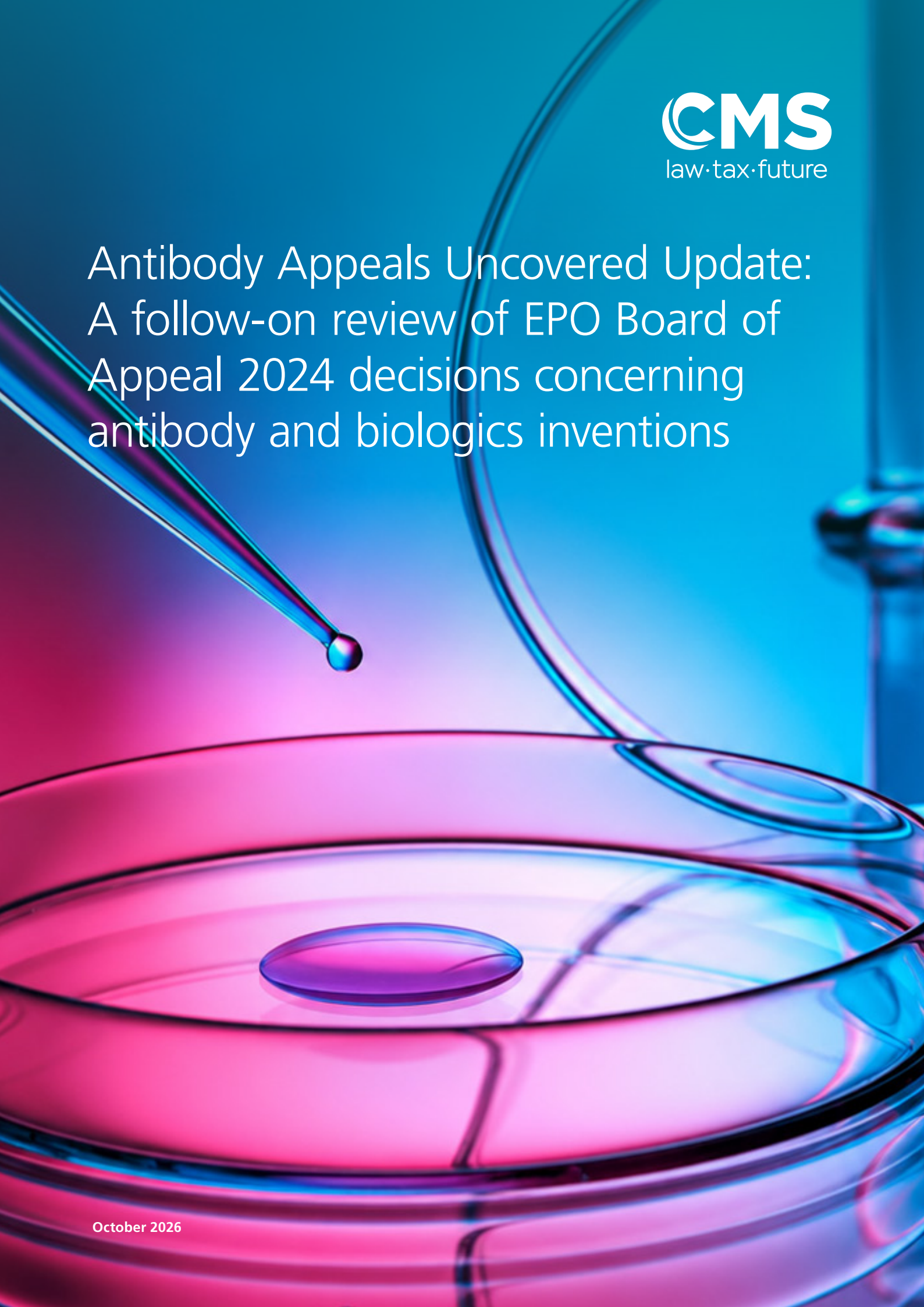


Antibody Appeals Uncovered Update: A follow-on review of EPO Board of Appeal 2024 decisions concerning antibody and biologics inventions

October 2026



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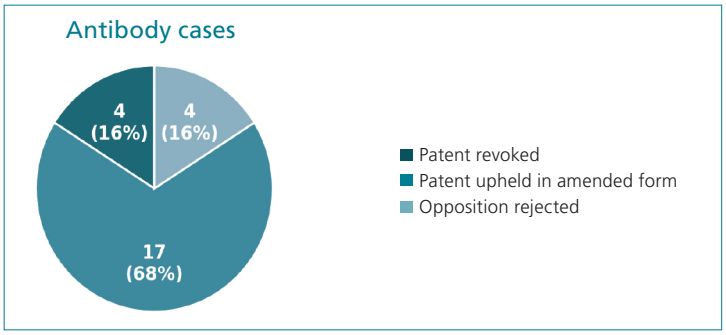
This article follows on from our earlier 2023 analysis of European Patent Office (EPO) antibody-related appeals by considering Board of Appeal decisions issued in 2024. The 2024 decisions again show that antibody-related patents remain fertile ground for appeal, and that patentees should not assume that a favourable first instance decision will necessarily survive before the Boards of Appeal.

The number of decisions is modest, so the figures below should not be treated as statistically definitive. Nevertheless, the same broad themes identified in our earlier analyses continue to appear; appeals often create material downside for patentees, inventive step and sufficiency remain central in antibody cases, and added matter remains a significant risk where claims have been amended during prosecution or opposition.

Statistics

I. First instance: The majority of patents survive

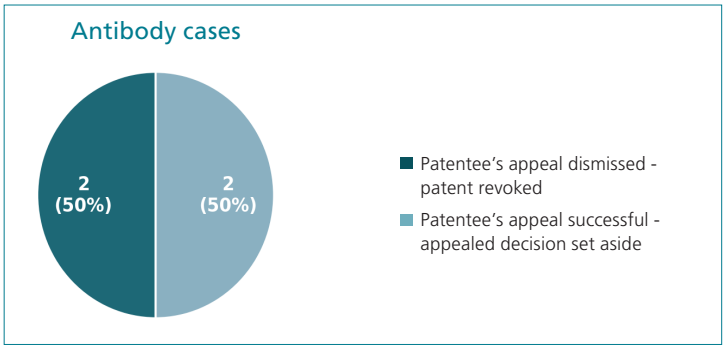
Figure 1. The outcome of the OD's interlocutory decision at first instance in the 2024 antibody appeal decisions:



The 2024 update considers 25 Board of Appeal decisions arising from opposition proceedings. For those decisions, we analysed the first instance finding. Maintenance of the patent in amended form formed the largest group (17 decisions), followed by maintenance of the patent as granted (i.e. rejected oppositions) and patent being revoked (4 decisions each)

II. Patentee appeal after first instance revocation of patent: A narrow route back for patentees

Figure 2. The outcome of antibody cases at appeal stage following revocation of the patent by the OD at first instance.

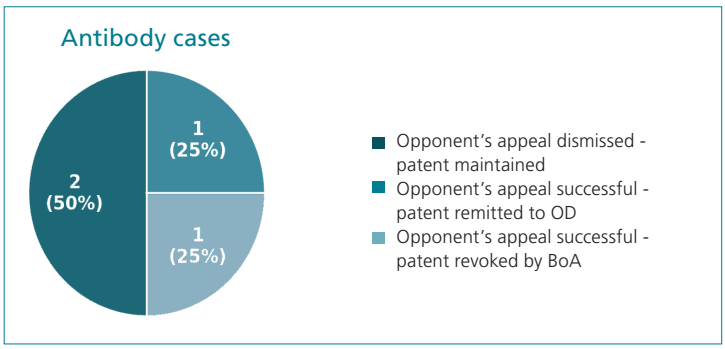


This data set is made up of 4 decisions. Since the appeal followed revocation of the patent at first instance, the appeals were patentee driven.

In 2 of the 4 appeals the patentee's appeal was dismissed, meaning that the patent was revoked by final decision of the BoA. T 1006/21 illustrates the consequences of an unsuccessful priority claim: once the claimed combination of features was not found directly and unambiguously disclosed in the priority document, intervening prior art became relevant for inventive step. T 1731/22 also ended with the revocation standing after novelty, inventive-step and clarity objections defeated the requests. Specifically, the main request was rejected for lack of novelty since method steps disclosed in the prior art would inevitably result in an antibody (scFv) as claimed.. The remaining 2 of the 4 cases show that revocation at first instance is not necessarily fatal since the decision under appeal was set aside. In T 0025/23, the Board disagreed with the OD's sufficiency analysis for a second medical use claim and remitted the case for consideration of novelty and inventive step. In T 1916/21, claim construction was at issue regarding whether the claims were directed to processes resulting in products referred to in Article 64(2) EPC and thus not subject to the special treatment established under G 2/88 and G 6/88, even though they contained the word "use". Although the main request was found to lack novelty, auxiliary request 1 was allowable. The small sample therefore cuts both ways: revocation at first instance may well be made final on appeal, but a carefully targeted appeal may still produce a materially better outcome for the patentee.

III. Opponent appeal after first instance rejection of opposition: No guaranteed safe harbour for patentees

Figure 3. The outcome of antibody appeal cases at appeal stage following rejection of the opposition by the OD at first instance.



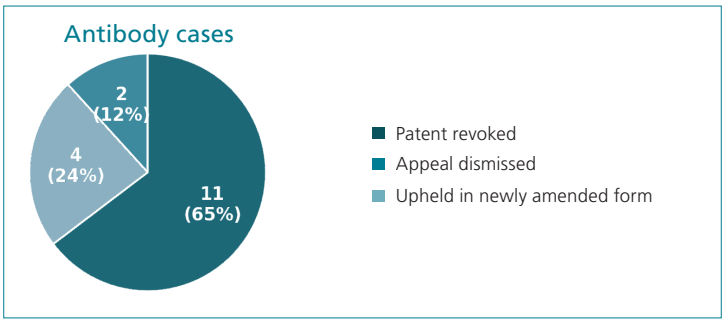
This data set is made up of 4 decisions. Since the appeal followed rejection of the opposition at first instance, the appeals were opponent driven.

Only T 0466/23 ended with dismissal of the appeal, leaving the single claim of the patent maintained as granted. That case concerned a liquid adalimumab formulation, and the Board rejected attacks based on added matter, novelty, inventive step and sufficiency.

The remaining 3 appeals all resulted in different outcomes from the interlocutory decision at first instance. In T 1019/22, the BoA did not agree with the OD's finding to reject the opposition and remitted the case to the OD for further consideration of inventive step objections. Two appeals (T 0880/21 and T 1262/22) resulted in revocation of the patent despite the first instance rejection of the opposition, in both cases for lack of inventive step.

IV. Patents amended at first instance?

Figure 4. The outcome of antibody appeal cases at appeal stage following maintenance of the patent in amended form by the OD at first instance.



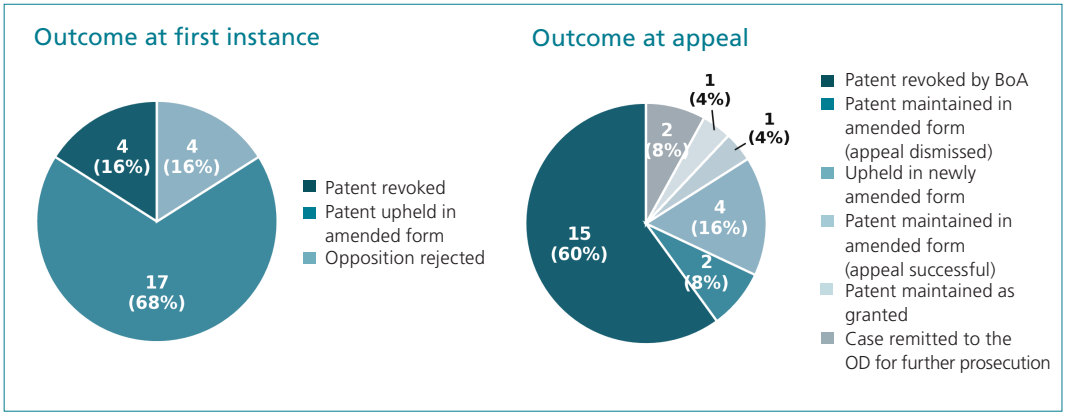
This data set is made up of 17 decisions. Since the appeal followed maintenance of the patent in amended form at first instance, the patentee and/or opponent(s) may have appealed.

2 appeals were dismissed. 4 cases resulted in the patent being upheld in newly amended form. 11 cases ended in revocation, including cases concerning cell-culture compositions, protein purification, protein manufacturing, immune-checkpoint combinations, CAR-T technology, antibody-derived cell therapies and automated T-cell manufacturing.

The decisions show that an amended patent may remain exposed on appeal even after surviving opposition in narrowed form. In several cases, the Board's analysis turned on objections that are particularly difficult to repair late in the proceedings, such as added matter arising from multiple so-called 'selections', loss of priority, or a failure to show that an asserted technical effect was achieved by the distinguishing features. For patentees, the practical risk is that an auxiliary request accepted by the OD may still leave unresolved weaknesses.

V. Overall comparison: First instance versus appeal outcomes

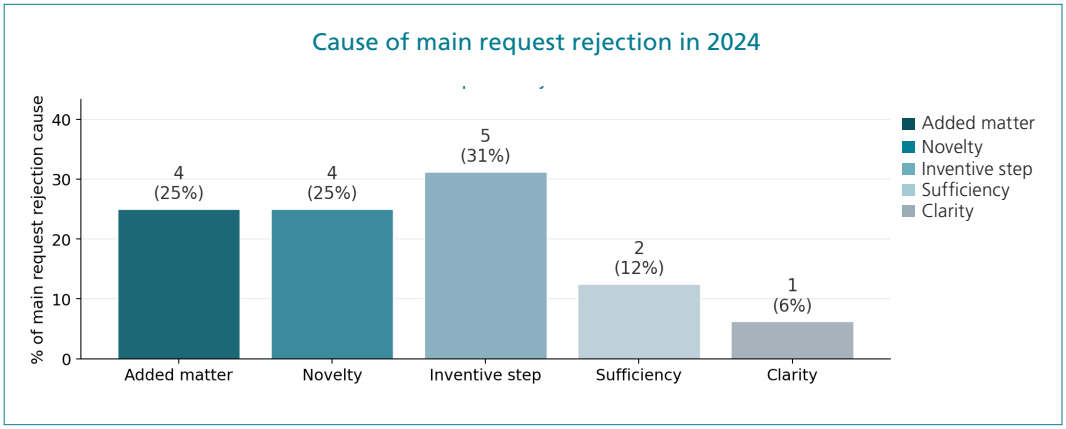
Figure 5. Comparison of the overall distribution of outcomes at first instance and at appeal in the 2024 antibody appeal decisions.



Taken together, the figures show a marked shift between first instance and appeal outcomes. At first instance, only 4 of the 25 cases (16%) ended in revocation before the OD. By the end of the appeal, however, 15 of the 25 cases (60%) had ended in revocation before the Board. The appeal data also distinguish between cases in which a patent maintained in amended form simply survived because the appeal was dismissed (2 cases), and cases in which the patent was upheld in newly amended form on appeal (4 cases). One further case resulted in maintenance in amended form after the Patentee successfully appealed a first instance revocation. The remaining outcomes were 2 remittals to the OD for further prosecution and 1 patent maintained as granted.

VI. Grounds for rejection of the main request

Figure 6. The grounds on which the proprietor's main request was rejected in the 2024 antibody appeal decisions.



Inventive step was the most frequent ground on which the main request failed, accounting for 5 of the 16 rejected main requests. Added matter and novelty followed closely, each arising in 4 decisions, while sufficiency was decisive in 2 cases and clarity in 1.

The distribution shows that risk is not confined to a single area: substantive patentability objections remain prominent, but amendments made during prosecution or opposition continue to create significant added-matter exposure.



Detailed discussion of selected 2024 decisions

T 0326/22 – sufficiency for functionally defined Ab claims

This decision confirms the EPO's approach to sufficiency for functionally defined Ab claims. In line with the criteria that was considered in previous decisions T 1394/21 (where sufficiency was acknowledged) and T 1345/20 (where sufficiency was not acknowledged), the BoA in T 0326/22 came to their conclusion on the basis that the patent application provided the SKP with: 1) The antigen, 2) the epitope (which was a feature of this claim), 3) the assays needed for selecting antibodies with the claimed properties and for assessing the antibodies' binding to the claimed epitope, 4) structural information of several exemplary antibodies. In doing so, the claim to a "pool" of functionally defined human CD47 Abs and fragments was found to be sufficient.

In relation to inventive step, D1 (which disclosed the full-length Ab) provided no pointers for the SKP to select the claimed epitope in order to achieve no cell agglutination (a feature of claim 1).

D13 disclosed anti-CD47 ScFv monomers and dimers and taught that the epitope bound by the Ab imposes different functional properties on these Ab depending on their format: full-length Abs agglutinate cells, while ScFvs do not. Even though the epitope was the sole distinguishing feature compared to the D13 ScFv, the BoA considered the selection of the epitope was not arbitrary because it removed restrictions on the format of the antibody whereas claim 1 imposed functional properties irrespective of the Ab format.

T 0810/22 – inventive step in formulation optimisation

This decision demonstrates the challenges under inventive step when attacking a claimed formulation as obvious. In this case, the CPA, D1, dealt with the preparation and the therapeutic use of anti-human PD-1 Ab, but not their formulation as a stable form suitable for human use.

The OTP for the main request (originally filed as AR6) was defined as providing a formulation of pembrolizumab that can be marketed for human therapeutic use. In this regard, a high, optimised stability was considered necessary. This was a more ambitious OTP than for the MR and AR1-5 (which was "to provide a stable formulation suitable for use in humans" – requests which were withdrawn at opposition) and was considered to be solved due to the "consists essentially of" language in the claim (which required four components (a)-(d)).

The Opponent argued that, at an early stage of clinical development, the SKP would apply the teaching of CGK references D16 and D6 and, by doing so, would arrive at the formulation of claim 1 by routine testing. The fact that the formulation was not only suitable for early clinical trials but that its stability was high enough for marketing was merely an enhanced effect that could not justify the acknowledgement of an inventive step.

The Board said the SKP person applying the rationale of D16 and D6 to pembrolizumab could potentially arrive at different formulations with sufficient stability for early clinical trials by routine testing. However, the Board concluded that the formulation of claim 1 was the result of an optimisation process for late clinical development and marketing rather than the outcome of a quick routine search for a formulation sufficiently stable for early clinical trials which, by chance, appeared to have an enhanced effect. They decided that, as apparently acknowledged by D16 and D6, such an optimisation process requires an amount of time and effort that goes beyond routine work.

T 1913/21 – technical effect pertaining to a product doesn't impart a limitation on the use claim

At opposition, the OD upheld the patent in amended form with a claim directed to "use of an inhibitor of cysteine degradation for reducing the formation of trisulfide bonds in proteins". The key point at appeal was whether the stated effect of "reducing the formation of trisulfide bonds in proteins" amounted to a functional technical feature that limited the use claim or not. As prescribed in Enlarged Board of appeal decisions G 2/88 and G 6/88, in order to be a limiting technical feature of the claim, the (new) purpose must relate to the use rather than to a property of the product.

The OD had concluded that the claim was correctly formatted as a second non-medical use claim. However, the BoA ultimately disagreed. They held that when construing a claim, the claimed subject-matter is determined by applying the established principles of claim construction, in other words, giving the terms used in a claim their ordinary meaning in the context of the claim. Importantly, this principle also applies when determining which "category" a claim is in. Building on this, the Board noted that the invention related to "methods of preventing and eliminating the formation of trisulfide bonds in proteins during protein production". The claims, when correctly construed therefore, were directed to processes resulting in products

"*Thus the new technical effect recited in the claim of reducing the formation of trisulfide bonds in proteins pertains to the product (the protein produced) and cannot be considered a technical limiting feature of the "use" according to G 2/88. Indeed, where an invention relates to a new technical effect of a physical entity that can only occur as part of a process for the production or manufacture of a product, such that this effect is inextricably linked to and cannot occur in isolation from the production process, a claim directed to that "use" of the physical entity to achieve that effect must be regarded as directed to the production process per se.*" (reasons 23).

Consequently, the claim was not eligible for the G 2/88 exception which applies only to new uses for a known substance, not to processes resulting in a product. Thus, the effect was deemed a property of the resulting protein, not a limiting technical feature of the use. Therefore, prior disclosures of the same process (D3 and D24) anticipated the claim and the patent was revoked for lack of novelty.

T 1754/22 – the EPO's two-hurdle inventive step approach and the added-matter trap

T 1754/22 provides a useful example of the EPO's two-hurdle approach to computer-implemented process claims in the life sciences. First, the claim must contain a technical feature for the purposes of Article 52 EPC. Secondly, the claimed distinguishing features must contribute to a technical purpose for inventive step under Article 56 EPC.

The original PCT claim concerned generating a PD-1:PD-Ligand proximity score from an image of tumour tissue and classifying the tumour as biomarker-positive or biomarker-negative.

To overcome the first hurdle, the claim was amended from "obtaining" an image to "obtaining, by imaging" an image. This introduced an express step of a technical nature rather than encompassing the mere provision of an existing image. To overcome the second hurdle, the claim was amended to require "using the classification to predict if a subject is likely to respond to a PD-1 antagonist". This linked the classification result to a technical purpose rather than leaving the claim at the level of calculating and presenting information.

However, the amendment introduced to satisfy the inventive-step requirement ultimately resulted in the patent being revoked for added matter. The application disclosed identifying biomarkers and predicting responsiveness to PD-1 antagonists, but did not directly and unambiguously disclose the specific process step of using the classification generated by the preceding claim steps to make that prediction.

The case therefore illustrates the importance of drafting the original application with both EPO hurdles in mind. The technical acquisition step and the subsequent technical use of the computational result should be expressly and coherently disclosed from the outset. Here, the later amendment needed to secure patentability could not satisfy the EPO's "gold standard" for basis.

T 0419/16 – inventive step for an antibody defined by its target

In a rare case for current times, the patenteePatentee claimed a 1st medical use with a broad definition of the Ab by target. The difference between the disclosure of an anti-ST2 mAb in the CPA (D6) and the claimed antibody was the target and its medical use (no medical use was disclosed for the D6 anti-ST2 mAb). The appellants argued that the identification of IL-33 as the ligand of ST2 was an obvious solution to the OTP of either providing of an alternative medicament or alternatively, the de-orphaning of the T1/ST2 receptor to provide Ab against its ligand.

However, the Board decided both formulations were inappropriate and not derived from the difference between the claimed subject-matter and the disclosure in CPA and the technical effects related to the difference. The Board formulated the objective technical problem as the provision of a medicament, for treating e.g. asthma, allergy, multiple sclerosis and arthritis. The Board found there was no pointer in the CPA that would have motivated the skilled person to undertake the research project of trying to identify the unknown ligand for the ST2. They commented that while undertaking a search for the ST2 ligand might have been desirable, it was however not known: what the ligand would be, what its specific biological functions would be, and whether (either agonistic or antagonistic) antibodies to the, as yet unknown, ligand could reasonably be expected to be useful as therapeutic agents.

Therefore, the claimed anti-IL-33 antibody was inventive, and the patent was maintained on the basis of AR1.

T 1809/20 – pointers, lists and multiple selections under Article 123(2) EPC

T 1809/20 concerned an affinity-chromatography method defined by a combination of selected proteins, concentration ranges and pH. The Board found that these features involved multiple selections made at "different levels of preference", without a pointer to their specific combination.

For the arginine and salt concentration ranges, the Patentee relied partly on the examples. Although the concentrations used in the examples fell within the claimed ranges, they also fell within narrower or more preferred ranges disclosed in the application. The examples therefore did not point specifically to selecting the claimed intermediate ranges.

The claimed pH of greater than 8.0 was described in places as "preferably" or "typically", but the disclosure also identified progressively narrower and more preferred pH ranges. Therefore, according to the BoA, viewed "in the context of the whole disclosure", the broadest range was not presented as the preferred selection.

The claimed list of proteins, an antibody, antibody fragment or Fc fusion protein-also required two selections from separate passages. One passage disclosed antibodies and antibody fragments among a broader group of proteins, while another disclosed antibodies, Fc-containing antibody fragments and Fc fusion proteins. Rather than treating the claim as merely shrinking a combined list, the Board treated it as combining a first selection of antibodies and antibody fragments from one passage with a second selection of Fc fusion proteins from another.

The BoA issued the reminder that an application cannot be treated as a reservoir from which features at different levels of preference could be assembled without a pointer to the resulting combination.

The claim therefore added subject-matter and the patent was revoked.

T 1103/22 – sufficiency of a claim to an Ab binding a specific target region

T 1103/22 considered the sufficiency requirements for antibodies defined functionally by binding to a specific region of a target. The claim required an antibody that specifically bound factor XI, bound "at the active site located in the light chain region", and inhibited FXIa activity in a chromogenic assay.

It was undisputed that identifying an antibody which inhibited FXIa activity in the assay did not "pose any particular difficulties". The key question was whether such inhibition necessarily meant that the antibody also bound at the active site.

The Board held that it did not. Antibodies could inhibit FXIa by other mechanisms, including allosteric inhibition. It also rejected the Patentee's argument that "binding at" the active site could encompass "binding near" or "binding close to" it.

Once the inhibition assay was found not to establish binding at the active site, the Board considered whether the skilled person could otherwise identify antibodies having that feature. The application disclosed no suitable assay for doing so. The active site therefore needed to be defined structurally, but the application provided neither the relevant structural information nor an exemplary antibody as a starting point.

The invention was therefore insufficiently disclosed and the patent was revoked. The decision is consistent with the EPO's approach that an antibody may be defined by its epitope or binding region, but the application must enable further antibodies having that property to be produced without undue burden and must define the relevant binding feature clearly. See also T 1911/17.

T 0025/23 – sufficiency for a second medical use covering a group of diseases

T 0025/23 concerned whether a second medical use claim covering epithelial ovarian cancer, fallopian tube carcinoma and primary peritoneal carcinoma was sufficiently disclosed – i.e. that the application credibly showed that the claimed therapeutic use was achieved.

The key issue was whether the three conditions constituted a "single group of diseases". The Board agreed with the OD that the skilled person would have regarded them as being managed in the same way, with treatment outcomes applicable to the group as a whole. This was supported by the design of the clinical trial reported in the patent and by other clinical trials in which patients with the three cancer types had been treated together.

The Board nevertheless disagreed with the OD's conclusion on sufficiency. Having found that no distinction was made between the three diseases and that they were treated as a single group, the Board stated that it "cannot be understood why" the patent should then be required to provide results stratified separately for each disease.

The reported clinical results were therefore applicable to the group as a whole. Separate data for epithelial ovarian cancer, fallopian tube carcinoma and primary peritoneal carcinoma were not required merely because the diseases were individually named in the claim.

The Board found the invention sufficiently disclosed and remitted the case for further prosecution.

T 1776/21 – no “link” between separately disclosed claim features

T 1776/21 concerned added matter and whether there was basis for a purpose-limited antibody product claim combining three features: pembrolizumab, treatment of lung cancer and selection of patients having at least 178 nonsynonymous mutations.

The application contained passages supporting each feature individually. However, the Board held that “while these passages may provide basis for each of the features of the claim, there is no basis in the application as filed for the claimed combination of features”. In particular, there was “no link” between the use of pembrolizumab to treat lung cancer patients and the specific mutational characteristics disclosed elsewhere in the application. The reported correlation between a mutation threshold and response to pembrolizumab did not directly and unambiguously disclose selecting patients using that threshold and then treating the selected subgroup.

The applicant argued that the application as a whole was directed to predicting response to immunotherapy so that suitable patients could be identified for treatment. It would therefore be bizarre to identify responsive patients but not treat them. The Board accepted the logic of that argument, but regarded it as a question of obviousness, and not the relevant standard under A123(2) EPC which is direct and unambiguous disclosure.

The decision illustrates the difficulty of relying on the general purpose or overall teaching of an application as a pointer for combining separate disclosures. The application must contain a sufficiently clear “link” between the particular therapeutic agent, disease and patient-selection characteristic.

The main and auxiliary requests therefore added subject-matter, and the appeal was dismissed.

Methodology

The dataset of antibody-related patents was generated using a search of the EPO BoA decisions database, using the search term ‘antibod’ in the full text search field. Decisions forming this dataset were limited to English language decisions and based on appeals from opposition division (OD) decisions.

The search identified 34 decisions for review. 9 were excluded because they did not concern antibodies as such. These are listed in the exclusion table at the end of this report. The figures and discussion below are based on the remaining 25 decisions.

Summary table of included 2024 decisions and outcomes

The table below summarises the 25 decisions considered in the figures and discussion above.

Decision	Title
T 0819/21	Cell culture compositions
T 0025/23	Bevacizumab for the treatment of ovarian cancer
T 1006/21	B7-H1 in RCC
T 1916/21	Protein refolding
T 0219/22	SerpinF2-Binding Molecules
T 1019/22	Bispecific nanobodies
T 1639/21	mRNA/anti-PD-1 combination vaccine
T 0203/22	Targeting B7-H6
T 1502/22	CD33-specific CAR
T 1005/22	Mycoplasma pneumonia
T 2342/22	Universal CAR-T cells
T 1809/20	Wash solution and method for affinity chromatography
T 1103/22	Anti-factor XI antibodies
T 0466/23	Liquid adalimumab pharmaceutical composition
T 0419/16	IL-33 antagonist antibody
T 1731/22	Alpha-synuclein oligomer antibodies
T 1754/22	Proximity assay
T 0326/22	CD47 antibodies
T 0880/21	Combined perfusion-fed-batch process
T 1262/22	Fibrosis
T 1032/22	Method for automated generation of genetically modified T cells
T1913/21	Preventing trisulfide bonds
T 0810/22	Pembrolizumab formulatio
T 0816/22	C1-esterase inhibitor for AMR
T 2192/22	Purifiying polypeptides

Excluded decisions

The following decisions were identified in the search results but excluded from the figures and substantive discussion because they were not about antibodies as such.

Decision	Title
T 1346/22	PCV2 vaccine/
T 0521/18	A liquid composition
T 0197/22	Delivery of mRNA II
T 0903/22	Conjugate vaccine
T 1601/22	IL-2 dosage regimen for treating systemic lupus erythematosus
T 0083/23	S.suis
T 0518/22	Type-A DNA polymerase mutants
T 1789/22	HCMV complexes
T 0963/22	Non-live Lawsonia vaccine







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CMS Cameron McKenna Nabarro Olswang LLP
Cannon Place
78 Cannon Street
London EC4N 6AF

T +44 (0)20 7367 3000
F +44 (0)20 7367 2000

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