Case (+ hyperlink)	Date	Board	1st OA	Claim	Summary	Outcome	Main Grounds at issue	Claim Type	1st Instance Decision	BoA Decision	More lenient than previous decision?	Agree with Preliminary Opinion?
28/03/2023	T 0835/21	3.3.08	OD	Claims to a monoclonal antibody or Ab-binding fragment against LRP6, defined by an epitope a.a. sequence, capable of antagonising the Wnt signalling pathway, and inhibits Wnt3- and Wnt3a-specific signalling, for use in treating cancer.	OD rejected opposition against the (divisional) application and maintained the patent as granted. Two opponents had raised objections on the grounds of lack of novelty and inventive step, sufficiency and added subject matter. The first opponent withdrew their opposition. The second opponent maintained their objections and appealed the decision, requesting the patent be revoked. In its PO, the BoA disagreed with the OD's interpretation of claim 1, and instead considered that the claimed Ab should specifically inhibit Wnt3- and Wnt3a-specific signaling, without affecting signaling through other Wnt ligands. This raised sufficiency concerns due to the absence in the patent of a proposed screening method for producing antibodies with the desired functional features. Suggested the patent would likely be revoked. The appellant didn't attend oral proceedings. At appeal, the respondent replaced the main request with AR1 but claim 1 remained unchanged. The BoA interpreted claim 1 differently than they had in their PO. They stated that the term "specific" meant to the SKP that the Ab was only required to inhibit Wnt3/Wnt3a signalling to a significantly higher degree than that initiated by other ligands and that complete inhibition went against scientific knowledge. They took the view that whilst the patent didn't disclose the structure or sequences of their 2 example Abs, A83 does not require an application to contain a reproducible example and it is generally routine for the SKP to produce Abs against a known target, regardless of whether or not it is "tedious".	The decision under appeal was set aside and the case remitted to the OD with the decision to maintain the patent on the basis of claims 1 to 9 of the main request (files as AR1 in reply to appeal) and a description possibly to be adapted thereto.	A83 A54 A56 A123(2) A 76(1)	Antibody Product by epitope	Patent maintained as granted.	Patent upheld with amended claims.	No	No
09/01/2023	T 3165/19	3.3.08	ED	Claims to Ab against PCSK9 for use in a method of reducing cardiovascular risk.	The ED refused the application finding the main request contained added-subject matter, the first AR lacked inventive step, ARs 2-5 were not novel, and AR6 contained added mater and lacked clarity. The patentee appealed the decision and requested the case be remitted to the ED for further prosecution. BoA agreed that the MR contained added matter but disagreed with ED's IS arguments against AR1. They reasoned that inhibiting the PCSK9-LDL receptor interaction with the claimed Ab didn't necessarily equate to the effect of a PCSK9 LOF mutation. Thus, reduced cardiovascular risk in patients with this LOF mutation didn't imply to the SKP that PCSK9 inhibition would have the same result. In their opinion, the teaching of D12/D13 would only present the SKP with "hope that the phase 3 clinical trial disclosed in D4 would succeed" but that this wasn't enough to deny IS. They also disagreed that a link between LDL levels and cardiovascular risk was established in the art. The Board considered the Patentee's reference to T 239/16 and noted that this reads (Reasons 6.5 on page 31): "The board considers that the mere fact that an active agent...is being tested in a clinical study for the treatment...leads to an expectation of success..". They qualified that this consideration is not absolute but must be understood in the context of decision T 239/16, where the expectation of the skilled person based on the ongoing clinical study was warranted. In addition, the Board noted that in T 239/16, it was recognised that the skilled person could be dissuaded from this expectation by the prior art (Reasons 6.5). In view of the positive PO, no oral proceedings were held. The patentee submitted AR1 as its main request. The BoA reversed the ED decision and the case was remitted to the ED for further prosecution.	Case remitted to ED for further prosecution	A56 A111(1)	Medical Use	Application Refused	Case remitted for further prosecution	Yes	Yes
16/02/2023	T 0654/20	3.3.04	OD	Claims to a composition comprising c-kit signaling-interfering antibody for use in a method for stem cell engraftment.	The patent was maintained in an amended form by the OD on the basis of the amended claims in the Patentee's main request in which the subject-matter of granted claims 4-6 was introduced into claim 1 - i.e. the treatment of human patients through the introduction of exogenous hematopoietic stem cells. Ab interferes with c-kit signaling and selectively ablates endogenous hematopoietic stem cells (HSCs) in bone marrow (New claim 1). The opponent appealed. The PO from the BoA was negative with respect to sufficiency, and lack of novelty and inventive step for the main request (which was the request upheld by the OD). In response to the PO, the Patentee amended their main request to be the claims of previous AR11. The Opponent did not attend the oral proceedings. The BoA concluded that limiting the claims to a subset of human severe combined immunodeficiency (SCID) patients addressed their concerns.	The decision under appeal was set aside and the case remitted to the OD with the decision to maintain the patent on the basis of the new main request.	A54 A56 A83 A123(2)	Medical Use	Patent upheld in amended form.	Patent upheld in a further amended form.	No	Yes
04/07/2023	T 2347/19	3.3.07	OD	Claims to the glucocorticoid (GC) for use in a method of prophylaxis of adverse events caused by the administration of a CD3 binding domain.	The patent was opposed by two opponents. The OD rejected the main request on the ground of insufficiency but upheld the patent in amended form according to AR1, where the CD3 binding domain was limited to a CD19xCD3 bispecific single chain Ab. Both the patentee and one opponent (other withdrew) appealed against the decision. The patentee requested the decision be set aside and the patent be maintained in an amended form. It submitted 3 new ARs between the MR and AR1 of the opposition which became AR4. The opponent requested the patent be set aside in it's entirety. In its PO, the BoA took a similar view to the OD. They disagreed with the appellant-patent proprietor's submissions that CD3 binding domains in general caused neurological effects and also indicated it would likely reject the opponent's objections. The BoA remained consistent with its PO in finding that the main request lacked sufficiency. It also refused to admit ARs 1-3 into proceedings as they should have been filed during opposition. It deemed that AR4 (previously AR1) however, satisfied the requirements of the EPC and rejected the appellant-opponents objections.	Both appeals dismissed, patent upheld in amended form.	A83 A56	Medical Use	Patent upheld in amended form.	Appeal Dismissed	Same	Yes
14/09/2023	T 0885/21	3.3.07	OD	Claims to an antibody-conjugate for use as a medicament wherein the antibody specifically binds a cancer antigen.	Opposition was raised by 3 opponents on the grounds of lack of novelty, inventive step, sufficiency and that the subject-matter extended beyond the content of the application as filed. The OD revoked the patent. The patentee appealed requesting the patent be maintained as granted, or on the basis of 15 ARs, 1-5 of which were filed at appeal. In its PO, the board indicated that the MR appeared to lack novelty and IS. They considered that the prior art anticipated the trimming the Ab of glycans to the core GlcNAc with endoglucosidases prior to their conjugation with a cytotoxin. The claims of AR1 however, were to an antibody-conjugate for use as a medicament, wherein the "molecule of interest" was limited to a cytotoxin, and the Ab binds specifically to cancer antigens. The board suggested that AR1 likely met the requirements of the EPC. The patentee withdrew its main request and renumbered AR1 as the MR. The BoA in keeping with its PO, held that the new main request dealt with sufficiency, IS and novelty objections. They formulated the objective technical problem as providing optimized glycan-linked conjugates of a cancer antigen-binding antibody with a cytotoxin for therapy and concluded that none of the prior art provided the SKP with a reasonable expectation that the subject-matter as claimed would solve it.	The decision under appeal was set aside and the case was remitted to the OD with the order to maintain the patent on the basis of claims 1-8 of the main request (previously filed as AR1).	A54 A56 A123(2) A83 A84 A114(2)	Medical Use	Patent revoked	Remitted to the OD for further prosecution in amended form.	Yes	Yes
05/07/2023	T 0047/22	3.3.04	OD	Claims to a method of designing an immunoglobin (Ig) library for optimisation of a biological property of a first lead Ig.	The patent was maintained in an amended form on the basis of amended claims in the patentee's main request. The opponent appealed the decision on the grounds of inventive step and sufficiency, and requested the patent be revoked in its entirety. The patent proprietor requested the patent be maintained as granted as its main request and filed an additional 39 ARs. In its PO, the BoA refuted the opponent's sufficiency objection that the SKP wouldn't be able to identify somatic hypermutation hot spots (SHHs), a requisite of claim 1c), and wouldn't be able to determine if variations in the Ig sequence arose at these sites only by comparing a.a. sequences of only two Igs. The board didn't give a clear opinion in relation to IS. The BoA deviated from its PO and found that the MR was in fact not sufficiently disclosed as the respondent failed to show that identifying SHHs was part of the CGK. In AR1, the patentee had amended claim 1 such that it required the comparison of at least 20 related Igs. The board was then convinced, in view of the CGK, that this would allow identification of SHHs and thus was sufficiently disclosed. Inventive step objections against AR1 were also dismissed.	The appeal was set aside and remitted to the OD on the basis that the patent be maintained according to AR1.	A83 A56 A113	Method claim	Patent upheld in amended form.	Patent upheld in a further amended form.	No	No

13/07/2023	T 1044/21	3.3.08	OD	Claims to a method of scoring PD-L1 expression in a tumour sample comprising contacting the tissue sample with an anti-PD-L1 antibody, a primary antibody directed to a tumour cell-specific marker and an antibody directed to an immune cell-specific marker, wherein each can be identified by a signal distinguishable from the signals of the other two.	The OD rejected the opposition on the grounds of lack of novelty, inventive step, industrial application, sufficiency and added subject matter and maintained the patent as granted. The opponent appealed the decision, requesting the patent be revoked in its entirety. The BoA indicated it was likely to overturn the decision of the OD. The CPA, D6, was a method in which cancer cells were double-stained to detect PD-L1 and a tumor cell-specific marker. Whilst the application was to triplex staining, the board took the view that this was simply an alternative method to D6. Considering IS, the board viewed that D6 in combination with D14, which disclosed triple and even quadruple staining, rendered the invention obvious. The BoA maintained its position that the method lacked inventive step. The board rejected the notion that the method was faster, more accurate and more reproducible since the patent provided no evidence through comparison with the CPA. They further stated that the definition of the claimed subject-matter merely amounted selection of one method and combining a number of equally-known methods and deemed that claim 1 of the MR and ARs 1-9 didn't meet the requirements of A56.	The decision under appeal was set aside and the patent revoked.	A56	Method claim	Patent maintained as granted.	Patent revoked	No	Yes
30/11/2023	T 0168/19	3.3.08	OD	Claims to a method of engineering an immunobinder with improved functional properties, the immunobinder comprising a heavy chain variable region, or fragment thereof, comprising VH framework residues, and a light chain variable region, or fragment thereof, comprising VL framework residues, the method comprising introducing selected mutations to the VH/VL regions.	The patent was opposed by three opponents. The OD revoked it in its entirety, finding that the main request constituted added matter and AR1 lacked inventive step. The patent proprietor appealed the decision and filed AR1 as its new main request and filed 5 new additional auxiliary requests. In its PO, the BoA concurred with the OD's findings. The OD identified D1 as the CPA and noted the patent's only difference was the nature of the mutations (i.e. specific residues chosen) to the VH/VL regions. The OTP could have been the provision of a method for introducing beneficial mutations. However, in the patent examples, not all mutations were over-represented in the quality control (QC) library, and only scFv molecules were tested. Thus, the OTP had to be reformulated to be the mutation of alternative VH/VL positions and screening for improved properties, which would have been obvious to the SKP. The BoA maintained the stance it had taken in its PO. They reiterated that the OTP was not resolved by the claimed subject matter since not all the mutations indicated in the claim were over-represented in the QC library. Reformulation of the OTP to a less ambitious one resulted in a problem that would be obvious for the SKP to solve. Additionally, the BoA rejected admission of AR1-5 since they saw no reason they weren't admitted during opposition and as a result prejudiced A12(4).	Appeal dismissed, patent remained revoked.	A56	Method claim	Patent revoked	Appeal Dismissed	Same	Yes
02/06/2023	T 1478/18	3.3.04	OD	Claims to an antibody preparation suitable for intravenous administration comprising IgG, IgA and IgM antibodies.	The OD upheld the patent in an amended form according to AR2. It found that claims 13 and 14 of the main request and AR1 contained added matter and as a result these requests were refused. Both the patentee and opponent appealed against the decision, with the former requesting the decision be set aside and the patent maintained as granted, whilst the opponent requested the patent be revoked in its entirety on the grounds of added matter, sufficiency and lack of novelty and inventive step. The BoA agreed with all aspects of the OD's decision. It considered claims 13 and 14 of the main request and AR1 constituted added matter since they weren't limited to an essential feature of the Ab preparation as disclosed in the application. It also disagreed with all the objections put forward by the appellant-opponent in their appeal. In keeping with its PO, the BoA dismissed both appeals. They found AR2 (upheld by the OD) didn't add subject-matter and overcame the objections raised against the main request and AR1, and further, that it overcame the objections raised by the appellant-opponent.	Both appeals dismissed, patent upheld in amended form.	A54 A56 A84 A83 A123(2) A125	Pharmaceutical composition claim	Patent upheld in amended form.	Appeal Dismissed	Same	Yes
21/09/2023	T 1515/20	3.3.04	ED	Claims to an Ab (eculizumab) that binds C5 comprising a heavy chain consisting of a SEQ ID NO:2 and a light chain consisting of residues 23-214 of SEQ ID NO:4	The ED refused the MR and ARs 1-3 of the grandchild divisional application for added matter. They considered that the limitation imposed by defining the specific residues of the light chain sequence extended beyond the content of the AAF. The patentee argued this decision during prosecution, stating that the reason for the limitation was that the original sequence "erroneously" included a leader sequence used in the purification process and that it was an obvious error. However, the ED disagreed, stating it would not be obvious to the SKP which residues amounted to this leader sequence. The patentee appealed. The patentee submitted a new main request and 11 ARs. In its PO, the board indicated that they agreed with the ED and that the appeal would likely be dismissed. The Board noted that ARs 5 and 11 might comply with A76(1) and 123(2) but raised concerns under A83. The BoA refused the MR and ARs 1-4 on the grounds of added matter, as it had discussed in its PO. They rejected the appellant's argument that limiting the sequence to specific residues corrected an obvious error which met the requirements of Rule 139 EPC. They took the view that the arguments put forward by the appellant failed to satisfy the two-step criterion for correction set out in G 3/89 as they considered the error made in the application wouldn't have been immediately obvious to the SKP. Regarding AR5, the board considered that it complied with A76(1) and A123(2) since it removed the limitation imposed on the light chain sequence. The patentee further convinced the board that the peptide leader sequence was sufficiently distanced from the CDRs that it wouldn't the SKP would dissuade the SKP from having doubts that the Ab would bind C5. Therefore, it was found AR5 was sufficiently disclosed and met all the requirements of the EPC.	Decision under appeal set aside, case remitted to ED with an order to grant the patent in amended form.	A123(2) A83 A54 A56 A76(1)	Product claim	Application Refused	Decision under appeal set aside, case remitted to ED with an order to grant the patent in amended form.	Yes	No
18/10/2023	T 0737/20	3.3.04	OD	Claims directed to a compound that reduces the activity or expression of a Programmed Cell Death-1 (PD-1) polypeptide for use in treating persistent viral infection in a subject wherein said compound is an anti-PD-1 / PD-L1 / PD-L2 antibody or RNAi or antisense RNA and the viral infection is selected from a list of multiple viruses.	The patent was opposed by three opponents and the OD revoked the patent finding that the subject matter of claim 1 lacked novelty over the disclosure in D1 and D20. The OD did find however that grounds for opposition under Article 100(b) and Article 100 (c) did not prejudice maintenance of the patent. The patentee appealed the decision and filed new auxiliary requests (1a-1o and 2a-2o) with the statement of grounds of appeal. The BoA indicated in their PO that they would be unlikely to admit any of the auxiliary requests as they saw no reason they couldn't have been filed during opposition. Claim 1 is a purpose-limited product under A54(4) with the therapeutic aim of treating persistent viral infection. The board noted however that whilst "persistent infection" was defined in the description, there was no definition in the claims and that it remained to be decided if this expression had clearly defined boundaries in the art. They further referred to Article 83 and the established case law that a sufficient disclosure of a medical use is present if the SKP would have considered the compounds referred to are suitable for achieving the therapeutic effect mentioned in the claim. Since the patentee had provided no substantive submissions on IS the BoA allowed 2 months to provide these prior to oral proceedings. The BoA rejected the patentee's request for remittal under Article 111(1), noting the OD had already provided a preliminary opinion on inventive step and that the appellant had had the opportunity to submit on this issue. The appellant's objection under Rule 106 was also rejected. D5 was deemed the CPA, and pertained to restoring CD8 T function via PD-L1 blockade during chronic viral infection. The OTP was formulated as providing an agent for treating "persistent" viral infections listed in claim 1. The BoA disagreed with the patentee's claim that the SKP would not the information provided in D5 credible, despite D5 being an abstract that was not peer-reviewed and lacking in experimental evidence. The board argued that, since D5 was published in a reputable journal by scientists from reputable institutions, the SKP would not dismiss it as unreliable. Moreover, the SKP would not expect detailed experimental results in an abstract and had no reason to disregard the information. Thus the main request was found to prejudice A56. The auxiliary requests were not admitted.	The appeal was dismissed and the patent remained revoked.	A56 A111(1) A113	Medical Use	Patent revoked	Appeal Dismissed	No	Yes

06/12/2023	T 1927/22	3.3.04	OD	Claim to a pharmaceutical composition comprising a PCSK9 inhibitor for use in reducing lipoprotein(a) (Lp(a)) in a patient who exhibits serum Lp(a) above 30 mg/ml and who is diagnosed with or identified at being at risk of developing cardiovascular disease or thrombotic occlusive disease and wherein the PCSK9 inhibitor is an antibody or antigen-binding fragment that binds to PCSK9.	The OD maintained the patent in amended form following objections from two opponents on the grounds of novelty, inventive step, sufficiency and added matter. The OD held that auxiliary request 12a satisfied the requirements of the EPC. Both the patentee and opponent 1 appealed the decision. Opponent 2 withdrew its appeal. The patentee requested the decision under appeal be set aside and the patent be maintained based on the main request. Opponent 1 requested the decision under appeal be set aside and the patent revoked in its entirety. In its opinion, the board considered the dispute between the parties about whether claim 1 (of all requests) was a purpose-limited product claim or whether it was directed to a product per se, e.g. a pharmaceutical composition. The board took the view that the patient group in the claim was not limiting since the point in time of, and the type of, diagnosis / identification is not defined. They further stated that since there was no evidence of a non-medical application of reducing Lp(a) levels, this would be excluded by the provisions of A 53(c) and consequently would allow the claim to be formulated instead as a purpose-limited product under A 54(5). D110 was considered the CPA and suggested that PCSK-9 can lower Lp(a) levels but without experimental evidence. The question was then whether this disclosure would have led the SKP to test this with a reasonable expectation of success. In the boards opinion, there were no conceivable hurdle to this experimentation as PCSK-9 Abs were already approved and therefore, that the subject matter of claim 1 (all requests) would lack IS. Agreeing with its PO, the BoA viewed claim 1 as a purpose-limited product claim, determining the patient group was not limiting. They found the claim novel because a patient group with Lp(a) levels of at least 30 mg/dL was not in the prior art. The definition of the patient subgroup was deemed non-arbitrary, given the correlation between elevated cardiovascular disease and plasma Lp(a) levels over 30 mg/dL. Under Article 12(4) RPBA, the BoA allowed additional arguments from the patent proprietor, which highlighted an error by the OD in interpreting key experimental data. Consequently, the BoA disagreed with the OD, ruling that the claims sufficiently disclosed the invention under Article 100(b). On inventive step, the patent proprietor convinced the BoA that there was no consensus in the art on how Lp(a) levels are regulated. Disclosures in D110 and D22 were isolated suggestions without supporting data. Thus, the SKP would have lacked a reasonable expectation of success that using PCSK-9 inhibitors would decrease Lp(a) levels, leading the BoA to consider the claimed subject matter inventive.	The decision under appeal was set aside and the patent was maintained as granted.	A56 A54 A83	Medical Use	Patent upheld in amended form.	Appeal set aside and patent to be maintained as granted.	Yes	No
30/01/2024	T 1006/21	3.3.08	OD	Claims to an Ab or Ab fragment that interferes with the interaction between B7-H1 and a receptor for B7-H1 for use in the treatment of immunosuppression characterised by an impaired function and survival of activated tumor-specific T-cells in a subject with cancer.	This decision concerns the validity of a priority claim and is a reminder of the potential consequences of the EPO's strict approach to 'direct and unambiguous' disclosure. The claim combined two features, an antibody against PD-1 and the treatment of an immunosuppression characterised by an impaired function and survival of activated tumour-specific T cells in a subject with cancer (RCC). Applying the standard of "direct and unambiguous" disclosure when considering what the SKP would derive from the application as filed, using the CGK, the board held that since the features of the claim were disclosed separately in P1, P1 did not disclose the same invention as defined in the claim. Consequently, the patentee was not entitled to their priority claim, which meant that D16 was prior art and rendered the claimed invention obvious. This decision serves as a reminder that general open-ended statements in the description which burden the skilled reader with having to work out which combinations of features from the detailed embodiments might be claimed together generally do not constitute a direct and unambiguous disclosure. Careful drafting is required to ensure there is a 'link' or 'pointer' that separate teachings could be combined.	Appeal Dismissed	A56 A87(1) A111(1)	Medical Use	Patent revoked	Appeal Dismissed	Same	Yes
24/06/2024	T 0419/16	3.3.04	OD	Claims to an IL-33 antagonist for use as a medicament, wherein the antagonist comprises a binding composition from an antibody that specifically binds to IL-33.	In a rare case for current times, the patentee 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 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 said 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.	Decision under appeal set aside, patent maintained in amended form.	A54 A56	Medical Use	Patent upheld in amended form.	Appeal Dismissed	Same	Yes
01/08/2024	T 0326/22	3.3.08	OD	Claims to a pool of functionally defined human CD47 monoclonal antibodies and fragments.	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 comparted 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.	Appeal Dismissed	A56 A83	Antibody Product by epitope	Patent upheld in amended form.	Appeal Dismissed	Same	Yes
24/10/2024	T 0810/22	3.3.08	OD	Claims to stable formulations of an anti-human PD-1 antibody for use in a method of treatment by therapy.	This decision demonstrates the challenges under inventive step when attacking a claimed formulation as obvious. In this case, 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 pembro 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 pembro 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.	Decision under appeal set aside, patent maintained in further amended form.	A84 A56	Medical Use	Patent upheld in amended form.	Patent upheld in further amended form.	No	Yes