

EPC Guidelines – 29th SACEPO WP/G meeting 8 May 2025

Consultation results

Comments marked in **green** were discussed during the meeting.

The Office’s replies to comments that are not marked in colour were communicated to the members in writing prior to the meeting.

#	General remarks	Comment	Suggestion	Office replies / Consultation results
1	Cover page	The cover page of the prepublication still indicated “March 2025, while it should have read “April 2025”	Please be consistent and correct in naming of documents and indications of versions.	<p>The Office thanked the respondent for the comment. The fact that the date on the title page of the pre-published version of the EPC GL 2025 had not been changed had been noticed. All these kinds of errors were corrected before publication of the Guidelines on 1 April. The cover is only published for the version coming into force, not the pre-publication version.</p> <p>There were no further comments from SACEPO WP/G members.</p>
2	Pre-publication	There will/may be differences between the prepublished draft versions of all 3 Guidelines	Please provide the committee members with a track-change version showing all differences (substantial as well as minor/typos)	<p>The Office thanked the respondent for the comment and explained that there are no differences in content between the pre-publication version of the Guidelines and the version coming into force on 1 April. Some formatting issues may be corrected, such as typos, spaces or margins, but the content will remain the same in both versions. Additionally, a list of all modifications, including editorial changes, is provided for both versions. This list is updated with new corrections made between pre-publication and publication, if any modifications are necessary during this period. To show readers what changes have been made, the pre-publication version and the version coming into force are published in two formats: a clean version and one with track changes. Therefore there is no need to prepare</p>

				<p>a separate list of differences between the 1 February version and the 1 April version. One member pointed out that there was indeed one major change in the PCT-EPO Guidelines, Part B-II, 1.1. The same practice was however, not also updated in the PCT-EPO Guidelines, Part C-II, 2. The Office was requested to do so for the Guidelines 2026.</p> <p>There were no further comments from SACEPO WP/G members.</p>
3	--	<p>General comment to the GL style:</p> <p>T 1741/22 refused to follow the Guidelines:</p> <p>“2.3.7 As to the Guidelines for Examination in the EPO (in its applicable version of March 2022 and also in its current version of March 2024), section G-II, 3.3, which relates to the technical contribution of mathematical methods, lists "providing a medical diagnosis by an automated system processing physiological measurements" among "examples of technical contributions of a mathematical method". As providing a "medical diagnosis" - whether done by a physician or by an automated system - is devoid of any technical character (see e.g. G 1/04, Reasons 5.3 and 6.3), this example is clearly erroneous. As there is no further explanation, let alone a reference to any case law, the board sees no reason to speculate on how the Guidelines came up with this example (cf. Article 20(2) RPBA).”</p>	<p>Please keep/add/reintroduce case law references in the Guidelines.</p>	<p>The Office thanked the respondent for the comment and takes note of the wish to continue providing case law references in the Guidelines. In general, while the Boards of Appeal (BoA) can take the Guidelines into account when reaching their decisions, they are not bound by them. Similarly, a decision taken by a Board has a binding effect only in the individual case underlying that decision. The Office also notes that the provision of case law references to earlier decisions will not guarantee that such decisions are followed by the BoA in future cases.</p> <p>More generally, the reason for not systematically referencing T decisions in the Guidelines is that they provide general guidance based on established case law for examiners to follow. Not referencing specific BoA decisions reflected in the Guidelines helps avoid misunderstandings, as the facts underlying individual cases often differ.</p> <p>One member made the point that the BoA will ignore any reference to the Guidelines in an argumentation if the practice outlined in them is not substantiated by the decision on which the practice is based.</p>

		<p>So, the absence of case law references results in legal uncertainty for parties and third parties: one does not know whether examples given in the GL will be accepted by the Boards.</p>		<p>The Office clarified that examples in the Guidelines are based on case law. References to individual decisions too often result in discussions focusing on the facts underlying the individual cases, rather than on the general principles expressed in the decisions. The Guidelines can only give general guidance. The example mentioned was based on decision G 1/04 from the Enlarged Board of Appeal.</p> <p>There were no further comments from SACEPO WP/G members.</p>
4	--	<p>I am sending a more complete feedback than the one I had previously sent via the contact form in November 2024 on the use of the word "unitary" in the Guidelines, this time taking into account the previews of the upcoming 2025 Guidelines.</p> <p>I have noticed that at some places in the upcoming 2025 guidelines, the word "unitary" was used, but not to refer to the Unitary Patent; I believe this use could create confusion for the reader who may think this refers in some way to the Unitary Patent (especially since the Unitary Patent is covered in the same 'Guidelines for Examination' where this same "unitary" word is used to refer to completely different things).</p> <p>While I do understand that the confusion would not exist if the reader is seasoned in EPO procedures, many readers unfamiliar with the EPO procedures (e.g., paralegals or patent engineers who begin their formation, inventors, etc.) may be unnecessarily</p>	<p>I suggest the EPO uses another word than "unitary" (e.g., cojoined, joint, amalgamated, associated, etc.) in instances where it does not refer to the Unitary Patent, or at least replaces "unitary" in as many of the current instances as possible, in order to avoid needless confusion for the reader.</p> <p>If the word "unitary" cannot be changed when it comes to designate the unity of an invention (even though I suggest this use be changed), I strongly advise that the word "unitary" be at least removed when it refers to the whole of a procedural act, i.e. in Guidelines for Examination, Part E, Ch. VIII, 2., and 3.1.3.</p>	<p>See comment 2.</p> <p>The Office took note of this comment. However, it seemed to be based on a misunderstanding.</p> <p>First, the Office would like to clarify that the Unitary Patent proceedings are not dealt with in the EPC Guidelines but in a separate publication.</p> <p>Second, the term "unitary" is a standing term used in the context of "unity of invention" (see Art. 82 EPC, Rules 44, 64 and 164 EPC), which by its nature cannot be confused with unitary patent protection. It is commonly used inside and outside the Office, as well as in numerous decisions of the Boards of Appeal. It is believed a change in terminology would create more uncertainty and is therefore unnecessary.</p> <p>The same applies to Part E, where the use of "unitary" to qualify the nature of a time limit in the context of legal remedies cannot be associated with the Unitary Patent.</p>

		<p>confused by the use of this specific word.</p> <p>I have noted the confusing use of "unitary" in the following sections (I tried to be exhaustive).</p> <p>1) 'Guidelines for Examination in the European Patent Office':</p> <p>---Part B, Ch. I: 2., 2.2.1 (including the title of the section itself), and 2.2.2 (including the title of the section itself)</p> <p>---Part B, Ch. VII: 1.1, 1.2, and 2.3</p> <p>---Part B, Ch. IX: 5.</p> <p>---Part C, Ch. III: 3.1, and 3.2.1</p> <p>---Part E, Ch. VIII: 2., and 3.1.3</p> <p>---Part F, Ch. V, 3.2, and 4.1</p> <p>---Part H, Ch. II, 6.1, and 6.2</p> <p>---Part H, Ch. IV, 4.1.2</p> <p>2) 'Guidelines for Search and Examination at the European Patent Office as PCT Authority'</p> <p>--Part B, Ch. VII, 6.3, and 7.2</p> <p>--Part B, Ch. XI, 3.4</p> <p>--Part C, Ch. IV, 2.2</p> <p>--Part C, Ch. V, 1., and 4.1</p> <p>--Part C, Ch. VIII, 3.</p>		<p>In view of the above, any confusion with proceedings before the Unitary Patent Division can be excluded.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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#	Part	Chapt	Section	Comment	Suggested improvement	Office replies / Consultation results
	GP					
5	GP	4		Reference to AI tools by applicants in this section was discussed in the previous SACEPO. Equally when AI tools are used by the Office (for example in classification)the responsibility lies with the Office and not with the tools.		<p>The Office may consider adding a general clarification. In the context of pre-classification it is established practice that any inaccurate (pre)-classification is noticed very soon and the file re-classified accordingly. The topic "classification" is also already covered in Part B-V, 2, I particular B-V, 2.1. Presently, any pre-classification is checked and any necessary re-classification based on human intervention. The same applies to IPC and CPC classification (B-V, 3.4 and B-V, 4).</p> <p>There were no further comments from SACEPO WP/G members.</p>
	A					
6	A	II	1.1.2	If a fax is received does the Office sends a note to the sender, indicating that applications/documents are not filed by fax?	Amend “Applications filed by fax with the EPO by fax are therefore deemed not to have been received” by “Applications sent to the EPO by fax are therefore deemed not to have been received”	<p>The Office agreed to the suggestion.</p> <p>Regarding the question in the comment, please see the consultation results of the SACEPO WP/G meeting on 9 October 2024, comments 24, 60 and 62. As stated therein, the Office considers it highly unlikely that any attempted fax transmission would be successful. However, if anything was received via fax, the applicant would be informed that the submission was considered invalid.</p> <p>There were no further comments from SACEPO WP/G members.</p>
7	A	II	5.1, 5.2	The reference to Rule 56a in 5.1 and 5.2 should be deleted, since the provisions of Rule 56a are addressed in section 6. The reference in 5.4.2 should remain.		<p>The Office did not agree.</p> <p>The communication sent by the Receiving Section referred to in these sections covers both Rules. In reply thereto the applicant may proceed under either Rule. This is why Rule 56a must be</p>

						mentioned in A-II, 5 and Rule 56 EPC in Part A-II, 6 when it is referred to this communication. Both sections contain corresponding cross references. There were no further comments from SACEPO WP/G members.
8	A	III	4.2.1	2 nd paragraph: What if the applicant has dual nationality. Does she/he have to indicate both?	Clarify what is the applicant has dual nationality (or even more than 2)	The Office explained that the Guidelines already clearly state that "applicants must always indicate their nationality or nationalities". This makes it clear that nationality must be indicated. In the online filing tools, one may be indicated in the corresponding section/box and any further nationalities can be added e.g. in the annotation field. One member explicitly requested that Office add general information. The Office pointed out that this information is already available in the Notes to forms EPA/EPO/OEB 1001 and 1200 . There were no further comments from SACEPO WP/G members.
9	A	III	5.6	Insertion noted.		Thank you.
10	A	III	6.7	A-III,6.7 has been divided into two. The information about EPO sending a communication with a 2 mo period for reply if no priority certificate is sent in time, is now under 6.7.2, i.e. electronic retrieval (second last §). Is this on purpose? I presume it still applies even in the case the priority certificate is not sent at all.	Shift the second last § in 6.7.2 to 6.7 or make the two last § the subject of 6.7.3.	The Office agreed to the proposal, and will likely create a new subsection 6.7.3. There were no further comments from SACEPO WP/G members.
11	A	III	11.2.4	See comment on A-III, 4.2.1 above	Clarify what is the applicant has dual nationality (or even more than 2)	See comment 8.
12	A	III	12	The difference between extension and validation states are not mentioned	Refer to any difference between extension and validation states.	The Office pointed out that the required information is already given in the first paragraph of A-III, 12.1. <i>".. patents can be extended to European states having an extension agreement with the EPO..."</i>

						<p><i>the same applies to requests for validation in European or non-European states having a validation agreement ..."</i></p> <p>The Guidelines provide guidance in respect of the practice in proceedings before the EPO in accordance with the European Patent Convention and its Implementing Regulations. The Office therefore re-affirmed that it does not consider it necessary to add any information going beyond the above definition, i.e. which is not considered relevant for proceedings before the EPO. Any additional general information concerning agreements between the EPO and non-contracting states can be retrieved from epo.org.</p> <p>One member asked the Office to look into the matter, in particular concerning possible differences in post-grant proceedings, and re-consider its position.</p> <p>There were no further comments from SACEPO WP/G members.</p>
13	A	III	12.1, 12.2	<p>GL (2024) A-III, 12.1 seems to indicate that re-establishment is not possible where the extension or validation fee has not been paid within the applicable time limit indicated and also the grace period for the extension fee was missed, as it says:</p> <p>GL (2024) A-III, 12.1 "The provisions of the EPC, its Implementing Regulations and the Rules relating to Fees do not apply to the extension and validation systems unless and only to the extent that those provisions are referred to by the applicable national law. Thus, the EPC provisions concerning applicants' legal remedies and appeals do not apply in respect of any action taken by the EPO under the extension or validation procedure (see J 14/00, J</p>	<p>It is suggested to clarify A-III, 12.1 to: "Thus, the EPC provisions concerning applicants' legal remedies and appeals do not apply in respect of any action taken by the EPO under the extension or validation procedure (see J 14/00, J 4/05 and J 22/10), e.g. where the extension or validation fee has not been paid within the applicable time limit indicated (see A-III, 12.2 <u>for details and exceptions</u>)."</p> <p>And to clarify the last paragraph of A-III, 12.2 to: "A request for re-establishment of rights according to Art. 122 and Rule</p>	<p>The Office did not agree to the proposal.</p> <p>The Office considers this to be a purely hypothetical question, as no such case has ever occurred in practice, and there is no authority for the conclusion drawn in the comment. The Guidelines are not intended to cover hypothetical situations or exam questions, but to give guidance on common general practice.</p> <p>One member mentioned that the EQE drafters of Paper D of EQE 2024 had been in contact with DG5 at the time, allowing the assumption that there is in fact authority for the conclusion drawn in the comment.</p>

			<p>4/05 and J 22/10), e.g. where the extension or validation fee has not been paid within the applicable time limit indicated (A-III, 12.2)."</p> <p>Thus, A-III, 12.1 may be understood as RE not being available for the missed grace period in case only the extension/validation fee was missed, nor when not paid along with the filing of a valid request for further processing concerning the designation fee within 2m from the loss-of-rights communication.</p> <p>GL (2024) A-III, 12.2 also provides that "A request for re-establishment of rights according to Art. 122 and Rule 136 is not possible in respect of payment of the extension or validation fee."</p> <p>A-III, 12.2 as currently phrased may be (mis)understood as re-establishment of rights not being available w.r.t. the missed 6m period, nor w.r.t. the grace period, nor w.r.t. the missed further processing period in respect of the designation fee to the extent that that related to the "parallel" payment of the extension/validation fee.</p> <p>However, it has become clear in the context of a discussion on Paper D of EQE 2024 that re-establishment is possible in the latter case, i.e., where the extension/validation fee as well as the designation fee were missed and re-establishment is requested in respect of the missed period for further processing (of the missed period for paying the designation fee), due to the accessory nature of the extension/validation fee.</p> <p>It seems appropriate to add this clarification to the GL.</p>	<p>136 is not possible in respect of <u>the 6 months time limits for payment of the extension or validation fee (under (i) and (ii) above), nor in respect of the grace period (under (a) above). However, when a request for re-establishment of rights according to Art. 122 and Rule 136 is filed in respect of the time limit for requesting further processing concerning the payment of the designation fee, the extension or validation fee may still be paid together with a 50% surcharge along with the filing of the request for further processing concerning the designation fee (as the omitted act in the meaning of Rule 136) as under (b) above mutatis mutandis; in this case, a single fee for re-establishment is due."</u></p> <p>Note that only a single fee for re-establishment is due as the only EPC time limit that was missed and re-established is the further processing period.</p>	<p>The Office replied that in the context of an exam question, several possible scenarios may be taken into account. This is why the Office is reluctant to include hypothetical scenarios into the Guidelines (see first paragraph).</p> <p>There were no further comments from SACEPO WP/G members.</p>
14	A	III	12.1	<p>In the Guidelines for Examination in the European Patent Office, Part A, 12.1, it is written:</p>	<p>The Office considered that this section of the GL was sufficiently clear.</p>

			<p>"The declaration in the appropriate section of the request for grant form (EPO Form 1001) or of EPO Form 1200 for entry into the European phase before the EPO where the applicant is asked to state whether they intend to pay the extension or validation fee is merely for information purposes and intended to assist in recording fee payments."</p> <p>However, my belief is that this does not cover three important points of the procedure. Thus, I think three precisions should be added to this section.</p> <p>1) It should be explained the reason why it is "merely for information purposes and intended to assist in recording fee payments" (I assume this is because the agreements signed between the EPO and the validation/extension countries always apply in any circumstance)</p> <p>2) It should also be added in the Guidelines that even if in EPO Form 1200 one is to *not* tick the box in point n°11 stating one wants to request the Euro-PCT application to extend to validation/extension states, the entry of the Euro-PCT application will nevertheless have the legal effect of requesting to extend to these validation/extension states.</p> <p>On this, please see in the support ticket CS205416 the question I raised on the possibility applicants have of not ticking this box in Form 1200 and its reply from the Patent Law and Processes.</p> <p>3) It should be added the fact that if the applicant is to state they will pay these fees, and the fees were not paid and the period for their payment has not expired when the EPO considers the patent application is ready for grant: the granting</p>		<p><u>Re. points 1 and 2:</u> A request that is subject to payment of a fee only becomes effective once it has been paid. This principle is laid down in the publications in the Official Journal listed in this Guidelines section (see e.g. OJ EPO 2023, A106, point 6). An extension or validation state is only eligible when the European or international patent application is filed on or after the entry into force of the respective extension/validation agreement. By payment of the extension/validation fee, the corresponding designations are confirmed. Selecting certain extension/validation states in filing forms 1001 and 1200 by ticking the respective boxes expresses applicants' intention to designate and pay for these states. This is particularly important if fees are paid by automatic debiting. The selected extension/validation fees will then only be automatically debited if the intention to designate these states was indicated, e.g. in F1001 or F1200.</p> <p><u>Re. point 3):</u> The situation described is extremely rare. As the commenter mentions, applicants are informed via F2012 if the grant would be blocked due to non-payment of the extension/validation fees. They can then act accordingly. Generally, applicants should be aware that grant may be delayed under Rule 71a(3) EPC if the intention to extend or validate the European patent to certain states has been indicated on filing but the fees are not paid before grant. Generally, applicants have the right to use the entire period to pay a fee; F2012 is a service letter reminding applicants of any outstanding fees that may delay publication of grant. In view of the extremely rare occurrences in practice, and the fact that applicants do receive the</p>
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				<p>of the patent will be blocked until either the fees are paid or the period to pay them has expired, and the EPO will tell us about this by sending EPO Form 2012.</p> <p>The reason why I believe it is important to add this third point in the Guidelines is as follows. The grant being blocked by the non-payment of the Designation fee or of the Renewal fee is predictable and intuitive; however, the grant being blocked for the non payment/non expiration of the period of payment of the validation/designation fees is not something that can be guessed or predicted due to the fact that these validation/designation fees are optional, non compulsory.</p>		<p>information, we do not consider it necessary to mention this extra service in the Guidelines.</p> <p>There were no further comments from SACEPO WP/G members.</p>
15	A	IV	1.1.1	<p>Will J 0001/24 (Divisional patent application) 16-04-2024 be followed and will A-IV, 1.1.1 be amended?</p> <p>https://www.epo.org/en/boards-of-appeal/decisions/j240001eu1</p>	Please comment and/or amend	<p>The Office stated that it considered this decision an isolated one and will therefore not include the practice in the Guidelines. This is based on the following considerations:</p> <p>The factual situation underpinning decision J 1/24 is unusual, as it involved an appeal against a decision to grant a European patent. The appeal was withdrawn after a divisional application was filed, meaning the Technical Board of Appeal did not have the opportunity to decide on admissibility or the allowability of the appeal against the decision to grant the parent application. Given the specific circumstances surrounding this decision, which is only binding on the individual case concerned, the Office continues to follow the previous case law, i.e. J 28/03. This decision deals with the validity of divisional applications filed while an appeal against a decision to grant the earlier application is pending. According to J 28/03, the validity of a divisional application in this particular situation depends on the outcome of the appeal</p>

						<p>proceedings, i.e. the decision taken by the Boards of Appeal, in the parent application.</p> <p>There were no further comments from SACEPO WP/G members.</p>
16	A	IV	1.2.1, 1.2.2, 1.3.4	We appreciated that the 's-constructs have been reversed		The Office thanked the respondent for the positive comment.
17	A	V	General remark	We appreciated that the 's-constructs have been reversed		The Office thanked the respondent for the positive comment.
18	A	VI	3	GL A-VI, 3 Response to search opinion (see also B-XI, 8). The applicant shall be obliged to provide substantive arguments already at this stage (to check).		<p>The Office did not consider it necessary to update this section.</p> <p>Part A of the Guidelines deals with formalities examination. The Office therefore believes that the practice does not need to be further outlined in this section, which already lists the requirements under Rule 70a EPC, not least in order to avoid duplication with Part B-XI, 8, where the procedure is described in detail (see para. 5).</p> <p>There were no further comments from SACEPO WP/G members.</p>
19	A	VIII	1.8	<p>Legal basis for invitation is not mentioned: is the invitation issued under R.58?</p> <p>Please clarify that/if Rule 50(3) is applied for subsequently filed documents and how (the section is not limited to the filing stage, and it could be that a document, e.g., the translation under Art.14(2), is filed after the filing date but before the time limit to appoint a representative has expired)</p>	<p>Please clarify</p> <p>Please clarify</p>	<p>1) The Office agreed to add a legal basis to Rule 58 EPC. The invitation to appoint a representative where the requirements of Art. 133(2) are not fulfilled is issued under Rule 58 EPC (and Rule 163(5) EPC for Euro-PCT applications).</p> <p>2) The Office was of the opinion that section A-VIII, 3.1 already clarifies that Rule 50(3) EPC applies to subsequently filed documents. The Office does not consider an addition necessary here.</p>

20	A	VIII	1.8	The second paragraph, "If the representative withdraws from representation during the examination phase ", - is it correct this applies only to the case of compulsory representation?		The Office confirmed that applicants from EPC contracting states are not obliged to appoint a representative, thus there is no legal consequence at any stage in the proceedings if a representative is not appointed or withdraws their appointment. There were no further comments from SACEPO WP/G members.
21	A	VIII	3.3	"Where a document is filed on paper, a rubber stamp impression of a party's name, whether a natural or legal person, must be accompanied by a personal signature. Initials or other abbreviated forms will not be accepted as a signature. Where the party concerned is a legal person, a document may in general be signed by any person who purports to sign on behalf of that legal person. The entitlement of a person signing on behalf of a legal person is not checked by the EPO, except where there is reason to believe that the person signing is not authorised and in that case evidence of authority to sign should be called for."	Add a paragraph break before : "" Where the party concerned is a legal person,". A new topic starts with that sentence.	The Office agreed to the proposal.
22	A	X	4.2.1	The text is internally inconsistent, as it on one hand says that it is consolidated where says on the other hand days that it is not...: " <u>consolidated</u> version of the ADA was last published as Supplementary publication 2, OJ EPO 2024 (note that <u>this version does not reflect the subsequent amendments</u> made by decision of the President dated 25 September 2024, OJ EPO 2024, A81)."	Please correct	The Office agreed to the proposal.
23	A	X	4.2.3	"evidence is provided (e.g. in the form of screenshots) that the payee is affected by such unavailability" - I believe the payee is the recipient of the payment (i.e. the EPO).	"evidence is provided (e.g. in the form of screenshots) that the payer is affected by such unavailability"	The Office agreed to the proposal.
24	A	X	5.2.4	In Example 1 on page 10, the fee is refunded	Add at the end of the title of the example "and refunded" or do not use the term "payable".	The Office did not agree to the proposal.

						<p>The title "Example 1 of last renewal fee payable to the EPO" correctly reflects the example, which shows that the third renewal fee is payable to the EPO and the fourth renewal fee no longer so. Refunding of any undue fee paid is mentioned only for the sake of completeness; however, this is a generally known principle.</p> <p>There were no further comments from SACEPO WP/G members.</p>
25	A	X	7		Refer to the provisions of Article 7(3) RFees	<p>The Office did not agree. The section deals with purpose of payment, not what is considered the payment date. Section A-X, 4.1 already refers to Article 7(3) RFees.</p> <p>There were no further comments from SACEPO WP/G members.</p>
26	A	X	7.1.1	<p>A-X, 7.1.1 now includes:” Under certain circumstances, i.e. if the conditions established by the case law of the boards of appeal are fulfilled (see H-VI, 2), a debit order may be corrected under Rule 139.”</p> <p>However, this is too vague and insufficiently unspecific for an applicant to rely on; also in view of the case law not being 100% in agreement.</p>	<p>Please add under which circumstances and how, or at least add references to the case law that is applicable and is being followed by the EPO (rather than being considered isolated decisions that are not followed), so as to improve legal certainty and transparency.</p>	<p>The Office only partly agreed to the proposal. Requests for correction under Rule 139 EPC are considered on a case-by-case basis. The section already contains a reference to H-VI, 2, which further clarifies the applicable principles; but the Office will consider adding a reference to G 1/12.</p> <p>There were no further comments from SACEPO WP/G members.</p>
27	A	X	9.2	<p>“reduced twice” is not clear: additive or multiplicative?</p>	<p>Suggested to use the working or RFees 14(3): “If more than one reduction applies to the same fee for the same application, the reductions shall be calculated sequentially.”</p> <p>It is suggested to also give an example, e.g., by copying item 28 of OJ 2024, A8 in the GL: “28. For example, if a fee of EUR 1 000 is reduced by 30% to EUR 700 under Rule 7a(1) EPC, and a further</p>	<p>The Office stated it considered the sentence sufficiently clear, given the fact that the OJ notice and Art. 14(3) RFEEs are linked in this section.</p> <p>Current wording: "If applicants are eligible for a reduction under both schemes, the fee in question is reduced twice (see the decision)" + Art. 14(3) is quoted in the margin</p> <p>Proposed alternative: "if the applicant is eligible for a reduction under both schemes (...), both reductions are applied (see the decision)"</p>

					reduction of 30% is applied under Rule 7a(3) EPC, the second reduction will be calculated on the basis of EUR 700, resulting in EUR 490. In other words, the two reductions taken together lead to a reduction of 51%, from EUR 1 000 to EUR 490."	The Office will not consider adding the example of the OJ notice to the GL, since a link to this is provided in this section. There were no further comments from SACEPO WP/G members.
28	A	X	9.4.1	As 9.3.1 specifies "Within the SME category, a microenterprise is defined as...", it is necessary to clarify this text, as the current text excludes any SME from eligibility under R.7a(3)	It is necessary to add the underlined to 9.4.1: "It is to be noted that small and medium-sized enterprises (SMEs) <u>that are not a microenterprise</u> are not eligible for a fee reduction under Rule 7a(3).	The Office agreed to the proposal.
29	A	X	9.4.1	For fulfilling the requirement as micro-entity, the EPO refers to: "User guide to the SME definition (2020)", see data.europa.eu/doi/10.2873/255862 . Here it is specified in Article 4: 1. The data to apply to the headcount of staff and the financial amounts are those relating to the latest approved accounting period and calculated on an annual basis. They are taken into account from the date of closure of the accounts. The amount selected for the turnover is calculated excluding value added tax (VAT) and other indirect taxes. 2. Where, at the date of closure of the accounts, an enterprise finds that, on an annual basis, it has exceeded or fallen below the headcount or financial ceilings stated in Article 2, this will not result in the loss or acquisition of the status of medium-sized, small or microenterprise unless those ceilings are exceeded over two consecutive accounting periods.	After the sentence: "Within the SME category, a microenterprise is defined as an enterprise employing fewer than 10 persons and whose annual turnover and/or balance sheet total does not exceed EUR 2 million." Please add: "The headcount of staff and the financial amounts are those relating to the latest approved accounting period and calculated on an annual basis."	The assumption was that this comment was for A-X, 9.3.1. The Office did not agree to the proposal, but would be ready to consider adding an explanation that the data and reference period are also defined in the EC recommendation. The following wording could be considered: "...Staff headcount and financial ceilings are calculated in accordance with European Commission Recommendation 2003/361/EC, which also defines the data to be used for the staff headcount, the financial amounts and the reference period . This means that the economic autonomy of the company in question may have an impact on its qualification as a small, medium-sized or microenterprise (see Art. 3 and 6 of European Commission Recommendation 2003/361/EC). Further information and examples of calculations of staff headcount and financial ceilings can be found in the European Commission's "User guide to the SME definition (2020)", see data.europa.eu/doi/10.2873/255862 ."

				3. In the case of newly established enterprises whose accounts have not yet been approved, the data to apply is to be derived from a bona fide estimate made in the course of the financial year.		There were no further comments from SACEPO WP/G members.
	B					
30	B	I	2		Add: A search division has at least one member denoted "first member".	The Office did not agree to the proposal. The correct information and terminology are in B I 2: The member of the search division responsible for the search on a European application is normally also the first member of the examining division for that application. There were no further comments from SACEPO WP/G members.
31	B	I	2		Last paragraph, add "first": The first member of the search division ... A search division has at least one member denoted "first member".	See comment 30.
32	B	I	2.2		Amend headline to: Where a search division has more than one member	The Office took note of the comment and will have the wording reviewed by its language services. There were no further comments from SACEPO WP/G members.
33	B	I	2.2.2	Question: Can applicant see if second member(s) of a search division has been involved in the search?		The Office clarified that the applicant could not see this. There were no further comments from SACEPO WP/G members.
34	B	II	4.3	The change of the term "filing date" into "date of filing" seems to have been done without sufficiently careful review, as the original, correct term "international filing date" (see PCT Art.	Reverse the amendment: change "international date of filing" back to the correct legal term "international filing date", -- see also B-IV, 2.3, B-VI, 4.1, and F-VI, 6.5	The Office agreed to the proposal.

				11(1)) was changed to the incorrect term "international date of filing"		
35	B	II	4.4		Add "and the EPO-PCT Guidelines, Part B."	The Office agreed to the proposal. "PCT-EPO Guidelines" is the correct term There were no further comments from SACEPO WP/G members.
36	B	III	1.1	GL B-III, 1.1 According to this paragraph "...the aim of the search is to identify the prior art relevant for assessing novelty and inventive step." Furthermore, this paragraph states that "The search division already gives the applicant a reasoned assessment of whether the application and the claimed invention meet the EPC requirements in the search opinion." This paragraph should be more detailed. It shall be clearly stated that the search opinion must tackle all objections, that will be also relevant at examination stage, including Article 123(2) EPC. Furthermore, it shall encourage to provide an analysis of prima facie (potentially) suitable fall back positions. Actually, this is foreseen when interpreting the claims (B-III, 3.2 (iv)), whereas not indicated in the part relative to the opinion. The part relative to the opinion may rather be at the end of the text and may take on board all principles set for the scope and for the subject matter of the search.		The Office did not agree. This section deals with the characteristics of the search (scope, basis, etc.). It makes a general comment: "the search division already gives the applicant a reasoned assessment of whether the application and the claimed invention meet the EPC requirements in the search opinion". EPC requirements include Article 123(2) EPC. The details of the search opinion are set out in B-XI, to which this section refers to. This approach is preferable to avoid repetition and the risk of inconsistencies. There were no further comments from SACEPO WP/G members.
37	B	III	3.2.6	GL B-III, 3.2.5 This paragraph refers to fallback positions only in relation to claims containing unclear terms, which are clarified in the description and/or drawings. The paragraph shall rather refer to any possible fall back position, also those relative to ways of remedying to unambiguous and direct objections of lack of novelty and any other possible objection. B-III, 3.5 appears rather related to be related to		The Office did not agree. The proposal asks for "ways of remedying objections". This is addressed in B-XI, 3, in particular B-XI, 3.8 (positive suggestions). B-III, 3.2 is about "interpretation of claims" for the purpose of carrying out the search. B-III, 3.5 is considered sufficient to instruct examiners to anticipate possible amendments to the claims.

				extreme situations, not to usual fall back positions.		The Office does not consider it to refer to "extreme situations" only. There were no further comments from SACEPO WP/G members.
38	B	III	3.6	GL B-III, 3.6 can be misinterpreted. In fact the indication of this paragraph not to make special efforts to search a broad claim, is only valid and reasonable, when the objections under Article 84 EPC and 83 EPC are expected to be successful. I acknowledge that examples are present, but the text could be further developed.		The Office considered this section to be sufficiently clear. The proposal focuses on the introductory sentence. This general statement is followed by detailed instructions to examiners through four examples demonstrating the approach to be adopted in this section. There were no further comments from SACEPO WP/G members.
39	B	III	3.11	GL B-III, 3.11 can be misinterpreted, since this can be done after issuing a CLAR.		The Office stated that the Guidelines already provide for a dedicated section on CLAR, but agreed to review the wording. There were no further comments from SACEPO WP/G members.
40	B	IV	1, 1.1, 1.2	Paragraphs B-IV, 1.; 1.1; 1.2 provide information of processes of internal relevance. Similar considerations applies to B-IV, 2.1; B-IV, 2.2; B-IV, 2.4; B-IV, 2.5; B-IV, 2.6; B-IV, 3.1; B-IV, 3.2. It is questionable that it is needed to make them available to the public in the degree of detail and in the form in which they are now in the Guidelines.		The Office did not agree with the comment. The sections in B-IV are necessary for transparency, as they directly impact applicants and ensure procedural fairness. Hiding them would undermine users' ability to understand and navigate the European patent process. Further, GP, 3 says: "The present Guidelines are addressed primarily to examiners and formalities officers of the EPO,..."
41	B	IV	2.3	In item i(d), the term "international filing date" was changed to "international date of filing"	Reverse the amendment: change "international date of filing" back to the correct legal term "international filing date"	The Office agreed to the proposal.

42	B	VI	4.1	In the first sentence the term “international filing date” was changed to “international date of filing”	Reverse the amendment: change “international date of filing” back to the correct legal term “international filing date”	The Office agreed to the proposal.
43	B	VI	4.2	GL B-VI, 4.2 is deemed to provide Guidelines for Article 139(2) EPC (at least the amended version showing modifications relates only to this article. The version online refers also to 54(3) (only that 54(3) is not relevant when the prior application/patent is a national product)). Article 139(2) EPC is not concerned with national applications filed before the filing date or before the priority date, but rather on one of these days. I would understand that Article 139(2) EPC is thought for applications / patents from the same applicant. Therefore, the prior right applications / patents belong to the same family, so that they are known to the applicant. I cannot understand the reference to B-X, 9.2.6 in this paragraph. I think that there is something wrong to be recapped there.		<p>The Office did not agree.</p> <p>This section refers to Art. 139(2) EPC, which addresses the case where the national application or patent has the earlier date. In addition, the national application or patent does not have to have the same applicant as the processed European application. Relevant national applications or national patents are not a bar to grant of a European patent in proceedings before the EPO, but in proceedings before the Unified Patent Court (UPC) they can have the same effect as prior art under Article 54(3) EPC before the EPO. Therefore, where found to be prima facie relevant, they are cited in the search report. As a result, the reference to B-X, 9.2.6 is correct.</p> <p>The case of a European patent application and national patent application having the same effective date (see comment) is dealt with in Art. 139(3), but that is not the issue in this section.</p> <p>There were no further comments from SACEPO WP/G members.</p>
44	B	VIII	4.1	The “in the same way” is incorrect, as the procedures under R.62a and R.64 are different: R.62a does not first give a partial search report and does not provide for an invitation to pay for extra searches. This is a key difference, as R.64 allows to have all claims searched (if paid for), whereas R.62a provides just for a limited, partial search.	Correct the text	<p>The Office agreed to review the wording, e.g. by deleting parts of the first sentence:</p> <p>In the same way as for an invitation under Rule 64 (see B-VII, 2.2), If the search division considers that the claims as filed do not comply with Rule 43(2) (see F-IV, 3.2), it has the discretion either to invite the applicant to indicate,</p>

						<p>within two months, compliant claims on which the search can be based or to carry out a full search on all the claims and raise the objection under Rule 43(2) only in the written opinion. In the latter case, the claims will have to be amended to comply with the requirement of Rule 43(2) if the objection persists in examination (F-IV, 3.3).</p> <p>There were no further comments from SACEPO WP/G members.</p>
45	B	VIII	4.1	<p>The text wrongly uses the term “written opinion”. The correct legal term here is “search opinion”</p>	<p>Replace “written opinion”. by “search opinion”</p>	<p>The Office agreed to the proposal.</p>
46	B	VIII	4.1	<p>4.1 Invitation to indicate which independent claim to search In the same way as for an invitation under Rule 64 (see B-VII, 2.2), if the search division considers that the claims as filed do not comply with Rule 43(2) (see F-IV, 3.2), it may invite the applicant to indicate compliant claims on which the search can be based within two months. In the same way as for an invitation under Rule 64, it is left to the search division's has the discretion whether to send this invitation or instead either to invite the applicant to indicate, within two months, compliant claims on which the</p>	<p>Something went wrong, a word is missing between ...do not comply with Rule 43(2) (see F-IV, 3.2) and has...</p>	<p>The part of the sentence concerned is the following and appears correct: "... if the search division considers that the claims as filed do not comply with Rule 43(2) (see F-IV, 3.2), it has the discretion ... "</p> <p>Nevertheless, the Office takes note of the comment and will have this checked by its language services.</p> <p>There were no further comments from SACEPO WP/G members.</p>
47	B	X	9.1.3	<p>B-X, 9.1.3 specifies: “This machine translation will be made available to the applicant (see B-X, 12 and G-IV, 4).” However, we hardly every receive machine translations with cited Chinese, Japanese and Korean patent applications, even not when reference is not just made to the abstract but to specific paragraphs.</p>	<p>The EPO is urged to require the examiners to provide machine translations of any such cited prior art in such languages. Emphasizing this in the GL as a strict need seems necessary.</p> <p>It is also suggested to add: “Where translations were not made available, the examiner shall provide those without delay if the applicant so requests.”</p>	<p>The Office agreed to review the wording.</p> <p>A possible solution is to replace "will" by "must", as follows:</p> <p>"This machine translation will must be made available to the applicant (see B-X, 12 and G-IV, 4)."</p> <p>Supplying the missing translations on request does not need to be mentioned, since this would be a normal correction of an oversight.</p>

						There were no further comments from SACEPO WP/G members.
48	B	X	9.1.3	To the extent that this guideline indicates machine translations will be supplied to the applicant, this guideline is very rarely respected.	Keep the guideline – change the practice to match the guideline.	See comment 47.
	C					
49	C			<p>Many parts</p> <p>I do not have time to go into the details of into the remaining paragraphs of the Guidelines and into the Guidelines for the unitary patent. Any concrete reason to change filing date into date of filing? I put the comments relative to part C here being more pregnant for a target focused amendments plan. I would have comments on some paragraphs of D, E, F and G, but I do not have the time to go into the details. In any case I see a problem in the way the unity is argued at the present.</p> <p>1) According to C - I, 1: “C - II to IX set out the general procedure for examination and provide guidance on specific matters, where necessary. They do not include detailed instructions on matters of internal administration.” For obvious reasons this applies in the substance also to C - I.</p> <p>I think that these chapters of the Guidelines need to be reviewed in order to render the examination adaptive. Harmonisation is clearly an issue, however, it is also true that having an harmonized approach in all technical fields is neither efficient, nor effective. What count for the substantive quality is the claimed subject matter of the granted patent. For obvious reasons also timeliness counts in view of the provisional</p>		<p>The Office observed that the comment contains general suggestions rather than proposals:</p> <p>The reason for changing from filing date to date of filing was discussed in the previous revision cycle (see the consultation results). This was part of the exercise to modernise the Guidelines by using shorter and simpler expressions while ensuring consistent alignment of modern English with the provisions of the EPC.</p> <p>1) The Guidelines cannot include all aspects of each technical area. Part C sets out a general procedure for examination and provides guidance on specific matters where necessary (C-I, 1). As regards changes in C-I, 2, see comment 50.</p> <p>2 and 3) There is no proposal on how to make oral proceedings more efficient or extend the examination of replies. The Office understands that comment 2 refers to summons to oral proceedings as the first action in examination (C-III, 5).</p> <p>4) Section C-III, 4 defines a list of actions that are not regarded as a first communication from the Examining Division needed before issuing a negative decision or a summons to oral proceedings. The reason is that there has to be at least one substantive communication during the examination phase. The responsibilities of the Search Division under Art. 92 and Rule 62(1) - drawing up the extended European search</p>

			<p>protection. However, this latter aspect is open to discussion with the external stakeholders in the single technical fields. I am of the opinion that timeliness, as well as “patenting behaviour” are field depending.</p> <p>Similarly, the kind of process to be followed cannot be standardized to every technical field. This aspect is clearly related with the aspect above. I do not wish to go too much into details here. I think that these concepts are self-evident and I wonder why they have never been taken into account when reviewing the guidelines. I paste some points below, but they are not exhaustive.</p> <p>I acknowledge a positive amendment in lines 6 and 7 of GL C - I, 2 (“and focus on objections and suggestions that influence the progress of the proceedings”). However, this is too summarised to expect that EPO employees and external stakeholders will ever note it.</p> <p>2) The part relative to the OPs definitely needs to be reworked. OPs definitely need to become more efficient and to the target (see C-V, 5.).</p> <p>3) Another interesting topic is the extent of examination of replies (see C-IV, 2). This part also needs to be reworked to adapt to the wish of the majority of internal and external stakeholders in the specific technical environment. Actually, this applies to the whole C-IV.</p> <p>4) I do not understand the rationale of not regarding an EESR or an ESOP, as well as an opinion or report from a PCT procedure (or even a national procedure, in case the PCT is skipped) as representing a text suitable for a first communication.</p> <p>It actually goes against the principle of reusing the work already done.</p> <p>One only needs to pay attention, as to whether</p>		<p>reports, including the European search reports and the accompanying search opinions – differ from those of the Examining Division, which is ultimately responsible for ensuring compliance with the substantive requirements set out in Art. 94 and Rules 10 and 71 EPC. Neither an EESR or ESOP, nor any communication at the PCT or national stage at another office, are communications from the Examining Division. Therefore they cannot satisfy Art. 94(3), as they do not count as communications during the examination phase.</p> <p>Art. 124 and Rule 141 limit the obligation to provide information to search results. Reports from national or PCT procedures may be considered by the Examining Division, to the extent possible. In the context of international applications, Art. 42 PCT explicitly states that IPERs are not binding on national or regional offices such as the EPO. This means the EPO may consider these reports as a non-binding opinion, but their role is purely informative and does not replace the EPO's independent examination. This approach is confirmed in E-IX, 4.3.3.</p> <p>4) Section C-III, 4 defines a list of actions that are not regarded as a first communication from the Examining Division needed before issuing a negative decision or a summons to oral proceedings (except for cases falling in the ambit of C-III, 5). The reason is that there has to be at least one substantive communication by the Examining Division during the examination phase. While the Search Division is responsible for drawing up the extended European search reports, including the European search reports under Art. 92 and the accompanying search opinions under Rule 62(1), the Examining Division is ultimately responsible for ensuring</p>
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			<p>any objection based on national or international guidelines fits within the legal framework of the EPA. In that case amendments are required. In my view any possible objection (of eventual National and/or PCT previous phase), that can reasonably result (if founded) in revocation of the patent, shall be considered as a suitable objection for starting the examining procedure. I would be also very open as far as the kick off of examination is concerned, leaving it to discuss with the “relevant” stakeholders, internally and externally.</p> <p>5) Adaptation of the description is under the responsibility of the applicant. The timeliness in answering to a request of adapting the description is also under the responsibility of the applicant. I do not see a good reason to invest examiners’ time to make a “monk” type job. A shift to ask the external stakeholders to adapt the description, may create a short jet leg in the production, but I think that this can be managed.</p> <p>6) A similar approach goes as far as amendments are concerned (the use of Rule 137(4) shall be an obligation).</p> <p>7) I would have a more flexible approach with minutes of consultations. The public needs to be informed about the objections, but it does not necessarily need to be informed of the single arguments. This shall be left to the discretion of the applicant / attorney to decide the extend of the argumentation in the minutes.</p> <p>8) I acknowledge that GL C – VII, 2.6 makes a huge step forward in increasing collaboration with the applicants. However, I fear that teams is not our best choose for doing this job. It is true that one is at examination stage, but teams has access to the own servers and consequently the</p>		<p>compliance with the substantive requirements set out in Art. 94 and Rules 10 and 71 EPC. Neither an EESR or an ESOP, nor any communication at the PCT or national stage at another office, are communications from the Examining Division and cannot satisfy Art. 94(3); therefore they do not count as communications during the examination phase for the purpose of the requirement to have sent a communication before issuing a summons or a negative decision. Art. 124 and Rule 141 specifically limit the obligation to provide information to search results. Reports from national or PCT procedures may be taken into account by the Examining Division, to the extent possible. In the context of international applications, Art. 42 PCT explicitly states that IPERs are not binding on national or regional offices, such as the EPO. While the EPO may consider these reports as a non-binding opinion, their role is purely informative and does not replace the EPO's independent examination. This approach is confirmed in E-IX, 4.3.3.</p> <p>5) The examiner's role in adapting the description when sending a second Rule 71(3) communication is explained in C-V, 4.5. In practice, responsibility for adapting the description lies with the applicant, but the examiner ensures compliance. C-V, 4.5 clarifies how examiners may react, given that they should always strive to be constructive and helpful and try to avoid unnecessary delay in the procedure. Thus the examiner may adapt the description and issue a Rule 71(3) communication if the adaptation can reasonably be expected to be accepted by the applicant (C-V, 1.1).</p> <p>6) On the question of whether the use of Rule 137(4) is obligatory for the applicant, the provision indicates that the Examining Division may request correction of this deficiency within</p>
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				<p>know how and the “ideas” of the examiners and attorneys are at risk to be “stolen”. In my opinion, we need a platform on servers, which can be only accessed by our BITs (but even though with a sequential protection access). None of the available platforms are adequate.</p> <p>9) I see a problem with the minimum requirements for unity: https://www.epo.org/en/legal/guidelines-epc/2025/f_v_3_3_1.html</p>		<p>one month of notification. This allows the examiner to decide whether to issue such request. In some cases it may be more efficient for the examiner to identify the basis directly, rather than issuing an invitation under Rule 137(4). In other cases the examiner may reject an amendment without basis as inadmissible (H-III, 3.3.1).</p> <p>7) As regards the extent of the minutes of a consultation (C-VII, 2.4), responsibility for the minutes lies with the examiner and their extent is at the examiner's discretion. They must clearly indicate what was discussed during the consultation, if agreement was reached, and any amendments agreed must be identified as precisely as possible.</p> <p>8) C- VII, 2.6 indicates that MyEPO provides a <u>secure space</u> ("shared area") where the first member and applicant can jointly edit an uploaded document during a consultation. MyEPO and the shared area are not based on MS Teams.</p> <p>9) The Office noted that the reasoning for a lack-of-unity objection is addressed in Part F of the Guidelines (F-V, 3.3.1).</p> <p>There were no further comments from SACEPO WP/G members.</p>
50	C	I	2	<p>Comment: The Office addressed partially our concerns, although the insertion was refused during the last meeting; <i>“and focus on objections and suggestions that influence the progress of the proceedings”</i></p>		<p>The Office thanked the respondent for the comment. The inclusion of specific examples was not adopted because objections that advance the proceedings - or "influence the progress", as reflected in the updated wording - are case-specific. Including specific examples could therefore be misleading, or misinterpreted as exhaustive or prescriptive. This section of the Guidelines aims to provide a general overview of</p>

						<p>the examiners' role and responsibilities, and for this reason is deliberately kept at this level of generalisation.</p> <p>There were no further comments from SACEPO WP/G members.</p>
51	C	II	1.2	<p>How will the Office react if the deficiency is related to the form of the independent claim (two-part form) or even the use of a relative term in a dependent claim on one hand and inventive step is acknowledged on the other, and the applicant does not file any amendment or response within the 6-month period?</p>		<p>The Office noted that the phrase "If no deficiencies are noted" in the third paragraph of C-II, 1.2 refers specifically to deficiencies that would lead to a negative (supplementary) search opinion.</p> <p>To enhance clarity and avoid potential misunderstandings, the Office proposed amending the fourth sentence of the third paragraph of C-II, 1.2 as follows:</p> <p>"If no deficiencies are noted in the search opinion accompanying the supplementary European search report <u>is positive (see B-XI, 3.9)</u>, the response of the applicant is voluntary (see OJ EPO 2009, 533)."</p> <p>This would bring the text of C-II, 1.2 closer to the text in the fourth paragraph of B-XI, 8.</p> <p>SACEPO WP/G members agreed to the Office's proposal.</p>
52	C	III	5	<p>So I suggest adding the following paragraph between the first and second paragraphs of C-II, 5:</p>	<p>It is suggested to add:</p> <p><u>In some cases, the applicant may have already filed a statement that results of a search referred to in Rule 141(1) are not available to them, and will not be available to them. This may occur, for instance, when the priority application will not be search e.g. a provisional application and the authority with which it was filed does not carry out a search on provisional</u></p>	<p>The Office did not agree to the proposal. Rule 141 allows the EPO to request information on prior art that has been considered in national or regional patent proceedings. Adding the proposed paragraph would undermine the intent of this provision and could allow applicants to easily circumvent its purpose.</p> <p>SACEPO WP/G members agreed with the Office's position and noted that this issue could be better dealt with by amending Rule 141.</p>

					<p><u>applications. In these circumstances, an invitation under Rule 70b(1) is not warranted as it unduly delays examination of the case.</u></p>	<p>There were no further comments from SACEPO WP/G members.</p>
53	C	III	5	<p>Another option, change the current 1st paragraph of C-II, 5:</p>	<p>It is suggested to add the green portion: If, when the examining division assumes responsibility, the EPO notes that a copy of the results of a search on the claimed priority or priorities as referred to in Rule 141(1) has not been filed by the applicant and is not deemed duly filed under Rule 141(2) (see A-III, 6.12), <u>and if the applicant has not filed a statement that the results of the search referred to in Rule 141(1) are not, and will not be, available to them,</u> it invites the applicant to file, within a period of two months, the copy or a statement that the results of the search referred to in Rule 141(1) are not available to them. This requirement applies to European or Euro-PCT applications filed on or after 1 January 2011 (see OJ EPO 2009, 585). This communication is also sent in cases where the priority in question has since been withdrawn or has lapsed. Alternatively: <u>Unless the applicant has filed a statement that the results of the search referred to in Rule 141(1) are not, and will not be, available to them, if, if,</u> when the examining division assumes responsibility, the EPO notes that a copy of the results of a search on the claimed priority or priorities as referred to in Rule 141(1)</p>	<p>See previous comment.</p>

					has not been filed by the applicant and is not deemed duly filed under Rule 141(2) (see A- III, 6.12), it invites the applicant to file, within a period of two months, the copy or a statement that the results of the search referred to in Rule 141(1) are not available to them. This requirement applies to European or Euro-PCT applications filed on or after 1 January 2011 (see OJ EPO 2009, 585). This communication is also sent in cases where the priority in question has since been withdrawn or has lapsed.	
54	C	III	4	<p>See point 54 of 28th SACEPO:</p> <p><i>“The Office noted that C-III, 4 addressed the first communication during the examination stage. The list of examining division actions before a summons or a refusal. The Office explained that although invitations under Rules 70a and 161/162 were issued on behalf of the examining division, they had no substantive content and were sent before the division started its substantive work (i.e. before the marker indicating the start of substantive examination was triggered, C-IV, 7.1). Since these communications neither had substantive content, nor were sent after the start of substantive examination, they could not be confused with a first substantive communication from the examining division. This was not the case for the other actions listed, which either had substantive content (ESOP, WO-ISA, Rule 62a/63 invitations) or were generated after the that did not count as a</i></p>	<p>Add <i>“Invitations under Rule 161, 162 and 70a are not communications with substantive content”</i></p>	<p>The Office agreed with the comment and proposed the following amendment to the second paragraph of C-III, 4:</p> <p><u><i>“Invitations under Rules 161, 162 and 70a do not contain substantive content and are therefore not regarded as the first communication from the examining division. Likewise,</i></u> the following communications are not deemed to constitute substantive actions in examination proceedings and are thus not regarded as the first communication from the examining division:”</p> <p>SACEPO WP/G members agreed to the Office's proposal.</p>

				<p><i>substantive communication was provided to ensure that at least one substantive communication was sent marker was triggered (remaining actions). As a result, there was no need to include the suggested communications in the list.</i></p> <p><i>There were no further comments from the SACEPO WP/G members.</i></p>		
55	C	V	1.1	<p>1.1 specifies “Once the examining division decides that a patent can be granted, it must inform the applicant of the text it intends to use for the grant. This text may include amendments and corrections that the examining division made on its own initiative and can reasonably expect the applicant to accept”</p>	<p>To avoid irreparable errors analysed in T0423/21, T 0178/23 and T1224/24, it is proposed the specification that “the parts of the patent application as filed, neither appearing nor expressly deleted in the text in which the Examining Division intends to grant according to Rule 71(3), comprising the description, the claims and the drawings, would be deemed as belonging to the granted patent” .</p>	<p>The Office did not agree to the proposal. The purpose of the communication according to Rule 71(3) is precisely to avoid any ambiguity regarding the text and drawings that will form part the granted patent. Including a note in the Guidelines suggesting that parts of the application not reflected in the Rule 71(3) communication could nevertheless be part of the granted patent would be contrary to Rule 71(3) itself. This provision clearly requires the Examining Division to inform the applicant of the text intended for grant prior to the decision to grant.</p> <p>SACEPO WP/G members agreed with the Office's position and added that both applicants and the Office should be more careful when a communication under Rule 71(3) is issued and accepted. It was also noted that in some related cases the Office had accepted an administrative error had been made and was able to correct it.</p> <p>There were no further comments from SACEPO WP/G members.</p>
56	C	VII	2.4	<p>Grant after telephone call</p>	<p>Please include the reasons for patentability in the file</p>	<p>The Office did not agree to the proposal. C-V, 1.5 already states that where the Examining Division changes its opinion after an earlier negative communication, it will state its reasons for this in the Rule 71(3) communication unless they are clear from the applicant's reply, from a communication or from the minutes of a</p>

						consultation. In addition, any amendments agreed during a telephone consultation immediately preceding a Rule 71(3) communication must also be reflected in that communication (C-VII, 2.4). There were no further comments from SACEPO WP/G members.
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57	E	III	10.3		<p>1st § Delete “and not contained in the parties' written Submissions”</p> <p>Add that the minute should include all requests from the party.</p> <p>5th §: Requests from parties for recording specific statements are accepted if the statements form part of the essentials of the oral proceedings and are relevant for reaching the decision.</p> <p>7th § (a) arguments relevant for the decision or for any sub decisions as submitted by in the grounds for the decision the parties, which, if they are already known from the written procedure, can be referred to as such, (b) the substance of any new requests by the parties, preferably in the form of a brief statement referring to documents containing these requests, which must be attached to the minutes, and</p>	<p>The Office did not agree to the proposals: E-III, 10.3. already mentions that new requests by the parties (see point b) and final requests are included in the minutes. The concept of sub-decisions is not known under the EPC. Accordingly, and in line with Rule 124(1) the Office does not see a need to change this section.</p> <p>There were no further comments from SACEPO WP/G members.</p>

					(c) objections, arguments and/or requests to the parties voiced by a member of the division, focusing on the points relevant for the decision <u>or for any sub decisions</u> which are developed	
58	E	VI	3	<p>The EPO's practice is diverging:</p> <ul style="list-style-type: none"> - Depends on the technical filed (difficulties with parameter inventions) - Complex cases are less successful - Filing shortly before or after the R71(3) communication lowers success of the observations to be considered - The EPO is rather liberal with clarity objections - Sufficiency of disclosure is not consistently handled. 	<p>Substantive examination of any issues raised at any time before grant could help to avoid opposition procedures.</p> <p>Proposals:</p> <ul style="list-style-type: none"> - Workshops and internal audits - SQAP on TPO - KPI on the number of patents revoked or changed in Opposition based on TPO - Adoption of the Guidelines 	<p>The Office did not see any need to change the Guidelines. However, as communicated in the Quality Action Plan, the Office strives to improve consistency in the handling of third-party observations. We will make third-party observations more visible to the divisions and provide training to raise awareness of requirements, so divisions handle the observations in accordance with the Guidelines. A follow-up study will be conducted to assess the impact of our actions.</p> <p>There were no further comments from SACEPO WP/G members.</p>
59	E	IX	2	The added paragraph that starts with "The same requirements apply for the EPO acting as an elected Office. ..." may lead to confusion as there is no difference in entry requirements for EPO as dO vs EPO as eO. E.g., even if the election was withdrawn, there is no difference in response to the WO-ISA requirement (Rule 161), examination fee and possible reduction therein (Art. 14(2) RFees).	It is suggested to delete the added paragraph that starts with "The same requirements apply for the EPO acting as an elected Office. ...",	<p>The Office noted the comment and will look into how best to reflect it in the new chapters.</p> <p>There were no further comments from SACEPO WP/G members.</p>
60	E	IX	2.1.1	First item was unamended to specify: "– supply the translation if the Euro-PCT application was not published in one of the EPO's official languages (see E-IX, 2.1.3)" However, section 2.1.3 has been renumbered to 2.1.4	Correct to: "– supply the translation if the Euro-PCT application was not published in one of the EPO's official languages (see E-IX, 2.1.4)"	<p>The Office agreed to take the user's comment into account when drafting the new chapters in part A.</p> <p>There were no further comments from SACEPO WP/G members.</p>
61	E	IX	2.1.5.2		Please add the Russia-clause to "Upon entry into the European phase, the designation in a Euro-PCT	The Office did not agree to the proposal. This clause is already present in E-IX; 2.1.5.2. The Office will, however, consider clarifying the

					application of those contracting states that are Member States of the European Union will be deemed to be withdrawn in accordance with Rule 39(2a) (see OJ EPO ...; see also A-III, 11.2.4 and 11.2.5).”, as this paragraph may otherwise misunderstood.	present text by including a clear reference to the applicants concerned, similar to A-III, 11.2.4. There were no further comments from SACEPO WP/G members.
62	E	IX	2.1.5.4		Please add the underlined to: “The required written request for examination is automatically made if EPO Form 1200 for entry into the European phase is filed in due time since the appropriate checkbox is preselected, <u>provided that the examination fee is also duly paid at the same time</u> ”, as the request is not considered filed (“made”) if the fee is not paid.	The Office agreed to take the user's comment into account when drafting the new chapters in part A. There were no further comments from SACEPO WP/G members.
63	E	IX	2.1.5.5	(Also A-X, 5.2.4) if renewal fee paid at end of 29th month (when also doing acts for entry in all 30m dOs) with full 12m priority, it is refunded – this seems to be at odds with Art.27(7) PCT and at odds with the intention of the 6m clause of R.51(2): yes, it is just before the prepayment period, but the change of 3m to 6m was to prevent refunds of payments paid at entry → propose to accept those payment, but only make effective on 31m date (as with the acts for filing documents) – similar as is done for early-paid designation fee (GL A-X, 5.2.2) Note some accountants do not seem to allow / advise against automatic debiting which would be an alternatively way of payment and which would not have this issue (even if wrong amount, corrected ex-officio).	It is proposed to add to E-IX, 2.1.5.5 as well as A-X, 5.2.4 (text inspired by A-X, 5.2.2): Where the renewal fee is paid before the permissible prepayment periods, e.g. in the 29 th month from the priority date for an application claiming the full 12 month priority period, the renewal fee will however be retained by the EPO. These payments will only be considered valid from the first day of the permissible prepayment periods, provided that the amount paid corresponds to the amount payable on the date of payment (see A-X, 5.1.2).	The Office did not agree to the proposal: it applies the prepayment period strictly. This is an automated procedure and the fee will be automatically rejected at source if paid too early; see ADA 9.1 and 9.2 (OJ EPO 2024, A81 and OJ EPO 2024, A82). However, clarifying the information is envisaged in the new chapters on the Euro-PCT in Part A. One member mentioned that the practice of retaining a renewal fee paid too early if this occurred shortly before the pre-payment period was outlined in OJ EPO 2009, 118. The Office agreed to verify whether this notice has been superseded, and if so when the announcement was made. There were no further comments from SACEPO WP/G members.
64	E	IX	2.1.5.6	Euro-PCT Guide (2023) 5.10.012 was very explicit and clear w.r.t. the situation that neither the written request for examination was filed in	Please add the text of Euro-PCT Guide (2023) 5.10.012, including the emphasis that that text has:	The Office agreed to take the user's comment into account when drafting the new chapters in part A.

				time nor the examination fee was paid in time. In the current text in IX, 2.1.5.6 that is only implicit: please make it explicit,,	“If the applicant neither filed the request for examination nor paid the examination fee in due time, further processing must be requested in respect of both omissions , i.e. in respect of filing the request for examination and paying the examination fee. It follows that the applicant must not only file the request for examination and pay the examination fee but also pay two fees for further processing, namely the flat fee for further processing in respect of the omitted act (i.e. the request for examination) and 50% of the late-paid examination fee.”	There were no further comments from SACEPO WP/G members.
65	E	IX	2.3.5.3	Is “If these results are not available on entry into the European phase, they should be filed without delay after they have become available to the applicant (Rule 141(1)).” fully correct as it is phrased? Shall it not be extended with “ <u>or, if later, once the examining division has become responsible. If they are not supplied, the examining division will invite the applicant under Rule 70b.</u> ”	Please review and correct/clarify.	This comment seems to relate to E-IX; 2.3.5.2. The Office did not agree to the proposal, as the present wording reflects R 141(1) EPC. Consideration will be given to referring to the case addressed in Rule 70(b). There were no further comments from SACEPO WP/G members.
66	E	IX	2.3.8	The first paragraph suggest that claims fees in excess of 15 need to be paid at 31m. However, that is incorrect and inconsistent with A-IX, 2.8 (where it is correct)	Add “Claims fees for any claims in excess of fifteen need only be paid before expiry of the period under Rule 162(2).” (wording taken from A-IX, 2.8).	The Office did not agree to the proposal. A-IX, 2.8 does not exist and A-IX, 2 relates to representation of drawings, not claims fees. The Office considers that the information provided in E-IX, 2.3.8 correctly reflects R 162(1) and is thus correct. It will look into clarifying the role of the 31-month time limit in the new chapters to Part A of the Guidelines. There were no further comments from SACEPO WP/G members.
67	E	IX	2.8	2.8 mentions the right to waive R.70a invitation, but one shall waive the R.70(2) communication (not 70a).	To be corrected.	The Office agreed to take the user's comment into account when drafting the new chapters in part A

						There were no further comments from SACEPO WP/G members.
68	E	IX	2.8		<p>Switch these two paragraph:</p> <p>On the other hand, if, on the date the request for early processing is filed, any necessary requirement is not complied with, the request will be effective only from the date on which all necessary requirements have been complied with.</p> <p>This means, for instance, that the EPO as designated/elected Office will issue the communication under Rules 161 and 162 directly after it has established that the request for early processing is effective and on condition that the international search report has already been established (see E-IX, 3).</p>	<p>The Office did not agree to the proposal. However, it will reconsider the presentation of the information in the new chapters in part A.</p> <p>There were no further comments from SACEPO WP/G members.</p>
69	E	IX	3		<p>Before “Whether or not a...”, add: “If the EPO did not act as main ISA nor as SISA, amendments are optional.”</p>	<p>The Office did not agree to the proposal. Amendments are not mandatory, even if the EPO did not act as main ISA or SISA. The applicant can also file comments with the WO-ISA.</p> <p>The Office will, however, consider adding a clarification in the new chapters in part A that any reaction (amendments and/or comments) is voluntary if the EPO was not (S)ISA.</p> <p>There were no further comments from SACEPO WP/G members.</p>
70	E	IX	3		<p>Amend “EPO Forms 1226AA and 1226BB)” into “EPO Forms 1226AA, 1226BB and 1226CC)”</p>	<p>The Office agreed to the proposal to the extent that clarification is needed (i.e. which forms are used in the various constellations). This will be reflected in the new chapters in part A.</p> <p>There were no further comments from SACEPO WP/G members.</p>

71	E	IX	3.1		amend “or not issued” into “ nor issued”.	The Office agreed to take the user's comment into account when drafting the new chapters in part A. There were no further comments from SACEPO WP/G members.
72	E	IX	3.1	(EPO was not ISA): Add possibility to waive right to remaining part of 161 not described, was in Euro-PCT Guide 5.4.020	Add the text from Euro-PCT Guide 5.4.020: Applicants who do not want to use the entire six-month time limit under Rules 161(2) and 162 EPC for filing further amendments can shorten this time limit and request the immediate start of the supplementary search by explicitly waiving their right to use the remainder of the six-month period.	The Office agreed to the proposal, and will reflect as to whether this should be added at a suitable place in the new chapters in part A. There were no further comments from SACEPO WP/G members.
73	E	IX	3.2		Consider to add: “If the EPO as ISA or SISA has issued a declaration under Art. 17(2)(a) PCT as ISA or SISA, the application is not subject to a supplementary European search under Art. 153(7). However, a Rule 164(2) invitation will be issued possibly in combination with or followed by a Rule 63 invitation of the objections raised in the declaration have not been overcome within the Rule 161/162 time limit.”	The Office did not agree to the proposal but will consider clarifying the Guidelines, possibly C-III, 3.1. It clarified that an invitation under Rule 164(2) will only be issued for any claimed invention or group of inventions within the meaning of Art. 82 not searched by the EPO in its capacity as ISA or SISA. This can be combined with or followed by an invitation under Rule 62a or 63 EPC. However, if the claims upon entry into the EP phase belong to the same invention in the sense of Art. 82 as in the PCT search phase, no invitation under Rule 164(2) will be issued. If the applicant provides convincing arguments or amendments that overcome the reasons underlying the limitation of the search or the declaration of no search, the examiner will perform an additional search in examination at no extra cost (see C-IV, 7.2). If the reason underlying the limitation of the search or the declaration of no search is still present in the

						claims, the examiner will object under the relevant provision of the EPC, e.g. Rule 43(2) or Art. 84 as the case may be. The Office agrees to review whether changes to the EPC and PCT-EPO Guidelines are necessary to better describe the relationship between Art. 17(2)(a) PCT and Rule 164(2), Rule 62a and Rule 63 EPC. There were no further comments from SACEPO WP/G members.
74	E	IX	3.2	(EPO was ISA): Add possibility to waive right to remaining part of 161 not described, was in Euro-PCT Guide 5.4.030	Add the text from Euro-PCT Guide 5.4.030: If applicants do not wish to wait until expiry of the six-month time limit under Rules 161(1) and 162 EPC for examination to start, they may request the immediate start of examination by explicitly waiving the right to use the remainder of the six-month period.	See comment 72
75	E	IX	4		Add the underlined: “in the respective registers by the relevant national authorities and, <u>if applicable,</u> in the Unitary Patent Register”	This comment seems to refer to E- XIV , 4. The Office agreed to the proposal.
76	E	IX	6		E-IX, 6: add the underlined: “Licences and other rights cannot be registered in the European Patent Register after the decision to grant has become effective (Art. 97(3)), <u>but, if applicable, they can be registered in the Unitary Patent Register (see Unitary Patent Guidelines).</u> ”	This comment seems to refer to E- XIV , 6. The Office agreed to the proposal.
77	E	X	2.1	T 1588/22 20-12-2024: Catchword Principle of the protection of legitimate expectations not observed by the examining division (see points 1.3 to 1.5 of the Reasons)	Suggested to add in E-X, 2.1 or at another appropriate place: “The principle of the protection of legitimate expectations must be observed, such that issuance of a	The Office did not agree to the proposal. In the decision cited the overriding problem was the right to be heard that was not respected, rather than the principle of legitimate expectations. In addition, the Office believes that the Guidelines,

			<p>Reasons 1.3 The examining division's announcement in its communication of 27 July 2021 (resent to the appellant on 4 November 2021), that the appellant "may also choose to submit further arguments along with a new claim set satisfying the requirements of EPC. In the latter case the applicant is kindly reminded that the examination procedure would continue with oral proceedings for the sake of efficiency and better communication" appears nonsensical or at least misleading in the given circumstances. The only way for the appellant to make sense of the examining division's statement was to assume that this statement actually meant to refer to a situation where a new claim set was filed that would NOT meet the requirements of the EPC, in which case the proceedings would be continued with the holding of oral proceedings.</p> <p>This created the legitimate expectation on the appellant's part that, after having filed a new set of claims on 6 November 2021 (refiled on 24 November 2021), these claims would either be found allowable or oral proceedings would be held and that, in the latter case, the appellant would have the opportunity to provide, during the oral proceedings, submissions on the allowability of the set of claims filed on 6 November 2021 (refiled on 24 November 2021). In the same way, the examining division's communication of 7 December 2021 created the legitimate expectation that the appellant would have the opportunity to receive a communication or at least a summons to oral proceedings in response to the set of claims filed on 6 November 2021 (refiled on 24 November 2021).</p> <p>In view of the communication of 27 July 2021, the appellant could not have expected as the next</p>	<p>decision, e.g., a decision of the examining division refusing the application, does not come as a surprise for the party/parties (T 1588/22, reason 1.3-1.5)."</p>	<p>e.g. E-X, 2.1, already make it clear that a party may not be taken by surprise by a decision.</p> <p>SACEPO WPG members argued that the catchword of the decision focuses on protection of legitimate expectations. Furthermore, the Guidelines should cover not only the overriding principle but also more detailed scenarios.</p> <p>The EPO explained that the substantial procedural violation established by the BoA was due to non-observance of the right to be heard (Art.113 EPC). Legitimate expectations triggered but not observed by the division were the element that led to that violation. The right to be heard has already been covered by GL, E-X, 2.1 without the need to add any particularities of the case.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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			<p>action of the examining division that a decision refusing the patent application would be issued. This is exacerbated by the communication of 7 December 2021 informing that the examining division would "supply a communication within 2 months".</p> <p>It follows that instant issuance of the decision of the examining division refusing the application was a surprise for the appellant.</p> <p>Thus, the principle of the protection of legitimate expectations has not been observed in the case at hand.</p> <p>1.4 In its decision (point II. 12), the examining division stated:</p> <p>"Issue of a decision is possible since the applicant did not request in any of their responses, including the last one received on 24.11.2021, oral proceedings in view of Article 116(2) EPC [sic]. Additionally, all the objections mentioned in this refusal had already been communicated to the applicant more than once, where they had a chance to provide counter-arguments or submit amendments in order to overcome said objections. Hence, the applicant's right to be heard in view of Article 113 EPC is respected."</p> <p>The board does not agree. Even if the appellant had not submitted any request for oral proceedings, for the reasons set out above, the examining division had created the legitimate expectation that rather than a decision to refuse the application, the next step would be either oral proceedings, arranged by the examining division of its own motion in accordance with Article 116(1) EPC as considered expedient, or a further communication.</p>		
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				<p>In view of these legitimate expectations, the appellant had to assume that it would be given a further opportunity to provide counterarguments or submit amendments prior to any decision to refuse its application.</p> <p>1.5 Issuance of the decision refusing the patent application without holding oral proceedings or issuing a further communication as announced had thus the effect of depriving the appellant of any such further possibility to provide comments.</p> <p>Consequently, the appellant's right to be heard has been violated (Article 113(1) EPC). The examining division's decision to refuse the application thus constitutes a substantial procedural violation.</p>		
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78	F	II	7.4	<p>Irrelevant or unnecessary matter</p> <p>“The matter to be removed may already be obviously irrelevant or unnecessary in the original description. It may, however, be matter which has become obviously irrelevant or unnecessary only in the course of the examination proceedings, e.g. owing to a limitation of the claims of the patent to one of originally several alternatives.”</p>	<p>Is this correct? Should be amended in line with T56/21 sections 96-98</p>	<p>The Office did not agree.</p> <p>The practice described in F-II, 4.7 is correct. However, details regarding the requirement to adapt the description to amended claims are described in F-IV, 4.3.</p> <p>Decision T 56/21, which questions the legal basis for adapting the description to the claims, should not be followed, as it is an isolated decision not in line with well-established case law of the boards of appeal. It is an individual decision only binding in the specific case at issue.</p> <p>There were no further remarks from SACEPO WP/G members, as the comments related to adaptation of the description to claims were taken up under comment 82.</p>

79	F	III	3	<p>2nd §, new text:</p> <p>Another example can be found in the field of artificial intelligence if the mathematical methods and training datasets are disclosed in insufficient detail for the skilled person to be able to reproduce the technical effect without undue burden using common general knowledge over the whole scope of the claim</p>	<p>Amend the marked text with “reproduce the claimed subject matter”</p> <p>There is no requirement in A. 83 EPC that the “technical effect should be reproduced.</p> <p>This is a matter of inventive step.</p>	<p>The Office agreed to the proposal.</p> <p>The sentence will be reworked, in particular based on wording from T 1191/19 and T 161/18.</p> <p>There were no further comments from SACEPO WP/G members.</p>
80	F	IV	4.1	<p>There is no precise, complete and positive definition of the concept of clarity given anywhere, as is for instance the case with the opening item in the GL for the Inventive Step or Support by Description. All we currently have is an atomized and negative definition provided by the different items themselves (e.g. F-IV.4.6 Relative terms indicates that relative terms may cause the claim not to be clear). This is the key issue at the heart of current clarity discussions: there is no clear objective definition provided, meaning that no ground truth is provided for discussions.</p> <p>Clarity is the requirement that claims should allow the person skilled in the art to determine whether any given embodiment falls in the scope of the claim or not. This is theoretical in the sense that it should be feasible from the language of the claim alone, but also practical and should be a reality on the level of the involved testing, which should thus not rely on anything else but established experimentation. Decisions which echo this definition are provided. We selected the most relevant decisions, including G2/88 (reason 7). Numerous further T decisions hint at this notion being the meaning of clarity (cf. Case Law of the Boards of Appeal II.A.3.1: T 586/97, T 642/05, T134/10, T 1129/97, T 274/98, etc.). For further information, this definition is exactly the definition given by the Guidelines of the JPO</p>	<p>The clarity of the claims is of the utmost importance in view of their function in defining the matter for which protection is sought.</p> <p>The purpose of the clarity requirement is to allow the person skilled in the art to determine whether a given embodiment, be it from the prior art or not, falls within the scope of a claim or not (see G2/88, T 2290/12 and T 0129/13). In other words, it is a matter of the person skilled in the art being able to differentiate what is in the scope of the claim from what is not without any doubt.</p> <p>The clarity requirement is key not only to allow for precise novelty (Art. 54 EPC) and inventive step (Art. 56 EPC) assessments, but also precise freedom-to-operate assessments.</p> <p>The clarity requirement is both theoretical and practical. Indeed, not only must the language of the claim theoretically allow the person skilled in the art to situate any given embodiment relative to the scope thereof without ambiguity, but this must be achievable in practice while</p>	<p>The Office will look into this matter and consider a proposal for a more general definition of the concept of clarity, in view of the second meeting of the SACEPO WP on Guidelines.</p> <p>There were no further comments from SACEPO WP/G members.</p>

			<p>(II.2.3.2.1) and the meaning of that given by the USPTO (MPEP 2173).</p> <p>A warning has been added to stay away from objections which invite the Applicants to “explain” their features for clarity reasons as this strays away from the definition of clarity. This is the most problematic practice point at present, and deserves a mention in 4.1.</p>	<p>relying only on established experimentation (see T 849/11). This carries the notion that the requirement for clarity is only satisfied if a skilled person, for distinguishing between claimed and non-claimed subject matter, does not depend on additional sources of information beyond those they would habitually consult, i.e. technical documentation and experimentation generally established in the technical field.</p> <p>Care should be taken to avoid lending a different meaning to the Art. 84 clarity requirement. In particular, objections under the Art. 84 clarity requirement should not be an invitation to restrict the scope of a claim, e.g. to “explain” a feature allegedly lacking clarity by restricting its scope, but merely an invitation to dissipate any doubt regarding the scope of protection that the claim seeks to cover.</p> <p>The requirement that the claims must be clear applies to individual claims, i.e. to independent and dependent claims alike, and also to the claims as a whole. Therefore, the meaning of the terms of a claim must, as far as possible, be clear for the person skilled in the art already from the wording of the claim alone (see also F IV, 4.2). In view of the differences in the scope of protection which may be attached to the various categories of claims, the division must ensure that the wording of a claim leaves no doubt as to its category.</p>	
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					<p>Where it is found that the claims lack clarity under Art. 84, this may have led to the issuing of a partial European or supplementary European search report under Rule 63 (see B VIII, 3.1 and 3.2). In such cases, in the absence of appropriate amendment and/or convincing arguments from the applicant as to why the invitation under Rule 63(1) was not justified, an objection under Rule 63(3) will also arise (see H II, 5). Art. 84</p>	
81	F	IV	4.1	<p>F-IV.4 contains no information about how to process the clarity of a claim in the general case, i.e. outside of the handful of cases which are echoed by the items themselves, like 4.4, 4.6, 4.7, 4.8, etc. In other words, there is no such thing as an algorithmic approach comparable to the problem-solution approach. An item could be added in this regard, which closely ties into the modified and proposed 4.1.</p> <p>A new 4.2 could thus created as detailed handbook for the practical assessment of the clarity of claims in the general case, i.e. outside of the atomized examples targeted by the other items of F-IV.4. The practical and theoretical requirements are both developed. A list of examples is given with the corresponding discussion points, and so both for the theoretical and practical requirements. The crux is to show the key steps of the line of reasoning one needs to follow to assess the clarity of any claim. A complete description of the process is provided for the theoretical requirement. The practical requirement would eventually need to be sourced by decisions, which is only partly the case at</p>	<p>The clarity of a claim is analyzed in view of the knowledge of the person skilled in the art and the meaning that the expressions used in the claim have in the corresponding technical field. Although the clarity of a claim should arise from the claim itself, the meaning of expressions in a claim may be further examined in the light of the content of the description, for instance to determine whether the meaning of these expressions indeed corresponds to the meaning which is customary in the art or to assess whether any inconsistency is present.</p> <p>It is advisable to assess the clarity of claims before that of the patentability requirements of Art. 52 et seq. EPC as clarity defects may condition the outcome of the discussion on patentability or even possibly prove a hindrance in that respect.</p> <p>For the practical assessment of the</p>	<p>The Office will look into this matter.</p> <p>It will be considered together with the proposal for a more general definition of clarity (see comment 80) because it essentially addresses the same subject.</p> <p>In more detail:</p> <ul style="list-style-type: none"> - The proposal partly covers the topic of claim interpretation based on the description addressed in the currently pending referral G 1/24. The current practice, as defined e.g. in the Guidelines F-IV, 4.2, will continue to apply and not be amended until the decision in G 1/24 has been issued. - The question of whether clarity has to be addressed before or after patentability requirements needs to be decided on a case-by-case basis. Where clarity has a direct impact on patentability, it obviously needs to be discussed first.

			<p>present. The current items are highly inconsistent between one another: 4.11 defines the tests as having to be easy and unambiguous, whereas 4.10 as having to not be undue. Moreover, they disagree as to whether the tests need to be present in the claims (4.11), in the “patent document” (4.21), in the description or in the general knowledge (4.10). We have therefore been unable to provide a precise positive characterization of what an acceptable test is, and have resorted to approach the notion in negative fashion and present what testing scenarii would seem to be unclear, with the important information that the burden of proof lies with the Applicant.</p>	<p>clarity of a claim, two questions should be answered: (i) Can the person skilled in the art theoretically determine what is in the scope of the claim from what is not? (ii) Practically, can this determination be carried out and does it require more than routine tests?</p> <p>For the purpose of answering question (i), what needs to be analyzed is whether the language of the claim itself allows the person skilled in the art to determine whether a given embodiment of a comparable device finds itself within its scope or outside of it. Whether the embodiment is within its scope or outside is per se not relevant as this question pertains to the result of the determination rather than to its feasibility, the latter being the crux of the discussion.</p> <p>For the purpose of answering question (ii), what needs to be analyzed is whether the person skilled in the art would be able to conduct a practical determination of whether an embodiment falls within the scope of a claim or not using established experimentation. In other words, the practical process of determining whether a given object or embodiment falls within the scope of a claim or not should be feasible and rely on routine tests. This dimension of the clarity requirement is fundamental, and is intended to ensure that third parties to a claim retain their ability to assess whether a product they consider marketing falls within the scope of</p>	<ul style="list-style-type: none"> - The proposed test including two questions may define sufficient conditions for establishing a lack of clarity. However, the test does <u>not</u> reflect <u>necessary and sufficient</u> conditions for the assessment of clarity, because there are claims that will meet the test but are unclear for other reasons, e.g. because of undue disclaimers, results to be achieved, missing essential features, etc. <p>The Office does not recommend including fictitious examples apparently not based on generally accepted jurisprudence. For instance, with regard to the first example, a claim directed to a "vehicle comprising wheels" may be objectionable under Art. 84 depending on the particular circumstances, for instance if the description gives a special meaning to the term "wheel" (e.g. a steering wheel of a vessel) or essential features are missing.</p> <p>SACEPO WP/G members expressed different views about the order of objections. For some it seemed counter-intuitive that novelty objections could be raised before clarity objections. Others expressed the view that the order of objections was not essential, as long as a logical sequence was respected and corresponding references made.</p>
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				<p>claim or not or whether a claim complies with the requirements of Art. 54 and 56 EPC on the level of the practical tests that may be required to that end.</p> <p>As in Examples 1 to 4 below, it may be that the claim pertains to a field within which determining whether an embodiment falls within the scope of a claim or not is almost always feasible using routine tests or without any test at all. In such cases, it may be assumed that question (ii) is positively answered, and the clarity of a claim may be assessed using only question (i).</p> <p>For example:</p> <p>“1. A vehicle, comprising wheels”. (Example 1)</p> <p>In such a case, the person skilled in the art would indeed be able to understand precisely where the scope of the claim ends and begins and whether a given embodiment falls in it or not: if the embodiment, for instance related to a vehicle they consider marketing, is a vehicle which includes wheels, then the embodiment falls within the scope of the claim. If this vehicle does not include wheels, or even if the embodiment merely relates a set of wheels not operatively coupled to a vehicle, they will not. The person skilled in the art being able to identify without serious doubt what the boundary of the claimed subject matter is, this claim is clear (cf. T</p>	
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				<p>0238/88). A key thing to note is that the absence of recitation of further information regarding the wheels, for instance related to their function or their structure, does not render the claim unclear. Indeed, the person skilled in the art is able to determine whether an embodiment falls within the scope of this claim regardless of the structural details or function the wheels exhibit, the presence or absence of wheels in the considered vehicle §being the decisive factor.</p> <p>Example 1 illustrates the fact that a broad claim may very well be clear, and that the examination of the clarity of a claim is not one of the breadth of its scope, of its novelty and inventive step etc. Indeed, in the general field of wheeled vehicles, one can conclude that this claim exhibits an obvious novelty problem (Art. 54) as wheeled vehicles have been known for thousands of years. In addition, to the claim may not be correctly supported by the description (Art. 84) as the description possibly implies e.g. that the wheels have a specific function, and the invention may not be sufficiently disclosed (Art. 83), but this claim is nonetheless clear.</p> <p>Consequently, objections under the Art. 84 clarity requirement inviting the Applicant to restrict the scope of a claim, for instance by specifying the function or the structure of the wheels, would be improper as such considerations do not pertain to clarity but the rather to the requirements of</p>	
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				<p>Art 54, Art 56 and Art. 84 support by description.</p> <p>Example 2:</p> <p>“1. A vehicle, comprising large wheels”. (Example 2)</p> <p>In this claim, the relative term “large” has been introduced and results in a doubt about the protection of the scope which is sought (see F-IV.4.6.). Indeed, what is the meaning of “large”? Is this notion related to the width of the wheel, to its diameter, to the thickness of a certain portion thereof or else? In other words, when would a wheel be considered large in the sense of the claim? The claim does not allow any answer to be given to this question. Consequently, the person skilled in the art considering marketing a vehicle with wheels would not be in a position to determine whether the wheels of their vehicle would amount to large wheels in the sense of the claims and would therefore not be able to determine whether their vehicle falls within the scope of the claim or not. Likewise, the skilled person would not be in a position to unambiguously compare the claimed subject matter to the prior art. As a result, the claim is not clear.</p> <p>As shown by Example 2, a clarity problem may arise in a claim when the meaning of a word or expression is insufficiently developed in the claim itself and results in a doubt about the definition of the boundary of the scope</p>	
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				<p>of the claim. Care should however be taken to exclusively examine whether the person skilled in the art can determine whether any embodiment falls within its scope or not, and expressions or terms which are broad and not specified further may very well be acceptable, as exemplified by Example 1 above and by further Example 3 below.</p> <p>Example 3:</p> <p>1. A hinge assembly having:</p> <ul style="list-style-type: none"> • a frame mountable portion and • a sash mountable portion in slidable engagement with the frame mountable portion, • a braking means for applying a braking force between the sash mountable portion and the frame mountable portion of the hinge assembly during at least a portion of a sliding movement therebetween, characterized in that the hinge assembly further comprises control means configured to engage the braking means to adjustably control the braking force applied by the braking means. <p>The expression “braking means” is functional (see F IV, 6.5) and seeks to encompass different realizations of the corresponding function. This expression is broad, but is nonetheless theoretically clear as the skilled person readily understands what the expression means and is without doubt capable of determining whether any given device qualifies as</p>	
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					<p>a braking means in the sense of the claim As such, the absence of any structural consideration regarding the precise form of these braking means introduces no doubt regarding the boundary of the scope of the claims, and so regardless of the structure they have.</p> <p>Although Example 3 relates to functional expressions, broad expressions which are themselves not functional may also be clear, as shown below by Example 4 which includes an example of a broadly worded feature which creates no clarity problem, and another feature which does create a clarity problem.</p> <p>Example 4:</p> <p>1. A device, comprising: - a sensor configured to provide a sensor output, - a motor, and - a processing module configured to generate a command signal for varying a rotation speed of the motor, wherein the processing module is configured to optimize a magnitude of the command signal based on the sensor output.</p> <p>In Example 4, the term “optimize” creates a clarity problem. Indeed, what is the meaning of this expression? When would a magnitude of a command signal generated in a comparable device be considered optimized in the sense of the claim? The claim provides no answer to this</p>	
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				<p>question, and thus fails to allow the person skilled in the art to unambiguously determine where the scope of the claim begins and where it ends.</p> <p>However, the feature “a sensor configured to provide a sensor output” does not create a clarity problem, as discussed in Example 3. Indeed, the absence of precision regarding its nature or function does not prevent the person skilled in the art from understanding precisely what is in the scope and what is not: any sensor would qualify as a sensor in the sense of the claim, and so regardless of the observable (parameter) of the sensor and of the sensor output.</p> <p>As opposed to Examples 1 to 4, in certain cases, one’s ability to practically test whether a given product falls within the scope of a claim or not is a critical discussion point, and certain formulations may comply with the theoretical requirement of clarity yet fail to comply with its practical requirement.</p> <p>This may for instance be the case for features defined through parameters, whether explicitly in their language or implicitly through the need to transpose the associated features into parameters for testing for their presence or absence (cf. F-IV.4.11 Parameters)</p> <p>As an example, a claim which imposes an unusual combination of</p>	
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				<p>tests which may themselves be routine tests may prove unclear, for instance when the tests must be carried out in a specific sequence to provide unambiguous and conclusive results. The claim may be considered clear only if instructions as to the sequence that should be carried out are available in the description or general knowledge and the sequence itself allows for an easy verification of the presence or absence of the features of the claim in a given product (cf. F-IV.4.11 and F-IV.4.21).</p> <p>In general, any requirement of resourcefulness or creativity in the process of testing whether an object falls within the scope of a claim is in an indication that the claim does not comply with the practical requirement of clarity, and so whether or not one uses common knowledge or follows instructions provided by the description or the claim itself.</p> <p>It may also happen that testing the features of a claim requires an unusual combination of skills, i.e. that it requires the involvement of an unusual combination of persons skilled in the art. The process of testing the features of the claim may consequently extend well beyond routine tests normally encountered in the field, providing an indication that the claim is unclear.</p> <p>It may also be that the testing process of a claim involves unusual substances or equipment in the</p>	
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				<p>considered field. In such a case, the claim may be objected to under the clarity requirement if the features that give rise to the reliance on the unusual substances or equipment are generally recognized in the art as having a straightforward conversion into features which themselves rely on routine substances or equipment (cf. F-IV.4.11.1).</p> <p>In case of doubt as to whether a test or a testing process imparted by a feature is indeed routine or not, the onus of proof lies with the Applicant.</p> <p>The following items provide detailed discussions on specific cases in which clarity problems may arise.</p>	
82	F	IV	<p>In March 2021, extensive changes were made to the EPO Guidelines to impose a stricter standard for adapting descriptions to the allowed claims. Despite recognizing the efforts of the EPO and providing extensive feedback during successive user consultations, these changes have resulted in a substantial divergence between the EPO's requirements and the expectations of the users. The subsequent amendments in the 2023 and 2024 Guidelines have made only limited adjustments, failing to address many user concerns adequately.</p> <p>The new guidelines insist that "the applicant must remove any inconsistencies", a requirement not explicitly stipulated in the European Patent Convention (EPC). This requirement has introduced an unduly strict standard that places an unnecessary burden on applicants. According to Article 84 EPC, the claims must be supported by the description, meaning the subject matter of the claims must find a basis in</p>	<p>The guidelines should incorporate more flexible language, ensuring that the removal of inconsistencies is required only when they are substantial enough to affect the clarity and support of the claims under Article 84 EPC. Furthermore, it should be more emphasized that it is important to ensure that the subject matter of the claims is clearly supported by the description without imposing overly rigid requirements for verbal consistency that do not impact the legal and substantive quality of the patent. A more nuanced language is suggested that balances the need for clarity with practical considerations, such as "appropriately" or "does not present conflicting information."</p>	<p>The Office did not agree.</p> <p>The practice of the Office has not changed since 1978 and was clarified and harmonised in 2021 through careful redrafting of F-IV. 4(iii). According to the Guidelines, the applicant must remove any inconsistencies by amending the description, either by deleting the inconsistent embodiments or by marking appropriately so it is clear they do not fall within the subject-matter for which protection is sought. This practice is in line with the case law of the Boards of Appeal, and notably with most decisions issued after clarification of the Guidelines in 2021: T978/16, T1941/18, T626/18, T1024/18, T212/20, T2293/18, T2766/17, T1516/20, T2685/19 and T438/22.</p> <p>The Guidelines F-IV, 4.3 state: "Any inconsistency between the description and the claims must be avoided if it casts doubt on the</p>

			<p>the description. However, the new guidelines overemphasize the removal of inconsistencies, which could lead to an excessive focus on verbal and formal consistency rather than substantive patent quality. There remains a significant divergence of view between the EPO and users regarding the necessity and extent of these amendments. The guidelines overlook the users' suggestions to include more mitigating language, such as "appropriately" or "does not present conflicting information," which could reduce the mandatory nature of these changes.</p> <p>The stricter standards and requirements to amend the description impose increased workloads on applicants and examiners alike, potentially leading to delays and increased costs in the patent granting process.</p>		<p>subject-matter for which protection is sought, thereby rendering the claim either unclear or unsupported".</p> <p>Accordingly, inconsistencies must only be removed if they affect clarity or support. The section goes on to give examples of situations where inconsistencies can lead to a lack of clarity requiring adaptation of description or claims, but also provides positive examples where no adaptation is required.</p> <p>Decision T 56/21, which questions the legal basis for adapting the description to the claims, should not be followed, as it is not in line with well-established case law of the Boards of Appeal. It is an individual decision only binding in the specific case at issue.</p> <p>Therefore, and in view of referral G1/24 and the intended referral on the requirement to adapt the description to amended claims announced in case T 0697/22, current practice will be continued and the corresponding sections of the Guidelines will not be amended.</p> <p>Comments 83, 84, 85, 86 and 87 were taken up together with comment 82.</p> <p>SACEPO WPG members fiercely opposed the approach explained by the Office:</p> <ul style="list-style-type: none"> • The authority of T56/21 should not be ignored but followed by the Office, given the thorough analysis contained in the decision: there is no legal basis in the EPC for requesting adaptation of the description to the claims. • The practice of the Office has dramatically changed since 2001. At that time there was no obligation to earmark
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						<p>embodiments as "not according to the invention".</p> <ul style="list-style-type: none"> • The Enlarged Board of Appeal has already taken position on the issue in G2/10: "It is in principle for the applicant to determine the scope of protection he desires by the manner in which he drafts his claims. There is no provision in the EPC which would oblige an applicant to seek, in the individual application under consideration, a protection corresponding to the broadest possibility offered by the disclosure of the application. Nor is there an obligation to draft claims in such a way as to include the preferred embodiment in their scope". (Reason 4.5.5) • The obligation to adapt the description is prejudicial to the patent proprietor in the event of litigation before national courts/the UPC. • None of the decisions of the Boards of Appeal quoted by the Office necessarily support adaptation of the description to the claims. <p>There were no further comments from SACEPO WP/G members.</p>
83	F	IV	4.3	Any reference to T 0056/21 (Hoffmann La Roche) is missing. This very detailed decision rules out Art 84, 69 and Rules 42, 43, 48, 49 ECP as basis for extensive adaptation of the description.		See comment 82.
84	F	IV	4.3	T 0056/21 (Adaptation of the description/HOFFMANN-LA ROCHE) 04-10-2024 did not consider it necessary to refer questions to the Enlarged Board, as they concluded that there was no doubt as to how the legal provisions should be understood. T 56/12 concluded: <i>"In examination of a patent application, neither Article 84 nor Rules 42, 43 and 48 EPC provide a</i>	It is requested to bring the GL, in particular F-IV, 4.3 and 4.4, into conformity with T 56/21.	See comment 82.

				<p><i>legal basis for requiring that the description be adapted to match allowable claims of more limited subject-matter.</i></p> <p>https://www.epo.org/en/boards-of-appeal/decisions/t210056eu1</p>		
85	F	IV	4.3-4-4	<p>According to T 56/21 there is no legal basis in the EPC for the requirement to adapt the description, e.g., to remove claim-like clauses, inconsistencies and the like. This point is unequivocal according to that Board.</p>	<p>Removal of "must" language suggesting the description must be adapted to remove inconsistencies. Removal of "must" language in relation to the removal of claim-like clauses.</p>	See comment 82.
86	F	IV	4.3-4.4	<p>Adapting description (F-IV,4.3) -</p> <p>Extensive changes were made in the EPO Guidelines of 1 March 2021 to impose a stricter standard for adaptation of the description to the allowed claims. EFPIA recognised the effort made by the EPO to adapt the Guidelines after receiving feedback during successive user consultations. Further extensive comments were provided by users, including EFPIA, resulting, however, in only limited changes in the 2023 and 2024 Guidelines.</p> <p>There still exists a significant divergence of view between the EPO and users on this matter. Although additional wording could mitigate the mandatory nature of these changes, such as "appropriately" or "does not present appropriately" or "does not present conflicting information," the new Guidelines still set out an unduly strict standard requiring that the "applicant must remove any inconsistencies," which is not a requirement stipulated in the EPC.</p> <p>Moreover, despite all changes and adaptations made by the EPO since 2021, the new Guidelines are still difficult to implement for users and open to subjective interpretation, thereby leading to non-uniform application of the law and ultimately becoming counter-productive to the stated objective of achieving quality of granted</p>	<p>Proposal for amendments of EPO guidelines, Part F, Chapter IV, sections 4.3 and 4.4 -</p> <p>4.3 Inconsistencies Any inconsistency between the description and the claims must be avoided if it may throw doubt on the extent of protection and therefore render the claim unclear or unsupported under Art. 84, second sentence, or, alternatively, render the claim objectionable under Art. 84, first sentence. Such inconsistency can be of the following types:</p> <p>(i) Simple verbal inconsistency - For example, there is a statement in the description which suggests that the invention is limited to a particular feature but the claims are not thus limited; also, the description places no particular emphasis on this feature and there is no reason for believing that the feature is essential for the performance of the invention. In such a case, the inconsistency can be removed either by broad</p>	See comment 82.

			<p>patents and ensuring consistency between examiners. There is now a higher burden on the applicant and examiner to check each embodiment throughout the description for issues after adaptation, which is time-consuming for both sides. This labor-intensive practice also adds to the cost for the applicant and the resources needed at the EPO, with no added value overall. It is noted that there seems to be an increase of rule 71.3 EPC communications in which the examining division has made amendments in the description which are clearly unnecessary and undesirable. Many of these unwanted amendments have in common that they are based on a clear misunderstanding of the invention by the examiners.</p> <p>Furthermore, statements such as "so that it is clear that they do not fall within the subject-matter for which protection is sought" go beyond what EFPIA believes is the role of the Guidelines and of the EPO, which should not define what is or is not part of the scope of patent protection or about what can be considered as equivalents. It is not justified for the Guidelines to go beyond what the Articles and Rules of the EPC have set out to be the instruments with which to achieve balance on issues of interpretation (see Art 69, and the associated Protocol on the Interpretation of Article 69 EPC). The Guidelines should not impinge on that position regarding the methods of claim interpretation or equivalents.</p> <p>Applicants are disadvantaged in either of the two narrow options given to them by the new Guidelines of (1) deleting or (2) disclaiming features in the description. To disclaim a feature is a statement from the applicant - not only in the prosecution history, which is relevant in some jurisdictions, but in the patent itself - that this subject matter is not within the scope of protection.</p> <p>Equivalents exist as a concept enshrined under</p>	<p>ening the description or by limiting the claims. Similarly, if the claims are more limited than the description, the claims may be broadened or the description may be limited. See also paragraph (iii) below.</p> <p>(ii) Inconsistency regarding apparently essential features -</p> <p>For example, it may appear, either from general technical knowledge or from what is stated or implied in the description, that a certain described technical feature not mentioned in an independent claim is essential to the performance of the invention, or, in other words, is necessary for the solution of the problem to which the invention relates. In such a case, the claim does not meet the requirements of Art. 84, because Art. 84, first sentence, when read in conjunction with Rule 43(1) and (3), has to be interpreted as meaning not only that an independent claim must be comprehensible from a technical point of view but also that it must clearly define the subject-matter of the invention, that is to say indicate all the essential features thereof (see T 32/82). If, in response to this objection, the applicants show convincingly, e.g. by means of additional documents or other evidence, that the feature is in fact not essential, they may be allowed to retain the unamended claim and, where necessary, to amend the description instead. The opposite situation - in which an independent claim includes features which do not</p>	
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			<p>the Protocol, and an overzealous approach in the EPO Guidelines - forcing applicants to disclaim or delete subject matter in the description or be threatened with refusal of otherwise patentable subject matter - is manifestly unjustified. Notably, the Protocol is a part of the EPC, and it therefore takes precedence over the Guidelines which are not themselves part of the EPC.</p> <p>A third party, when assessing the scope of a claim, will be aware of potential issues of equivalence. A degree of uncertainty will naturally exist in Europe since different national courts or the Unified Patent Court may come to different interpretations. It is, however, for the courts, not the EPO examiners, to make this assessment regarding equivalence.</p>	<p>seem essential for the performance of the invention - is not objectionable. This is a matter of the applicant's choice. The division therefore does not suggest that a claim be broadened by the omission of apparently inessential features;</p> <p>(iii) Part of the subject matter of the description and/or drawings is not covered by the claims - According to Art. 84, second sentence, the claims must be supported by the description. This means that the subject matter of the claims must find basis in the description.</p> <p>An inconsistency may exist if an embodiment of the description comprises a feature which is demonstrably incompatible with an independent claim. In this case, the applicant must remove any inconsistencies by amending the description either by deleting the inconsistent embodiment or marking appropriately so that it is clear that it does not fall within the subject-matter for which protection is sought. However, it is not an inconsistency when an embodiment comprises further features which are not claimed as dependent claims, as long as the combination of the features in the embodiment is encompassed by the subject-matter of an independent claim. Similarly, it is not an inconsistency when an embodiment fails to explicitly mention one or more features of an independent claim as long as they are present by reference</p>	
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				<p>to another embodiment or implicit. Example: Where the claim comprises features A, B and C taken in combination, the passages dealing individually with how each of A, B and C are realised are normally understood as describing the refinements of the combination defined in the claim unless there are clear indications to the contrary. The passages which describe only the realisation of feature A, for example by introducing features A1-A3 and discussing their advantages, but which can be interpreted as meant for being combined with the other features of the claim, would not need an amendment caused by the limitation of the claim from B to B2 unless one of A1-A3 is incompatible with B2.</p> <p>Subject-matter in the description regarded as an exception to patentability under Art. 53 needs to be excised, reworded such that it does not fall under the exceptions to patentability, or prominently marked as not being according to the claimed invention (see G II, 4.2 for adaptation of the description for methods of treatment of the human and animal body, G II, 5.3 for adaptation of the description for the use of human embryonic stem cells and G II, 5.4 for adaptation of the description for plant and animals).</p> <p>An inconsistency between the description/drawings and the claims may frequently occur when, after a limitation of the claims following an invitation under Rule 62a(1) or Rule</p>	
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				<p>63(1), the subject-matter excluded from the search is still present in the description. Unless the initial objection was not justified, such subject-matter is objected to under Art. 84 (inconsistency between the claims and the description). Furthermore, an inconsistency between the description/drawings and the claims will occur when, after a non-unity objection (Rule 64 or Rule 164), the claims have been limited to only one of the originally claimed inventions: the embodiments and/or examples of the non-claimed inventions must be either deleted or clearly indicated as not being covered by the claims.</p> <p>4.4 General statements, "spirit of the invention", claim-like clauses - General statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way are not allowed. In particular, any statement which refers to the extent of protection being expanded to cover the "spirit of the invention" or "all equivalents" of the claims must be deleted. Statements that refer to the extent of protection covering the "scope of the claims" or the invention being "defined in the claims" are allowed. Analogously, in the case where the claims are directed to a combination of features, any statement that seems to imply that protection is nevertheless sought not only for the combination as a whole but also for individual features</p>	
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					or sub-combinations thereof must be deleted.	
87	F	IV	4.4	<p>The requirement to adapt the description is in contrast to the recent BoA decision T 0056/21 or clearly stating that "neither Article 84 nor Rules 42, 43 and 48 EPC provide a legal basis for requiring that the description be adapted to match allowable claims of more limited subject-matter".</p>	<p>Delete the following part: "Finally, claim-like clauses must also be deleted or amended to avoid claim-like language prior to grant since they otherwise may lead to unclarity on the subject-matter for which protection is sought.</p> <p>"Claim-like" clauses are clauses present in the description which despite not being identified as a claim, appear as such and usually comprise an independent clause followed by a number of clauses referring to previous clauses. These claim-like clauses are usually found at the end of the description and/or in the form of numbered paragraphs, particularly in divisional or Euro-PCT applications, where the original set of claims from the parent or PCT application is appended to the description."</p>	See comment 82.
88	F	IV	4.5	<p>This item is problematic on two front: (i) T 32/82 is grossly incorrect in its connection between essential features and clarity. Being the only element that bridges essential features to clarity, the result is that essential features are strictly a support by description requirement, and should thus be relocated to F-IV.6 (ii) 4.5.4. is a highly problematic discussion.</p> <p>Regarding (i), T 32/82 states in Reason 15 that : "Article 84 EPC requires amongst other things that the claims, which define the matter for which protection is sought (i.e. the object of the invention as implied by Article 52(1) EPC) be clear. The Board of Appeal considers that this</p>	<p>Remove F-IV.4.5. from F-IV.4 and relocate it to F-IV.6. In addition, remove any reference to T 32/82 from the 4.5, as the latter is grossly incorrect.</p> <p>The overall modified wording would be the following:</p> <p>4.5.1 Objections arising from missing essential features</p> <p>The requirement of Art. 84 that the claims be supported by the description applies to features which</p>	<p>The Office did not agree.</p> <p>(i) T 32/82, which connects the requirement to indicate all essential features to clarity, is not an isolated event, but has been confirmed by numerous T decisions (see Case law book II.A.3.2) and even by the Enlarged Board of Appeal in G 1/04 (see point 6.2 of the reasons). In other decisions, the requirement for all essential features to be indicated is inferred from the support requirement in Art. 84 (see Case law book II.A.5.1). Since the Guidelines F-IV, 4.5.1 already mention that essential features may be linked to the</p>

		<p>has to be interpreted as meaning not only that a claim from a technical point of view must be comprehensible, but also that it must define clearly the object of the invention, that is to say indicate all the essential features thereof.”</p> <p>The highlighted part creates a logical connection between clarity on the one hand, and essentiality on the other hand, and does so in a fashion that amounts to establishing that a claim that has an essentiality problem also has a clarity problem. This statement is precarious from a logical perspective as it states that every claim that does not belong to the set of claims that have no essentiality problem necessarily does not belong to the set of claims that are clear. This is incorrect and can be proven to be so by exhibiting a single example of a claim that has an essentiality problem but no clarity problem.</p> <p>The following claim is such an example:</p> <p>1. A system, comprising; - a processor, and - a power module configured to supply electrical energy to the processor, the power module being configured to perform function A.</p> <p>Let us place ourselves under the assumption that:</p> <ul style="list-style-type: none"> - the recitation of function A is itself clear, and - the problem that the invention proposes to solve is one pertaining to improving the efficiency of power modules supplying electrical energy to Artificial Intelligence accelerators. <p>Since we assumed that function A is recited clearly, this claim is clear. However, it is missing the essential feature that the processor is an Artificial Intelligence accelerator.</p>	<p>are explicitly presented in the description as being essential for carrying out the invention (see T 1055/92). A lack of essential features in the independent claim(s) is therefore to be dealt with under the support requirement.</p> <p>4.5.2 Definition of essential features</p> <p>Essential features of a claim are those necessary for achieving a technical effect underlying the solution of the technical problem with which the application is concerned. The problem is usually derived from the description, and by default differs from the problem of obtaining a claimed invention that functions as a product or a method. In other words, the essentiality of a feature only depends on its contribution to the solution for the specific problem the invention is concerned with, and not whether its presence is necessary in a product or in a method for the latter to be operated or practiced by an end user. For instance, the “wheels” are a necessary component of a bicycle for the latter to operate, but are not an essential feature of a claim related to a bicycle if the invention is concerned with solving a problem which does not involve the wheels.</p> <p>The independent claim(s) must therefore contain all features explicitly described in the description as being necessary to carry out the invention.</p>	<p>support requirement in Art. 84, the Office sees no need to change them.</p> <p>(ii) The Office agrees that the applicant is responsible for defining the subject-matter of claims (Art. 113(2); see also, e.g., Guidelines B-XI, 3.8). However, the Office does not agree with the statement that "there is no such thing as an implicit feature". According to established jurisprudence, the explicitly specified features of a claim may imply other features not explicitly set out. For instance, the generic term bicycle implies the presence of two wheels.</p> <p>As set out in F-IV, 4.5.4, a claim directed to a bicycle does therefore not need to mention the presence of wheels (even if these are necessary to achieve a technical effect underlying the solution of the technical problem with which the application is concerned).</p> <p>SACEPO WP/G members had divergent opinions on this section. One supported the view that essential features could not be connected to the requirement for clarity, and an independent claim by definition comprised all essential features; others had different opinions and found the Guidelines perfectly correct on this subject.</p> <p>One member suggested considering the results of the last Stakeholder Quality Assurance Panels (SQAP) on refusals to amend the Guidelines.</p> <p>The discussion also considered the role of functional features in claims, with members presenting opposing views. One member referred to the burden on third parties in determining the scope of protection when a functional feature has no immediately apparent effect on the structure. Others considered the possibility of including</p>
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			<p>This example thus demonstrates that a claim can exhibit a problem of Essentiality yet be perfectly clear, and that the logical connection created in T 32/82 is incorrect.</p> <p>The issue in the line of reasoning in T 32/82 is that it takes place on the language level rather than on that of the meaning of the concepts themselves. It ends up carrying out a discussion on what the meaning of the concepts could be instead of what it actually is. This is a severe flaw of reasoning, and no apparent attempt at checking whether the result is correct was made since disproving the connection between essentiality and clarity is extremely simple.</p> <p>What cannot be created is a claim that has an essentiality problem but no support by description problem, establishing that essentiality is a matter of support by description, and nothing else. To be specific, essentiality is a sub-component of the support requirement which targets a specific part of the description, namely the problem that the invention proposes to solve.</p> <p>Regarding (ii) and 4.5.4, this item exhibits two problems:</p> <ol style="list-style-type: none"> 1. One of the misapplication of the definition of essentiality 2. One of the introduction of the highly problematic notion of implicit features <ol style="list-style-type: none"> 1. As clearly stated in F-IV.4.5.2, Essentiality has a strict definition that relates to the problem that the invention proposes to solve. The drafter has control over the recitation of this problem and will usually be very careful in stating the problem precisely to avoid essentiality problems. 	<p>Any features which, even if consistently mentioned in the context of the invention throughout the application, do not actually contribute to the solution of the problem are not essential features.</p> <p>For example, it may appear, from what is stated or implied in the description, that a certain described technical feature not mentioned in an independent claim is essential to the performance of the invention, or, in other words, is necessary for the solution of the problem to which the invention relates. In such a case, the claim does not meet the requirements of Art. 84, second sentence, if the presence of said technical feature is not necessarily implied according to the skilled person's general technical knowledge, as the claim fails to include features which are necessary for the solution of the problem at hand, and therefore is not appropriately supported by the description. If, in response to this objection, the applicants show convincingly, e.g. by means of additional documents or other evidence, that the feature is in fact not essential, they may be allowed to retain the unamended claim and, where necessary, to amend the description instead. The opposite situation in which an independent claim includes features which do not seem essential for the performance of the invention is not objectionable. This is a matter of the applicant's choice. The division therefore does not</p>	<p>functional features to be very important and argued against any further restrictions in this respect in the Guidelines.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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89	F	IV	4.5.4	<p>My comments specifically relate to the following paragraph: “In the case of a product claim, if the product is of a well-known kind and the invention lies in modifying it in certain respects, it is sufficient that the claim clearly identifies the product and specifies what is modified and in what way. Similar considerations apply to claims for an apparatus.”</p> <p>Isn't an apparatus-claim a type of product claim? What does it add to explicitly mention an apparatus claim here? And what about method claims? Or was “claims for a method” intended instead of “claims for an apparatus”?</p>	<p>Improvement depends on what actually intended by the last sentence of the cited paragraph.</p>	<p>The Office will look into this matter.</p> <p>In view of the reference in Rule 43(2) to both product and apparatus claims, it makes sense to mention the two claim categories in this chapter even though, according to F-IV, 3.1, both product and apparatus claims in fact belong to a first basic kind of claim relating a physical entity.</p> <p>The Office will investigate whether the same considerations also apply for a method claim.</p> <p>There were no further comments from SACEPO WP/G members.</p>
90	F	IV	4.5.4	<p><u>F-IV, 4.5.4 – Essential features, implicit features</u> “In the case of a product claim, if the product is of a well-known kind and the invention lies in modifying it in certain respects, it is sufficient that the claim clearly identifies the product and specifies what is modified and in what way. Similar considerations apply to claims for an apparatus.”</p> <p>Comment: Isn't an apparatus-claim a type of product claim? What does it add to explicitly mention an apparatus claim here? And what about method claims?</p>	<p>Please clarify the difference between product and apparatus, or delete the emphasized sentence.</p>	<p>See comment 89.</p>
91	F	IV	4.6	<p>In 4.6.1., there is an imprecisions as to why relative terms tend to generate clarity issues (it's not about the meaning changing per se).</p> <p>Moreover, the cross-connection between novelty and Art. 123(2) is incorrect: a feature is clear or not. If it is not, it should be objected to no matter what, regarding of its status wrt novelty/IS. The same applies to the next paragraph: if the term is unclear, it needs to be clarified, Art. 123(2) issue</p>	<p>4.6.1 Clarity objections</p> <p>Relative or similar terms such as "thin", "wide" or "strong" constitute a potentially unclear element due to the fact that their meaning may be vague and consequently result in the inability of the person skilled in the art to determine whether certain embodiments fall in the scope of the</p>	<p>The Office will look into this matter.</p> <p>The statement in F-IV, 4.6 that an unclear term may remain in the claim where there is no basis in the disclosure for a clear definition and the term is no longer the only distinguishing feature does not appear to be supported by case law.</p> <p>To the contrary, recent decisions have confirmed that this principle should not be followed:</p>

				<p>or not. In case it cannot be remedied without complying with Art. 123(2), the claim should be rejected. This is confirmed by T 1099/21. Generally, cross-connection between concepts of the EPC are incorrect. The only acknowledged exception is the tandem Novelty/IS: a claim lacking novelty necessarily lacks an IS, and an inventive claim is necessarily novel. A possible connection of the same sort may exist between support by description and Art. 123(2) EPC (a violation of Art. 123(2) causes the claim to necessarily not be correctly supported). The conclusion is definitive: the status of a claim relative to a concept of the EPC has no effect of the status relative to another concept, except for N/IS (and perhaps for Support/Art. 123(2) EP). Therefore cross-connections are necessarily incorrect. Please note: the scope of the discussion is the concepts of the EPC, not that of the guidelines, which are for the most part at a higher granularity level and are also for the most part in the dependency of a concept of the EPC (e.g. essential features is a concept of the Guidelines which depends on the EPC concept of support by description)</p>	<p>corresponding claim or outside of it.</p> <p>For these terms to be allowed, their meaning must be precise in the context of the whole disclosure of the application or patent.</p> <p>The use of a relative term is objected to under Art. 84 unless the term has a well-recognised meaning in the particular art, e.g. "high-frequency" in relation to an amplifier, and this is the meaning intended.</p> <p>Where the relative term has no well-recognised meaning the division invites the applicant to replace it, if possible, by a more precise wording found elsewhere in the disclosure as originally filed.</p>	<p>T 362/17, reasons 23-24 T 869/20, reasons 2.4.2</p> <p>On the other hand, T 1099/21 cited in this comment does not directly relate to the issue in question, but to a case where in response to a clarity objection the proprietor deleted an unclear feature from the claim, which was then objected to under Art. 100(c) in opposition proceedings.</p> <p>There were no further comments from SACEPO WP/G members.</p>
92	F	IV	4.6.2	<p>My comment relates specifically to the following paragraph: "When the use of a relative term is allowed in a claim, this term is interpreted by the division in the least restrictive possible way when determining the extension of the subject-matter of the claim. As a consequence, in many cases, a relative term is not limiting the extension of the subject-matter of a claim."</p> <p>Comment: The words "extension of the subject-matter" are generally linked to Art. 123 EPC, Art. 100c EPC etc.. However, this part of the GL does not seem to have any link with Art. 123EPC. In the context</p>	<p>Proposed amended wording: "When the use of a relative term is allowed in a claim, this term is interpreted by the division in the least restrictive possible way when determining the scope of protection of the claim. As a consequence, in many cases, a relative term is not limiting scope of protection of a claim."</p>	<p>The Office will look into this matter.</p> <p>In the given context, the term "extension" must indeed be interpreted as "scope". Since the term "extension" is in fact often associated with the requirements of Art. 123(3) EPC, it may not be the most appropriate term here.</p> <p>There were no further comments from SACEPO WP/G members.</p>

				of the rest of F-IV, 4.6.2 it looks like “scope of protection” may have been meant instead of any matters relating to amendments.		
93	F	IV	4.6.2	<p>F-IV, 4.6.2 – interpretation of relative terms “When the use of a relative term is allowed in a claim, this term is interpreted by the division in the least restrictive possible way when determining the extension of the subject-matter of the claim. <i>As a consequence, in many cases, a relative term is not limiting the extension of the subject-matter of a claim.</i>”</p> <p>Comment: The “extension of the subject-matter” is linked to Art. 123 EPC, Art. 100c EPC etc. Is this what is meant here? In the context of the rest of F-IV, 4.6.2 it looks like “scope of protection” is meant instead of any matters relating to amendments.</p>	Proposed amended wording: “When the use of a relative term is allowed in a claim, this term is interpreted by the division in the least restrictive possible way when determining the extension of the subject-matter scope of protection of the claim. As a consequence, in many cases, a relative term is not limiting the extension of the subject-matter scope of protection of a claim.”	<p>The Office agreed to the proposal.</p> <p>The expression "extension of the subject-matter" is indeed often used in connection with the requirement of Art. 123(3) EPC. To avoid possible misunderstandings, a more appropriate formulation will be sought.</p> <p>There were no further comments from SACEPO WP/G members.</p>
94	F	IV	4.7.2	The explanation of why an Art. 84 objection should be raised is not entirely in line with the definition of clarity.	<p>4.7.2 Clarity objections</p> <p>If the application suggests that the use of terms such as "about", "approximately" or "substantially" extends either the interval claimed by a value and/or range outside the error margins of the measurement system or the structural unit beyond the manufacturing tolerances or any other tolerance that the skilled person would take into consideration in the technical field concerned, then the wording of the claims becomes vague and undefined. This leads to an objection under Art. 84 because the presence of this wording prevents the person skilled in the art from being able to unambiguously differentiate what is in the scope of the claim from what is not.</p>	<p>The Office will look into this matter in light of the proposal for a more general definition of the concept of clarity, in particular with regard to the coherence of the wording.</p> <p>There were no further comments from SACEPO WP/G members.</p>

					<p>For example, if the application suggests that an icosagon (20-sided polygon) is also a "substantially circular circumference" for a metal tray realised by a CNC waterjet cutting machine, this renders the scope of the claims unclear because:</p> <p>(i)the tolerance indicated by the application is outside the tolerance of the manufacturing method (a CNC waterjet cutting machine approximates a circular circumference by using a polygon with hundreds of sides); and</p> <p>(ii)if an icosagon is also a "substantially circular circumference", what about an enneadecagon (19-sided polygon) or an octadecagon (18-sided polygon)? When does a polygon stop being a "substantially circular circumference"? How can this be assessed objectively by the person skilled in the art?</p>	
95	F	IV	4.9	<p>F-IV, 4.9 – Optional Features “Optional features, i.e. features preceded by expressions such as "preferably", "for example", "such as" or "more particularly" are allowed if they do not introduce ambiguity. <u>In such a case, they are to be regarded as entirely optional.</u></p> <p>Comment: These expressions introduce ambiguity and <u>render the scope of the claim unclear if they do not lead to a restriction of the subject-matter of the claim.</u>”</p>	<p>Proposed amended wording: “These expressions introduce ambiguity and render the scope of the claim unclear if they do not lead to a restriction further specification of the subject-matter of the claim.”</p>	<p>The Office did not agree.</p> <p>Optional features can render the scope of the claim unclear if they do not lead to a restriction of the subject-matter. For instance, the optional feature may be contradictory to other features of the claim. One example given in the Guidelines concerns "an artificial stone, such as a clay brick". Here, the optional feature "clay brick" does not restrict the claim "artificial stone", but is in contradiction to it and thus renders it unclear.</p> <p>The proposed change does not appear necessary, because "restriction" and "further</p>

				How can a feature that is entirely optional lead to a restriction of the claim?		specification" appear equivalent and the meaning is further clarified by the examples. There were no further comments from SACEPO WP/G members.
96	F	IV	4.10	The item does not bring up the most important problem pertaining to these formulations: they frequently prevent patentability assessments from being conducted. The language could also use some emphasis on the practical requirement of clarity and its importance in these discussions.	The area defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention by a result to be achieved are not allowed, in particular if they only amount to claiming the underlying technical problem. However, they may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (see T 68/85). <u>The notion that result to be achieved formulations should not impose undue experimentation upon third parties is of utmost importance. In case of doubt, for instance when the result cannot be verified by tests commonly known to the person skilled in the art, an objection should be raised under the Art. 84 EPC clarity requirement. Indeed, the impossibility to rely on routine experimentation is not justified and indicates of a lack of clarity of the formulation. The burden of proving that the result to be achieved formulation relies on established tests then lies with the Applicant.</u>	The Office did not agree to the proposal. The added wording did not seem appropriate: <ul style="list-style-type: none"> - Partly, it repeats content that is already stated in this section; - A possible inability to assess novelty and inventive step is not only linked to this clarity deficiency, but may generally happen for unclear claims; - The suggestion implies that the clarity objection for a result to be achieved should be raised depending on the content of an available prior art document. This does not appear to be compliant with Art. 84. There were no further comments from SACEPO WP/G members.

				<p><u>A result to be achieved formulation may result in the inability to assess whether the subject-matter of the claim is novel and inventive. Indeed, unless the achieved result happens to be disclosed as such in the prior art, which prior art documents may not have a reason to disclose by default if for instance these documents are concerned with another problem or the achieved result is narrowly formulated, the result to be achieved formulation prevents the skilled person from determining whether these documents disclose or suggest the claimed subject-matter or not.</u></p> <p><u>In such cases, result to be achieved formulations should be objected to as lacking clarity, even if the invention cannot be defined more precisely without unduly restricting the scope of the claims and even if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation.</u></p> <p><u>The notion that result to be achieved formulations should not impose undue experimentation upon third parties is of utmost importance as these formulations usually rely on implicit parameters (cf. F-IV.4.11). In case of doubt, for instance when the result cannot be verified by tests commonly known to the person skilled in the art, an objection should be raised under the Art. 84 EPC clarity requirement.</u></p>	
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				<p><u>Indeed, the impossibility to rely on routine experimentation is not justified and indicates of a lack of clarity of the formulation. The burden of proving that the result to be achieved formulation relies on established tests then lies with the Applicant.</u></p> <p>For example, the invention may relate to an ashtray in which a smouldering cigarette end will be automatically extinguished due to the shape and relative dimensions of the ashtray. The latter may vary considerably in a manner difficult to define whilst still providing the desired effect. So long as the claim specifies the construction and shape of the ashtray as clearly as possible, it may define the relative dimensions by reference to the result to be achieved, provided that the specification includes adequate directions to enable the skilled person to determine the required dimensions by routine test procedures (see F III, 1 to F III, 3).</p> <p>However, these cases have to be distinguished from those in which the product is defined by the result to be achieved and the result amounts in essence to the problem underlying the application. It is established case law that an independent claim must indicate all the essential features of the object of the invention in order to comply with the requirements of Art. 84 (see G 2/88 and G 1/04). Art. 84 also reflects the general legal principle that the extent of monopoly conferred by a patent, as defined in the claims,</p>	
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					<p>must correspond to the technical contribution to the art. It must not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art (T 409/91). The technical contribution of a patent resides in the combination of features which solve the problem underlying the application. Therefore, if the independent claim defines the product by a result to be achieved and the result amounts in essence to the problem underlying the application, that claim must state the essential features necessary to achieve the result claimed (T 809/12), see also F IV, 4.5.</p> <p>The above-mentioned requirements for allowing a definition of subject-matter in terms of a result to be achieved differ from those for allowing a definition of subject-matter in terms of functional features (see F IV, 4.22 and F IV, 6.5).</p>	
97	F	IV	4.17	<p><u>F-IV, 4.17 - References to the description or drawings (minor issue)</u> “The emphatic wording of the excepting clause is to be noted.”</p> <p>Comment: Beautiful English, but non-native speakers will have to look up what “empathic” means in this context.</p>	<p>Proposed amended wording: “The emphasis on this being the exception should be noted”</p>	<p>The Office did not agree to the proposal.</p> <p>The current wording is unambiguous as to the intended meaning of this section.</p> <p>There were no further comments from SACEPO WP/G members.</p>
98	F	IV	4.18	<p>At present this guideline is interpreted by some examiners as precluding the introduction and use of acronyms. For example, if a claim integer is introduced as “1,2-bucklemyshoeane (12BMS)” the argument presented by some examiners is that brackets are only for references to the</p>	<p>It is therefore suggested that Guideline F-IV, 4.18 be amended to include a sentence on the lines “The use of brackets to define an acronym for an integer or concept, referred to elsewhere in the claims or dependent</p>	<p>The Office did not agree to the proposal.</p> <p>According to this section, a lack of clarity can arise with bracketed features that do not include reference signs. However, bracketed expressions with a generally accepted meaning are allowable.</p>

			<p>drawings and so this presentation of the integer is objectionable..</p> <p>Some examiners would require “1,2-bucklemyshoeane (12BMS)” to be replaced by “1,2-bucklemyshoeane ,12BMS,” [which could be argued to introduce a lack of clarity as to whether 1,2-bucklemyshoeane and 12BMS are the same or different integers].</p> <p>Other examiners would ask for deletion of 12BMS. If 1,2-bucklemyshoeane is referred to elsewhere in the claims as 12BMS without the full name, this would require amendment, lengthening the claims to no objective benefit.</p> <p>This practice provides no benefit to the users, nor to the general public who generally can understand the use of acronyms, [European Patent Office (EPO) is perfectly understandable] and represents a triumph of form over substance. Of course, if the acronym chosen would confuse the person skilled in the art [e.g. by being identical to one used in the art for something else] then objections should be raised.</p>	<p>claims by that acronym, is acceptable practice provided it does not lead to confusion to the person skilled in the art. ”</p>	<p>The proposal to generally allow definitions of acronyms using brackets bears significant risks:</p> <ul style="list-style-type: none"> - It would open the door to arbitrary abbreviations/acronyms in claims, as in the given fictitious example suggesting using 12BMS as acronym for 1,2-bucklemyshoeane. This would in many cases significantly compromise the legibility and clarity of the claim. - Where the acronym itself has a different meaning than the concept, a lack of clarity arises. <p>There were no further comments from SACEPO WP/G members.</p>
99	F	IV	<p>4.18</p> <p>My comments relate specifically to the following paragraphs</p> <p>“Optional features, i.e. features preceded by expressions such as "preferably", "for example", "such as" or "more particularly" are allowed if they do not introduce ambiguity. In such a case, they are to be regarded as entirely optional.</p> <p>These expressions introduce ambiguity and render the scope of the claim unclear if they do not lead to a restriction of the subject-matter of the claim.”</p> <p>How can a feature that is entirely optional lead to a restriction of the claim?</p>	<p>Proposed amended wording:</p> <p>“These expressions introduce ambiguity and render the scope of the claim unclear if they do not lead to a further specification of the subject-matter of the claim.”</p>	<p>This seems to relate to F-IV, 4.9. See comment 95.</p>

100	F	IV	<p>4.20</p> <p>4.20 "Comprising" vs. "consisting of"</p> <p>Second paragraph: "A claim directed to an apparatus/method/product "comprising" certain features is interpreted as meaning that it includes those features, but that it does not exclude the presence of other features, as long as they do not render the claim unworkable."</p> <p>Comment: The meaning of the terms "certain features" and "other features" is not ambiguous: does the term "other features" a) mean different features than the "certain features" that are listed, but not more of (some of the) same "certain features", or b) mean additional different or additional more of the same features. Interpretation a) is based on the interpretation that "other" means "different than certain". Interpretation b) is based in the interpretation that "other" may mean "more" without the intention to distinguish from "certain". The difference in interpretation is relevant when some of the "certain features" are defined to be present in a certain number (N, range N-M) or a certain amount (x%, x%-y%), in particular when not explicitly being defined as an open-ended range (at least N, at least x%)..</p> <p>One of us has the first interpretation, the other of us has the second interpretation. This leads to quite different results for scope of protection as well as in assessing novelty and/or inventive step, so that there is a clear a need for clarification in this GL section.</p> <p><i>Example 1:</i> Claim: Composition X comprising A, 5% of B and 10-20% of C:</p>	<p>Proposed wording: add to the cited paragraph: Herein, when some of the "certain features" are defined to be present in a certain number or a certain amount, the term "other features" is to be understood as referring to different features than the "certain features" that are listed, but not more of (some of the) same "certain features. I.e., when some of the "certain features" are defined to be present in a certain number (discrete values: N, range N-M) or a certain amount (continuous values: x%, x%-y%), the claim does not cover an apparatus/method/product with a larger a number of amount. <i>[for the proposal, we assumed interpretation a) to be correct; else formulate to reflect interpretation b]</i></p> <p>It is suggested to also add Examples 1 and 2 (fixed discrete value, fixed percentage, closed range of discrete values, closed range of continuous values/%)</p>	<p>The Office did not agree to the proposal.</p> <p>Since the Guidelines do not give further details on "other features", the term must be interpreted as meaning that they may be of the same kind as the "certain features" the claimed apparatus/method/product necessarily comprises.</p> <p>To explain this interpretation using the given examples, a table comprising five legs falls within the scope of a claim directed to a table comprising three legs.</p> <p>This interpretation is consistently applied when a range for an amount of a feature or substance is defined. For instance, a claim directed to a table comprising three to four legs is to be interpreted such that:</p> <ul style="list-style-type: none"> - The table comprises at least three legs AND - The table comprises not more than four legs. <p>Therefore a table comprising five legs does not fall within the scope of that claim.</p> <p>It is believed that the Guidelines are sufficiently clear in this respect.</p> <p>SACEPO WP/G members expressed opposing views on this matter. One insisted on the need for clarification in particular regarding the limitative effect of closed ranges. An example given was that the Guidelines do not provide an unambiguous answer to the question of whether a table comprising three to four legs also covers a table with five legs. Other members had different views and stated that the definition of ranges in claims was common practice correctly reflected in the Guidelines. For instance, there</p>
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			<p>i. The “comprising” allows the presence of an “other feature” D (as long as the total of all percentages do not exceed 100%).</p> <p>ii. Is that claim limited to compositions X having 5% of B, but not more (nor less)? I.e., is “A, 8% of B and 10-20% of C” outside the claim scope?</p> <p>a. Interpretation a): yes, outside: 8% is significantly different from 5% and claim is limited to exactly 5;</p> <p>b. Interpretation b): no, inside: 8% is 5% plus another 3%, so the 8% is covered by the certain feature 5% of B plus a other feature 3% of B, i.e. “comprising 5% of B is interpreted to mean “comprising at least 5% of B”;</p> <p>iii. Is that claim limited to compositions X having 10-20% of C, but not more (or less)? I.e., is “A, 5% of B and 40% of C” outside the claim scope?</p> <p>a. Interpretation a): yes, outside – ii.a mutatis mutandis: 40% is significantly outside 10-20% and claim is limited to 10-20% of C;</p> <p>b. Interpretation b): no, inside – ii.a mutatis mutandis: 40% of C is covered by the certain feature 10-20% of C plus a other feature “an additional amount of C whereby the total is 40 if C”, i.e. “comprising 10-20% of C is interpreted to mean “comprising at least 10-20% of C”;</p> <p><i>Example 2:</i> Claim: A chair comprising a seat, 3 legs and one backrest having 3-6 rungs:</p> <p>i. The “comprising” allows the presence of 1 or more armrests as an “other feature”.</p>		<p>was no doubt that a claim directed to a product comprising 10-20% of substance A did not cover products comprising 30% of substance A.</p>
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			<p>ii. Is that claim limited to chairs having 3 legs, but not more (nor less)? I.e., is “A chair comprising a seat, 4 legs and one backrest having 3-6 rungs” outside the claim scope?</p> <p>iii. Is that claim limited chairs having one backrest having 3-6 runs, but not more (or less)? I.e., is “A chair comprising a seat, 3 legs and one backrest having 9 rungs” outside the claim scope?</p> <p><i>Comparative example 3 (no interpretation issues):</i> Claim: A chair comprising a seat and at least 3 legs:</p> <p>i. The “comprising” allows the presence of other features, such as 1 or more armrests and/or a backrest</p> <p>ii. The “at least 3 legs” allows the presence of more. “A chair comprising a seat, 4 legs and one backrest having 3-6 rungs” is in the claim scope</p>		
101	F	IV	<p>4.21</p> <p>This item should ideally be deleted: the removal of this item is recommended as the degree of incorrectness of the discussion is very significant and the result is anyway within the scope of 4.10. A mention of the underlying decision could be added in 4.10</p> <p>Two defining elements were not seen in the decision and are thus not reported on correctly in the item:</p> <p>(i) The language under scrutiny is first and foremost a result to be achieved formulation, which has a functional layer superimposed on it</p> <p>(ii) The functional layer is in itself unclear</p> <p>These two elements not having been seen</p>	<p>remove F-IV.4.21 and add a reference to the underlying decision in F-IV.4.10</p>	<p>The Office did not agree to the proposal.</p> <p>The definition of a pathological condition in F-IV, 4.21 concerns medical uses under Art. 54(4) and (5).</p> <p>The specific legal framework and the very specific technical field involved justify treating this topic in a separate section.</p> <p>Moreover, the cited decision T 241/95 represents commonly accepted jurisprudence. The criticism of this decision does not appear to be based on case law.</p> <p>There were no further comments from SACEPO WP/G members.</p>

			<p>caused the discussion to give far more credit to the expression than what was due and therefore caused the discussion to be far more complicated than needed. This creates a needlessly complex precedent as to how similar expressions should be handled in practice.</p> <p>Regarding (i), let us analyze the expression in question, which is “any condition susceptible of being improved by selection occupation of a specific receptor”.</p> <p>The core of this expression is the following: “any condition is improved”. This is without a doubt a result to be achieved formulation. This expression is then “functionalized”, but in an untypical fashion. A typical functionalization would for instance yield “any condition is configured to be improved”. Instead, the functionalization revolves around the word “susceptible”: “any condition is susceptible of being improved”. A circumstantial feature specifying the pathway through which this result is obtained is then added:” by selective occupation of a certain receptor”.</p> <p>Neither the functionalization nor the circumstantial feature change anything to the fact that the core of the formulation is a result to be achieved. Therefore, the discussion is first and foremost one directed to F-IV.4.10. As discussed in 4.10, the main issue with these formulations is their tendency to prevent patentability assessments as the claimed effect may not have a reason to be disclosed in the prior art, e.g. if it is very narrowly formulated, or if the prior art is not concerned with verifying if the effect is present or not. Interestingly, in T 241/95, this did not prevent the BoA from running a patentability assessment (reason 4.1.1), which caused the BoA to get creative and look into the practical</p>		
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			<p>requirement of clarity, here to determine if the feature was reducible to practice – the conclusion being that it was not the case -.</p> <p>The reflex to look into the practical requirement is indubitably the correct one, but the line of reasoning which focused on the functional layer is not.</p> <p>As far as (ii) is concerned, the core of the functional layer is the word “susceptible”. The Board did not perceive that this expression is in itself not clear: it creates a doubt as to whether the scope includes conditions for which the effect is not present in case the occupation criterion is fulfilled. Indeed, an event which is susceptible to happen may or may not happen as both cases are envisaged by the word “susceptible” itself, thus creating as doubt as to what conditions are actually targeted by the expression.</p> <p>All in all, this case is first and foremost interesting as it targets an unusual configuration in which a result to be achieved formulation does not prevent the patentability assessment from being run, and led to the assessment of the practical requirement of clarity, which thus served as a basis to deem the claim unclear.</p> <p>This case is arguably encompassed by the modified language of F-IV.4.10, which shines more light on the patentability assessment issue yet leaves open the possibility of this issue not being present, and also stresses the importance of the practical requirement for result to be achieved formulations.</p> <p>In this sense, the entire item 4.21 could be removed and replaced by a reference to the decision T 241/95 in the appropriate location of F-IV.4.10.</p>		
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102	F	IV	4.22	<p>Various language precisions should be added to introduce clarity, relax the connection between support and breadth, and also between sufficiently of disclosure and breadth as there is no necessary connection between them. Reminder added about a claim being broad not necessarily being unclear, even if overly broad.</p>	<p>4.22 Broad claims</p> <p>The Convention does not explicitly mention overly broad claims. Objections to such claims may arise for various reasons.</p> <p>Where there are discrepancies between the claims and the description, the claims may not be sufficiently supported by the description (Art. 84), may not be clear (Art. 84) and the invention may not be sufficiently disclosed (Art. 83) (see T 409/91, F IV, 6.1 and F IV, 6.4).</p> <p>However, there is no direct connection between the breadth of a claim and its clarity, and a broad claim, even an overly broad one, may very well be clear (see F-IV.4.2. and Case Law of the Boards of Appeal – 3.3 Clarity of broad claims)</p> <p>Art. 84 and Art. 83</p> <p>Sometimes an objection of lack of novelty arises, for example if the claim is formulated in such broad terms that it also covers known subject-matter from other technical fields. Broad claims may also cover embodiments for which a purported effect has not been achieved. On raising an objection of lack of inventive step in such cases, see G VII, 5.2.</p> <p>For broad claims in opposition proceedings, see also D V, 4 and 5.</p>	<p>The Office will analyse whether the wording in this section can be improved. In particular, a revision could be based on case law II.A.3.3, e.g. that a broad claim is not unclear per se.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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103	F	IV	4.24	<p>There is no mention of the absence of calculation method for identity/similarity causing a clarity issue</p> <p>In addition, the conditioning of clarity problem by status relative to novelty is incorrect</p>	<p>Amino acid or nucleic acid sequences can be defined by a percentage of identity. The percentage of identity determines the number of identical residues over a defined length in a given alignment. If no algorithm or calculation method for determining the percentage of identity is defined, <u>the corresponding claim lacks clarity (cf. F-IV.4.11). For the assessment of other patentability criteria, the broadest interpretation will be applied using any reasonable algorithm or calculation method known at the relevant filing date.</u></p> <p>Amino acid sequences can be defined by a degree of similarity (expressed as a percentage of similarity). The term similarity is broader than the term identity because it allows conservative substitutions of amino acid residues having similar physicochemical properties over a defined length of a given alignment. The percentage of similarity is determinable only if a similarity-scoring matrix is defined. If no similarity-scoring matrix is defined in the application as filed, a claim referring to a sequence displaying a percentage of similarity to a recited sequence <u>lack clarity (cf. F-IV.4.11). For the assessment of other patentability criteria, this claim is further considered to cover any sequence fulfilling the similarity requirement as determined with any reasonable similarity-scoring matrix known at the relevant filing date.</u></p>	<p>The Office did not agree to the first two proposals.</p> <p>Claims defining amino acid or nucleic acid sequences by a percentage of identity without indicating an algorithm for determining the percentage of identity cover all reasonable algorithms known at the filing date and are thus considered clear.</p> <p>The same considerations apply to amino acid sequences defined by a degree of similarity.</p> <p>However, the Office will look into the wording of the last paragraph on clarity objections regarding a percentage of homology, in particular in light of the discussion on F-IV, 4.6.1 (see comment 91).</p> <p>There were no further comments from SACEPO WP/G members.</p>
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					For amino acid sequences, if a percentage of homology is used by the applicant, <u>its use is objected to under Art. 84 (cf. F IV, 4.6.1)</u> unless the determination or calculation of the percentage of homology is clearly defined in the application as filed. For nucleic acid sequences, homology percentage and identity percentage are usually considered to have the same meaning.	
104	F	V	3.2	<p>According to the Guidelines a lack of unity may be evident a priori, i.e. prior to carrying out a prior-art search, (uncritical in the present evaluation) or may become apparent a posteriori, i.e. after taking into account the prior art revealed by the search in terms of novelty and inventive step. If the main claim is considered to be not patentable, the EPO analyzes the dependent claims if the dependent claims diverge in such a way that they form inventions that have to be researched independently of each other.</p> <p>The guidelines (Part F, Chapter V.3.2) propose the following (highlighting added):</p> <p><i>“By doing so, groups of inventions are identified wherein each group of inventions relates to unitary subject-matter in view of the prior art at hand. If, in the course of grouping, the same special technical feature, which provides a contribution over the prior art, is identified in two groups of inventions, both groups of inventions need to be combined into one single group. Conversely, if, within one initial single group of inventions, claims or alternatives in claims are identified that are not linked by a potentially special technical feature, which provides a contribution over the prior art at hand, they will normally be separated into different groups of inventions. See also FV, 3(iii) for analysing</i></p>	<p>Consequently, the Guidelines should be revised so as to harmonise the assessment of lack of unity "a posteriori" across the Examining Divisions, particularly in view of common embodiments.</p> <p>As cited above, a hint is presently given in Part F – Chapter V.3.2 (grouping of inventions):</p> <p><i>“Typically, different groups of inventions are based on different independent claims of the same category, alternatives defined in one independent claim (see F-V, 3.2.1) or dependent claims defining alternative embodiments, provided that the independent claim is either not novel or not inventive”.</i></p> <p>A clarification could comprise that dependent claims relating to a common embodiment are normally considered to share a single general inventive concept.</p> <p>Moreover, it should be added that examiners are required to identify whether the (possibly non-unitary)</p>	<p>The Office did not agree to the proposal.</p> <p>Section F-V, 3 provides very detailed guidance on the assessment of unity. When determining common matter between claims and determining whether technical features correspond, the technical problems solved must not be too narrow or too general.</p> <p>When grouping inventions, the technical problems associated with different claims must be formulated carefully. In particular, a very narrow approach should be avoided, since the objective is to see whether any commonality between inventions can be established. It is therefore often necessary to redefine the specific problems associated with each claim to arrive at a more general problem, bearing in mind the context in which the relevant features are disclosed.</p> <p>Whether different claims belong to a same embodiment of the description is not a condition for non-unity. Different features of a single embodiment do not necessarily share a single general inventive concept. In addition, if the proposal was followed, it would still be unclear which additional "explicit reasons" – other than the non-unity reasoning defined in the Guidelines – would need to be given to justify a non-unity</p>

			<p><i>features in their context rather than in isolation. The initial grouping of claims and alternatives in claims into different inventions may require re-evaluation during the course of assessment of unity of invention”.</i></p> <p><i>“Typically, different groups of inventions are based on different independent claims of the same category, on alternatives defined in one independent claim (see FV, 3.2.1) or on dependent claims defining alternative embodiments, provided that the independent claim is either not novel or not inventive. However, different groups of inventions may also be based on independent claims in different categories if lack of unity is present between these claims”.</i></p> <p>Description of the problem As lack of unity “<i>a posteriori</i>” is assessed by the researcher / examiner based on the results of the research, it cannot be foreseen when the application is drafted.</p> <p>However, it is noted that the “<i>a posteriori</i>” assessment can lead to huge amounts of search fees based on dependent claims, only. The amount of search fees highly depends on the individual examiner. Below, a contradicting example of the EPOs assessment of unity is presented for two overlapping applications being filed in parallel, but differing by about 19.525 EUR of proposed search fees for the search of dependent claims.</p> <p>On the one hand, it is acknowledged that there may be a need for the EPO not to open the door for super broad main claims and an excessive number of dependent claims protecting different embodiments. However, the issue becomes particularly relevant, if the inventions under</p>	<p>dependent claims under examination share a common embodiment. Where the features actually share a common embodiment - examiners should be required to give explicit reasons on absence of a single general inventive concept despite the common embodiment.</p>	<p>finding for dependent claims covering a same embodiment of the description.</p> <p>It was also noted that the common practice on examination of unity of invention established in 2020 does not mention the proposed further requirement to identify whether dependent claims share a common embodiment.</p> <p>The need for more harmonised assessment of unity at the EPO was expressed during the meeting. The suggestion was made to add further examples regarding assessment of unity to the Guidelines.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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			<p>consideration share a common embodiment. Typically, features of the same embodiment are derived from a product developed under a general concept of improvement in the respective market.</p> <p>Less experienced applicants, e.g. SMEs, may be shocked when confronted with high amounts of additional search fees and refrain from filing patent applications in the future. Therefore, the present assessment of the lack of unity in some Examining Divisions contradicts several European initiatives to promote IP assets, particularly for SMEs. Furthermore, a divergent assessment of the lack of unity within the EPO contradicts the principle of equal treatment of applications and applicants</p> <p>At present, it appears that some examiners lack guidance as to the level of abstraction when assessing the (sub-)effect of the dependent claims with regard to the grouping of inventions.</p> <p>For example, the feature of a sensor that is added to a known floor heating system may be viewed in a narrow way by having the effect of enabling a detecting. Considering the invention as a whole, however, the additional sensor forms a dual system (heater and sensor) thereby simplifying the installation of the system as a separate step for installing the sensor (in addition to a step installing the heater) can be avoided.</p> <p>Thus, the level of abstraction of the effect has a significant influence on the assessment of common matter. The narrower the (sub-)effect of each dependent claim is defined by the examiner, the greater the chance of finding lack of unity a posteriori (as acknowledged in the Guidelines Part F – Chapter V-3. (iii): “Analysis of the remaining technical features”).</p>		
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			<p><u>Practical (Bad) Example</u> As mentioned above, an example of the EPO's assessment of unity "<i>a posteriori</i>" is visual in the following two related publications.</p> <p>Application A: WO 2019162336 A1 unity (1 invention); Application B: WO 2019162335 A2 lack of unity (12 inventions)</p> <p>The two applications comprise essentially identical drawings (some exceptions included). Application A is directed to a mat having a basic arrangement and a sensor while application B is directed to a mat having the same basic arrangement and a heater. Both applications have a dependent claim converging the mat to have both of sensor and heater. In essence, the two applications have a different starting point for covering different aspects, but are based on mostly overlapping embodiments. The international search reports considered both main claims not novel.</p> <p>Consequently, the assessment of unity should lead more or less to the same result. However, application A was found to have unity (no diverging inventions in the claims), whereas application B was considered to lack unity with 12 diverging inventions in the dependent claims resulting in proposed additional search fees of 19.525 EUR (at that time). In addition, the combination of heater and sensor in the mat was considered to be unitary in application A (dependent claim 11) and considered to form a separate invention in application B (claim 7; invention 3 in the search report).</p>		
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				Apparently, the assessment of unity by the two examiners was very individual and not harmonized.		
105	F	V	3.2.1	<p>In the draft version, a sentence reads:</p> <p>“Examples of inventions in the same category are alternative forms of an invention or interrelated inventions provided that they share a single general inventive concept.”</p> <p>While I understand the intention is to stress that a single general inventive concept is still required, the current formulation introduces redundancy and may confuse the reader. In the context of the other sentences in this section, it turns illustrative examples into a circular definition. The current wording seems like a tautology to me.</p>	<p>“A plurality of inventions in the same category may constitute a group of inventions so linked as to form a single general inventive concept. Examples include alternative forms of an invention or interrelated inventions. It is essential that such inventions share a single general inventive concept.”</p> <p>This structure preserves the examples and places the legal requirement in a separate sentence, making the logic clearer for readers.</p> <p>Thank you for considering this suggestion.</p>	<p>The Office did not agree to the proposal.</p> <p>The current wording is considered to adequately convey the intended message that there are cases where a plurality of inventions in the same category constitutes a group of inventions sharing a single general inventive concept. Examples correspond to the cases listed in Rule 43(2), namely interrelated inventions or alternative solutions, provided they share a single general inventive concept.</p> <p>There were no further comments from SACEPO WP/G members.</p>
106	F	VI	6.5	The change of the term “filing date” into “date of filing” seems to have been done without sufficiently careful review, as the term “international filing date” was changed to “international date of filing”	Reverse the amendment: change “international date of filing” back to the correct legal term “international filing date”, in F-VI, 6.5	<p>This comment seems to relate to F-III, 6.5.</p> <p>The Office agreed and will make the proposed change.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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107	G		several	<p>Suggestions for improving the quality</p> <ul style="list-style-type: none"> - If a decision deviates from the GL and/or BoA decisions: examiners should provide an explanation - Clarity/sufficiency of disclosure to be checked not only for serious issues - The scope of protection needs to be clear 	<p>Clarity/sufficiency of disclosure:</p> <ul style="list-style-type: none"> - Check method for determination - Ask the applicant to show comparison with prior art (novelty and inventive step) 	<p>The Office thanked the respondent for the suggestion. It was noted that the Guidelines are constantly updated and aligned with established practice and legal developments; however, as stated in General Part, 3, examiner decisions are expected to be in accordance with the Guidelines and not necessarily with every BoA decision, some of which may be divergent.</p> <p>There were no further comments from SACEPO WP/G members.</p>

108	G	II	<p>3.3 Guideline passage G-II, 3.3, paragraph 13, generalizes beyond and directly contradicts the teaching of enlarged board decision G 1/19. Board of appeal decision T 1910/20, reason 2, has explicitly called this specific GL passage “misleading”, “erroneous”, and “wrong”. The GL passage also contradicts multiple other board decisions.</p> <p>The erroneous GL passage reads: “If steps of a mathematical method are used to derive or predict the physical state of an existing real object from measurements of physical properties, as in the case of indirect measurements, those steps make a technical contribution regardless of what use is made of the results of the derivation or prediction.”</p> <p>The GL passage generalizes beyond what G 1/19, passage 99, supports, namely that indirect measurements – not broader “predictions” based on measured values – are automatically technical. For instance, following the logic of the GL passage, a weather forecast would be technical. Weather is defined as the state of the atmosphere (Wikipedia, “Weather”, very first sentence). Consequently, weather that is predicted based on, for instance, atmospheric pressure constitutes a physical state, i.e. the temperature, of an existing real-world object, i.e. the atmosphere.</p> <p>This directly contradicts G 1/19, passage 131 which states that a weather forecast algorithm that processes measured (real) weather data to predict future weather is not technical. Rather, a further technical use, such as the automatic operation of window shutters based on the predicted weather, is necessary to confer technical character upon the prediction algorithm. Accordingly, the statement of the GL that a</p>	<p>Direct and indirect measurements make a technical contribution regardless of what use is made of the results of the measurements. However, an algorithm that further processes measured values needs to be limited to a specific technical purpose to contribute to an invention's character.</p>	<p>The Office noted that the passage in the GL does not contradict G 1/19. A reference to G 1/19 could be added to clarify this point. The passage in question reads:</p> <p>"If steps of a mathematical method are used to derive or predict the physical state of an existing real object from measurements of physical properties, as in the case of indirect measurements, those steps make a technical contribution regardless of what use is made of the results of the derivation or prediction."</p> <p>In this passage, “the results of the derivation or prediction” refer to the indirect measurement itself, as can be understood from the phrase “<u>derive or predict</u> the physical state of an existing real object from measurements of physical properties, as in the case of indirect measurements”. The meaning is thus that an indirect measurement is technical, regardless of whether it is used for a technical purpose, which is also the meaning of paragraph 99 of G 1/19. The phrase “of the derivation or prediction” was added in the last GL revision precisely to avoid misconstruing the passage as claiming that the results <u>of the mathematical method</u> can be used for a non-technical purpose (i.e. not for an indirect measurement) and yet providing a technical contribution.</p> <p>With this clarification in mind, it was noted that the GL are not at odds with G 1/19. The GL passage does not imply that a weather forecasting model would necessarily provide a technical contribution, but an indirect measurement of weather or atmospheric conditions <u>from measurements of physical properties</u> would. Paragraph 131 of G 1/19 and T 1978/13 are about using weather forecasting for non-technical purposes and predicting a value of</p>
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				<p>prediction of an existing real world object's physical state from measurements is technical *regardless of its use* cannot be true.</p> <p>The GL passage contradicts multiple other decisions of the Boards: T 1615/17, reason 2.4: the technical character of input data does not render any algorithm processing said data technical; T 3226/19, reason 2.7: measurement is technical but the use of measured values for "analysis" is not necessarily; and T 1741/22, reason 2.3.6: a prediction based on measured values is not automatically technical and the word "measurement" needs to be interpreted narrowly ("vener of technicality").</p> <p>In conclusion, as explicitly stated by the boards, the GL passage is erroneous and needs timely rectification.</p>		<p>a weather-based structured financial product based on the input of real weather data, not measuring a physical system.</p> <p>The important phrase in the GL passage is "from measurements of physical properties", which distinguishes (non-technical) simulations of physical systems from (technical) indirect measurements of physical systems.</p> <p>It was noted that the GL passage is also in line with T 1615/17, T 3226/19 and T 1741/22, and even emphasises their conclusions by specifically requiring an interaction with physical reality at the outset ("derive or predict the physical state of an existing real object") and the use of the measurement of a physical entity as an input ("from measurements of physical properties") in order to constitute an indirect measurement.</p> <p>There were no further comments from SACEPO WP/G members.</p>
109	G	II	3.3.1	<p>G-II, 3.3.1, paragraph 1, reads: "the computational models and algorithms themselves contribute to the technical character of the invention if they contribute to a technical solution to a technical problem, for example by being applied in a field of technology and/or by being adapted to a specific technical implementation."</p> <p>The passage implies that it is sufficient for an algorithm to "be applied in a field of technology" to contribute to an invention's technical character. However, this assertion is misleading, if not plainly wrong and inconsistent with well-established jurisprudence and the Guidelines.</p> <p>First, the contested assertion directly contradicts the COMVIK approach (T 641/00) and landmark decision G 1/19 which refers to it (passage 77):</p>	<p>In such cases, the computational models and algorithms themselves contribute to the technical character of the invention if they contribute to a technical solution to a technical problem, for example by serving a specific technical purpose and/or by being adapted to a specific technical implementation.</p>	<p>The Office noted that the phrase "applied in a field of technology" is also present in G-II, 3.3 (7th and last paragraph) as an example of how a mathematical method can contribute to the technical character of the invention. The application of a mathematical method (and by inclusion an AI algorithm) in a field of technology is not unconditionally sufficient for the mathematical method to have a technical contribution, and of course it needs to have a specific purpose; the claim also has to be functionally limited to that purpose, as explained in GL C-II, 3.3.</p> <p>It is generally accepted that the application of an AI algorithm, and a mathematical method in general, in a field of technology can (under the conditions mentioned above) cause the</p>

		<p>"By contrast, the COMVIK approach and the present referral turn rather on how a claimed invention makes a technical contribution, whatever the field of technology may be."</p> <p>In fact, nowhere does G 1/19 or any other pertinent case law, for that matter, indicate the "technical field in which an algorithm is applied" as a sufficient criterion for establishing the algorithm's technical character. Rather G 1/19 (passages 98 and 137) refers to a "(further) technical use" and landmark decision T 1227/05 (reasons 3.1 and 3.1.1) refers to an "adequately defined technical purpose" (cf. GL G-II, 3.3, paragraph 10, "specific technical purpose").</p> <p>Second, under the contested section, in a claim along the lines of "A computer-implemented method using a neural network for cybersecurity" the neural network would qualify as technical for being "applied in a field of technology" (cybersecurity). However, the mere "application in a field of technology" in this case constitutes a "generic technical purpose" as opposed to a specific one. The Guidelines G-II, 3.3, paragraphs 10 and 11 read: "A generic purpose such as "controlling a technical system" is not sufficient to confer a technical character to the mathematical method. The technical purpose must be a specific one. [...] The claim is to be functionally limited to the technical purpose, either explicitly or implicitly. This can be achieved by establishing a sufficient link between the technical purpose and the mathematical method steps, for example, by specifying how the input and the output of the sequence of mathematical steps relate to the technical purpose so that the mathematical method is causally linked to a technical effect."</p> <p>Consequently, identifying "application in a field of</p>		<p>mathematical method to contribute to the technical character of the invention. T 0208/84 (see Reasons 12) and T 0338/00 (see Reasons 3) are notable examples. The conditions mentioned above do not negate the fact that an application in a field of technology is <u>an example of</u> how a computational model or an algorithm can contribute to the technical character of the invention, the other example being a specific technical implementation. The first paragraph of GL C-II, 3.1.1 does not imply that <u>any</u> application in a field of technology is <u>sufficient</u> to infer a technical character to an AI algorithm.</p> <p>The proposed wording of "serving a specific technical purpose" instead of "being applied in a field of technology" is not wrong <i>per se</i>, but in the context of the sentence would imply that a specific technical implementation does not serve a specific technical purpose, which would be wrong. Both the application of an algorithm in a field of technology and a specific technical implementation can serve a specific technical purpose, and that is the intended meaning of the first paragraph of G-II, 3.3.1.</p> <p>To emphasise that the general principles expressed in G-II, 3.3 also apply to AI and ML-related cases, the Office proposed to amend the relevant passage to "the computational models and algorithms themselves contribute to the technical character of the invention if they <u>serve a specific technical purpose and thus</u> contribute to a technical solution to a technical problem, for example by being applied in a field of technology and/or by being adapted to a specific technical implementation."</p> <p>SACEPO WP/G members agreed to the Office's proposal.</p>
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			<p>technology" as a sufficient criterion to establish an algorithm's technical character also contradicts Guideline section G-II, 3.3 and will mislead applicants and examining divisions.</p> <p>On that note, the decision T 2330/13 quoted in G-II, 3.3, the section whose wording the contested Guideline section G-II, 3.3.1 is partially copying, is only directed at an algorithm's "specifically adapted implementation" (parallel computing). Nowhere does this decision state that the mere "application in a field of technology" confers technical character upon an algorithm - and if it did, it would contradict G 1/19 and would thus be obsolete.</p> <p>In conclusion, the assertion that artificial intelligence (an algorithm) becomes technical by simply "applying it in a field of technology" is erroneous, misleading, and contradicts the Guidelines and the case law.</p>		
110	G	II	<p>3.3.1</p> <p>The examination of AI-related applications is inconsistent:</p> <p>Article 56 discussions are unpredictable</p> <ul style="list-style-type: none"> • In particular, technicality assessments of certain objects such as training or training data • Resistance to arguments about technical effect achieved beyond what is strictly disclosed (proof of technical effect in different use cases is unrealistic in AI), yielding discouraging bare scopes <p>The footing of Art. 83 EPC discussions is precarious:</p> <ul style="list-style-type: none"> • Very little information anywhere in the texts past the idea that a minimum of information is needed 	<p>More guidance for examination of AI inventions is required due to:</p> <ul style="list-style-type: none"> • High technical complexity of the topic in general • High degree of abstraction of the technical notions onto which claim language abstract in itself is built • Extremely fast evolutions, causing technical knowledge to quickly become obsolete • Presence of an exclusion of patentability right at the heart of it (models as such) • Some questions have no obvious answer, such as that of Art. 83 benchmarks 	<p>The Office thanked the respondent for the comment and noted that the Guidelines are regularly updated based on the latest legal developments. The Office acknowledged that clarity is needed when addressing specific topics, but at the same time one must not be too restrictive, especially in fast changing areas of technology. As case law develops, the Guidelines will continue to be enriched with examples of established practice.</p> <p>SACEPO WP/G members agreed with the Office's position and added that it would be premature to have specific guidance before case law settles.</p>

				<ul style="list-style-type: none"> There is no intuitive response to some important questions such as: when is training data sufficiently characterised? <p>Some stakeholders report the removal from the scope of the search and examination of features, even if the situation is salvageable.</p> <p>Clarity issues may arise due to the complexity of the cases. An unclear practice may also lead to improper clarity objections, which are far more frequent in AI inventions.</p>		
111	G	II	3.3.1	<p>Modernisation of the practice of clarity with a view to AI:</p>	<p>Acceleration of the development of the Guidelines wherever feasible:</p> <ul style="list-style-type: none"> Topic is not new anymore but G-II.3.3.1 contains 6 paragraphs Training activities and training data are critical but are barely touched upon either for Art. 56 or Art. 83 No benchmark for Art. 83 EPC requirements on data, training, topology No precise technicality discussion except for that of models <p>Adoption of a more open definition of technology for new technological developments</p> <p>Organisation of exchange sessions between examiners/attorneys/applicants (e.g. on view on pain points, realities, expectations, trends)</p>	<p>This was discussed along with the previous comment and the same conclusion applies.</p>
112	G	II	3.3.1	<p>It is appreciated that the proposal from epi EPPC ICT group, after several rounds of discussions with you, has been (largely) followed so as to reduce the risk of bias.</p>		<p>The Office thanked the respondent for the comment.</p>

113	G	II	6.2	<p>There is no legal support for require that inventions involving antibodies should meet an additional requirement relative to other inventions.</p> <p>A dedicated section for antibody inventive step assessment creates unjustified differential treatment compared to other technologies. The current Guidelines create an artificial barrier to patenting antibody inventions by establishing a prima facie assumption of non-inventiveness, which:</p> <ul style="list-style-type: none"> • Lacks legal basis under the EPC • Discriminates against antibody technology • Misinterprets case law (particularly T 187/04) • Ignores the unpredictability of antibody structure-function relationships <p>Reference is made to the article in the epi Information 4, 2024 “The Barrier Around Antibody Inventions at the European Patent Office” by T. Bucher: https://information.patentepi.org/issue-4-2024/the-barrier-around-antibody-inventions.html</p>	Delete whole section 6.2	<p>The Office appreciated the comment but did not agree to delete section G-II, 6.2.</p> <p>The section on antibodies has been welcomed by users and the public. It outlines the principles underlying current examination practice and is based on numerous BoA decisions.</p> <p>The Office has taken note of the article cited as well as another article in the epi Information, which endorses the EPO approach (https://information.patentepi.org/issue-1-2021/patenting-of-antibodies-in-the-epo-and-the-new-guidelines.html).</p> <p>The article to which this comment refers advocates for "structural non-obviousness" in the field of antibodies, which is not based on case law. The EPO approach summarised in the GL, by contrast, does find support in case law (see for instance the recent decision T 1911/17, reasons 35). Reference is also made to the approach taken by the UPC with regard to antibody patentability and inventive step (Sanofi v. Amgen, UPC 1/2023).</p> <p>The Office proposed to address this complex issue in a dedicated meeting with the epi Bio Committee and the involvement of technical experts in the field.</p> <p>There were no further comments from SACEPO WP/G members.</p>
114	G	II	6.2	<p>In the alternative the section 6.2 should be amended along the line provided by T. Bucher in the article in the epi Information 1, 2025 “The Barrier Around Antibody Inventions at the European Patent Office, part 3” also by T. Bucher:</p>		<p>The Office thanked the respondent for the comment but did not agree to amend this section, for the reasons set out in comment 113.</p>

				https://information.patentepi.org/issue-1-2025/the-barrier-around-antibody-inventions-at-epo.html		
115	G	II	6.2	<p>The antibody-based biologics field is critical for the advancement of public health and economic development. The EPO Guidelines section G.II.6.2 has established an unjustified barrier for pharmaceutical products by presuming that antibody-based inventions are prima facie non-inventive and unpatentable unless they meet specific exceptions. This approach undermines the crucial role patents play in incentivizing the research and development of biologics. The singling out of antibody inventions for unfavorable treatment compared to other technological fields lacks justification under both the European Patent Convention and established case law. An urgent revision of these Guidelines is necessary to align the inventive step standard for antibodies with that applied to other technologies.</p> <p>Antibodies are presumed non-inventive by default. The EPO Guidelines state: “The subject-matter of a claim defining a novel antibody binding to a known antigen does not involve an inventive step...”. Even if the sequence is unpredictable the antibody is considered not inventive. The EPO Guidelines state: “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is Dâ not a reason for considering the antibody as non-obvious”. According to the Guidelines, an antibody may be inventive only if it shows a surprising technical effect is shown, if there was no reasonable expectation of success of obtaining antibodies having the required properties, if there were difficulties in generating or manufacturing the claimed antibody, or if a novel type of functional antibody format is used.</p>	EPO Guidelines Part G.II.6.2 (all 3 paragraphs) should be removed entirely from the Guidelines. A dedicated section for antibody inventive step assessment is unnecessary and creates unjustified differential treatment compared to other technology areas (e.g. small molecule pharmaceuticals, peptide drugs, antisense oligonucleotides). The practice at the EPO must be revised to eliminate i) the assumption of prima facie obviousness of antibodies and ii) any sweeping, automatic prejudice of use of a ‘routine method(s)’.	The Office thanked the respondent for the comment but did not agree to amend this section, for the reasons set out in comment 113.

				<p>Incorrectly assumes all antibody generation is routine regardless of complexity. The EPO Guidelines state that: Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. This reflects a pervasive mindset among EPO examiners that ‘making antibodies is routine.’</p> <p>There is no ‘one-stop shop’ which will always produce a binder (let alone a binder exhibiting each and all the required activities), and there are very often no clear pointers about which method or sub-method to choose in a given instance. The list of techniques to discover novel antibodies that the skilled person has to choose from includes inter alia phage display, yeast display, mammalian cell surface display, ribosome display, bacterial display, mRNA display, DNA display, immunisation of rodents, rabbits, camelids or transgenic animals, as well as B-cell based screenings: each with its own advantages and disadvantages.</p> <p>Moreover, there is a high degree of unpredictability involved - knowing even the desired target epitope does not predict which particular amino acid sequences of the antibody will be useful as the paratope of the antibody. Even a single amino acid difference in an otherwise identical sequence may entirely disrupt its properties. Rather, the lack of predictability in developing commercially relevant antibodies with meaningful affinity and biological activity, particularly those suitable for diagnostic or therapeutic use, should be considered in the understanding of the problem solved.</p>		
116	G	II	6.2	Section G-II-6.2 relates to the inventive step of antibodies. This section seems to be misplaced, and would be better co-located with the other		The Office thanked the respondent for the comments but did not agree to the suggestions which can be identified but are not outlined as such.

			<p>discussion of inventive step in G-VII, and in particular in G-VII-13.</p> <p>Furthermore, antibodies are the only subject matter discussed in the guidelines where a presumption of non-inventiveness is expressed:</p> <p>“The subject-matter of a claim defining a novel antibody binding to a known antigen does not involve an inventive step unless the application shows a surprising technical effect or there was no reasonable expectation of success in obtaining antibodies having the required properties (see G-VII, 13).” [see G-VII-6.2]</p> <p>Such a presumption is not in accordance with TRIPS (in particular, Article 27.1), which states that “... patents shall be available ... without discrimination as to the ... the field of technology ...”</p> <p>Furthermore, the negative premise cannot simply be based on the two Board of Appeal decisions cited in the Guidelines (T 187/04 and T 605/14) as individual decisions at this level are not strictly binding on subsequent Boards and therefore cannot create such an unequivocal premise about the patentability of an entire field. T187/04 has been misinterpreted and does not provide support for this statement in the Guidelines that “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious.” T 187/04 concerned a monoclonal antibody that was defined by reference to a deposited hybridoma, which could be used to produce the antibody itself. No sequence was disclosed or claimed in the patent, so the Board could not have deliberated on the (un)predictability of amino acid sequence information, nor therefore have created an</p>		<p>The most relevant information on antibodies is provided in a single place in the GL. The Office trusts that this approach is more user-friendly than splitting up the information into clarity and inventive step sections in two separate places. This issue has repeatedly been discussed with users.</p> <p>According to current examination practice at the EPO, antibodies can be considered inventive if they exhibit a surprising technical effect, there was no reasonable expectation of success of obtaining antibodies having the required properties, or the application overcomes technical difficulties in generating or manufacturing the claimed antibodies (G-II, 6.2). The doctrine of "structural non-obviousness" is not applied, i.e. an antibody is not considered inventive because its "sequence could not be predicted". This is fully in line with established case law. Antibodies can be defined by functional and/or structural features (G-II, 6.1).</p> <p>There were no further comments from SACEPO WP/G members.</p>
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				<p>explicit, extensive exclusion to assessing structural information in the inventive step analysis.</p> <p>The Guidelines ignore two other Board of Appeal decisions which recognise the unpredictability of the impact of amino acid structural differences on functional properties in an inventive step analysis (T 67/11 and T 1171/18), so the Guidelines are not an accurate reflection of the decisions of the Boards of Appeal.</p>		
117	G	II	6.2	<p>Lif – the Research-Based Pharmaceutical Industry in Sweden – aligns with the joint submission provided by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and The Institute of Professional Representatives before the European Patent Office (epi) regarding the interpretation of the EPO Guidelines section G.II.6.2. It is important that antibody-based inventions are not excluded from patentability as a matter of principle. A general presumption against the patentability of antibodies unless specific exceptions apply, creates significant legal uncertainty and risks undermining incentives for innovation. This is particularly concerning in light of ongoing and future research efforts in the antibody field, where continued innovation is expected to yield important medical advances across a wide range of therapeutic areas. This development has far-reaching negative consequences for Europe's and Sweden's competitiveness and diminishes the region's attractiveness for biomedical research and investment.</p> <p>The Barrier Around Antibody Inventions at the European Patent Office</p> <p>The EPO Guidelines section G.II.6.2 has established an unjustified barrier for pharmaceutical products by presuming that antibody-based inventions are prima facie non-</p>	<p>Proposal to align the problem-solution approach with the approach applied to other chemical inventions</p> <ul style="list-style-type: none"> • Currently, after beginning with the negative premise, EPO examiners typically turn to assessing whether a "surprising technical effect" is present. If no improvement is identified, the practice is to re-define the objective technical problem as the provision of an alternative antibody to the target or for use in the same purpose. A finding of obviousness usually follows. • The objective technical problem should instead more accurately focus the examination on the actual claimed solution and the problems solved. For a sequence defined antibody claim, the problem is not whether any antibody in a general sense can be made, but rather it should be appreciated that specific structural information that has a certain functional activity has been provided. The problem needs to be commensurate with the solution provided. • Thus, the problem should be 	<p>The Office thanked the respondent for the comment but did not agree for the following reasons.</p> <p>This comment appears to endorse the position taken in comment 113, with further explanations, and is addressed above.</p> <p>The Office note that the introduction to this section has not changed examination practice, and is intended to provide valuable, publicly available information on that current practice.</p> <p>The problem-solution approach, particularly the definition of the problem, is in line with the GL (G-VII, 5.2). When defining the problem to apply the problem-solution approach the BoA also refers to an antibody (see recent decisions T 1911/17, reason 34; T 0326/22, reason 23.2).</p> <p>The Office does not share the view that T 187/04 has been "misinterpreted". It is not immediately apparent how provision of the sequence of an antibody deposited as a hybridoma cell can render an otherwise non-inventive antibody inventive. Recent BoA decisions, e.g. T 1911/17, reason 35, endorse T 187/04 and are fully in line with the principles outlined in G-II, 6.2.</p> <p>While there is no requirement that practice be in line with all relevant BoA decisions, the Office</p>

			<p>inventive and unpatentable unless they meet specific exceptions. This approach undermines the crucial role patents play in incentivizing the research and development of biologics. The singling out of antibody inventions for unfavorable treatment compared to other technological fields lacks justification under both the European Patent Convention and established case law. An urgent revision of these Guidelines is necessary to align the inventive step standard for antibodies with that applied to other technologies.</p> <p>The importance of antibody inventions Antibody inventions have revolutionized medicine and biotechnology, transforming treatment approaches for conditions such as cancers, autoimmune disorders and infectious diseases. Their remarkable specificity in binding to targets provides clinicians with precise tools for both diagnosis and therapy. These advancements continue to drive progress in medical research and patient care outcomes. Given the substantial financial risks and extensive research investments required, robust patent protection is essential to incentivize continued innovation in this critical field.</p> <p>The negative premise about the inventive step of antibodies in the EPO Guidelines Part G.II.6.2 Examiners must currently adhere to the following problematic guidelines when assessing antibody product claims, regardless of how specifically defined the claimed antibodies may be:</p> <ul style="list-style-type: none"> • The negative premise that new antibody inventions are prima facie non-inventive subject matter. (“The subject-matter of a claim defining a novel antibody binding to a known antigen does not involve an inventive step...”). • This premise may not be overturned by the assessment of the unpredictability of the amino acid sequence. (“The fact that the structure of an 	<p>formulated as the provision of a specific alternative molecular structure (or sequence) for use in achieving the functional activity Y’ {e.g. a mode of action such as an antagonistic or agonistic activity, driving the internalisation of antigen X or achieving a certain effect on a cell that expresses antigen X}.</p> <ul style="list-style-type: none"> • If the word “antibody” is omitted in the problem, this removes the bias that what is provided is merely a similar overall structural compound, with the CDRs being overlooked as minor, arbitrary variations to the overall structure. • The proposed analysis would be: starting from the closest prior art (e.g. from a particular prior art antibody possessing specific CDRs which bind to the target X), and in light of the objective technical problem (more correctly formulated as the provision of an alternative structure/sequence for achieving the desirable activity Y), would it have been obvious to the skilled person to modify the known structure (at least in its CDR sequences) in such a manner as not only to arrive at the structure that is claimed, but to do so with a reasonable expectation of success, i.e. of achieving the desirable activity? • For low molecular weight chemical compounds, the structures are claimed as graphical representations: examiners look to the depicted structures when assessing inventive step and, therefore, they more easily take account of their structural 	<p>notes that the section is in line with T 1171/18, which acknowledges inventive step due to the lack of expectation of success (r. 29) and refers to T67/11 as well.</p> <p>There were no further comments from SACEPO WP/G members.</p>
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			<p>antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”).</p> <ul style="list-style-type: none"> • According to the Guidelines this negative premise can only be overturned by showing one of a limited set of four exceptions: (1) a surprising technical effect, (2) no reasonable expectation of success of obtaining antibodies having the required properties, (3) technical difficulties in generating or manufacturing the claimed antibody, or (4) a novel type of functional antibody format may be inventive. <p>The standards in the EPO Guidelines Part G.II.6.2 lack legal basis: The antibody-specific standards in the EPO Guidelines lack proper legal basis for several critical reasons:</p> <ul style="list-style-type: none"> • Contravenes EPC Article 56: Art. 56 EPC does not start with a strong negative presumption that needs to be overturned – i.e. that claimed subject matter prima facie does not have an inventive step. • Discriminatory Treatment: Nor is this presumption applied in other technical fields, whether chemical or non-chemical. • Absence of Authoritative Precedent: This premise is not based on reasoning established in an Enlarged Board of Appeal decision – there has been no decision at this level which specifically addresses the inventive step analysis of antibodies. • Misapplication of Case Law: This negative premise cannot simply be based on the two Board of Appeal decisions cited in the Guidelines (T 187/04 and T 605/14) as individual decisions at this level are not strictly binding on subsequent Boards and therefore cannot create such an unequivocal premise about the patentability of an entire field. • Misinterpretation of Case Law: Importantly, T 	<p>differences.</p> <ul style="list-style-type: none"> • In contrast, for antibody inventions, where the arrangements of atoms are not specified in the claims, but are instead represented by the seemingly generic terms of “SEQ ID No. Z” or “SEQ ID No. ZZ”, the differences between the respective three-dimensional structures are markedly less apparent. As such, the structural differences from the prior art compounds are easy to overlook, and the solution itself is then underappreciated. Therefore, the Guidelines should actively direct the examiner towards looking at the differences between the CDR and/or VH/VL regions which have an important role in the functional activity. • Critical in the analysis is not only the consideration of the structural difference, but the effect of the difference on the functional activity. • For the scenario of a sequence defined antibody suitable for pharmaceutical use, the objective technical problem could be formulated as the provision of “a pharmaceutically acceptable structure/sequence for achieving the desirable activity Y”. • Thus, overall the analysis should take into account various scenarios: (i) if the binding sequences of a claimed antibody are dissimilar to the corresponding sequences of the closest prior art antibody for achieving the same function, then this structural dissimilarity should be considered in the obviousness 	
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			<p>187/04 has been misinterpreted and does not provide support for this statement in the Guidelines that “[t]he fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious.” T 187/04 concerned a monoclonal antibody that was defined by reference to a deposited hybridoma, which could be used to produce the antibody itself. No sequence was disclosed or claimed in the patent, so the Board could not have deliberated on the (un)predictability of amino acid sequence information, nor therefore have created an explicit, extensive exclusion to assessing structural information in the inventive step analysis.</p> <ul style="list-style-type: none"> • Misrepresentation of Case Law: The Guidelines ignore two other Board of Appeal decisions which do recognise the unpredictability of the impact of amino acid structural differences on functional properties in an inventive step analysis (T 67/11 and T 1171/18), so the Guidelines are not an accurate reflection of the principles in the antibody case law. • Inconsistent Application of Principles: The Guidelines fail to apply established structural similarity principles (CLBA, Section I.D.9.9.2) to antibodies and no justification is given for this in either the Guidelines or in the cases cited in the Guidelines (T 187/04 and T 605/14). • Narrowness of Exceptions Unjustified: Exceptions to legal principles are often interpreted narrowly, and by unjustly starting with the negative premise that antibodies are prima facie non-inventive subject matter, the facts under the four listed exceptions tend to be considered narrowly. Moreover, examiners tend to reduce the analysis to the exception relating to proving whether a “surprising technical effect” is present. However, it is not a mandatory requirement under the EPC to show an 	<p>analysis. The complexity of the function/activity may also be taken into account (e.g. simply exhibiting low affinity binding or at the other end of the scale, exhibiting a combination of properties suitable for pharmaceutical use): the assessment is whether a claimed antibody which has those differences is a predictable solution to the objective technical problem of achieving that activity;</p> <ul style="list-style-type: none"> (ii) if the CDRs and VH/VL sequence, as well as the overall structure of the claimed antibody are extremely similar to those of the prior art antibody, then as very similar structures might be expected to behave similarly, the claimed antibody could be considered obvious; (iii) nevertheless inventiveness could still be shown if a novel technical effect or improvement in activity was exhibited by the claimed antibody resulting from those small differences in the amino acid sequences, and it was not predictable from the state of the art that those differences would lead to that effect, (i.e. it was surprising how that further technical effect/improvement was achieved). Inventiveness could also still be shown if small differences in the amino acid sequences do not lead to a novel technical effect or improvement in function but lead to an acceptable alternative which was unexpected (e.g. mutations that the skilled person would have expected to decrease or abolish one or more desired functions or impact 	
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			<p>improvement (thus even less a requirement to show a surprising technical effect), as is clearly confirmed in the Case Law of the Boards of Appeal (July 2022, 10th edition I.D.4.5).</p> <p>The EPO Guidelines Part G.II.6.2 are inconsistent and unclear The Guidelines only permit the assessment of structure-function predictability in an inconsistent, unclear, and arbitrarily restricted manner: Arbitrary Structural Analysis Boundaries</p> <ul style="list-style-type: none"> • Examiners may consider unpredictability in the structure-function relationship at the level of the overall architecture of an antibody, as a novel format may be inventive. Yet they are explicitly discouraged from zooming in any further to the level of the amino acid sequence (from the guidance that “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”). • Therefore, they may assess how antibody domains/regions are positioned overall, but in a glaring inconsistency are guided away from assessing the structure within such domains/regions in particular within a variable region, because this is typically provided as amino acid sequence information. Rather astonishingly, therefore, the Guidelines direct examiners away from assessing the details of key parts of the product - the CDRs and VH/VL regions which are most directly involved in binding and for achieving the intended function of the product. <p>Paradoxical Treatment of Critical Regions</p> <ul style="list-style-type: none"> • In practice, examiners often require that the framework sequences of the variable region be recited in the claims, in addition to the CDR sequences, on the basis that the particular framework sequences may also influence the 	<p>negatively the structure/stability.)</p> <ul style="list-style-type: none"> • Such a mode of analysis would bring the approaches used in low molecular weight and antibody based biologic inventions into alignment. <p>Urgent Revision of the Guidelines needed</p> <ul style="list-style-type: none"> • Fundamentally, the EPO Guidelines do not need a dedicated section for the assessment of the inventive step of antibodies as differential treatment compared to other areas of technology is unjustified and is not needed. The EPO Guidelines Part G.II.6.2 should be eliminated entirely. • The practice at the EPO must be revised to eliminate (1) the assumption of prima facie obviousness of antibodies and (2) any sweeping, automatic prejudice of the use of “routine method(s).” • Structural similarity and structure-function relationships should be considered when assessing antibody claims defined by amino acid sequence information, including in the CDRs and VH/VL regions. In particular, the principles applied by the EPO for antibodies should be made consistent with the principles as applied to low molecular weight chemical compound inventions as set out in the Case Law of the Boards of Appeal of the EPO (CLBA) I.D.9.9.2: ‘Structural Similarity.’ • When formulating the technical problem in the problem-solution approach, examiners should consider 	
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			<p>desired activity (which should not be the rule but be considered in light of available data).</p> <ul style="list-style-type: none"> • Yet paradoxically, when assessing inventiveness, the specific sequence information in both CDRs and frameworks is dismissed. • Thus, even if those sequences are not a predictable solution to the underlying technical problem, that is still not available as a reason for finding the claimed antibody inventive – another perplexing inconsistency in the currently practised approach. <p>Misguided "Surprising Technical Effect" Exception</p> <ul style="list-style-type: none"> • The creation of an exception with the shorthand phrase "surprising technical effect" is an oversimplification, which leads to a misunderstanding of the underlying principle. Such an antibody product claim which is associated with a surprising technical effect is inventive as the manner in which that effect was achieved was not predictable from the art, in the sense that neither how the particular result was achieved, nor which particular product would give that effect was predictable. Thus, it is the inability to identify a priori which particular structure within the general class of antibodies that is able to achieve that effect/function that is actually being recognised. By creating an isolated exception with the short-hand phrase "surprising technical effect" a confusion arises as to whether it is the effect per se that needs to be surprising or whether, as should be the case, it is which structure (that causes the effect) that is surprising. <p>The EPO's "Routine Method" Approach to Antibody Patentability</p> <ul style="list-style-type: none"> • The EPO Guidelines state that: Arriving at 	<p>the activity (agonism, antagonism, effect on target cell, etc.), and the word 'antibody', that has become somewhat of a distraction at the EPO, could be replaced with a term such as 'molecular structure/sequence.' The aim would be to bring focus on the sequence information provided in a claim, including in the CDRs and VH/VL regions and to assess this in conjunction with a functional activity/purpose, to reflect both the complexity of the technical problem and the specificity of the solution provided.</p> <ul style="list-style-type: none"> • The antibody-based biologics field is critical for the advancement of public health and economic development. Removing the artificial barrier to antibody patenting that is currently embedded in the EPO Guidelines will significantly benefit and stimulate biologics research and innovation. 	
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			<p>alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. This reflects a pervasive mindset among EPO examiners that “making antibodies is routine.”</p> <ul style="list-style-type: none"> • The “routine method mindset” originated from the early hybridoma antibody case law – where the views were expressed that the preparation of monoclonal antibodies by the Köhler- Milstein hybridoma method had become routine work after a certain period of time (in T 735/00: 13 yrs), and the product was not inventive (unless there were unexpected properties). • However, applying this historical perspective to all antibody-derived products has created an inappropriate prejudice that all antibody generation work is inherently routine. The Guidelines effectively establish that every antibody is prima facie obvious by default unless proven otherwise - a position inconsistent with Article 56 EPC. • The Guidelines have expanded this concept beyond its original rationale that the method has become routine. Now, regardless of complexity, as soon as the technique is simply known in the art, the resulting antibody structures are assumed to be obvious. • A ‘routine method mindset’ is particularly problematic for structural claims as it ignores the actual claimed solution. It automatically disadvantages sophisticated, recombinantly-produced and engineered antibody products, severely underestimating the complex problems solved by modern antibody technology during inventive step analysis. • Antibody engineers typically make a number of choices when determining a strategy for obtaining antibodies in a particular situation. • The list of techniques to discover novel antibodies that the skilled person has to choose from includes inter alia phage display, yeast 		
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			<p>display, mammalian cell surface display, ribosome display, bacterial display, mRNA display, DNA display, immunisation of rodents, rabbits, camelids or transgenic animals, as well as B-cell based screenings: each with its own advantages and disadvantages.</p> <ul style="list-style-type: none"> • Moreover, multiple (often sequential) methods are utilised in the testing and selection of the desired characteristics. This is true for a diagnostic antibody for in vitro use (which must fulfil e.g. specificity, sensitivity, and stability criteria); it is especially valid for antibodies used in vivo (i.e. as a therapeutic or in vivo diagnostic). 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, absence of undesirable post-translational modifications such as proteolysis, as well as biological activity. It is incorrect to simply dismiss the product claimed as resulting from routine work, as it ignores the technical complexity involved in (1) attaining each individual characteristic and (2) the complexity faced when a combination of characteristics needs to be optimised in parallel via multiple methods. • Additionally, in the context of an inventiveness analysis, it is inaccurate to label the work as simply routine, as not only may multiple characteristics and methods be involved, but the optimisation of one criterion may negatively impact another. As such, a given development project as a whole does not have an obvious trajectory. • Antibody engineering typically involves sequences in the variable regions and, accordingly, a claim to such a defined set of CDRs or VH/VL sequences does not represent a mere arbitrary selection from a process of 		
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			<p>immunisation or from antibody display libraries.</p> <ul style="list-style-type: none"> • The listed exceptions in the Guidelines that focus on consideration of the method (that there were (a) technical difficulties in generating or manufacturing the claimed antibody; or (b) there was no reasonable expectation of success of obtaining any antibody with the desirable properties), should not merely be recognised as specialised exceptions and therefore interpreted narrowly. • Rather, the technical challenges involved in developing commercially relevant antibodies with meaningful affinity and biological activity, particularly those suitable for diagnostic or therapeutic use, should be considered in the understanding of the problem solved. • In a claim to an antibody that is defined by its sequences, it is not the method of making the antibody that is being claimed, and a structure-function analysis should be applied commensurate with the claimed solution. • If the principles set out in the CLBA I.D.9.9.2: Structural Similarity are applied to sequence defined antibody claims, then the predictability of the claimed sequence for achieving the desired function/activity would need to be assessed. • On the policy level, it is not needed to brand all antibodies as obvious, unless proven otherwise, to prevent the granting of patents to a subset of antibodies that may be considered relatively easy to make, as this unfairly prejudices the entire field of technology. Rather, if the long-standing principles of assessing the predictability of the claimed structure for achieving the desired function/activity is applied, the consideration of the function/activity will adequately reflect the complexity of the claimed solution. A negative premise is therefore not needed to separate out antibodies which are less complex to make from those that are more complex and involve more inventive skill to make, let alone the fact that it is 		
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				<p>not legally justified under Art 56 EPC.</p> <ul style="list-style-type: none"> • Furthermore, if the EPO were to assess the predictability of the claimed structure for achieving the desired function/activity in relation to sequence defined claims (such as CDRs and/or VH/VL sequences), these could hardly be considered from a policy perspective as overly broad patents, as these would be relatively narrow claims relating to the product. • Under the current situation, however, some EPO examiners are applying the “routine method” assumption to any claim that recites an immunological sequence, beyond the antibody field, despite the fact that Art 56 EPC does not start with a presumption of non-obviousness of subject matter. If this trend continues, the negative presumption will be over applied to new creative fields involving sequence-based information and would negatively impact the development of innovative biologics in the future. 		
118	G	II	6.2	<p>The Confederation of Swedish Enterprise represent 69 000 companies in all types of industries. Development of patentability in various fields has been a priority for some time. Lif – the Research-Based Pharmaceutical Industry in Sweden is a member organization. Confederation of Swedish Enterprise align with the joint submission provided by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and The Institute of Professional Representatives before the European Patent Office (epi) regarding the interpretation of the EPO Guidelines section G.II.6.2. It is important that antibody-based inventions are not excluded from patentability as a matter of principle. A general presumption against the patentability of antibodies, unless specific exceptions apply, creates significant legal uncertainty and risk undermining incentives for innovation. This is particularly concerning in</p>		<p>The Office thanked the respondent for this comment, which appears to endorse the points raised in comment 117 and is addressed above.</p>

				light of ongoing and future research efforts in the antibody field, where continued innovation is expected to yield important medical advances across a wide range of therapeutic areas. This development has far-reaching negative consequences for Europe's and Sweden's competitiveness and diminishes the region's attractiveness for biomedical research and investment. From the Confederations perspective, the question of patentability in all emerging technologies should be brought up to a general discussion.		
119	G	II	6.2	<p>The Barrier Around Antibody Inventions at the European Patent Office</p> <p>The EPO Guidelines section G.II.6.2 has established an unjustified barrier for pharmaceutical products by presuming that antibody-based inventions are prima facie non-inventive and unpatentable unless they meet specific exceptions. This approach undermines the crucial role patents play in incentivizing the research and development of biologics. The singling out of antibody inventions for unfavorable treatment compared to other technological fields lacks justification under both the European Patent Convention and established case law. An urgent revision of these Guidelines is necessary to align the inventive step standard for antibodies with that applied to other technologies.</p> <p>The negative premise about the inventive step of antibodies in the EPO Guidelines Part G.II.6.2 Examiners must adhere to the following problematic guidelines when assessing antibody product claims, regardless of how narrowly defined the antibody sequence may be:</p> <ul style="list-style-type: none"> • The negative premise that new antibody inventions are prima facie non-inventive subject matter. ("The subject-matter of a claim defining a 	<p>Urgent Revision of the Guidelines needed</p> <ul style="list-style-type: none"> • Fundamentally, the EPO Guidelines do not need a dedicated section for the assessment of the inventive step of antibodies as differential treatment compared to other areas of technology is unjustified and is not needed. The EPO Guidelines Part G.II.6.2 should be eliminated entirely. • The practice at the EPO must be revised to eliminate i) the assumption of prima facie obviousness of antibodies and ii) any sweeping, automatic prejudice of use of a 'routine method(s)'. • Structural similarity and structure-function predictability should be considered when assessing antibody claims defined by amino acid sequence information, including in the CDRs and VH/VL regions. In particular, the principles applied by the EPO for antibodies should be made consistent with the principles as applied to low molecular weight chemical compound inventions as set 	<p>The Office thanked the respondent for the comment.</p> <p>The points appear to be the same as those in comment 117 and have been addressed above.</p>

			<p>novel antibody binding to a known antigen does not involve an inventive step...”).</p> <ul style="list-style-type: none"> • This premise may not be overturned by the assessment of the unpredictability of the amino acid sequence. (“The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”). • According to the Guidelines this negative premise can only be overturned by showing one of a limited set of four exceptions: 1) a surprising technical effect, 2) no reasonable expectation of success of obtaining antibodies having the required properties, 3) technical difficulties in generating or manufacturing the claimed antibody, or 4) a novel type of functional antibody format may be inventive. <p>The standards in the EPO Guidelines Part G.II.6.2 lack legal basis The antibody-specific standards in the EPO Guidelines lack proper legal basis for several critical reasons:</p> <ul style="list-style-type: none"> • Contravenes EPC Article 56: Art. 56 EPC does not start with a strong negative presumption that needs to be overturned – i.e. that claimed subject matter prima facie does not have an inventive step. • Discriminatory Treatment: Nor is this presumption applied in other technical fields, whether chemical or non-chemical. • Absence of Authoritative Precedent: This premise is not based on reasoning established in an Enlarged Board of Appeal decision – there has been no decision at this level which specifically addresses the inventive step analysis of antibodies. • Misapplication of Case Law: This negative premise cannot simply be based on the two Board of Appeal decisions cited in the Guidelines 	<p>out in the Case Law of the Boards of Appeal of the EPO (CLBA) I.D.9.9.2: ‘Structural Similarity.’</p> <ul style="list-style-type: none"> • When formulating the technical problem in the problem-solution approach, examiners should consider the activity (agonism, antagonism, effect on target cell etc), and the word ‘antibody’, that has become somewhat of a distraction at the EPO, could be replaced with a term such as ‘molecular structure/sequence.’ The aim would be to bring focus on the sequence information provided in a claim, including in the CDRs and VH/VL regions and to assess this in conjunction with a functional activity/purpose, to reflect both the complexity of the technical problem and the specificity of the solution provided. • The antibody-based biologics field is critical for the advancement of public health and economic development. Removing the artificial barrier to antibody patenting that is currently embedded in the EPO Guidelines will significantly benefit and stimulate biologics research and innovation. 	
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			<p>(T 187/04 and T 605/14) as individual decisions at this level are not strictly binding on subsequent Boards and therefore cannot create such an unequivocal premise about the patentability of an entire field.</p> <ul style="list-style-type: none"> • Misinterpretation of Case Law: Importantly, T 187/04 has been misinterpreted and does not provide support for this statement in the Guidelines that “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious.” T 187/04 concerned a monoclonal antibody that was defined by reference to a deposited hybridoma, which could be used to produce the antibody itself. No sequence was disclosed or claimed in the patent, so the Board could not have deliberated on the (un)predictability of amino acid sequence information, nor therefore have created an explicit, extensive exclusion to assessing structural information in the inventive step analysis. • Misrepresentation of Case Law: The Guidelines ignore two other Board of Appeal decisions which do recognise the unpredictability of the impact of amino acid structural differences on functional properties in an inventive step analysis (T 67/11 and T 1171/18), so the Guidelines are not an accurate reflection of the principles in the antibody case law. • Inconsistent Application of Principles: The Guidelines fail to apply established structural similarity principles (CLBA, Section I.D.9.9.2) to antibodies and no justification is given for this in either the Guidelines or in the cases cited in the Guidelines (T 187/04 and T 605/14). • Narrowness of Exceptions Unjustified: Exceptions to legal principles are often interpreted narrowly, and by unjustly starting with the negative premise that antibodies are prima facie non-inventive subject matter, the facts 		
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			<p>under the four listed exceptions tend to be considered narrowly. Moreover, examiners tend to reduce the analysis to the exception relating to proving a ‘surprising technical effect’ is present. However, it is not a mandatory requirement under the EPC to show an improvement (thus even less a requirement to show a surprising technical effect), as is clearly confirmed in the Case Law of the Boards of Appeal (July 2022, 10th edition I.D.4.5).</p> <p>The EPO Guidelines Part G.II.6.2 are inconsistent and unclear The Guidelines only permit the assessment of structure-function predictability in an inconsistent, unclear, and arbitrarily restricted manner:</p> <ul style="list-style-type: none"> • Arbitrary Structural Analysis Boundaries: Examiners may consider unpredictability in the structure-function relationship at the level of the overall architecture of an antibody, as a novel format may be inventive. Yet they are explicitly discouraged from zooming in any further to the level of the amino acid sequence (from the guidance that “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”). • Therefore, they may assess how antibody domains/regions are positioned overall, but in a glaring inconsistency are guided away from assessing the structure within such domains/regions in particular within a variable region, because this is typically provided as amino acid sequence information. Rather astonishingly, therefore, the Guidelines direct examiners away from assessing the details of the most important parts of the product - the CDRs and VH/VL regions which are most directly involved in binding and for achieving the intended function of the product. 		
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			<ul style="list-style-type: none"> • Paradoxical Treatment of Critical Regions: In practice, examiners often require that the framework sequences of the variable region be recited in the claims, in addition to the CDR sequences, on the basis that the particular framework sequences may also have an unpredictable influence on the desired activity (which should not be the rule but be considered in light of available data). • Yet paradoxically, when assessing inventiveness, the specific sequence information in both CDRs and frameworks is dismissed. • Thus, even if those sequences are not a predictable solution to the underlying technical problem - that is still not available as a reason for finding the claimed antibody inventive – another perplexing inconsistency in the currently practised approach. • Misguided ‘Surprising Technical Effect’ Exception: The creation of an exception with the shorthand phrase ‘surprising technical effect’ is an oversimplification, which leads to a misunderstanding of the underlying principle. Such an antibody product claim which is associated with a surprising technical effect is inventive as the manner in which that effect was achieved was not predictable from the art, in the sense that neither how the particular result was achieved, nor which particular product would give that effect was predictable. Thus, it is the inability to identify a priori which particular structure within the general class of antibodies that is able to achieve that effect/function that is actually being recognised. By creating an isolated exception with the short-hand phrase ‘surprising technical effect’ a confusion arises whether it is the effect per se that needs to be surprising or whether, as should be the case, it is which structure (that causes the effect) that is surprising. 		
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			<p>The EPO's "Routine Method" Approach to Antibody Patentability: overapplied and unjustified</p> <ul style="list-style-type: none"> • The EPO Guidelines state that: Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. This reflects a pervasive mindset among EPO examiners that 'making antibodies is routine.' • The 'routine method mindset' originated from the early hybridoma antibody case law – where the view was expressed that the preparation of monoclonal antibodies by the Köhler- Milstein hybridoma method became routine work after a certain period of time (in T 735/00: 13 yrs), and the product was not inventive (unless there were unexpected properties). • However, applying this historical perspective to all antibody-derived products has created an inappropriate prejudice that all antibody generation work is inherently routine. The Guidelines effectively establish that every antibody is prima facie obvious by default unless proven otherwise - a position inconsistent with Article 56 EPC. • The Guidelines have expanded this concept beyond its original rationale that the method has become routine. Now, regardless of complexity, as soon as the technique is simply known in the art, the resulting antibody structures are rendered obvious. • A 'routine method mindset' is particularly problematic for structural claims as it obscures the actual claimed solution. It automatically disadvantages sophisticated, recombinantly-produced and engineered antibody products, severely underestimating during the inventive step analysis the complex problems solved by modern antibody technology. • A 'routine method mindset' may perhaps be 		
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			<p>appropriate if only a single method step was involved to make a finished antibody product, and there was only a choice of one technique for that step that had become entirely routine over time. This is far from the technical reality.</p> <ul style="list-style-type: none"> • There is no 'one-stop shop' which will always produce a binder (let alone a binder exhibiting each and all the required activities), and there are very often no clear pointers about which method or sub-method to choose in a given instance. The list of techniques to discover novel antibodies that the skilled person has to choose from includes inter alia phage display, yeast display, mammalian cell surface display, ribosome display, bacterial display, mRNA display, DNA display, immunisation of rodents, rabbits, camelids or transgenic animals, as well as B-cell based screenings: each with its own advantages and disadvantages. • Moreover, nor is just one method step involved in the development of a pharmaceutical antibody as the product is required to do more than simply bind to its target. Other characteristics may also be important and multiple (often sequential) methods are utilised in the testing and selection. This is true for a diagnostic antibody for in vitro use (which must fulfil e.g. specificity, sensitivity, and stability criteria); it is especially valid for antibodies used in vivo (i.e. as a therapeutic or in vivo diagnostic). 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, absence of undesirable post-translational modifications such as proteolysis, as well as biological activity. It is incorrect to simply dismiss the product claimed as resulting from routine work, as it ignores the technical complexity involved in i) attaining each 		
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			<p>individual characteristic and ii) the complexity faced when a combination of characteristics needs to be optimised in parallel via multiple methods.</p> <ul style="list-style-type: none"> • Additionally, it is inaccurate to label the work as simply routine, as not only may multiple characteristics and methods be involved, but the optimisation of one criterion may negatively impact another, which means the development project as a whole does not have an obvious trajectory. • Antibody engineering typically involves sequences in the variable regions and, accordingly, a claim to such a defined set of CDRs or VH/VL sequences does not represent a mere arbitrary selection from a process of immunisation or from antibody display libraries. • Unpredictability is also reflected in the typically very low number of final lead candidates compared to the number of antibodies obtained after an initial screen. • The listed exceptions in the Guidelines that focus on consideration of the method (that there were (a) technical difficulties in generating or manufacturing the claimed antibody; or (b) there was no reasonable expectation of success of obtaining any antibody with the desirable properties), should not merely be recognised as specialised exceptions and therefore interpreted narrowly. • Rather, the lack of predictability in developing commercially relevant antibodies with meaningful affinity and biological activity, particularly those suitable for diagnostic or therapeutic use, should be considered in the understanding of the problem solved. • In a claim to an antibody that is defined by its sequences, it is not the method of making the antibody that is being claimed, and a structure-function analysis should be applied commensurate with the claimed solution. 		
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			<ul style="list-style-type: none"> • If the principles set out in the CLBA I.D.9.9.2: Structural Similarity are applied to sequence defined antibody claims, then the predictability of the claimed structure for achieving the desired function/activity would need to be assessed. Consideration of the predictability of the structure for achieving a function allows the appreciation of the complexity involved in the particular solution – to distinguish, for example, the obviousness of antibodies merely having a very low affinity for a target, but unable to fulfil any further functional requirements, from others which have been laboriously selected for their advantageous behaviour and/or highly engineered to fulfil a combination of complex requirements. • On the policy level, it is not needed to brand all antibodies as obvious, unless proven otherwise, to prevent the granting of patents to a subset of antibodies that may be considered relatively easy to make, as this unfairly prejudices the entire field of technology. Rather, if the long- standing principles of assessing the predictability of the claimed structure for achieving the desired function/activity is applied, the consideration of the function/activity will reflect the complexity of achieving the claimed solution. A negative premise is therefore not needed to separate out antibodies which are less complex from those that are more complex and involve more inventive skill to make, let alone the fact that it is not legally justified under Art 56 EPC. • Furthermore, if the EPO were to recognise the unpredictability of the effect of structural changes on functional properties in relation to CDRs and/or VH/VL sequences, these could hardly be considered from a policy perspective as overly broad patents, as these would be relatively narrow claims relating to the product. • Under the current situation, however, some EPO examiners are applying the 'routine method' assumption to any claim that recites an 		
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			<p>immunological sequence, beyond the antibody field, despite the fact that Art 56 EPC does not start with a presumption of non-obviousness of subject matter. If this trend continues, the negative presumption will be over applied to new creative fields involving sequence-based information and would negatively impact the development of innovative biologics in the future. Proposal to align the problem-solution approach with the approach applied to other chemical inventions</p> <ul style="list-style-type: none"> • Currently, after beginning with the negative premise, EPO examiners typically turn to assessing whether a 'surprising technical effect' is present. If no improvement is identified, the practice is to re-define the objective technical problem as the provision of an alternative antibody to the target or for use in the same purpose. A finding of obviousness usually follows. • The objective technical problem should instead more accurately focus the examination on the actual claimed solution and the problems solved. For a sequence defined antibody claim, the problem is not whether any antibody in a general sense can be made, but rather it should be appreciated that specific structural information that has a certain functional activity has been provided. The problem needs to be commensurate with the solution provided. • Thus, the problem should be formulated as the provision of a specific alternative molecular structure (or sequence) for use in achieving the functional activity Y' {e.g. a mode of action such as an antagonistic or agonistic activity, driving the internalisation of antigen X or achieving a certain effect on a cell that expresses antigen X}. • If the word "antibody" is omitted in the problem, this removes the bias that what is provided is merely a similar overall structural compound, with 		
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			<p>the CDRs being overlooked as minor, arbitrary variations to the overall structure.</p> <ul style="list-style-type: none"> • The proposed analysis would be: starting from the closest prior art (e.g. from a particular prior art antibody possessing specific CDRs which bind to the target X), and in light of the objective technical problem (more correctly formulated as the provision of an alternative structure/sequence for achieving the desirable activity Y), would it have been obvious to the skilled person to modify the known structure (at least in its CDR sequences) in such a manner as not only to arrive at the structure that is claimed, but to do so with a reasonable expectation of success, i.e. of achieving the desirable activity? • For low molecular weight chemical compounds, the structures are claimed as graphical representations: examiners look to the depicted structures when assessing inventive step and, therefore, they more easily take account of their structural differences. • In contrast, for antibody inventions, where the arrangements of atoms are not specified in the claims, but are instead represented by the seemingly generic terms of “SEQ ID No. Z” or “SEQ ID No. ZZ”, the differences between the respective three-dimensional structures are markedly less apparent. As such, the structural differences from the prior art compounds are easy to overlook, and the solution itself is then underappreciated. Therefore, the Guidelines should actively direct the examiner towards looking at the differences between the CDR and/or VH/VL regions which have an important role in the functional activity. • Critical in the analysis is not only the consideration of the structural difference, but the predictability of the difference on the functional activity. • For a specific antibody which not only has a binding affinity in vitro, but is suitable for 		
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			<p>administration to a subject as a diagnostic or therapeutic molecule, there are many additional requirements that must be fulfilled, while still retaining an acceptable level of affinity.</p> <ul style="list-style-type: none"> • The complexity of the problem is inversely related to the expectation of success. The fact that the individual properties may be recognised as being desirable – or that known techniques may be used to assess and modify that property – does not negate the fact that attaining a suitable balance of those properties in combination is a priori unpredictable. • Accordingly, in such a scenario the objective technical problem could be formulated as the provision of “a pharmaceutically acceptable structure/sequence for achieving the desirable activity Y”. • Thus, overall the analysis should take into account various scenarios: <ul style="list-style-type: none"> i) if the binding sequences of a claimed antibody (either its CDRs or, if applicable to the case, its VH/VL sequences) are dissimilar to the corresponding sequences of the closest prior art antibody that achieves the same function, then this structural dissimilarity should be considered in the obviousness analysis. The complexity of the function/activity may also be taken into account (e.g. simply exhibiting mere low affinity binding or at the other end of the scale, exhibiting a combination of properties suitable for pharmaceutical use): the assessment is whether a claimed antibody which has those differences is a predictable solution to the objective technical problem of achieving that activity; ii) if the CDRs and VH/VL sequence, as well as the overall structure of the claimed antibody are extremely similar to those of the prior art antibody, then as very similar structures might be expected to behave similarly, the claimed antibody could be considered obvious; iii) nevertheless inventiveness could still be 		
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				<p>shown if a novel technical effect or improvement in activity was exhibited by the claimed antibody resulting from those small differences in the amino acid sequences, and it was not predictable from the state of the art that those differences would lead to that effect, (i.e. it was surprising how that further technical effect/improvement was achieved). Inventiveness could also still be shown if small differences in the amino acid sequences do not lead to a novel technical effect or improvement in function but lead to an acceptable alternative which was unexpected (e.g. mutations that the skilled person would have expected to decrease or abolish one or more desired functions or impact negatively the structure/stability.)</p> <ul style="list-style-type: none"> • This brings the approaches used in low molecular weight and antibody based biologic inventions into alignment. 		
120	G	II	6.2	<p>The Barrier Around Antibody Inventions at the European Patent Office -</p> <p>The EPO Guidelines section G.II.6.2 has established an unjustified barrier for pharmaceutical products by presuming that antibody-based inventions are prima facie non-inventive and unpatentable unless they meet specific exceptions. This approach undermines the crucial role patents play in incentivizing the research and development of biologics. The singling out of antibody inventions for unfavorable treatment compared to other technological fields lacks justification under both the European Patent Convention and established case law. An urgent revision of these Guidelines is necessary to align the inventive step standard for antibodies with that applied to other technologies.</p> <p>The importance of antibody inventions - Antibody inventions have revolutionized medicine</p>	<p>Proposal to align the problem-solution approach with the approach applied to other chemical inventions -</p> <ul style="list-style-type: none"> • Currently, after beginning with the negative premise, EPO examiners typically turn to assessing whether a “surprising technical effect” is present. If no improvement is identified, the practice is to re-define the objective technical problem as the provision of an alternative antibody to the target or for use in the same purpose. A finding of obviousness usually follows. • The objective technical problem should instead more accurately focus the examination on the actual claimed solution and the problems solved. For a sequence defined antibody claim, the problem is not whether any antibody in a general 	<p>The Office thanked the respondent for the comment but did not agree.</p> <p>The problem-solution approach, particularly the definition of the problem, is in line with the GL (G-VII, 5.2). The problem defined by the BoA for applying the problem-solution approach also refers to an antibody (see recent decisions T 1911/17, reason 34; T 0326/22, reason 23.2).</p> <p>As explained above, the principle of "structural non-obviousness" is not endorsed by the BoA (see recent T 1911/17, reason 35). Specific sequences of humanised antibodies have been granted in T 67/11 and T 1171/18 due to the lack of expectation of success of arriving at the claimed antibodies.</p> <p>There were no further comments from SACEPO WP/G members.</p>

			<p>and biotechnology, transforming treatment approaches for conditions such as cancers, autoimmune disorders and infectious diseases. Their remarkable specificity in binding to targets provides clinicians with precise tools for both diagnosis and therapy. These advancements continue to drive progress in medical research and patient care outcomes. Given the substantial financial risks and extensive research investments required, robust patent protection is essential to incentivize continued innovation in this critical field.</p> <p>The negative premise about the inventive step of antibodies in the EPO Guidelines Part G.II.6.2 - Examiners must currently adhere to the following problematic guidelines when assessing antibody product claims, regardless of how specifically defined the claimed antibodies may be:</p> <ul style="list-style-type: none"> • The negative premise that new antibody inventions are prima facie non-inventive subject matter. (“The subject-matter of a claim defining a novel antibody binding to a known antigen does not involve an inventive step...”). • This premise may not be overturned by the assessment of the unpredictability of the amino acid sequence. (“The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”). • According to the Guidelines this negative premise can only be overturned by showing one of a limited set of four exceptions: (1) a surprising technical effect, (2) no reasonable expectation of success of obtaining antibodies having the required properties, (3) technical difficulties in generating or manufacturing the claimed antibody, or (4) a novel type of functional antibody format may be inventive. <p>The standards in the EPO Guidelines Part</p>	<p>sense can be made, but rather it should be appreciated that specific structural information that has a certain functional activity has been provided. The problem needs to be commensurate with the solution provided.</p> <ul style="list-style-type: none"> • Thus, the problem should be formulated as the provision of a specific alternative molecular structure (or sequence) for use in achieving the functional activity Y’ {e.g. a mode of action such as an antagonistic or agonistic activity, driving the internalisation of antigen X or achieving a certain effect on a cell that expresses antigen X}. • If the word “antibody” is omitted in the problem, this removes the bias that what is provided is merely a similar overall structural compound, with the CDRs being overlooked as minor, arbitrary variations to the overall structure. • The proposed analysis would be: starting from the closest prior art (e.g. from a particular prior art antibody possessing specific CDRs which bind to the target X), and in light of the objective technical problem (more correctly formulated as the provision of an alternative structure/sequence for achieving the desirable activity Y), would it have been obvious to the skilled person to modify the known structure (at least in its CDR sequences) in such a manner as not only to arrive at the structure that is claimed, but to do so with a reasonable expectation of success, i.e. of achieving the desirable 	
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			<p>G.II.6.2 lack legal basis - The antibody-specific standards in the EPO Guidelines lack proper legal basis for several critical reasons:</p> <ul style="list-style-type: none"> • Contravenes EPC Article 56: Art. 56 EPC does not start with a strong negative presumption that needs to be overturned – i.e. that claimed subject matter prima facie does not have an inventive step. • Discriminatory Treatment: Nor is this presumption applied in other technical fields, whether chemical or non-chemical. • Absence of Authoritative Precedent: This premise is not based on reasoning established in an Enlarged Board of Appeal decision – there has been no decision at this level which specifically addresses the inventive step analysis of antibodies. • Misapplication of Case Law: This negative premise cannot simply be based on the two Board of Appeal decisions cited in the Guidelines (T 187/04 and T 605/14) as individual decisions at this level are not strictly binding on subsequent Boards and therefore cannot create such an unequivocal premise about the patentability of an entire field. • Misinterpretation of Case Law: Importantly, T 187/04 has been misinterpreted and does not provide support for this statement in the Guidelines that “[t]he fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious.” T 187/04 concerned a monoclonal antibody that was defined by reference to a deposited hybridoma, which could be used to produce the antibody itself. No sequence was disclosed or claimed in the patent, so the Board could not have deliberated on the (un)predictability of amino acid sequence information, nor therefore have created an explicit, extensive exclusion to assessing 	<p>activity?</p> <ul style="list-style-type: none"> • For low molecular weight chemical compounds, the structures are claimed as graphical representations: examiners look to the depicted structures when assessing inventive step and, therefore, they more easily take account of their structural differences. • In contrast, for antibody inventions, where the arrangements of atoms are not specified in the claims, but are instead represented by the seemingly generic terms of “SEQ ID No. Z” or “SEQ ID No. ZZ”, the differences between the respective three-dimensional structures are markedly less apparent. As such, the structural differences from the prior art compounds are easy to overlook, and the solution itself is then underappreciated. Therefore, the Guidelines should actively direct the examiner towards looking at the differences between the CDR and/or VH/VL regions which have an important role in the functional activity. • Critical in the analysis is not only the consideration of the structural difference, but the effect of the difference on the functional activity. • For the scenario of a sequence defined antibody suitable for pharmaceutical use, the objective technical problem could be formulated as the provision of “a pharmaceutically acceptable structure/sequence for achieving the desirable activity Y”. • Thus, overall the analysis should 	
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			<p>structural information in the inventive step analysis.</p> <ul style="list-style-type: none"> • Misrepresentation of Case Law: The Guidelines ignore two other Board of Appeal decisions which do recognise the unpredictability of the impact of amino acid structural differences on functional properties in an inventive step analysis (T 67/11 and T 1171/18), so the Guidelines are not an accurate reflection of the principles in the antibody case law. • Inconsistent Application of Principles: The Guidelines fail to apply established structural similarity principles (CLBA, Section I.D.9.9.2) to antibodies and no justification is given for this in either the Guidelines or in the cases cited in the Guidelines (T 187/04 and T 605/14). • Narrowness of Exceptions Unjustified: Exceptions to legal principles are often interpreted narrowly, and by unjustly starting with the negative premise that antibodies are prima facie non-inventive subject matter, the facts under the four listed exceptions tend to be considered narrowly. Moreover, examiners tend to reduce the analysis to the exception relating to proving whether a “surprising technical effect” is present. However, it is not a mandatory requirement under the EPC to show an improvement (thus even less a requirement to show a surprising technical effect), as is clearly confirmed in the Case Law of the Boards of Appeal (July 2022, 10th edition I.D.4.5). <p>The EPO Guidelines Part G.II.6.2 are inconsistent and unclear -</p> <p>The Guidelines only permit the assessment of structure-function predictability in an inconsistent, unclear, and arbitrarily restricted manner:</p> <p>Arbitrary Structural Analysis Boundaries</p> <ul style="list-style-type: none"> • Examiners may consider unpredictability in the structure-function relationship at the level of the overall architecture of an antibody, as a novel 	<p>take into account various scenarios:</p> <p>(i) if the binding sequences of a claimed antibody are dissimilar to the corresponding sequences of the closest prior art antibody for achieving the same function, then this structural dissimilarity should be considered in the obviousness analysis. The complexity of the function/activity may also be taken into account (e.g. simply exhibiting low affinity binding or at the other end of the scale, exhibiting a combination of properties suitable for pharmaceutical use): the assessment is whether a claimed antibody which has those differences is a predictable solution to the objective technical problem of achieving that activity;</p> <p>(ii) if the CDRs and VH/VL sequence, as well as the overall structure of the claimed antibody are extremely similar to those of the prior art antibody, then as very similar structures might be expected to behave similarly, the claimed antibody could be considered obvious;</p> <p>(iii) nevertheless inventiveness could still be shown if a novel technical effect or improvement in activity was exhibited by the claimed antibody resulting from those small differences in the amino acid sequences, and it was not predictable from the state of the art that those differences would lead to that effect, (i.e. it was surprising how that further technical effect/improvement was achieved). Inventiveness could also still be shown if small differences in the</p>	
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			<p>format may be inventive. Yet they are explicitly discouraged from zooming in any further to the level of the amino acid sequence (from the guidance that “The fact that the structure of an antibody, i.e. its amino acid sequence, is not predictable is not a reason for considering the antibody as non-obvious”).</p> <ul style="list-style-type: none"> • Therefore, they may assess how antibody domains/regions are positioned overall, but in a glaring inconsistency are guided away from assessing the structure within such domains/regions in particular within a variable region, because this is typically provided as amino acid sequence information. Rather astonishingly, therefore, the Guidelines direct examiners away from assessing the details of key parts of the product - the CDRs and VH/VL regions which are most directly involved in binding and for achieving the intended function of the product. <p>Paradoxical Treatment of Critical Regions</p> <ul style="list-style-type: none"> • In practice, examiners often require that the framework sequences of the variable region be recited in the claims, in addition to the CDR sequences, on the basis that the particular framework sequences may also influence the desired activity (which should not be the rule but be considered in light of available data). • Yet paradoxically, when assessing inventiveness, the specific sequence information in both CDRs and frameworks is dismissed. • Thus, even if those sequences are not a predictable solution to the underlying technical problem, that is still not available as a reason for finding the claimed antibody inventive – another perplexing inconsistency in the currently practised approach. <p>Misguided "Surprising Technical Effect" Exception</p>	<p>amino acid sequences do not lead to a novel technical effect or improvement in function but lead to an acceptable alternative which was unexpected (e.g. mutations that the skilled person would have expected to decrease or abolish one or more desired functions or impact negatively the structure/stability.)</p> <ul style="list-style-type: none"> • Such a mode of analysis would bring the approaches used in low molecular weight and antibody based biologic inventions into alignment. <p>Urgent Revision of the Guidelines needed -</p> <ul style="list-style-type: none"> • Fundamentally, the EPO Guidelines do not need a dedicated section for the assessment of the inventive step of antibodies as differential treatment compared to other areas of technology is unjustified and is not needed. The EPO Guidelines Part G.II.6.2 should be eliminated entirely. • The practice at the EPO must be revised to eliminate (1) the assumption of prima facie obviousness of antibodies and (2) any sweeping, automatic prejudice of the use of “routine method(s).” • Structural similarity and structure-function relationships should be considered when assessing antibody claims defined by amino acid sequence information, including in the CDRs and VH/VL regions. In particular, the principles applied by the EPO for antibodies should be made consistent with the principles as applied to low molecular weight chemical compound inventions as set 	
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			<ul style="list-style-type: none"> • The creation of an exception with the shorthand phrase “surprising technical effect” is an oversimplification, which leads to a misunderstanding of the underlying principle. Such an antibody product claim which is associated with a surprising technical effect is inventive as the manner in which that effect was achieved was not predictable from the art, in the sense that neither how the particular result was achieved, nor which particular product would give that effect was predictable. Thus, it is the inability to identify a priori which particular structure within the general class of antibodies that is able to achieve that effect/function that is actually being recognised. By creating an isolated exception with the short-hand phrase “surprising technical effect” a confusion arises as to whether it is the effect per se that needs to be surprising or whether, as should be the case, it is which structure (that causes the effect) that is surprising. <p>The EPO's "Routine Method" Approach to Antibody Patentability -</p> <ul style="list-style-type: none"> • The EPO Guidelines state that: Arriving at alternative antibodies exclusively by applying techniques known in the art is considered to be obvious to the skilled person. This reflects a pervasive mindset among EPO examiners that “making antibodies is routine.” • The “routine method mindset” originated from the early hybridoma antibody case law – where the views were expressed that the preparation of monoclonal antibodies by the Köhler- Milstein hybridoma method had become routine work after a certain period of time (in T 735/00: 13 yrs), and the product was not inventive (unless there were unexpected properties). • However, applying this historical perspective to all antibody-derived products has created an inappropriate prejudice that all antibody 	<p>out in the Case Law of the Boards of Appeal of the EPO (CLBA) I.D.9.9.2: ‘Structural Similarity.’</p> <ul style="list-style-type: none"> • When formulating the technical problem in the problem-solution approach, examiners should consider the activity (agonism, antagonism, effect on target cell, etc.), and the word ‘antibody’, that has become somewhat of a distraction at the EPO, could be replaced with a term such as ‘molecular structure/sequence.’ The aim would be to bring focus on the sequence information provided in a claim, including in the CDRs and VH/VL regions and to assess this in conjunction with a functional activity/purpose, to reflect both the complexity of the technical problem and the specificity of the solution provided. • The antibody-based biologics field is critical for the advancement of public health and economic development. Removing the artificial barrier to antibody patenting that is currently embedded in the EPO Guidelines will significantly benefit and stimulate biologics research and innovation. 	
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			<p>generation work is inherently routine. The Guidelines effectively establish that every antibody is prima facie obvious by default unless proven otherwise - a position inconsistent with Article 56 EPC.</p> <ul style="list-style-type: none"> • The Guidelines have expanded this concept beyond its original rationale that the method has become routine. Now, regardless of complexity, as soon as the technique is simply known in the art, the resulting antibody structures are assumed to be obvious. • A 'routine method mindset' is particularly problematic for structural claims as it ignores the actual claimed solution. It automatically disadvantages sophisticated, recombinantly-produced and engineered antibody products, severely underestimating the complex problems solved by modern antibody technology during inventive step analysis. • Antibody engineers typically make a number of choices when determining a strategy for obtaining antibodies in a particular situation. • The list of techniques to discover novel antibodies that the skilled person has to choose from includes inter alia phage display, yeast display, mammalian cell surface display, ribosome display, bacterial display, mRNA display, DNA display, immunisation of rodents, rabbits, camelids or transgenic animals, as well as B-cell based screenings: each with its own advantages and disadvantages. • Moreover, multiple (often sequential) methods are utilised in the testing and selection of the desired characteristics. This is true for a diagnostic antibody for in vitro use (which must fulfil e.g. specificity, sensitivity, and stability criteria); it is especially valid for antibodies used in vivo (i.e. as a therapeutic or in vivo diagnostic). An antibody for therapeutic use may need to meet several criteria, including for instance selectivity for the target antigen, species cross- 		
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			<p>reactivity, immunogenicity profile in preclinical tests, stability in solution, solubility, viscosity, aggregation tendency, purity, absence of undesirable post-translational modifications such as proteolysis, as well as biological activity. It is incorrect to simply dismiss the product claimed as resulting from routine work, as it ignores the technical complexity involved in (1) attaining each individual characteristic and (2) the complexity faced when a combination of characteristics needs to be optimised in parallel via multiple methods.</p> <ul style="list-style-type: none"> • Additionally, in the context of an inventiveness analysis, it is inaccurate to label the work as simply routine, as not only may multiple characteristics and methods be involved, but the optimisation of one criterion may negatively impact another. As such, a given development project as a whole does not have an obvious trajectory. • Antibody engineering typically involves sequences in the variable regions and, accordingly, a claim to such a defined set of CDRs or VH/VL sequences does not represent a mere arbitrary selection from a process of immunisation or from antibody display libraries. • The listed exceptions in the Guidelines that focus on consideration of the method (that there were (a) technical difficulties in generating or manufacturing the claimed antibody; or (b) there was no reasonable expectation of success of obtaining any antibody with the desirable properties), should not merely be recognised as specialised exceptions and therefore interpreted narrowly. • Rather, the technical challenges involved in developing commercially relevant antibodies with meaningful affinity and biological activity, particularly those suitable for diagnostic or therapeutic use, should be considered in the understanding of the problem solved. 		
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			<ul style="list-style-type: none"> • In a claim to an antibody that is defined by its sequences, it is not the method of making the antibody that is being claimed, and a structure-function analysis should be applied commensurate with the claimed solution. • If the principles set out in the CLBA I.D.9.9.2: Structural Similarity are applied to sequence defined antibody claims, then the predictability of the claimed sequence for achieving the desired function/activity would need to be assessed. • On the policy level, it is not needed to brand all antibodies as obvious, unless proven otherwise, to prevent the granting of patents to a subset of antibodies that may be considered relatively easy to make, as this unfairly prejudices the entire field of technology. Rather, if the long- standing principles of assessing the predictability of the claimed structure for achieving the desired function/activity is applied, the consideration of the function/activity will adequately reflect the complexity of the claimed solution. A negative premise is therefore not needed to separate out antibodies which are less complex to make from those that are more complex and involve more inventive skill to make, let alone the fact that it is not legally justified under Art 56 EPC. • Furthermore, if the EPO were to assess the predictability of the claimed structure for achieving the desired function/activity in relation to sequence defined claims (such as CDRs and/or VH/VL sequences), these could hardly be considered from a policy perspective as overly broad patents, as these would be relatively narrow claims relating to the product. • Under the current situation, however, some EPO examiners are applying the “routine method” assumption to any claim that recites an immunological sequence, beyond the antibody field, despite the fact that Art 56 EPC does not start with a presumption of non-obviousness of subject matter. If this trend continues, the 		
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				negative presumption will be over applied to new creative fields involving sequence-based information and would negatively impact the development of innovative biologics in the future.		
121	G	IV	6.1.2	<p>T 0295/22 (Orally administered apremilast/AMGEN) 20-11-2024 has Catchwords: <i>"The requirement underlying the specificity of the use within the meaning of Article 54(5) of the EPC 2000 is according to the explicit conclusion in G 2/08 (see reasons 5.10.3) to be construed merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, and is in principle not confined to a particular medical indication (see reasons 4.1)."</i></p> <p>Reasons 4.1: "Interpretation of claim 1 of "Main request A" Claim 1 of "Main request A" is formulated in the "compound for use" format of Articles 54(4) and 54(5) EPC, wherein the utility as a medicament is further specified as the use as a medicament which is administered orally. The Guidelines for Examination G-VI 6.1.2 (2024) (see example 2: "Composition comprising X for use in therapy by topical administration") suggest with reference to T 51/93 that in a claim which only defines the mode of delivery but no specific therapeutic effect, the definition of the mode of delivery is merely illustrative and not a restrictive technical feature capable of establishing novelty. However, the requirement underlying the specificity of the use within the meaning of Article 54(5) of the EPC 2000 is according to the explicit conclusion in G 2/08 (see reasons 5.10.3) to be construed merely by contrast to the generic</p>	Correct G-VI, 6.1.2, Example 2 according to the interpretation given by T 295/22 of T 51/93.	<p>The Office thanked the respondent for the comment and will consider it and assess the need for clarification.</p> <p>There were no further comments from SACEPO WP/G members.</p>

			<p>broad protection conferred by the first claimed medical application of a substance or composition, and is in principle not confined to a particular medical indication.</p> <p>Contrary to the suggestion in the Guidelines the decision in T 51/93 actually recognizes without reference to any requirement regarding the definition of a specific medical condition that the definition of the mode of administration of a medicament represents a characterizing feature of a claim formulated in the so-called "Swiss-type" format as approved according to G 5/83 for defining inventions relating to new medical uses of known pharmaceuticals under the provisions of the EPC 1973 (see T 51/93, reasons 3.1.2).</p> <p>The decision in T 51/93 further confirms that in a claim formulated as a "Process for making X for use Y comprising the steps of..." the definition of a specific medical purpose under Y illustrates what X can be used for, but does not further characterize the claimed subject-matter under the provisions of the EPC 1973 (see T 51/93, reason 2.2.2). However, the format of the claim discussed in this part of the decision neither corresponds to the "Swiss-type" format as approved according to G 5/83 for defining inventions relating to new medical uses nor to the format outlined in Article 54(5) EPC 2000.</p> <p>In line with the considerations in G 2/08 (see reasons 5.10.3) the Board therefore considers that the oral administration as defined in claim 1 of "Main request A" represents, in accordance with Article 54(5) EPC, a characterizing feature of the claimed subject-matter."</p> <p>https://www.epo.org/en/boards-of-appeal/decisions/t220295eu1</p> <p>To quote the LinkedIn post from Rose Hughes (https://www.linkedin.com/posts/rose-hughes_a-new-mode-of-administration-is-a-new-specific-</p>		
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				<p>activity-7293558264678473728-IN2V): “The EPO Guidelines for Examination indicate that you can’t base a second medical use solely on the mode of administration.</p> <p>By contrast, in this recent decision the Board of Appeal rejected the approach of the Guidelines, and found that a mode of administration (e.g. oral administration) was a specific second medical use. In other words, broad second medical use claims based on mode of administration (not limited by dose or indication) may be possible at the EPO.“</p>		
122	G	IV	7.5.4	<p>The section of 7.5.4 is erroneous and misleading, since it leads the reader to believe that search engine indexing dates are valid proof of publication date according to T1961/13. This decision however states that such indexing dates are NOT valid proof, see section 5.1.5 of the decision: "a date reported by google is inherently unsuitable ...".</p> <p>Contrary to what section 7.5.4 further says, search engines (at least the google one) base the date they provide on the content of a page, NOT on the date that the page was first indexed (This is also illustrated by the example in T1961/13, and can be deduced from information on this topic given on the internet).</p>	<p>Either section 7.5.4(d) should be removed, or it should express the opposite of what it says at present, namely that indexing dates provided by search engines are not valid proof of publication date according to T1961/13.</p>	<p>The Office will look into this matter.</p> <p>There were no further comments from SACEPO WP/G members.</p>
123	G	V	4	<p>This section still indicates that “The exhibitions recognised are published in the Official Journal.” However, that practice was stopped.</p>	<p>Please correct</p>	<p>The practice has not stopped, and exhibitions have been published with EPO OJ 2024, A53.</p> <p>There were no further comments from SACEPO WP/G members.</p>
124	G	V	5	<p>Problem and solution approach is very interesting but not applied by most larger national courts. The UPC decisions to date do not appear to follow the problem and solution approach and</p>	<p>No action suggested now other than to watch the UPC to see whether a trend develops.</p>	<p>The Office thanked the respondent for the comment. The EPO is monitoring UPC case law closely.</p>

				indeed have noted that it is not required by the EPC. What will the EPO do?		There were no further comments from SACEPO WP/G members.
125	G	V	5.2	Cases after G2/21 seem to have deprived the limitations of meaning. Particularly T116/18 appears to reward the very speculative inventions sought to be prevented.	No action suggested now other than to watch development of case law	The Office thanked the respondent for the comment.
126	G	VI	7	I agree with the blog author of the blog below that T 989/22 <i>seems to contradict the Guidelines G-VI, 7 and G-VII, 12, when it comes to the notion of "seriously contemplating"</i> . In particular, as <i>"in the meantime it is well established that direct and unambiguous disclosure is the indisputable criterion for assessing novelty."</i> https://blog.ipappify.de/t-989-22-the-criterion-of-seriously-contemplating-vs-novelty/	Please review	The Office thanked the respondent for the comment. The EPO constantly monitors the development of case law, including in this regard. Until a clear trend emerges from the case law of the Boards of Appeal it seems premature to change practice. Please also refer to the comment and result in the user consultation regarding GL 2025. The situation will be assessed throughout the revision cycle and reassessed for the 2027 cycle. There were no further comments from SACEPO WP/G members.
127	G	VII	3.1	T 1249/22 (Development and deployment of analytical models/ACCENTURE) 13-01-2025 Headnote 3: <i>Regarding reliance on a book as evidence for common general knowledge, see point 14. The pertinent passage of the Guidelines for Examination in the EPO, G-VII, 3.1, needs nuance (see point 14.4).</i> https://www.epo.org/en/boards-of-appeal/decisions/t221249eu1	Please review and nuance this section	The Office will look into this matter. One possible amendment could be to take into account the nuance of " <i>normally</i> " and " <i>usually</i> " in T766/91 (reasons 8.2) and the analysis in T1249/22 (reasons 14) in view of EPC Guidelines section G-VII,3.1. Possible amendment: <i>"Information does not <u>usually</u> become common general knowledge because it has been published in a particular textbook, reference work, etc.; on the contrary, it appears in books of this kind because it is <u>normally</u> already common general knowledge (see T 766/91). This means that the information in such a publication must<u>will generally</u> have already become part of common general knowledge some time before the date of publication (T1249/22)."</i>

						There were no further comments from SACEPO WP/G members.
128	G	VII	11			Also refer to G 2/21, Headnote II. The Office noted that section G-VII, 11 as recently amended now refers to section G-VII, 5.2 in the context of a technical effect being encompassed by the technical teaching and embodied by the same original disclosed invention. Section G-VII, 5.2 refers to G2/21 Headnote II. There were no further comments from SACEPO WP/G members.
	H					
129	H	II	2.6	<p>This section refers to G7/93 and in paragraph 1 refers to two circumstances in which amendment post-approval of the text will be permitted “<i>A clear example of an admissible request is where the applicant files separate sets of claims for designated states for which prior national rights exist (see H-III, 4.4). Similarly, it is appropriate to admit minor amendments which do not require re-opening of the substantive examination and which do not appreciably delay the issue of the decision to grant (see G 7/93)</i>”.</p> <p>However, this does not clearly address the many cases where post-approval amendment is sought (and normally allowed), namely when new art comes to light that makes it clear the Examining Division is about to grant a patent that is invalid on the date of grant. At present the Guideline is capable of being misunderstood to only apply to separate claims or to minor amendments.</p>	<p>Amend paragraph 1 by inserting after the first sentence a passage incorporating more of the reasoning of G7/93 and specifically mentioning the issue of new highly relevant art</p> <p><i>“When considering the possible circumstances when it may be appropriate for an Examining Division to exercise its discretion EPC to allow an amendment after approval, it should be borne in mind that a request for amendment at that stage may arise either as a result of a realisation by the applicant of a need for amendment, or as a result of a point raised by the Examining Division, or as a result of consideration of observations made by a third party pursuant to Article 115 EPC. In any of these circumstances, the discretion to allow amendment should be exercised according to the same principles. Newly cited art that prima facie indicates lack of novelty or inventive step is a good reason for</i></p>	<p>The Office did not agree to the proposal to incorporate more reasoning from G 7/93. However, consideration could be given to adding a reference to E-VI, 3, which refers to resumption of examination after receipt of third-party observations citing highly relevant new prior art, and to C-V, 6.1 which explains when the examining division may resume examination after approval.</p> <p>The suggestion is to include reason 2.4 of G7/93. However, in reasons 2.3. and 2.5 the EBoA states that even when the applicant files amendments motivated as outlined in reason 2.4 it will normally be the rule that they will NOT be admitted; “<i>As stated in paragraph 2.3 above, the allowance of a request for amendment at that stage will be an exceptional case</i>”.</p> <p>In 2.5 the EBoA provided only a single example where it might be likely that a late amendment will be admitted. This example is the example in the GL. The references to C-V, 6.1 and E-VI, 3 would account for resuming examination in cases of</p>

					<i>applying discretion to admit an amendment at this stage.”</i>	new prior art and address the concern of the user. There were no further comments from SACEPO WP/G members.
130	H	V	3.2.1	3.2.1 specifies “When evaluating whether the limitation of a claim by a feature extracted from a combination of features fulfils the requirements of Art. 123(2), the content of the application as filed must not be considered to be a reservoir from which <u>individual features pertaining to separate embodiments can be combined in order to artificially create a particular combination.</u> ”	This part would be strictly interpretable, requiring the unlikely provision of a specific feature in all the embodiments, without considering the possibility by a skilled person to recognize the implicit application of said feature (eventually replacing a further feature) in a further described embodiment. On this purpose it is proposed: “When evaluating whether the limitation of a claim by a feature extracted from a combination of features fulfils the requirements of Art. 123(2), the content of the application as filed must not be considered to be a reservoir from which individual features pertaining to separate embodiments can be combined in order to artificially create a particular combination <u>not immediately and unequivocally recognizable by a skilled person as an obvious alternative combination from the totality of the disclosure when read contextually</u> (in line with the case T1500/07, reason 4.5 (see also T1501/07 and T1502/07))	The Office did not agree to the proposal. This sentence should be read in the context of the rest of the section, which already refers to overall disclosure. The subsequent passage specifies that the ultimate test is according to the Gold Standard: <i>“These conditions are to be understood as an aid to assessing, in the particular case of an intermediate generalisation, if the amendment fulfils the requirements of Art. 123(2). In any case it has to be ensured that the skilled person is not presented with information which is not directly and unambiguously derivable from the originally filed application,”</i> The proposed amendment is not supported, since an obvious alternative combination is not the same as information directly and unambiguously derivable. Clarification is also not required, since cases where the combination would be directly and unambiguously derivable would not be regarded as an artificial combination within the meaning of the sentence concerned. There were no further comments from SACEPO WP/G members.
131	H	V	3.2.1	Following the paragraph above, 3.2.1 specifies that “When a feature is taken from a particular embodiment and added to the claim, it has to be established that:”	Following the proposal above, it is proposed: “When a feature is taken from a particular embodiment and added to	The Office did not agree to the proposal. The passive voice is used here to refer to the work of the examining division. The amendment would be incorrect, as it is the division that assesses for compliance with A123(2). It is clear

					the claim, <u>the skilled person</u> has to be established that.”	from the paragraph below that the examining division carries out the assessment from the perspective of the skilled person. There were no further comments from SACEPO WP/G members.
132	H	V	3.3	Deletion of part of the claimed subject-matter	It would be proposed to combine with an and/or operation the first and the second paragraphs, not limiting the allowance of the deletion to the sole literal support in the description and/or the claims as filed, but also to the directly and unambiguously derivable disclosed information. An example would be: “It is permissible to delete parts of the claimed subject-matter if the corresponding embodiments were originally described, e.g. as alternatives in the claim or as embodiments explicitly set out in the description, <u>and/or</u> if this does not result in the creation of new technical information that is not directly and unambiguously derivable from the application as originally filed.”	The Office did not agree to the proposal. The first paragraph talks about deleting an alternative from a single list, whereas the second talks of deleting alternatives from more than one list. These are two scenarios, and should not be combined in a single sentence. The penultimate paragraph this section also states that what counts is the Gold Standard: "What is required is an analysis of whether the claimed subject-matter is explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed." The Office therefore sees no need for this amendment. Participants referred to a SQAP panel where similar concerns were raised. The Office will look into this. There were no further comments from SACEPO WP/G members.
133	H	VI	--	The headers of the odd-numbered pages (in the preview version) are incorrect: <p style="text-align: center;">Draft 2025</p> <p style="text-align: center;">April 2025 Computer-Implemented Inventions – 1</p> Chapter VI – Correction of errors 1. Introduction Documents filed with the EPO may contain errors, e.g. in the bibliographic data, the description, the claims or the drawings (see H-VI, 2). Errors may also occur in the decision to grant or other decisions of the EPO	Please correct	The Office thanked the respondent. This has now been corrected.