above. See **Figure 6** for an overview.

As the EPO, the LD Munich did not consider prior art on the ongoing Phase III clinical trial to anticipate the claimed treatment. According to the LD Munich, such clinical trial-related disclosure only discloses the treatment "in the form of a hypothesis that is currently being verified".⁶⁷ This would imply that also at the UPC, an implicit disclosure is very hard to establish. However, while the EPO held the claimed treatment inventive, the UPC concluded that it was obvious since there was a reasonable expectation of success. As the EPO, the UPC evaluated "various indicators in the prior art" and provided an overall assessment.⁶⁸ According to the LD Munich, "reasonable expectation of success is not the certainty or even the near certainty of success."⁶⁹ Next to defining the technical problem differently and weighing the prior art pointers differently compared to the EPO, one important point for the Court appears to have been that the ongoing Phase III clinical trial was near completion. According to the Court, "the crucial point in the present case is not the authorisation of the trial, it



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is the course of the trial without incident and the near ending of the trial, which leads to an expectation of success",⁷⁰ while

the Board in **T 136/24** considered that "[t]he fact that a study is nearing completion per se... is neither a positive nor a negative pointer when assessing expectation of success."⁷¹

As the UPC's decision was rendered in first instance, it remains to be seen how the UPC's Court of Appeal will assess cases with clinical trial-related disclosure in the prior art.⁷² However, this first insight would indicate an even more difficult situation for inventive step at the UPC and therefore speak even more for an early filing of a patent application completely avoiding clinical trial-related disclosure or, as an alternative, at least mandate a very good control of such disclosure in case of a later filing.

VI. Conclusion and Practical Recommendations

The new EU regulatory transparency requirements and corresponding mandated early and more detailed disclosures are a challenge for the patent system in a sector where patents play a very important economic role. The disclosures are global and thus have implications on patent filings around the world with different legal standards in different jurisdictions.⁷³ Courts will be asked to find a way of dealing with these challenges while maintaining a coherent interpretation of the law. Pharmaceutical companies, however, will also have to do their best to navigate simultaneously the regulatory and patent law requirements. The following practical recommendations for pharmaceutical companies may be derived:

- **Minimize the information included in relevant clinical trial documents at draft stage:** What is scientifically really relevant and absolutely necessary? For example, according to the EMA guidance mentioned above, the background and rationale for a trial does not necessarily have to be included in the clinical trial protocol (which is published), but could also be included in other protocol referenced documents. Thus, mentioning the rationale in the Investigator Brochure (which is not published) appears to be possible.

66 Headnote 2 and 3 of *Amgen v. Sanofi and Regeneron*, emphasis added.
 67 Section B.3.c.dd.(2) of the grounds for the decision.
 68 Section B.3.c.dd.(4) of the grounds for the decision.
 69 Section B.3.c.ee.(6) of the grounds for the decision.
 70 Section B.3.c.ee.(10) of the grounds for the decision.

71 T 136/24, reason 7.15.5.
 72 The decision from the LD Munich is currently under appeal (UPC_CoA_22/2026 to 27/2026).
 73 Reference is also made to an article of October 2024 in *Managing IP* co-authored by Eva Ehlich and Anja Fux ("Patenting medical treatments in the US and Europe – a guide for practitioners").

- **Establish clear communication between research and regulatory teams:** What is already in the public domain? What could qualify as CCI – now or in the future?
- **Engage external specialists** with relevant scientific and technical expertise early in the process such as medical writers.
- **Align regulatory and patent law advisors** through close, ongoing coordination.
- **Ensure consistency** among all structured data fields and related documents.
- **Implement a robust redaction process:** Which documents do I need to redact? How do I redact parts of the protocol or patient facing documents?
- **File patent applications before clinical trial disclosures** become public under the EU transparency rules and when enough data are available to establish a **credible disclosure**.

- **If patent applications are filed after clinical trial disclosures became public under the EU transparency rules:** Provide claims with **new treatment features** arising from the results of the study or features, which have been successfully redacted (e.g. dosing) in case the treatment effect in itself will not be considered patentable.
- **In evaluating the circumstances of an individual case:** Be aware not only of the **technical evaluation** of the clinical trial disclosures, **but also take into account the regulatory circumstances**, such as the status of the overall development or the status of the individual trial.

Disclaimer: the views and opinions presented in this article are solely personal views and do not necessarily reflect the views, policies, or positions of Heuking and Maiwald. The information provided is intended for information purposes only and should not be construed as legal advice or as representing the official position of Heuking and Maiwald.

Reminder: Use of the Title European Patent Attorney/EPA is Reserved

T. Powell (GB) on behalf of the Professional Conduct Committee

The 100th Meeting of the **epi** Council in Nice on 8 November 2025 approved revised rules governing **epi** studentship.

The revised rules¹ prohibit use by admitted students of misleading expressions or titles which falsely or inaccurately imply qualification to act before the European Patent Office. In particular, titles such as “*Part-Qualified European Patent Attorney*” and related derivatives/abbreviations are specified as being unacceptable.

The Professional Conduct Committee (PCC) of **epi** wishes to emphasise the importance of complying with rules limiting use of the title “*European Patent Attorney*” exclusively to those who have (a) passed the European Qualifying Examination (EQE); and (b) are on the European List maintained by the EPO. The standing of the qualification “*European Patent Attorney*” (and abbreviations or derivatives) must not be diminished through use of it to describe those who are not qualified and entitled to provide representation before the EPO.

The PCC moreover wishes to draw attention to decision D 0001/20² of the Disciplinary Board of Appeal of the EPO. This concludes that the term “*IP attorney*” used in the website of a firm of European Patent Attorneys to describe

individuals providing services in the realm of intellectual property, and who had not passed the EQE, was likely to be misleading to the target audience of the website. Misleading information given knowingly by a European Patent Attorney transgresses Article 1(1), second sentence, of the Regulation on Discipline³ (RDR).



Tim Powell

The PCC is available to provide advice to members in cases of uncertainty concerning the RDR and the **epi** Code of Conduct⁴ (CoC). Any requests for advice should be routed via the **epi** Secretariat. The Committee welcomes all such requests that assist to clarify acceptable practices for members.

1 <https://patentepi.org/r/info-2601-21>

2 <https://patentepi.org/r/info-2601-16>

2 <https://patentepi.org/r/info-2601-17>

4 <https://patentepi.org/r/info-2601-18>

Opinion from PCC on consent to use generative AI agents

The Professional Conduct Committee (PCC) provides opinions upon enquiries from epi members under Art. 7(c) of the epi Code of Conduct. Any opinion given does not have regulatory force and is prepared with the intention to provide helpful assistance. No liability of any kind attaches to the epi, the Professional Conduct Committee or any members of that Committee in respect of these opinions. In accordance with Article 7(c) CoC, opinions of the Professional Conduct Committee shall not be binding on the disciplinary bodies. The following opinion has been considered useful for epi members as the questions it addresses are particularly significant. Hence, it has been decided to publish it, in anonymised form.

Note to readers: This opinion relates to an aspect of the use of generative AI agents in the work of patent attorneys. This is a fast-changing area in which developments may render the opinion less relevant than at the time it was drafted. Members are encouraged to interpret the opinion in line with relevant developments; and/or to seek an updated opinion from the Professional Conduct Committee.

Summary of enquiry

The Enquiring Member wishes to know whether the recommendation, in Guideline 4 of the recently published Guidelines on Use of Generative AI in the Work of Patent Attorneys¹ (herein “Guidelines”), requires the obtaining of specific consent from a client to the use of generative AI when drafting text summarising existing prior art in a patent application or response.

Relevant Provisions

Guideline 4 of the aforementioned Guidelines; and the Guidelines generally

“Guideline 4: Members must in all instances establish, in advance of using generative AI in their cases, the wishes of their clients with regard to the use of generative AI.”

Opinion

General Principles Underlying Guideline 4

As a preliminary remark, it is important to keep in mind that the Guidelines are neither Rules of Professional Conduct

nor formal recommendations on conduct of epi members. Rather, they are intended to assist members to judge what are appropriate practices in an area of activity that is recognised as being contentious and imprecise.

Hence there is no directly applicable sanction for any failure to observe the provisions of the Guidelines. However the Disciplinary Bodies of epi and the EPO may interpret non-observance of the Guidelines as evidence that a European Patent Attorney may have breached for example an Article of the Regulation on Discipline.

Guideline 4 is intended to assist Members of epi to avoid liabilities that may result from any failure to understand the wishes of a client concerning the use of generative AI tools. Guideline 4 urges Members to establish the wishes of their clients with regard to the use of generative AI tools; but it does not prescribe how, or how frequently, such wishes are to be identified or recorded.

In view of this it firstly is clear that any form of establishing the wishes of a client is likely to comply with the Guideline, as long as it achieves the objective of allowing the Member clearly to know whether in given circumstances the use of AI tools is accepted by the client.

Obviously a written form of consent is easier to recall and refer to than for example verbal consent; but whether a written record of consent to use generative AI (or indeed a prohibition on its use) is created is a matter of practical organisation for the European Patent Attorney and the client.

Secondly the Guideline does not call for the obtaining of consent more than once, although as explained below in some situations this may be desirable.

In particular in this regard if the areas of endeavour of the client alter over time depending on the nature of the change it may be prudent not to assume that consent given in the past continues to be valid. In such a situation it would be desirable to assess whether previously given consent remains applicable; and if necessary to obtain renewed consent.

Additionally, developments in the capabilities of AI tools and, somewhat distinctly, changes in the ownership of the client entity may make it desirable to update any consent previously obtained.

Such aspects are matters of risk evaluation, and if in the professional judgement of the Member an existing consent

¹ <https://patentepi.org/r/info-2601-13>

remains valid (or on the balance of probabilities is likely to remain valid) there is no need repeatedly to update the consent. Indeed, unnecessarily asking for consent updates may irritate clients and thereby harm the reputation of the European Patent Attorneys' profession.

It follows that a European Patent Attorney in obtaining consent to use generative AI tools should take the minimum steps that are consistent with achieving a clear understanding within the meaning of Guideline 4.

As a practical matter a private practice attorney probably can satisfactorily comply with Guideline 4 by including consent provisions in for example correspondence (such as terms of engagement, or an engagement letter) exchanged at the commencement of a working relationship with a client. In this case, the principal areas and the extent in which generative AI is to be used should be indicated.

It may also be possible to comply with Guideline 4 through the posting of a statement on a firm's website. In particular a statement to the effect that a firm intends to use generative AI tools unless the client indicates a contrary wish in the view of the author would comply with Guideline 4.

In either of these cases any indication of an intention to use generative AI tools should not be anything other than clear and readily available to the client. Obscure references to consent, or references that are not prominent in a firm's website, are unlikely to comply with Guideline 4.

European Patent Attorneys working in-house should interpret the foregoing *mutatis mutandis* with regard to their precise circumstances. It seems very likely that many internal policy statements will give rise to compliance with Guideline 4.

A further overarching principle is that a Member must be alert to possible misunderstandings of the operation of AI tools by clients. In particular, Members should be alert to signs of clients not being aware of the risks of loss of confidentiality of information through use of generative AI tools.

Specific Aspects of the Enquiry

The enquiry is right to imply that statements of prior art in patent specifications are in a different category than, for example, patent claims which must be novel and hence cannot usually be prepared using anything other than closed AI systems (which for the most part are not available to patent attorneys).

It is reasonable to conclude that, assuming the client consent explained above has been obtained, statements of prior art in specifications may be prepared using AI tools.

Consent to use AI tools for this purpose is likely to be long-lasting or perhaps even (in practice) perpetual. This is

because the drafting of statements of prior art is an activity unlikely to give rise to circumstances creating a need to renew any usage consent given, unless there is a change of ownership of the client entity.

Statements of prior art in responses require more care, since the choice of prior art references relied on and the emphases given to them are likely to reflect the instructions of the client. These of course are confidential and, in most situations, legally privileged. The patent attorney is not at liberty to place this confidentiality or privilege at risk, even if consent to use AI tools has clearly been provided. When using AI tools in the preparation of responses therefore Members must remain constantly alert to the risk that one may inadvertently release confidential information that may harm the client.

It should of course be repeated that compliance with the Guidelines is not mandatory, although it is recommended. The Guidelines should be viewed independently of any regulatory obligations, and no aspect of complying with the Guidelines may substitute for compliance with any other obligations attaching to the work of a European Patent Attorney.

Summary of Opinion

Guideline 4 is intended to assist patent attorneys to avoid liabilities that could arise through the use of generative AI tools without the consent of clients. Compliance with Guideline 4 is not mandatory, although failure to comply may have implications in for example cases that may be heard by the disciplinary bodies of **epi** and the EPO.

The requirement in Guideline 4 to learn the wishes of clients concerning the use of AI tools is not intended to create an onerous work burden; and indeed excessive seeking of consent is not recommended.

With the recommended client consent, drafting of prior art statements seems to be permissible, under Guideline 4, in patent specifications.

Drafting of prior art statements also is permissible in responses but Members must be alert to the chance that AI prompts selecting or emphasising particular prior art documents (or combinations of documents) may breach the confidentiality and/or privilege of clients. Hence care must be exercised when using AI tools to indicate prior art in responses.

This opinion does not have regulatory force and is prepared with the intention to provide helpful assistance. An opinion provided in accordance with Article 7(c) CoC is not binding on the Disciplinary Bodies. No liability of any kind attaches to **epi**, its Professional Conduct Committee or any members of that Committee in respect of this opinion.

Are you a UPC representative?

F. Leyder (BE), on behalf of the Professional Conduct Committee

A little-known competence of Council in disciplinary matters is its power to make recommendations on conduct within the terms of the Regulation on Discipline.¹

On 8 November 2025, Council met in Nice (France) with the reform of the disciplinary system as main item on its agenda, in particular the amendment of the Regulation on Discipline. Almost unnoticed, another agenda item was the adoption of a recommendation regarding the title to be used by European Patent Attorneys who are entitled to represent parties before the Unified Patent Court (UPC).

Whilst parties must normally² be represented by lawyers authorised to practise before a court of a State where the UPC Agreement is in force, European Patent Attorneys may also represent parties if they have appropriate qualifications and have been entered in the list kept by the UPC Registrar.



Francis Leyder

The question of representation already came twice before the UPC.

In case UPCCoA563/2024 (Suinno v. Microsoft), the question before the Court of Appeal was whether the

owner and CEO of a company, who was a European Patent Attorney entered on the list kept by the Registrar, was allowed to represent the company. In the Order³, there are four references to representation, two in the Headnotes and three in the Grounds for the Order:

- *qualified to act as a UPC representative in accordance with Art. 48(1) or (2) UPCA* (first headnote)
- *the lawyer or the European patent attorney, qualified as a representative under Art. 48(1) or (2) UPCA* (third headnote)
- *qualified to act as a UPC representative in accordance with Art. 48(1) or (2) UPCA* (grounds 20 and 22)
- *"the UPC representative of a party"* (ground 21)

The Court of Appeal later quoted literally passages from this Order in case UPC CoA 635/2024.

This confirmed that "UPC representative" as a title is widely used and understood in the IP community – not only by **epi** members and attorneys-at-law, but even by the UPC itself. On this basis, Council decided to amend its recommendation concerning the title (professional designation), thereby expressly endorsing the use of UPC Representative as (additional) title for European Patent Attorneys on the list maintained by the UPC Registrar. At the same time, Council decided to continue to allow the use of European Patent Litigator as title, obviously less preferred because it does not specifically refer to representation before the UPC but quite extensively used after a decision (now repealed) adopted by Council in Málaga on 22 October 2022.

The amended recommendation can be found on the **epi** website⁴ (item 4.2.2.2. in the Collection of Decisions).

1 Article 9(3) of the Regulation on the establishment of an institute of professional representatives before the European Patent Office (also known as the Founding Regulation).

2 Article 48 UPCA, except in proceedings under Article 32(1)(i), i.e. actions concerning decisions of the EPO in carrying out the tasks entrusted to the EPO according to Article 9 of Regulation (EU) No 1257/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection.

3 <https://patentepi.org/r/info-2601-17>

4 <https://patentepi.org/r/info-2601-18>

Titel in Verbindung mit dem EPG

Der folgende berufliche Titel wird für ein Mitglied, das gemäß Art. 48.2 des Übereinkommens über ein Einheitliches Patentgericht (EPGÜ) befugt ist, Parteien vor dem Einheitlichen Patentgericht (EPG) zu vertreten, und das in Art. 48.3, letzter Satz, des EPGÜ erwähnte Verzeichnis eingetragen ist, zusätzlich zum Titel „European Patent Attorney“ oder zu einem der oben genannten, dazu äquivalenten Titel empfohlen:

„UPC Representative“

oder äquivalente Varianten wie „Representative before the Unified Patent Court“, „Vertreter vor dem Einheitlichen Patentgericht“, „Représentant devant la Juridiction unifiée du brevet“.

Alternativ kann der Titel „European Patent Litigator“ zusätzlich zum Titel „European Patent Attorney“ oder zu einem der oben genannten, dazu äquivalenten Titel genutzt werden.

Title in connection with the UPC

The following professional title is recommended for a member who is authorized to represent parties before the Unified Patent Court (UPC) according to Art 48.2 of the Agreement on a UPC (UPCA) and who is registered on the list mentioned in Art. 48.3, last sentence, in addition to the title “European Patent Attorney” or to any of its equivalent titles referred to above:

“UPC Representative”

or equivalent versions such as “Representative before the Unified Patent Court”, “Vertreter vor dem Einheitlichen Patentgericht”, “Représentant devant la Juridiction unifiée du brevet”.

Alternatively, the professional title “European Patent Litigator” may be used in addition to the title “European Patent Attorney” or to any of its equivalent titles referred to above.

Titre en lien avec la JUB

Le titre professionnel suivant est recommandé pour un membre qui est habilité à représenter des parties devant la Juridiction unifiée du brevet (JUB) en application de l’article 48.2 de l’Accord relatif à une juridiction unifiée du brevet et qui est inscrit sur la liste visée à l’article 48.3, dernière phrase, en plus du titre “European Patent Attorney” ou d’un des titres équivalents mentionnés ci-dessus :

« UPC Representative »

ou des versions équivalentes telles que « Representative before the Unified Patent Court », « Vertreter vor dem Einheitlichen Patentgericht », « Représentant devant la Juridiction unifiée du brevet ».

À titre alternatif, le titre professionnel « European Patent Litigator » peut être utilisé en plus du titre « European Patent Attorney » ou d’un des titres équivalents mentionnés ci-dessus.



Case Law

Aligning Claims and Description Why G 1/25 Matters for Legal Certainty

A practitioner's view on description amendments and their impact on legal certainty under the EPC

C. D. Schober, Professional Representative before the EPO;
part-time Technically Qualified Judge at the Unified Patent Court¹

This article discusses the pending referral G 1/25 concerning the adaptation of the description under the EPC. It analyses the legal basis, practical implications, and the broader impact on legal certainty within the European patent system.

Procedural Background

On 29 July 2025, Technical Board of Appeal 3.3.02 issued its interlocutory decision in case T 0697/22², referring the following legal questions to the

Enlarged Board of Appeal under Article 112(1)(a) EPC. The referral was registered as G 1/25:

1. Is the description of a European patent required to be adapted in opposition or opposition appeal proceedings to remove inconsistencies with amended claims?
2. If so, what is the legal basis in the European Patent Convention for this obligation?
3. Does the answer to question 1 differ if the inconsistency arises during examination or examination appeal proceedings?

The referral was officially announced in the Official Journal of the European Patent Office³ and seeks to resolve diverging

¹ This article reflects the personal opinion of the author in his capacity as a legal practitioner. It does not express any view in his judicial capacity as a technically qualified judge at the Unified Patent Court, nor does it represent the position of any professional body or organisation in which he is involved.

² <https://patentepi.org/r/info-2601-14>

³ Notice from the EPO President concerning referral G 1/25, OJ EPO 2025, A59.

lines of case law within the EPO – specifically, decisions that require alignment between amended claims and the description versus those that tolerate discrepancies – to promote legal uniformity and procedural predictability.

The Question at Stake

The referral in G 1/25 crystallises a long-standing divergence in EPO case law. Some Boards, such as T 1024/18, require strict consistency between claims and description, whereas others accept certain inconsistencies, for example, when broader embodiments remain in the description but are evidently no longer covered by the amended claims, and the examining division considers that no legal uncertainty arises.

This divergence reaches beyond internal EPO practice. It affects legal certainty for third parties, the integrity of the granted patent, and ultimately the credibility of the European patent system.

The Broader Debate Reflected in the Amicus Curiae Submissions⁴

The extraordinary interest in G 1/25 is reflected in the number and scope of the amicus curiae submissions. In total, thirty-nine submissions were filed, amounting to approximately seven hundred pages of argumentation⁵.

A clear majority advocates answering Question 1 in the negative. While the number of submissions is not determinative, it illustrates the practical sensitivity of the issue within the profession. Many of these contributions focus on the absence of an explicit legal basis in the EPC, the one-directional wording of Article 84 EPC, and concerns regarding procedural economy, litigation risk, and the proliferation of auxiliary requests. In this view, potential inconsistencies should be addressed, if at all, through substantive validity analysis and claim interpretation rather than through a structural requirement of adaptation.

A smaller but institutionally weighty group supports an affirmative or qualified affirmative answer. The President of the European Patent Office argues that the internal coherence of the patent text follows from the combined effect of Articles 84 and 69 EPC, and that G 1/24 reinforces this systemic requirement. The Patentanwaltskammer likewise stresses structural consistency, limiting the obligation to cases of genuine technical contradiction. The Institute of Professional Representatives before the European Patent Office adopts a differentiated position, recognising that adaptation may be necessary where genuine lack of clarity arises, while cautioning against formalistic excess.

⁴ The author acted as first drafter of the amicus curiae submission of the Patentanwaltskammer and participated in the working group preparing the epi submission. The views expressed in this article are strictly personal.
⁵ based on compilation of amicus filings as of 26 February 2026, see <https://patentepi.org/r/info-2601-15>

The divergence of views illustrates that the referral concerns more than a question of drafting practice. It ultimately raises a constitutional question within the EPC framework, namely whether interpretation alone can remedy internal inconsistency, or whether the European patent must meet a structural standard of coherence at the moment it is granted or maintained.

Legal Certainty as the Guiding Principle

In daily practice, clients and third parties rely on the published patent specification to assess risks and plan commercial activities. When the granted claims define one subject-matter, yet the description continues to discuss broader, unqualified embodiments, ambiguity results.

It becomes unclear whether such unclaimed embodiments are definitively excluded, possibly protected under the doctrine of equivalents, or merely editorial remnants. This uncertainty undermines the reliability of the patent as a legal title and increases the risk of costly litigation.

This concern is not theoretical. In proceedings before national courts and the Unified Patent Court (UPC), the description plays a vital role in claim interpretation. The Enlarged Board in G 1/24⁶ reaffirmed that the description and drawings must always be consulted when construing claims.



Christoph D. Schober

The Legal Basis for Adaptation

The obligation to adapt the description is embedded in the internal logic of the EPC. Several provisions, read together, make clear that the claims and description must form a consistent whole.

- i. Article 84 EPC provides that “*the claims shall define the matter for which protection is sought*” and “*shall be clear and concise and be supported by the description.*” The requirement of support establishes a substantive link between the claims and the technical teaching presented in the description. Where the description continues to present, as part of “*the invention,*” subject-matter that no longer falls within the amended claims, this link is disrupted. In such circumstances, the specification no longer presents a coherent account of the invention as claimed, and adaptation becomes necessary to restore conformity with Article 84 EPC.

⁶ Decision of the Enlarged Board of Appeal G 1/24, OJ EPO 2025, A60 (“*Interpretation of patent claims*”).

- ii. Article 69 EPC, together with the Protocol on Interpretation, confirms that the description is integral to determining the extent of protection. The claims cannot be interpreted in isolation; they must be read in the light of the description and drawings. Internal inconsistency between these parts risks distorting the scope of protection, contrary to the intent of Article 69 EPC.
- iii. Rule 42(1)(c) EPC adds a procedural dimension: the description must disclose the invention as claimed in such terms that the technical problem and its solution can be understood. When claims are amended, the invention “as claimed” changes; leaving outdated embodiments in the description would therefore contravene this rule.
- iv. Rule 48(1)(c) EPC reinforces this structural requirement by prohibiting statements that are obviously irrelevant or unnecessary under the circumstances. While not every non-claimed embodiment is irrelevant, passages that continue to present excluded subject-matter as forming part of the invention may, in certain cases, fall within this prohibition and require correction.

Taken together, these provisions provide a coherent and sufficient legal basis for requiring adaptation. No new doctrine or interpretation is needed: the EPC itself, through the combined effect of Articles 84 and 69 and Rules 42 and 48, already demands that the patent specification form a single, self-consistent instrument.

Examination vs. Opposition: No Difference in Outcome

Some argue that the adaptation requirement may apply differently depending on whether the inconsistency arises during examination or opposition. The procedural framework indeed differs in the two stages, in particular with regard to the scope of Article 84 EPC in opposition proceedings.

However, from the perspective of legal certainty and third-party reliance, the decisive factor is the final text in which the patent is maintained. Regardless of the procedural route by which amendments are introduced, the patent must ultimately present a coherent and self-consistent specification. The stage of the proceedings may affect the procedural mechanism, but it should not alter the substantive requirement that the maintained text accurately reflects the invention as claimed.

Cost Considerations Are Not a Valid Objection

It has been suggested that adapting the description imposes an unreasonable cost burden on applicants. In my view, this concern is overstated.

Such adaptation is usually a minor editorial task that arises only when the applicant chooses to amend the claims. It is a natural and expected consequence of claim limitation – one that clarifies and strengthens the intended scope of protection. Moreover, the modest effort required is far outweighed by the systemic benefit of ensuring that the granted patent is legally coherent. The cost of not adapting, i.e., the risk of interpretative ambiguity, inconsistent enforcement, and increased litigation, is much higher for both applicants and third parties.

Patent rights confer exclusive legal power. With this privilege comes the responsibility to define the protected subject-matter clearly and consistently. Editorial alignment is therefore part of good practice and an established element of the dialogue between applicants and the EPO.

National Decisions vs. the European Context

While national case law may offer useful reference points, it can only serve as a limited guide for interpreting the EPC framework. National court decisions may have precedent-setting effects, whereas the prosecution history before the EPO typically plays little or no interpretative role.⁷

As a result, the structure and coherence of the granted text, including the alignment between claims and description, carry particular weight in the European context. This underscores the importance of the Enlarged Board’s role in providing a harmonised and authoritative interpretation, particularly where national and institutional practices diverge and where applicants, courts, and third parties alike require legal certainty.

Conclusion

The Enlarged Board in G 1/25 now has the opportunity to bring long-awaited clarity to this issue. It should confirm that adaptation of the description is required where amended claims give rise to a technical inconsistency between the claimed subject-matter and the description as maintained.

Such confirmation would enhance legal certainty, reduce interpretative ambiguity, and preserve the integrity of the European patent system – both during examination and in post-grant proceedings. It would also assist national courts and third parties, who rely on a coherent and unambiguous patent specification to assess infringement risks and determine the boundaries of protection.

⁷ See, e.g., BGH, judgments of 12 March 2002 – X ZR 43/01 (“Kunststoffrohrteil”), GRUR 2002, 511 (headnote 1), and 14 June 2016 – X ZR 29/15 (“Pemetrexed”), GRUR 2016, 921 [35 ff.]: events during prosecution are generally not relevant for claim interpretation; statements made in examination may indicate the skilled person’s understanding but do not form part of the public disclosure.

Antibody Claims: Routinely Sufficient?

T. Bucher (CH), European Patent Attorney

ABSTRACT: The purported rationale of the EPO for granting broad, functionally defined antibody claims, despite a minimal disclosure in the application itself, is the assumption that work in this area is 'routine'. Yet there is a serious consequence in adopting a 'routine methods mindset'. It leads to the position still held in the 2026 Guidelines that "[a]rriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person" i.e. *prima facie* obviousness of an entire developing field of biotech inventions. This article questions the appropriateness of the 'routine methods mindset' in relation to meeting the sufficiency of disclosure requirement. There should necessarily be an analysis of the specific facts of each case to determine if the invention is sufficiently disclosed. In this analysis, the function and subset of antibodies being claimed must be considered. This is important to prevent assessments made, for example, about diagnostic antibodies for *in vitro* use, being overapplied to each and every functionally defined antibody claim, including the important class of therapeutic antibodies.

Antikörper-Ansprüche: Routinemäßig ausreichend?

ZUSAMMENFASSUNG: Die angebliche Begründung des EPA für die Erteilung breit gefasster, funktional definierter Antikörperansprüche trotz minimaler Offenbarung in der Anmeldung selbst ist die Annahme, dass die Arbeit in diesem Bereich 'Routine' ist. Die Denkweise, nach der von Routineverfahren ausgegangen wird, hat jedoch ernstzunehmende Folgen. Sie führt zu der in den Richtlinien von 2026 immer noch vertretenen Position, dass „[a]lternative Antikörper ausschließlich zu erzeugen, indem man aus dem Stand der Technik bekannte Techniken anwendet, gilt als für die Fachperson naheliegend“, mit anderen Worten das *prima-facie-Naheliegen* eines ganzen sich entwickelnden Gebiets biotechnologischer Erfindungen. In diesem Artikel wird hinterfragt, ob die Denkweise, nach der von Routineverfahren ausgegangen wird, die Anforderung des Ausreichens der Offenbarung erfüllt. Es sollte zwangsläufig eine Analyse der jeweiligen spezifischen Fakten erfolgen, um festzustellen, ob die Erfindung ausreichend offenbart ist. Bei dieser Analyse sind die Funktion und Untergruppe der beanspruchten Antikörper zu berücksichtigen. Dies ist wichtig, um zu verhindern, dass beispielsweise Beurteilungen von diagnostischen Antikörpern für die *in-vitro*-Anwendung übermäßig auf jeden funktionell definierten Antikörperanspruch, einschließlich der wichtigen Klasse therapeutischer Antikörper, angewendet werden.

Revendications d'anticorps: couramment suffisantes?

ABRÉGÉ: La prétendue justification de l'OEB pour l'octroi de revendications d'anticorps larges et fonctionnellement définies, malgré une divulgation minimale dans la demande elle-même, est le principe que les travaux dans ce domaine sont « courants ». Pourtant, il y a une conséquence sérieuse à adopter un « état d'esprit des procédés courants ». Ce dernier mène à la position encore maintenue dans les directives de 2026, à savoir « Aboutir à des variants d'anticorps exclusivement en appliquant des techniques connues de l'état de la technique est considéré comme évident pour la personne du métier. », c'est-à-dire l'évidence *prima facie* de tout un domaine en développement d'inventions biotechnologiques. Cet article met en doute le caractère approprié de « l'état d'esprit des procédés courants » pour satisfaire à l'exigence de suffisance de description. Il devrait nécessairement y avoir une analyse des faits spécifiques à chaque cas pour déterminer si l'invention est suffisamment divulguée. Dans cette analyse, la fonction et le sous-ensemble des anticorps revendiqués doivent être pris en compte. Ceci est important pour éviter que les évaluations faites, par exemple, au sujet d'anticorps diagnostiques pour usage *in vitro* ne soient systématiquement appliquées à chaque revendication d'anticorps défini fonctionnellement, y compris la classe importante d'anticorps thérapeutiques.

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Introduction

The standards applied to the patenting of antibodies at the EPO play an integral role in supporting innovation in the biotechnological sector. This article aims to continue the analysis of those standards as published in a series of three articles in **epi** Information concerning the inventive step assessment of antibodies¹. Those articles focused on the inventive step standards outlined in the EPO Guidelines Part G.II.6.2 (2024 version), in particular on how those standards were being applied to antibodies claimed by their sequence information. They investigated the presumption of obviousness embedded in the Guidelines and the related concept of the 'routine methods' analysis. The latter has become a mindset which has intruded into the examination of this field of antibody engineering, unfettered from the original context from which it arose in relation to murine antibodies suitable for *in vitro* use. This article will continue this work and examine this 'routine methods mindset' in relation to the disclosure requirements under Art. 83 EPC.

Functionally defined antibody claims: Art. 83 EPC

Art. 83 aims to govern one of the fundamental concepts of the patent system – a patent is granted giving the patentee certain rights over a new invention as claimed, in exchange for disclosing to the public sufficient details to be able to carry out the invention. The subject matter must, of course, also be inventive and, as a result, there is a necessary interplay between on the one hand, the assessment of inventive step, and on the other, the disclosure of this inventive subject matter.



Tamaris Bucher

The 2020 article by Storz² discusses functionally defined antibody claims in relation to these two criteria of inventive step and disclosure. Storz postulates that the justification of the EPO for granting these claims which have a broad scope, despite a minimal disclosure in the application itself, is the assumption that work in this area is 'routine.'

"In target-based claims, which do not only protect the one or more antibodies that are explicitly disclosed in a patent application, but all antibodies binding the respective target, the test the EPO applies is quite simple. De facto, the finding and proper characterization of a new target,

e.g., a new receptor or cytokine, combined with any kind of data that suggest a physiological role thereof which may [sic] antibody binding appear feasible to cause some effect, is deemed sufficient to meet the inventive step criterion. This has been confirmed even in cases where the respective applicant has only made and demonstrated a single antibody, or even no antibody at all (T18/09).

EPO's rationale to award such broad scope for such little disclosure is that, once a target is sufficiently characterized, making of an antibody against the same would be in the routine of the skilled person."³

Thus, according to this view, the disclosure requirements of Art. 83 can be satisfied for a functionally defined antibody, e.g. an antibody binding to a new target, by the somewhat diffuse concept that making antibodies is routine work. Storz presents this rationale as an explanation for the granting of such broad claims, but it must be pointed out that the EPO does not explicitly state this reasoning in their Guidelines.

It would be a very bold position to take in patent law that a constantly developing field of technology is inherently routine. Therefore, the appropriateness of this mindset deserves to be carefully analysed. On the one hand, and in relation to Art. 83, the question must be addressed – is it necessary to assert this view in order to enable broad, functionally defined antibody claims? A concern may arise that without this mindset the applicant may be unable to sufficiently disclose such claims and obtain adequate breadth to protect their invention. On the other hand, its appropriateness must be evaluated in relation to Art. 56 EPC and the consequence in the obviousness assessment of assuming the field is routine.

The following analysis will examine the sufficiency standard – i) the general height of the standard itself and ii) the amount of detail required to meet the standard.

The height of the sufficiency standard

- Art. 83 EPC: *The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.*

Art. 83 ensures that the invention is *clearly* and *completely* described, so that the information can be understood and so that the disclosure is not lacking in the essential information needed to work the invention. However, it is interesting that the adverb "sufficiently" is used to qualify the level of the clear and complete disclosure. The word "sufficiently" in its ordinary meaning implies that there needs to be enough information to meet the hurdle, but the information only needs to be *adequate* to meet that hurdle. It does not imply it needs to be more than that *i.e.* not *copiously* or *profusely*

1 Bucher, T. "The Barrier Around Antibody Inventions at the European Patent Office" Parts 1 & 2; *epi Information* 4/2024, Dec 2024, pages 22- 31 and Part 3, *epi Information* 1/25, March 2025, pages 6-14
2 Storz, U "The nine lives of epitope-based antibody patents"; *Human Antibodies*; Vol. 28, Issue 2; May 2020; pages 89-110

3 *Ibid*, at page 92

described beyond that threshold or beyond all doubt. In practice, the assessment focuses on the standard in the negative – what information is lacking to reproduce the invention and thus has it been insufficiently described?

The question of when an objection to a lack of sufficient disclosure can be validly raised has been addressed by various Boards of Appeal. The well-established case law in this area is reflected in the instructions to examiners in the EPO Guidelines:

“With regard to an objection for lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts (see T 409/91 and T 694/92).”⁴

Furthermore, in opposition proceedings, the opponent has the burden of proof when raising an objection of lack of sufficient disclosure⁵ and thus to establish that this threshold of ‘serious doubts, substantiated by verifiable facts’, is met.

Therefore, this means an objection of a lack of sufficiency of disclosure is far from a facile objection to make. Conversely, from the perspective of the applicant/patentee, the sufficiency standard is in practice a comparatively low standard to meet.

The amount of detail required to meet the sufficiency standard: the test under Art. 83

The burden on the applicant to meet this comparatively low standard is further alleviated by the ability to rely on common general knowledge to supplement the information disclosed in the patent application. Consequently, not every detail concerning how to work the invention has to be disclosed within the application itself.⁶

It would appear that for a broad, functionally defined claim to an antibody to a new target, as described above by Storz, in which one or only a very small number of antibodies are specifically exemplified, there may be a desire to fill in any gaps in explicit description by the belief that it is common general knowledge that making antibodies is routine work.

It is important then to look at the assessment of Art. 83 that has been developed in the case law for broad, functionally defined claims: is it a necessary and/or sufficient condition to establish that ‘routine methods’ are present?

In fact, the biotech case law with respect to broad claims having functionally defined features generally focuses on the concept of whether the invention can be reproduced over the whole area claimed without ‘undue burden’ and without

‘inventive skill’⁷ Moreover, in keeping with the examination of whether there has been a lack of sufficient disclosure, the test more appropriately is around the concept of whether something is lacking, rather than whether ‘routine methods’ are available. As such, a reliance on ‘routine methods’ does not seem to be necessary.

The Guidelines themselves in relation to antibodies, also do not refer to ‘routine methods’, but confirm that the test is that:

“The application must enable the skilled person to produce further antibodies having the claimed functional property without undue burden...”⁸

This ‘undue burden’ test has been applied in many cases concerning antibody claims with broad scope. This was confirmed for example, in T 2045/09, involving a claim⁹ to any antibody binding to the same epitope as a particular antibody obtainable from a deposited hybridoma cell line. Interestingly, the broad claim was held to be sufficiently disclosed, yet the word “routine” does not appear in the reasoning of the decision.

The next question that arises is whether invoking an assumption of ‘routine methods’ is sufficient to fill gaps in the disclosure?

Assumption of ‘routine methods’: not sufficient to fill in all gaps of a disclosure under Art. 83

Importantly, a ‘routine methods mindset’ is not enough to off-set any ‘undue burden’, and thus to prevent a finding of insufficient disclosure in the following two situations i) if certain critical details are deemed lacking in the specification to be able to reproduce the invention and ii) if there is too much experimentation needed to test whether the compound meets the parameters of the claim.

In relation to the first category, see for example, T 1466/05, which related to a claim to an antibody with a particular selectivity for different forms of its target.¹⁰ The Board noted that there was an ‘undue burden’ because although techniques for the production and screening of hybridomas were available in the art,¹¹ the disclosure was

⁴ EPO Guidelines (GL) Part F. III.1 Sufficiency of Disclosure, para 3 (version 2026)

⁵ Case Law of the BoA (CLBA) II.C.9.1 para 1 (11th edition, July 2025)

⁶ CLBA II.C.4.1, para 1, (11th edition, July 2025)

⁷ See, for example, T 0694/92 relating to an invention in the field of biotechnology, which generally articulated the principles to be applied in Reason 5: “...In certain cases a description of one way of performing the claimed invention may be sufficient to support broad claims with functionally defined features ... However, in all these cases, the guiding principle is always that the skilled person should, after reading of the description, be able to readily perform the invention over the whole area claimed **without undue burden and without needing inventive skill...**” (emphasis added). See also EPO Guidelines (GL) Part F. III.1 Sufficiency of Disclosure, para 1 (version 2026)

⁸ EPO GL Part G. II.6.1.3, para 4 (version 2026)

⁹ T 2045/09 Claim 8. An antibody which binds to the epitope bound by the 8B8 antibody obtainable from the hybridoma cell line ATCC no. HB-12070.

¹⁰ Claim 1 of the main request in T 1466/05: 1. An antibody reactive with the pyridinoline in peptide-linked pyridinoline[sic] and not free pyridinoline which is useful in an assay to indicate bone resorption.

"...insufficient with respect to both the antigen required to raise further antibodies as claimed, and the screening process for the specific selection of the same".¹²

The functional effect was a feature in the claim – a functionally defined binding specificity – so without a disclosure of both the antigen and a screening assay able to achieve the generation of that particular selective binding ability, the 'routine methods mindset' was not enough.¹³

'Undue burden' was also established in T 2164/21, which related to a claim to a method of producing an antibody with reduced susceptibility to deamidation.¹⁴ The application was refused on the grounds of insufficient disclosure. The Technical Board of Appeal found that there was insufficient disclosure on the basis that:

"...without the confidence that such result can be achieved at all, this constitutes an undue burden, even if it involves routine experimentation"¹⁵

Interestingly, it was also acknowledged that 'routine methods' existed, yet nevertheless there was an 'undue burden'.¹⁶ That the existence of 'routine methods' did not lead to a finding of no 'undue burden' was because of the doubt in the expectation that such a result could be achieved.¹⁷ This seemingly acknowledges the unpredictability inherent in the generation of specific antibodies for a given function.¹⁸

So, even an abstract assumption that work in the field is routine, does not mean that there still could not be a finding of insufficient disclosure. Techniques exist which are part of the common general knowledge, and yet, nevertheless, the specific facts in these cases did not support a finding of no 'undue burden'. Interestingly, these two cases where insufficient disclosure was found, reflect another wider principle applied under Art. 83.

11 T 1466/05 Reason 14

12 T 1466/05 Reason 25

13 T 1466/05 Reason 22 "...This lack of disclosure forces the skilled person to embark on further experimentation which goes beyond the routine experiments required typically - i.e. when sufficient guidance is provided in the application - for the identification of monoclonal antibodies of a desired specificity."

14 T 2164/21 Claim 1 of the auxiliary request read as follows:

"1. A method of producing an antibody with reduced susceptibility to deamidation, wherein the method produces a mutant antibody, wherein the method comprises the step of substituting a glycine that is located adjacent to the C-terminal side of an asparagine of the original antibody with another amino acid, wherein the mutant antibody has a reduced susceptibility to deamidation relative to the original antibody before the amino acid substitution, wherein the mutant antibody has the same binding specificity as the original antibody, and wherein the asparagine exists in the complementary determining region 2 (CDR2) of the heavy chain as determined by Kabat numbering and wherein the antigen-binding activity of the mutant antibody is 70% or more of the antigen-binding activity of the original antibody before the amino acid substitution."

15 T 2164/21 Reason 49

16 T 2164/21 Reason 48. "The fact that methods for generating an antibody with a specific mutation, methods for assessing deamidation and methods for antigen-binding activity were described in the application, were well known to the skilled person of the application and were routine on the priority date of the application does not mean that the invention can be put into practice without undue burden." See also Reason 52.

17 T 2164/21 Reasons 47- 49

18 T 2164/21 Reasons 44- 46

The assessment of the detail required to meet the sufficiency standard: an abstract mindset encouraged?

The case law does not encourage the use of an abstract mindset in the analysis of Art. 83. Rather, the analysis should be fact specific, as explained in the following excerpt from the Case Law of the Boards of Appeal of the EPO (CLBA):

"The issue of whether the invention is disclosed in a manner sufficiently clear and complete and whether the claims have a basis in the description is a question of fact that has to be answered on the basis of the available evidence and on the balance of probabilities in each specific case."¹⁹ (underlining added)

Therefore, the assessment of a broad, functionally defined antibody claim should have regard to the particulars of the claim and invention in question, this being irrespective of whether the claim involves binding to a new target or some other function. In other words, a fact specific assessment should not encourage a situation in which all functionally defined claims are automatically held to be sufficiently disclosed, across their full scope, by the inflation into that space of the diffuse concept that the work in the field is routine – like simply blowing hot air into a balloon.

This emphasis on an examination of the specific case, the available evidence, and of the assessment being a question of fact, is crucial to prevent claims to mere *desiderata* – essentially wishes to have protection for features, but which side-step the fundamental requirement of providing sufficient information on actually how to perform the inventions with those features. The focus of the patent bargain is on what is provided – the public must actually be taught how to reproduce the invention. This then necessitates an investigation of the particular information itself to understand what exactly has been disclosed, and not disclosed, to understand if the invention has been taught. It calls for the facts to be considered in each category of information: the (functional and/or structural) features in the claim, the exemplified disclosure in the specification itself, and the common general knowledge of the skilled person. Logically, the common general knowledge in turn should concern the knowledge in relation to the specific feature(s) in the claim and in relation to the missing information not explicitly disclosed that it needs to supplement. Abstract analysis and mindsets are not encouraged in this approach.

In summary, therefore, the test under sufficiency of disclosure under Art. 83 is whether there is an 'undue burden' to perform the invention. The invocation of the 'routine methods mindset' is neither a necessary, nor a sufficient condition to prove that there was no 'undue burden'. An abstract mindset cannot automatically be applied to a category of invention, as the disclosure requirement is necessarily a fact specific analysis.

19 CLBA II.C.1, para 4 (11th edition, July 2025)

This is not to say, however, that the word “routine” has never appeared in the analysis of Art. 83 in connection to a positive finding of a sufficient disclosure of a broad, functionally defined antibody claim. In this regard, an examination of the facts and context in which it has arisen is important to understand how the abstract notion of ‘routine methods’ has been applied.

Early case law and application of the concept of ‘routine methods’

The CLBA lists case T 431/96 at the beginning of the section entitled ‘Level of disclosure required for antibodies’²⁰. This case related to a claim²¹ to a diagnostic antibody with a particular selectivity. The decision firstly confirms that the test under Art. 83 is without ‘undue burden’ and without ‘inventive skill.’²² The BoA further commented in Reason 6 that:

*“...the skilled person seeking to reproduce the invention will have to produce monoclonal antibodies by routine methods and test them singly in an assay. This may possibly involve some tedious and time-consuming work, but nothing out of the ordinary since the techniques for the **production and selection of hybridomas were common routine techniques** at the priority date of the patent in suit (i.e. 17 March 1983).”* (emphasis added)

This very early case concerned a murine monoclonal antibody made by hybridoma technology. The statement referring to “routine techniques” should be understood in the context of making an antibody that was suitable for the claimed feature of diagnostic use. This *in vitro* use implied nothing more than being able to specifically bind to the target. A method was disclosed to produce monoclonal antibodies, and a description was provided of the screening and testing of these monoclonal antibodies. In that particular case, for an antibody which merely had to be suitable for *in vitro* use, there was sufficient information to meet the no ‘undue burden’ test.

Overapplication of ‘routine methods mindset’

Before the reasoning set out in this early case concerning a murine antibody for *in vitro* use is more broadly applied, and in particular to pharmaceutical antibodies for *in vivo* use, such as therapeutic antibodies, it should be questioned whether it is actually technically correct to characterise the field of antibody engineering as routine. Perhaps, if there was only one generation method for antibodies available, which

had become entirely routine over time, there may be some justification to this notion. However, the attempt to apply a ‘routine methods mindset’ to the entire field of antibody engineering as it has developed, comes into immediate tension with the technical reality of the skilled person. Furthermore, it underestimates the serious challenges that must be overcome, in particular in the production of therapeutic antibodies.

Firstly, multiple methods to produce an antibody that binds to a target are available, but there are, very often, no clear pointers about which method or sub-method to choose in a given instance. Different methods can give different results. More importantly, however, not just one method step is involved in the development of a pharmaceutical antibody, as the product is required to do more than simply bind to its target antigen. Other characteristics/functional effects are usually important and multiple (often sequential) methods are utilised. For example, an antibody for therapeutic use may need to meet several criteria, including, for instance, selectivity for the target antigen, species cross-reactivity, immunogenicity profile in preclinical tests, stability in solution, solubility, viscosity, aggregation tendency, purity, and the absence of undesirable post-translational modifications such as proteolysis – all while retaining its biological activity. The sequence of the antibody may need to be optimised to meet these criteria. Antibody engineering typically involves sequences within the variable regions, including in the CDRs, and, accordingly, a claim to a defined set of CDRs or VH/VL sequences for a pharmaceutical antibody for *in vivo* use does not represent a mere arbitrary selection from the antibodies obtained from a process of immunisation or from the panning of an antibody display library. It is therefore inaccurate to view the sequence-defined product as claimed as resulting from routine work. That would ignore both i) the technical complexity involved in attaining each individual characteristic and ii) the additional complexity faced when a combination of characteristics needs to be optimised in parallel via multiple methods. Crucially also, the optimisation of one criterion may negatively impact another (e.g. stability may negatively impact affinity, and vice versa). This means the development project as a whole does not have an obvious trajectory and there is no reasonable expectation of success of obtaining a therapeutic antibody solely for the reason that methods of antibody generation and selection are allegedly ‘routine methods’.²³

It is therefore a technically inaccurate view that ALL antibodies are routine to make. In particular, when taken out of the context of diagnostic antibodies for *in vitro* use and applied to the entire class of antibodies *per se*, it becomes an inaccurate prejudice. This important area of biotechnological innovation

20 CLBA II.C.7.3, para 1 (11th Edition, July 2025)

21 T 431/96 Claim 1. *A monoclonal antibody raised against non-denatured D-dimer that may be utilised in a method of diagnosis of disseminated intravascular coagulation (DIC) or other thrombotic states using body fluid, such as lymph, serum, plasma or exudate, said monoclonal antibody having the essential characteristic of reactivity with D-dimer and other cross-linked fibrin derivatives and non-reactivity with fibrinogen or fibrinogen degradation products inclusive of fragment D and fragment E.*

22 T 431/96 Reason 5

23 For further reading on this topic see Bucher, T. “The Barrier Around Antibody Inventions at the European Patent Office” Parts 1 & 2; *epi Information* 4/2024, Dec 2024, pages 22- 31 and Part 3, *epi Information* 1/25, March 2025, pages 6-14

has developed to produce therapeutic antibody products that meet a complex set of functional criteria. It is disconcerting that the complexity involved in their development may be trivially dismissed by confusing the development of these products with the early generation of *in vitro* use products.

Consequence of applying a 'routine methods mindset' in the obviousness analysis under Art. 56 and the 2026 version of the Guidelines

It is important next to understand the effect of applying this 'routine methods mindset' to the entire field of antibody engineering in the obviousness analysis under Art. 56. The ordinary meaning of 'routine' implies the work is easily done, according to a set way or method, without creativity or inventive skill. Thus, the 'routine method mindset' has seemingly evolved into the position on obviousness as stated in the EPO Guidelines Part G.II.6.2:

"Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person."

This means that all new antibody inventions are prima facie obvious if one antibody to that target is already known. This is a position which is in immediate tension with the wording of Art. 56 and one that is simply not tenable.

This negative statement unfortunately remains in the 2026 version of the Guidelines. A brief mention must be made that this version, which will come into force on 1 April 2026, has softened the negative presumption of obviousness somewhat in comparison to the 2025 version. The opening phrase of the inventive step section has been changed from *"The subject-matter of a claim defining a novel antibody binding to a known antigen*

"does not involve an inventive step unless..." to "involves an inventive step if..." (bold added).

However, the 2026 Guidelines still retain the restrictive framework of listing four ways in which it is acceptable to show inventive step,²⁴ and one way in which it is not.²⁵ The restriction that *"However, inventive step cannot be established solely on the basis that an antibody is structurally different from the prior-art antibodies"*, goes against the reasoning in case law like T 67/11²⁶. Moreover, no other field of technology is subject to such a restrictive framework or, more

24 Namely, a surprising technical effect, no reasonable expectation of success of obtaining antibodies having the required properties, difficulties in generating or manufacturing the claimed antibody, or a novel type of functional antibody format

25 *"Inventive step cannot be not acknowledged solely on the basis that an antibody is structurally different from the prior-art antibodies" and "The fact that an antibody's structure, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody to be non-obvious"*

importantly, subject to a suppression of using a source of non-obviousness arguments.

Thus, the detrimental consequence of applying an underlying assumption of 'routine methods' to an entire field of developing technology is still evident in the inventive step section of the 2026 Guidelines.

The role of the functional feature: comparison of functional claims and sequence defined claims

In light of the above considerations, it is critical that an assumption of 'routine methods' is not overapplied in the wrong context. With that objective in mind, the following analysis shows how the functional effect of a claimed antibody can be taken into account in the assessment under both Art. 83 and Art. 56 to prevent this problem from occurring. It will look at this issue from the perspective of purely structurally defined claims and purely functionally defined claims.

It will also look at claims to antibodies which are both structurally and functionally defined – an interesting middle ground to be explored that is supported by the Guidelines:

*"Antibodies can also be defined by both functional properties and structural features. It is possible to claim an antibody characterised by the sequences of both variable domains or CDRs with less than 100% sequence identity when combined with a clear functional feature."*²⁷

Interestingly, in T 617/07, which involved a claim to an anti-TrkA antibody that was functionally defined and structurally defined as having at least one of a set of specified CDR sequences²⁸ the Board found the claim to be sufficiently disclosed. They reasoned that, although the structural definition included antibodies that did not have the desired function, it would not be burdensome for the skilled person to sort out the non-functional variants within the structural definition.²⁹

The Table below will look at how the functional effect, which is sometimes explicitly included in the claim, and other times implicitly included, has a bearing on the subset of antibodies that is being claimed and, in turn, on the analysis under Art. 83 and Art. 56.

The analysis above highlights the critical role of the functional effect of the claimed antibody in the assessment under Art. 83 and Art. 56. The functional effect has a role in defining which subset of antibodies is being claimed and it is a fact specific analysis whether there is an 'undue burden' to make

26 T 67/11 Reasons 20-24 and see also Bucher, T. "The Barrier Around Antibody Inventions at the European Patent Office" Part 2; *epi Information* 4/2024, Dec 2024; pp 27-31, in particular pp 30-31

27 EPO Guidelines Part G.II.6.1.4 (2026 version)

Claim type	Antibody fully defined by function	Antibody fully defined by sequence	Antibody defined by sequence + function
Example	<p>1a) An antibody which binds to the epitope of target X</p> <p>1b) An antibody which binds to target X and is capable of downstream activity Z</p>	Antibody defined by its 6 CDRs and/or by its VH/VL regions	<p>3a) Antibody to target X, wherein the antibody is defined by its 6 CDRs and/or by its VH/VL regions</p> <p>3b) Antibody to target X, wherein the antibody is defined by its particular VH/VL regions or by sequences having e.g. 95% sequence identity thereto; wherein the antibody is capable of downstream activity Z</p> <p>3c) Antibody to target X, wherein the antibody is defined by its 6 CDRs and by its ability to achieve downstream activity Z</p>
Structure	1a, 1b): Any antibody from the general class of antibodies <u>which has the specified function(s)</u> . It implicitly excludes antibodies which do not have those function(s)	Specified sequences	<p>3a) Specified sequences</p> <p>3b), 3c): Specified sequences <u>which also have the specified functions</u>. It implicitly excludes antibodies which do not have the function(s)</p>
Function	1a) 1b): Explicitly included in the claim, binding to the epitope or target and, for 1b), the downstream activity Z	Not explicitly specified (not even the target is specified), but inherent functions (<i>i.e.</i> at least binding to a target) are associated with the structure	<p>3a) Explicitly defined as binding to the target; potentially other inherent effects associated with the structure</p> <p>3b), 3c): Explicitly defined as binding to the target and having the downstream activity Z; potentially other inherent effects associated with the structure</p>

28 T 617/07 Claim 20. *Monoclonal antibody, synthetic and biotechnological derivatives thereof, able to recognise and bind the high affinity tyrosine kinase receptor of NGF (Nerve Growth factor), named TrkA, and act as antagonist for the binding of NGF to TrkA, and which prevents the functional activation of TrkA by NGF, and characterised by at least one CDR selected from: light chain CDRs defined by aa 46-55 of SEQ ID No 2, aa 71-77 of SEQ ID No 2 and aa 110-119 of SEQ ID No 2 and heavy chain CDRs defined by aa 176-185 of SEQ ID No. 2, aa 200-216 of SEQ ID No 2 and aa 249-262 of SEQ ID No 2.*

29 T 617/07 see Reason 32 "...Therefore, because the skilled person knows how to achieve antibodies with the desired function on the basis of a particular known antibody, he/she is not in the situation of having to sort out non-functional variants in a burdensome manner."

Claim type	Antibody fully defined by function	Antibody fully defined by sequence	Antibody defined by sequence + function
Analysis under Art. 56	<p>1a) 1b): The structure is broadly defined as anything within the class of antibodies, <u>which has the specified function(s)</u>. Thus, this a subset of structures within the overall class. The focus of examination is likely to be on whether the function(s) <i>per se</i> is (or are) inventive, (e.g. because of the novelty of the target X and/or its downstream activity Z). However, the analysis should also consider whether there is something inventive about using the general structure (<i>i.e.</i> the class of antibodies) to achieve the specified function(s).</p>	<p>The structural non-obviousness analysis should have at its core an assessment of the structure – function (un)predictability of antibodies. The function is inherently associated with the structure and therefore it should be taken into account in the analysis of whether it would have been obvious for the skilled person to make an antibody with that <u>particular structure in order to achieve that particular function</u>.</p>	<p>One or more functions are required by these claims, and so the examination here cannot be limited to an analysis of the obviousness (or otherwise) of making the structure. Moreover, an assessment of the structure – function (un)predictability of antibodies should be taken into account. This assessment should be applied to <i>all</i> of the function(s) <i>i.e.</i> not only to those functions that are explicitly recited in 3a), 3b) or 3c), but also any inherent functions that are associated with the recited structures. The analysis should consider whether it would have been obvious to make an antibody with that <u>particular structure in order to achieve those particular functions</u>.</p>
Analysis under Art. 83	<p>1a) 1b) The focus of the analysis also, initially, goes to the function – the relevant characteristics of the method used to determine and define the function(s) should be disclosed. Ideally, the application should provide at least one actual example of an antibody that has the specified function(s). However, the structure has been defined broadly and it must be examined whether the claimed antibodies have been enabled across their breadth. The test is not simply: are antibodies in general routine to make, but rather, is there an ‘undue burden’ to make the <u>subset of antibodies which have the specified function(s)</u>? This is necessarily a fact specific analysis, which does not simply default to a reliance on ‘routine methods’. Instead there must be ‘serious doubts, substantiated by verifiable facts’ to support a finding of ‘undue burden’ and insufficient disclosure. It is not enough to say that a broad claim <i>per se</i> results in this finding.</p>	<p>The skilled person can reproduce the claimed antibody from the disclosure of the sequences alone.</p>	<p>3a) The skilled person can reproduce the claimed antibody from the disclosure of the sequences alone</p> <p>3b) 3c) The skilled person can reproduce sequences, within the terms of the claim. However, an assessment should also be made of whether the skilled person is able to select sequences that have the specified function(s) (or rather to exclude the non-functional variants falling under the structural definition). As a result, the relevant characteristics of the method used to determine and define the function(s) must be disclosed. Nevertheless, there must, be ‘serious doubts, substantiated by verifiable facts’, before a finding of insufficient disclosure can be made. This is a fact specific analysis. Ideally the application should provide at least one actual example of an antibody with the specified function(s).</p>

that subset. A consideration of the actual antibodies being claimed is important to prevent assessments made, for example, about an antibody simply for *in vitro* use, being overapplied to each and every functionally defined antibody claim.

Functionally defined claims: other issues

The above analysis focused on the issues relating to Art. 83 and Art. 56, but mention should also briefly be made of other issues relating to broad, functionally defined antibody claims. While using a broad definition may be advantageous to the patentee in relation to the scope of protection, such claims may lack clarity from an infringement perspective and thus lead to a lack of legal certainty for the public. The Guidelines now try to prevent this with the inclusion of the following requirement:

*"In addition, the functional definition must allow the skilled person to easily and unambiguously verify whether they are working inside or outside the scope of the claim. The claim should therefore normally include the relevant characteristics of the method used to determine and define the functional property"*³⁰

From the applicant's perspective, in order to include these relevant details in the claim itself, this then may lead to issues with Art. 123(2), a requirement that is strictly dealt with at the EPO.

Furthermore, if any other prior art antibody binding to the same target antigen is known, the Guidelines specify that it is to be assumed that it will have the same functional properties as the claimed antibody. The functionally defined claim is then presumed to lack novelty, unless proven otherwise by the applicant.³¹ This becomes a resource burden for the applicant to overturn this negative presumption with experimental data.

Therefore, it seems that functionally defined claims face other potential significant hurdles (novelty, clarity, Art. 123(2)) in order to be granted. Thus, for these claims which in any event face these difficulties, the impact of maintaining the (erroneous) belief that all the work in the field is routine – simply to satisfy what is, after all, the low hurdle of Art. 83 – must be carefully considered. It must also surely be weighed against

the serious consequence of regarding the entire field as routine as part of the Art. 56 analysis. Even narrowly defined sequence claims are then negatively impacted by the view that *"Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person."*

Conclusion

The mindset that making antibodies is routine work has a detrimental effect on the assessment of the inventive step of the products in this field. This article has therefore dissected this mindset, to show that it is not technically accurate when applied to the entire class of products, in particular to antibodies which have been engineered to meet the complex requirements of a therapeutic antibody. It has also challenged the mindset in relation to Art. 83. Specifically, the article has established that it is neither necessary, nor sufficient, to assert this view of 'routine methods' to satisfy the disclosure requirements for broad, functionally defined antibody claims. Abstract mindsets do not have a role under Art. 83, as this is necessarily a fact specific analysis to prevent claims being granted to mere *desiderata*. Therefore, it is also crucial to consider the actual subset of antibodies being claimed, as defined by the functional feature. Art. 83 is a low hurdle and allowing the view to perpetuate that making antibodies is routine, merely to (over)satisfy this requirement, must be balanced against the serious consequence of viewing the field in this way in relation to Art. 56.

The presumption of obviousness is still evident in the 2026 version of the Guidelines, and this inappropriate view of the field of antibody technology needs to be removed. Finally, it must be stressed that a characterisation of the field of antibody engineering as only involving 'routine methods' is not only technically inaccurate, but a position adverse to supporting further innovation in the biotech sector.

³⁰ EPO Guidelines G.II.6.1.3, para 4 (2026 version, essentially unchanged from requirement introduced in 2024 version).

³¹ EPO Guidelines G.II.6.1.3, para 3 (2026 version)



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M. Mackett (GB), Chair, **epi** Students and EQE Candidates Subcommittee, Professional Education Committee

By the time you read this, another EQE has taken place – the last for the old Papers A, B, C & D and the first for Paper M1 and M2 (albeit not in the format for 2027). We hope that those who sat the EQE in 2026, whether it be the new Papers F and M1 (as well as the interim Paper M2) or Papers A, B, C & D, will be successful.

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Our podcast 'INSIGHT **epi**' continues to offer fascinating insights into the world of European patent attorneys. In addition to current developments in the European patent system, we now also cover future-oriented topics.

In the last episode, Nina Ferara talks with Victor Arribas, Stream Leader for Diversity and Transformation at the EPO's Observatory on Patents and Technology and Marc Nevant, Chair of **epi**'s DEI Committee, about the report "Advancing Women in STEM", recently published by the EPO.

They discuss the participation of women in science, innovation and the patent system, including the role of women inventors, researchers and European patent attorneys. The conversation explores key findings of the report, looks at geographic and technological differences across Europe, the representation of women in leadership roles within the IP ecosystem, and possible measures to encourage greater participation of women in innovation and the patent profession.



You can find this new episode and all the others here:

<https://patentepi.org/r/podcast>

Stay up to date and tune in!

Thank you for listening – we look forward to bringing you many more exciting episodes!

Education and Training within the epi

Working Together Towards the EQE 2027

As the profession moves towards the implementation of the reformed European Qualifying Examination (EQE) in 2027, both candidates and training providers are entering a significant period of transition. With the introduction of the new examination papers M2, M3 and M4, alongside the already established Papers F and M1, the training landscape is changing considerably. This shift does not simply require an adaptation of learning methods; it also provides a timely opportunity to further strengthen and modernise the education of future European Patent Attorneys.

Development of New Training Materials for the EQE 2027

The Professional Education Committee (PEC), together with its subcommittees, is currently engaged in the preparation of new example examination papers for M2, M3 and M4. These will be made available from November 2026 and will complement the existing example papers already published for Papers F and M1.

The aim of this work is clear:

to offer candidates greater transparency regarding the examination format, to support them in becoming familiar with the new question styles, and to help them refine their approach to tackling the papers effectively.

In addition to the example papers, further educational resources are being developed, including structured answer guidelines, common pitfalls, and practical advice on methodology, time management and exam technique. By building a comprehensive suite of preparation tools, the epi continues to strengthen its role as a central provider of high-quality training for the new EQE system.

The epi Depends on the Support of its Members

The creation of training materials, webinars, seminars and tutoring programmes relies heavily on the expertise and engagement of European Patent Attorneys who contribute their time and knowledge. For this reason, the PEC and its Education and Training teams are continuously seeking members who are willing to assist in various capacities, such as:

- acting as speakers for webinars or in-person seminars,
- contributing as tutors in the development of new training materials,
- supporting candidates during tutoring sessions or consultation hours, and
- assisting in the drafting and reviewing of example examination papers or guidance documents.

With the revised EQE approaching and candidates seeking orientation and support, the need for committed contributors is greater than ever. Participation in these activities offers not only the chance to support the next generation of professionals, but also the opportunity to expand one's own teaching skills and to play an active role within the epi community.

Why Member Engagement Matters

Experience shows that well-prepared and well-supported candidates are likely to become engaged and capable members of the profession. Those who teach today help define the quality and strength of the profession tomorrow.

Moreover, contributing to the PEC's work provides valuable opportunities for professional exchange, insight into current developments in education and qualification, and the chance to help shape the future framework of training for European Patent Attorneys.

Interested in Contributing?

Members who would like to become involved in education and training activities are warmly invited to contact the PEC or the Communication, Event and Training (CET) team. Any form of contribution – whether large or small – plays an important role in strengthening the training environment for candidates preparing for the EQE 2027.



Give to Gain: Unlocking the Full Potential of Women and IP

N. Ferara (GB), Member of the DEI Committee

International Women's Day has been celebrated for 115 years. This year's theme is Give to Gain – a strong call to action for all of us. While there has been incredible progress on the road to equal opportunities, there is still a lot of work to do.

The European Patent Office (EPO) has just released a new report, "Advancing women in STEM" covering a breadth of data regarding each stage of the "leaky pipeline" that still haunts women in science, technology, engineering, and mathematics (STEM) disciplines. The report discusses the role of women in Intellectual Property (IP) from various perspectives – covering women inventors as well as women in IP professions – while highlighting geographical and disciplinary differences. You can read the full report here:

<https://patentepi.org/r/info-2601-19>

The numbers speak for themselves: women inventors still represent only about 13.8% of inventors at the EPO, despite making up roughly 21-22% of STEM roles. On a brighter note, about 29% of European Patent Attorneys are women (hey, we must be doing something right!). You can find more details about some of these numbers here:

<https://patentepi.org/r/info-2601-20>.

While the numbers are slowly rising, there are clearly still unseen barriers limiting the potential of women in these roles, particularly in leadership positions and among startup founders. We are missing out on contributions and innovation potential that could lead to greater prosperity for everyone.



Nina Ferara

In a recent episode of the Insight **epi** podcast, Marc Nevant and I sat down with Victor Arribas Martinez, Stream Leader for Diversity and Transformation, EPO Observatory on

Patents and Technology, and one of the authors of the latest report. We discussed the findings, compared them with what



the **epi** DEI Committee (formerly the D&I Working Group) chaired by Marc has uncovered, and explored what each of us can "give" to "gain" better opportunities and innovation outputs by supporting women throughout their professional journeys. You can listen to the podcast here:

<https://patentepi.org/r/podcast>

We invite other **epi** members to share their thoughts on how we can #GivetoGain. Please share your views in the comments, write to the **epi** DEI Committee, or join the conversation on LinkedIn!

Starting the conversation is the first step toward meaningful impact. Tell us: what does Give to Gain mean to you?



Committee Reports

Report of the Disciplinary Committee

P. Rosenich (LI), Chair

The Disciplinary Committee (DC) hereby informs you of the key positions which it has taken – mainly through its Chair – in connection with the planned reform of the disciplinary system, and which have been set out in letters, e-mails, forum contributions and orally at Council 101e.

1. Basic position: reform yes, but with clearly recognisable added value

The DC does not reject a reform of the disciplinary system. On the contrary, it supports careful modernisation, in particular where significant weaknesses have emerged in practice (above all at the level of Disciplinary Board proceedings).

At the same time, the DC takes the view that a completely new first-instance system should only be introduced if it can be expected to function significantly better than the existing system – not if it is merely “different”. In this sense, the DC also supports the option of a “small” reform of the current system, focussing specifically on eliminating clearly identified deficiencies rather than undertaking a comprehensive reorganisation that leaves many questions open.

2. Independence and self-governance of the disciplinary body

The DC has repeatedly emphasised that DC/DB are not an administrative department of **epi**, but a court-like body responsible for professional supervision. From this, the DC derives several principles:

- The disciplinary body should be functionally independent, i.e. its decisions should not appear to be driven by day-to-day political majorities or internal association politics.
- A central element of this independence is that, once its members have been elected by Council, the body elects its own Chair. This corresponds to common practice in many professional and disciplinary courts.
- The DC should be able to draw up its own Additional Rules of Procedure; legal coherence is ensured by embedding these rules in the higher-level framework and by cooperation with the EPO disciplinary instances.

- The composition of the DC from **epi** members from all EPC states has proved its worth: the members are familiar with the professional realities in different countries and can thus contribute to a uniform and, at the same time, well-informed application of the rules.

Against this background, the DC views certain elements of the reform proposals critically, in particular those which:

- expressly assign the election of the DC Chair and Deputy Chair to Council,
- shift decisions on anonymous complaints and the shaping of key procedural issues more strongly to the Presidium/Board and Council, and
- systematically provide for the use of non-**epi** members as legally qualified members in the DC, although the DC has so far worked entirely with **epi** members and the external expert did not criticise this structure.

From the DC's perspective, these elements tend to weaken, rather than strengthen, the self-governance and perceived independence of the disciplinary body.

3. Specific substantive concerns regarding the current reform package (examples)

From the "list of weaknesses" submitted by the DC, a few points can be highlighted by way of example:

Election and dependence of the Chair

The draft links the appointment of the DC Chair even more closely to Council majorities. The DC is concerned that the position of Chair will thereby move closer to a "political" office, instead of being perceived as an expression of internal, judge-like self-organisation.



Paul Rosenich

Handling of anonymous complaints

The DC is in favour of not excluding anonymous complaints across the board, but – like other complaints – examining them on the basis of the facts and evidence presented. Responsibility for this should lie with the first instance of the disciplinary system, with

clear deadlines and procedural rules. In the DC's view, the current draft leaves too little room for appropriate and consistent handling of such complaints by the disciplinary body itself.

Design and practical operability of the new system

In several respects it remains unclear to the DC how the proposed system is supposed to work in practice. There is con-

cern that a formally "modernised" system could in fact prove more cumbersome or less predictable than the current one, in that structures from the existing DB – which there have contributed to lengthy proceedings – are now to be transferred into the new DC/DB.

Transparency and comprehensibility for the members

The reform package is complex, spread over several sets of rules and not always available in a consolidated, easily understandable form. The DC considers it necessary that the final amendments be presented in a clear, linguistically checked and consolidated version before the profession can vote on them and then has to live with their consequences.

4. Working methods and involvement of professional expertise

The DC has repeatedly pointed out that active members of the disciplinary bodies have so far been involved in the working structures only to a limited extent:

- The DC and its members were admitted to one online meeting and were able to express their views there,
- but they were not included, as experienced practitioners, in the decisive negotiation and decision-making rounds on the future structure of the system.

In the DC's view, it would be more sensible to set up a broadly based working group, with representatives of both "sides" and the participation of experienced DC members, in order to develop a proposal capable of achieving a broad consensus within Council.

5. DC recommendation for the way forward

In summary, the DC recommended – but council C101e decided in its second vote on the same topic against:

- not to adopt the present reform package, in its current form, as the final solution;
- instead, to remedy the clearly identified shortcomings of the existing system in a targeted manner in the short term ("small reform") and/or
- in parallel, and with sufficient time and a transparent composition, to work on an improved, consensus-oriented overall draft which preserves the independence and self-governance of the disciplinary body and whose practical added value compared with the status quo is clearly recognisable.

The DC remain now in function until the Dubrovnik Council Meeting. There a new DC will be elected and – in case

that the Admin Council of the EPOrg adopts the proposal for amendment – in January 2027 a new DC with the name Disciplinary Board of **epi** will be installed. The current DC is disappointed about the outcome of this hasty “reform process”, as its valuable input was only partially considered by the reform proponents.

Many organisational matters are still open to be defined for the new DB of the **epi** and more to be reported about this process can be expected in the near future.

Until then the Disciplinary Committee stays on duty and treats all complaints with the same quality and interest as in the last decades.

Report of the Committees Election Committee

A Meaningful New Beginning for the CEC

C. Mohr (DE), Chair

Every now and then, the **epi** offers moments that remind us why we serve: moments filled with teamwork, openness, and the genuine commitment that defines our community.

Our inaugural meeting of the new **Committees Election Committee (CEC)** was one of those moments.

When Adriaan, Zeljka, and I met for the first time as the newly elected CEC, we immediately experienced the warmth and professionalism of the people who support the Institute so tirelessly behind the scenes.



From the outset, the Legal Advisor and the responsible committee coordinators from the **epi** Secretariat brought structure, clarity, and deep knowledge to the table. But just as importantly, they created an atmosphere of kindness and trust that made collaboration feel both easy and natural.



Christian Mohr

This purpose matters.

Elections are not merely procedures; they are the democratic heartbeat of our Institute. They require diligence, transparency, and a shared commitment to doing things right. This is the approach that Zeljka, Adriaan, and I are determined to uphold as we begin our mandate.

The start of our work has been exceptionally encouraging. The Secretariat’s outstanding support gives us a strong foundation and the confidence that we can navigate even complex situations as a team. It is reassuring to know that we walk this path not alone, but with committed partners at our side.

Looking ahead, we aim to contribute to a strong, transparent, and vibrant **epi** – one where elections reflect both our rules and the values that guide us.

My heartfelt thanks go to Zeljka Brkic, Adriaan van Kooij, and especially to the committee coordinators and the Legal Advisor from the **epi** Secretariat for making this beginning not only smooth, but truly inspiring.

Report of the Biotechnological Committee

S. Wright (GB), Chair, B. Taravella (FR), Vice-Chair and M. Kawczyńska (PL), Secretary

Below is a summary of the activity of the Biotechnology Committee (BC) in 2025:

1. Executive Summary

Throughout 2025, the **epi** Biotechnology Committee engaged intensively with the European Patent Office (EPO), WIPO, the European Commission, and industry stakeholders to address key policy areas in biotechnology patenting. The Committee's primary focus remained on:

- Reforming antibody patentability practices and the problematic Guidelines section G-II, 6.2.
- Addressing issues with WIPO Standard ST.26 sequence listings.
- Monitoring and influencing EU plant-related regulatory developments, including NGT plants.
- Expanding training and educational outreach within **epi**.

This report consolidates all activities from January to December 2025.

2. Patentability of Antibodies – Year in Review

2.1 Early-year developments (Q1 2025)

The BC reiterated concerns raised during late-2024 meetings with DG1 that the EPO applied a too systematic, rigid approach to inventive step for antibodies.

EPO indicated examiners would be reminded to conduct case-by-case assessments. BC noted that internal EPO practices seemed to rely on unwritten standards and requested disclosure of any such internal guidance. Several articles by Tamaris Bucher published in **epi Information** further criticized the misleading interpretation of “surprising technical effect” case law and highlighted the unpredictability of antibody structure–function relationships.

The Committee recognized the need for systemic reform and prepared to escalate concerns through public consultation and coordinated stakeholder action.

2.2 Q2 2025 – Consolidation of analysis and external engagement

- March 2025: At the Krakow BC meeting, a dedicated working group was formed to draft formal proposals for Guideline changes.
- The BC collaborated with EPPC, EFPIA, and Business-Europe in the run-up to the EPO Guidelines consultation (deadline 7 April 2025).
- The BC's proposal: complete deletion of Guidelines section G-II, 6.2 due to its legal and scientific deficiencies.
- Despite these coordinated efforts, EPO maintained resistance, asserting that concerns reflected “misunderstandings,” and indicated that a technical meeting would be necessary for deeper discussion

2.3 Q3 2025 – Escalation & structured dialogue with EPO

The year's turning point came with a series of exchanges: April 2025 – BC submits major comments to SACEPO WPG. The BC highlighted:

- The unlawful presumption of non-inventiveness for antibodies.
- Misuse of case law (over-reliance on T 187/04, T 605/14; neglect of T 67/11, T 1171/18).
- Internal inconsistencies regarding sequence requirements.
- Lack of scientific accuracy in evaluating antibody development complexity.

May 8, 2025 – SACEPO WPG meeting. BC presented its concerns, leading EPO to agree to a dedicated technical meeting.

July 24, 2025 – Dedicated EPO–BC meeting. EPO acknowledged:

- Work in progress to eliminate negative presumptions from Guidelines.
- The need to review examination practices, which were stricter than Guidelines.
- Shared 14 foundational decisions shaping their practice.

A follow-up meeting was scheduled for October.

2.4 Year-end developments (October–December 2025)

October 13, 2025 – Bilateral BC/DG1 meeting. The BC completed an in-depth assessment of 15 EPO decisions, concluding they do not support the draft 2026 Guidelines' restrictive approach. Key conclusions:

- No case law supports a presumption that antibodies to known antigens lack inventive step.
- No legal basis for limiting assessment to four sub-tests.
- Many cited cases involve in-vitro mouse antibodies, not therapeutics.

BC recommended comprehensive revision of the 2026 Guidelines.

October 14, 2025 – SACEPO WPG meeting (The Hague). BC emphasized issues with the terminology (“surprising/unexpected”) and with antibody-specific conditional structures. EPO and BC agreed that amendments are needed, though not full deletion of section G-II, 6.2.

Planned 2026–2027 actions

- Spring 2026: In-depth case-law meeting (already scheduled on 26 May 2026).
- Target: inclusion in 2027 Guidelines.

3. SEQ Listings & WIPO ST.26

Sequence listing issues were a continuous topic throughout 2025, starting with the November 2024 DG1 meeting and continuing through Q1, Q2, and year-end.

3.1 Q1–Q2 2025 – Early activities

Key issues identified:

- ST.26 software difficulties and insufficient EPO support (FAQ gaps, no help desk).
- **epi** requested early access to the 2025 ST.26 tool update.
- BC coordinated **epi**'s contribution to the WIPO survey (feedback until 31 March 2025).

The BC also engaged with WIPO experts, including Emma Francis, and participated in the PCT Working Group. A position paper was assigned (Benjamin) focusing on issues with large sequence listings.

3.2 Q3–Q4 2025 Developments

EPO announced a new Presidential Decision effective 1 January 2026, mandating XML/ST.26 and clarifying accepted filing channels.

BC raised concerns:

- Burdensome correction procedure (added-matter declarations + fees).
- Inconsistency between EPO and UK IPO practice for divisionals.
- Need for flexibility for short sequences.

The BC confirmed willingness to assist EPO in shaping implementation.

4. Plant-Related Patent Developments (NGT & EPC Practice)

4.1 Q1–Q2 2025 – EU NGT regulation work

The BC became actively involved in developing **epi**'s response to the NGT Plants Regulation:

- Reviewed the Position Paper extensively in March 2025.
- Raised concerns about the draft's assumptions (“equitable conditions”, impact on breeder choices).
- Finalized the **epi** Position Paper and launched a communication strategy targeted at national authorities.



Simon Wright



Brigitte Taravella



Marta Kawczyńska

4.2 October 2025 – EPC-related plant discussions with DG1

BC raised major concerns:

- EU expert draft report suggesting “no patents = fewer worries for farmers”.
- Very low grant rate + high refusals in plant cases due to strict EPO positions.
- Criticism of “conceivable natural process” disclaimers considered speculative and discriminatory.

BC proposed the use of disclaimers for essentially biological processes as a compromise solution to avoid outright bans.

5. WIPO – Genetic Resources / Traditional Knowledge

Introduced in the October 2025 BC–DG1 meeting:

- Principle: disclose source of genetic material without impact on validity.
- BC expressed willingness to join future discussions once EPO–WIPO internal deliberations progress.

6. Education, Training & Outreach

2025 saw robust educational activity:

- 20 November 2024 webinar on biotech & life-science legal matters, with more specialized sessions planned.
- 28 May 2025 webinar on antibody patentability, with speakers Mattsson, Jaenichen, and Wright (moderator).
- BC contributed to podcasts, articles, and WIPO engagement to raise awareness of biotech patenting challenges.

7. Committee Composition & Meetings

New Members: Tamaris Bucher (CH) joined as Associate Member (Q2 2025).

Key Committee Meetings in 2025

- March 13–14 (Krakow): BC + EPPC; divisional applications, G2/24, exam quality.
- May–July: multiple meetings with EPO on antibody issues.
- October 13–14 (The Hague): major DG1 and SACEPO sessions.

8. Conclusions and Outlook for 2026

In 2025, the BC significantly strengthened its influence over biotechnology-related examination practice at the EPO. Notably:

- Antibody patentability reform is on track for multi-stage revision through 2026–2027.
- ST.26 implementation remains a top-priority technical topic.
- Plant-related patentability will remain volatile due to political and EPC-practice pressures.

The BC will continue to lead expert-level dialogue with the EPO and WIPO and will expand training and stakeholder engagement in 2026.

Call for Contributions on behalf of the European Patent Practice Working Group on Guidelines

Do you want to shape the future of the EPO Guidelines?

Every year, the European Patent Office revises its EPC Guidelines, PCT-EPO Guidelines, and UP Guidelines — and every year, European Patent system users have the opportunity to influence that process.

As part of the revision cycle, epi is collecting feedback from its members to submit as a consolidated response. If you have suggestions for improvement or comments on the draft proposals, now is the time to share them.

Key dates to keep in mind:

- epi internal deadline: 22 March 2026
- EPO feedback window closes: 3 April 2026

Review the draft guidelines provided on the bottom of the page for each of the guidelines: EPC Guidelines¹, PCT-EPO Guidelines² and UP Guidelines³.

Contribute to the epi feedback:

- Feedback on EPC Guidelines⁴
- Feedback on PCT-EPO Guidelines⁵
- Feedback on UP Guidelines⁶

This is a meaningful opportunity to help shape the tools we all work with daily. We are encouraging epi members to provide feedback via the surveys by 22 March 2026.

1 <https://www.epo.org/en/legal/guidelines-epc>

2 <https://www.epo.org/en/legal/guidelines-pct>

3 <https://www.epo.org/en/legal/guidelines-up>

4 https://www.surveymonkey.com/r/EPC_guidelines

5 https://www.surveymonkey.com/r/PCT-EPO_guidelines

6 https://www.surveymonkey.com/r/UP_guidelines



General Information

epi Board

Präsident / President / Président

CH – THOMSEN Peter

Vize-Präsident(in) / Vice-Presidents / Vice-Président(es)

CZ – HARTVICOVA Katerina

NL – REIJNS Tiemen

Generalsekretär / Secretary General / Secrétaire Général

PL – AUGUSTYNIAK Magdalena

Stellvertretender Generalsekretär

Deputy Secretary General / Secrétaire Général Adjoint

BE – DE CLERCQ Ann

Schatzmeister / Treasurer / Trésorier

HU – SZENTPÉTERI Zsolt

Stellvertretender Schatzmeister / Deputy Treasurer

Trésorier Adjoint

DE – WINTER Andreas

Next Board and Council Meetings

Board Meetings

138th Board Meeting in Munich/hybrid on 20 March 2026

139th Board Meeting in Munich/hybrid on 16 September 2026

Council Meetings

102nd Council Meeting in Dubrovnik, Croatia on 11 and 12 May 2026

103rd Council Meeting in Bratislava, Slovakia on 21 November 2026

104th Council Meeting in Reykjavik, Iceland on 24 April 2027

By-elections, Elections of the Auditors, Board and Disciplinary Committee

Notice

epl members wishing to contribute to the work of **epl** can be members of one or more **epl** Committees. At the 102nd Council meeting, there will be By-elections to fill vacant positions in several Committees.

epl members wishing to stand for election must submit their completed nomination form before the 102nd Council meeting scheduled for 11 – 12 May 2026. If a member wishes to stand as a candidate for more than one Committee, they must submit a completed nomination form for each Committee.

The By-Elections will be opened on 26 March 2026 on the **epl** website.

Additionally, elections of the Auditors, Board and Disciplinary Committee will take place at C102.

Mitteilung

epl Mitglieder, die einen Beitrag zur Arbeit des **epl** leisten möchten, können Mitglied in einem oder mehreren **epl** Ausschüssen werden. Auf der 102. Ratssitzung wird es Nachwahlen geben, um freie Positionen in mehreren Ausschüssen zu besetzen.

epl Mitglieder, die sich zur Wahl stellen möchten, müssen ihr ausgefülltes Nominierungsformular vor der 102. Ratssitzung am 11.-12.Mai 2026 einreichen. Wenn ein Mitglied für mehr als einen Ausschuss kandidieren möchte, muss es für jeden Ausschuss ein ausgefülltes Nominierungsformular einreichen.

Die Nachwahlen werden am 26.März 2026 auf der **epl** Webseite geöffnet.

Des Weiteren finden während C102 die Wahlen der Rechnungsprüfer, des Vorstandes und des Disziplinarrats statt.

Communication

Les membres de l'**epl** qui souhaitent contribuer au travail de l'**epl** peuvent être membres d'un ou de plusieurs commissions de l'**epl**. Lors de la 102^{ème} réunion du Conseil, des élections intermédiaires seront organisées afin de pourvoir les postes vacants au sein de plusieurs commissions.

Les membres de l'**epl** qui souhaitent se présenter aux élections doivent soumettre leur formulaire de candidature dûment rempli avant la 100^e réunion du Conseil prévue le 11-12 mai 2026. Si un membre souhaite se porter candidat pour plus d'une commission, il doit soumettre un formulaire de candidature complété pour chaque commission.

Les élections intermédiaires seront ouvertes le 26 mars 2026 sur le site web de l'**epl**.

Également les élections des Commissaires aux comptes, du Bureau et de la Commission de Discipline auront lieu lors du C102.

Disciplinary Bodies, Committees and Auditors

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

Disziplinarrat (epi)	Disciplinary Committee (epi)	Commission de Discipline (epi)
AL – NIKA Melina	GB – GRAY John	MT – SANSONE Luigi A.
AT – POTH Wolfgang ^{oo}	GR – TSIMIKALIS Athanasios	NL – VAN LOOIJENGOED Ferry A.T.
BE – DEBLED Thierry	HR – MARSIC Natasa	NO – THRANE Dag
BG – TSVETKOV Atanas	HU – KOVÁRI Zoltán	PL – ROGOZINSKA Alicja
CH – REUTELER Raymond	IE – SMYTH Shane	RO – PUSCASU Dan
CY – ROUSOUNIDOU Vasiliki	IS – FRIDRIKSSON Einar Karl	RS – BOGDANOVIC Dejan
CZ – FISCHER Michael	IT – MAURO Marina Eliana	SE – KARLSTRÖM Lennart
DE – FRÖHLING Werner ^o	LI – ROSENICH Paul*	SI – JAPELJ Bostjan
DK – KUHN Oliver Wolfgang	LT – GERASIMOVIC Jelena	SK – ČECHVALA Radovan
EE – KAULER Urmas	LU – KIHN Pierre	SM – MARTINI Riccardo
ES – STIEBE Lars Magnus	LV – SMIRNOV Alexander	TR – YURTSEVEN Tuna**
FI – WESTERHOLM Christian	MC – AMIRA Sami	MK – DAMJANSKI Vanco
FR – AJDARI Emmanuel	ME – LUTOVAC Vuk	

Disziplinarausschuss (EPA/epi)	Disciplinary Board (EPO/epi)	Conseil de Discipline (OEB/epi)
epi Mitglieder	epi Members	Membres de l'epi
DE – MÜLLER Wolfram	FR – MAROLLÉ Patrick Pierre Pascal	IS – HARDARSON Gunnar Örn
DE – VOGELANG-WENKE Heike		

Beschwerdekammer in Disziplinarangelegenheiten (EPA/epi)	Disciplinary Board of Appeal (EPO/epi)	Chambre de Recours en Matière Disciplinaire (OEB/epi)
epi Mitglieder	epi Members	Membres de l'epi
CH – WALSER Peter	FR – GENDRAUD Pierre H.	NL – BIJVANK Koen
DE – REBBEREH Cornelia	IT – COLOMBO Stefano	TR – ARKAN Selda
DK – FREDERIKSEN Jakob Pade		

Ausschuss für Standesregeln	Professional Conduct Committee	Commission de Conduite Professionnelle
Ordentliche Mitglieder	Full Members	Membres titulaires
AL – SHOMO Vjollca	GB – POWELL Timothy John	NL – BOTTEMA Johan Jan
AT – PREHOFER Boris André	GR – KOSTI Vasiliki	NO – HJELSVOLD Bodil Merete Sollie
BE – VAN DEN BOECK Wim	HR – DLACIC Albina	PL – DARGIEWICZ Joanna
BG – BENATOV Samuil Gabriel	HU – SOVARI Miklos	PT – ARAÚJO VIEIRA Sílvia Cristina
CH – KÖRNER Thomas Ottmar	IE – KELLY Donal Morgan	RO – TEODORESCU Mihaela
CY – CURLEY Donnacha John	IT – CHECCACCI Giorgio**	RS – Brkic Zeljka
DE – STORK Martina*	LI – KÜNSCH Joachim	SE – BJERNDÉLL Per Ingvar
ES – JORDÁ PETERSEN Santiago	LT – PETNIUNAITE Jurga	SI – LEYDER Francis ^o
FI – SAHLIN Jonna Elisabeth	MC – THACH Tum	SM – AGAZZANI Giampaolo
FR – DELORME Nicolas	MK – KJOSESKA Marija	TR – CAYLI Hülya
Stellvertreter	Substitutes	Suppléants
BE – VAN MINNEBRUGGEN Ewan Benito Agnes	FI – BOIJE AF GENNÄS Per Gustav	PL – CHIMIANK Monika
BG – NIKOLOV Vladislav Zdravkov	FR – TARAVELLA Brigittes	PT – DINIS ABRANTES Jorge Ricardo
CH – HOFFMANN Jürgen Gerhard	GB – DUNN Paul Edward	RO – GEORGESCU Cristina
DE – MOHR Christian	IE – O'CONNOR Cornelius John	SE – HOLMBERG-SCHWINDT Tor Martin
ES – SATURIO CARRASCO Pedro Javier	IT – MORABITO Sara	SM – MAROSCIA Antonio
	LI – BAZZON Andreas	TR – AKSOY Okan Alper
	NO – Read Howard Graham	

*Chair/ **Secretary ^oVice-Chair / ^{oo}Vice-Secretary

Ausschuss für Europäische Patent Praxis	European Patent Practice Committee	Commission pour la Pratique du Brevet Européen
AL – PANIDHA Ela	GB – MERCER Christopher Paul*	ME – LUTOVAC Vuk
AT – DONATELLO Daniele	GR – SAMOUILIDIS Emmanouil	MK – FILIPOV Gjorgji
BE – MICHALÍK Andrej	HR – HADZIJA Tomislav	NL – VAN WOUDEBERG Roel
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