

Case (+ hypertink)	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	I0835/21	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 signalling, 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) A76(1)	Antibody Product by epitope	Patent maintained as granted.	Patent upheld with amended claims.	No	No
16/02/2023	I0654/20	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
09/03/2023	I2034/21	3.3.04	OD	Claims to a composition comprising an anti-ICOS Ab for use in treating cancer wherein said Ab is for use in combination with an anti-PD-L1 Ab or an anti-CTLA-4 Ab (Claim 1) / an anti-PD-L1 Ab or an anti-CTLA-4 Ab for use in treating cancer wherein said Ab is for use in combination with an anti-ICOS Ab (Claim 2).	Patent was maintained on the basis of the granted claims having been opposed for lack of inventive step novelty and sufficiency. A key point of contention was interpretation of claims 1 and 2, specifically the phrase "for use in combination with". Appellant II argued this meant only that the first Ab be suitable for combining with the second, but not an actual combination in the treatment. In its PO, the BoA indicated they agreed with the OD's finding that the SKP would interpret claims 1+2 as relating to a combination of antibodies in the context of cancer treatment. In view of this they considered the added matter argument put forward by Appellant II moot. They also indicated a positive view with respect to novelty and sufficiency and that inventive step issues would be heard at appeal. Contrary to its preliminary view, the BoA raised concerns over the interpretation of claims 1 and 2. They agreed with the appellant's reasoning that the second "for use" was not semantically linked to the therapeutic use of the composition, implying only that the first Ab must be suitable for combination with the second Ab. They rejected the patentee's assertion that a mind willing to understand would rule out this interpretation - instead they said "it might be opportune or necessary to define compounds by characteristics other than the intended use" and as such this interpretation was valid. They held that since the patent failed to disclose compositions comprising a single antibody for cancer treatment, claims 1 and 2 constituted added matter.	The decision under appeal was set aside and the patent was revoked.	A123(2)	Medical Use	Patent upheld in amended form.	Patent revoked	No	No
25/07/2023	I1998/21	3.3.04	OD	Claims to a pharmaceutical formulation for use in the treatment of an autoimmune disorder, wherein said formulation comprises a buffer containing Adalimumab, defined by its properties to prevent aggregation and formation of acidic species of Adalimumab, and to retain its TNFalpha neutralising activity.	The OD found that the subject matter of the main request and ARs extended beyond the content of the application as filed and had revoked the patent in its entirety. The patentee had been opposed by three opponents. The patentee appealed and requested the appeal under decision be set aside and the case remitted to the OD for further prosecution. In its PO, the BoA took the same view as the OD that the claimed stable Adalimumab formulation constituted added matter. They stipulated that selection from multiple lists would be necessary to arrive at the claimed subject matter and that this wasn't unambiguously disclosed. All three of the respondents withdrew their oppositions during oral proceedings. Under RPBA A13(2), the board admitted a claim request filed during oral proceedings under the exceptional circumstances since it was submitted to address A84 objections that were raised ex officio. They found that whilst the previous claim had contravened A123(2), the amended claim overcame this, and that its basis could be found in a single list - the selection of the L-histidine citrate buffer from the list of three L-histidine buffers from claim 1 of the application as filed.	The decision under appeal was set aside and the case remitted to the OD for further prosecution.	A123(2) A113(1) A113	Medical Use	Patent revoked	Remitted to the OD for further prosecution in amended form.	Yes	Yes
14/09/2023	I0885/21	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 of the Ab of glycans to the core GcNac with endoglycosidases 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
07/11/2023	I2171/21	3.3.04	OD	Claims to Secukinumab (Ab) for use in treating ankylosing spondylitis (AS), characterised by a specific dosage regimen.	The divisional patent was opposed on the grounds of lack of inventive step and sufficiency and added subject matter. The OD rejected opposition from three opponents and maintained the patent as granted. One of the three opponents appealed the decision and requested the patent be revoked in its entirety. In its PO, the BoA disagreed with the OD. In order to arrive at the claimed subject matter it was necessary to select from multiple lists; the selection of AS from a list of four diseases, the selection of the claimed regimen from a list of nine regimens, and the selection of the 150 mg dosage from a list of two. As a result, they said they were unable to see how the claimed medical use is explicitly or implicitly, directly and unambiguously disclosed in the application as filed. The BoA reiterated its views from its PO and held that the claims amounted to added subject matter. The respondent had argued that "it was legitimate to claim only one of the conceptually individualised concepts". The Patentee argued that the way Table 5 and the introduction to it were drafted represented only shorthand for stating all the disclosed combinations individually. They argued that the disclosure, however, was the same. The BoA disagreed. They stated that a "difference exists between the conceptual disclosure of a number of possible combinations and the individualised disclosure of specific combinations". The former doesn't permit the SKP to derive "each and every individual combination directly and unambiguously".	The decision under appeal was set aside and the patent revoked.	A123(2) A76(1)	Medical Use	Patent maintained as granted.	Patent revoked	No	Yes
02/06/2023	I1478/18	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	I1435/20	3.3.04	ED	A pharmaceutical composition comprising an antibody that binds C5 in a 300mg single unit dosage form comprising 30 ml of a 10 mg/ml sterile, preservative free solution, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of residues 23 to 236 of SEQ ID NO: 4, for use in treating a patient suffering from paroxysmal nocturnal haemoglobinuria (PNH).	The ED refused the patent application on the grounds of added matter for claim 1 of the MR and ARs 2, 4 and 6 and claim 1 of ARs 3 and 5 for lacking inventive step. The patentee appealed the decision. In its PO, the BoA set out that they agreed with the OD and that the requests would likely be dismissed for added matter or sufficiency. The BoA took the same stance as it had in its PO and the appeal was dismissed. The arguments RE sufficiency and added matter were the same as for the two related decisions above. Request rejected for lack of sufficiency on the basis that the SKP wouldn't recognise the erroneous inclusion of the signal peptide. Requests rejected for added matter on the basis of a limitation to specific residues.	Appeal dismissed, patent remained revoked.	A123(2) A83 A84 A76(1)	Pharmaceutical composition claim	Application Refused	Appeal Dismissed	Same	Yes

21/09/2023	T1515/20	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 board 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
15/01/2024	T0025/23	3.3.04	OD	Claims to bevacizumab for use in a method of treating a patient diagnosed with a platinum-resistant primary peritoneal carcinoma.	The criteria established in the case law of the EPO boards of appeal for deciding on whether or not a claimed second medical use is sufficiently disclosed are that the application must credibly show that the claimed therapeutic use is achieved. In this decision, this was a particular consideration since a group of three diseases were listed in the claim. There were questions as to whether these diseases represented a "single group of diseases" and whether there was any "mismatch" between the patient group in the example and the patient group in the claim. On the first point, the board agreed with the OD and found that the skilled person would have regarded the 3 diseases defined in the claim as a single group, to be treated in the same way in terms of treatment and outcome. This view was supported by the set-up of the clinical trial reported in the example in the patent, which recruited patients with these cancer types. The board found no intention in the example to differentiate between these patients, but instead that the example implies that they were to be treated as a group. Furthermore, patients with these cancer types had been treated as a group in other clinical trials. However, their ultimate conclusion differed from that of the OD in that the board said it cannot be understood why, having concluded that no distinction was made between the 3 diseases and these were treated together as a group, it should then be necessary for the patent to provide results where these conditions are stratified separately. Rather, the board found that for a single group of diseases, the reported results are applicable to the group as a whole. On the second point, the board also did not agree with the OD that the skilled reader would consider that there was a mismatch between the inclusion and exclusion criteria in the example and the disease conditions specified in the claim. They said there is "nothing in these criteria" that would lead the skilled person to doubt that the results reported in the application are not applicable to patients diagnosed with one of the claimed diseases. The decision highlights the particular considerations for sufficiency of disclosure when individualising diseases in a claim. At the time of drafting, careful thought should be given as to whether the data provided supports all individualised diseases. One should pressure test an argument that the data does not support all individualised diseases and anticipate what the response to such an argument would be. If the argument relies on technical knowledge that might not be common general knowledge, then suitable references should be provided in the application as filed to refer to this since sufficiency of disclosure is assessed against the disclosure of the patent in combination with the common general knowledge at the relevant date.	Decision under appeal set aside and case remitted to the OD for further prosecution.	A123(2) A83 A111(1) A113(1)	Medical Use	Patent revoked	Decision under appeal set aside.	Yes	Yes
15/02/2024	T1776/21	3.3.08	ED	An anti-PD-1 antibody for use in a method of treating lung cancer in a human subject, wherein the anti-PD-1 antibody is pembrolizumab, wherein the subject is identified for treatment by assessing the number of nonsynonymous mutations in a lung cancer sample.	This decision related to a purpose-limited product claim to an anti-PD1 Ab (pembrolizumab). Again the requirement for 'direct and unambiguous' disclosure was set out. This time the decision was under A123(2) EPC (rather than priority as in T1006/21), but the same reminder applies. The claim combined three features: pembrolizumab, lung cancer and mutational characteristics. Using the terminology "no link", the Board found 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". The appellant argued that the entire application focused on determining the response to immunotherapy with the goal of identifying patients to be treated. They contended that it would be illogical to identify the specified patient subgroup (dependent on number of nonsynonymous mutations), and then not treat them. However, this argument was rejected as it related to obviousness rather than "direct and unambiguous" disclosure and the board held that there was no disclosure teaching treatment of this subgroup. Moreover, there were further objections that many of the passages disclosing pembrolizumab were not in the context of methods of treatment. Instead, they were in the context of identifying a candidate subject for treatment or predicting treatment responsiveness. Consequently, the main request and all ARs were rejected under A123(2). The decision demonstrates the difficulty in relying on the 'general disclosure of the entire application' being a 'pointer' that separate teachings could be combined. Again, careful drafting is required to ensure there is a 'link' or 'pointer' that separate teachings could be combined.	Appeal Dismissed	A123(2)	Medical Use	Patent revoked	Appeal Dismissed	Same	Yes
06/06/2024	T1809/20	3.3.02	OD	Claims to a method of purifying proteins of interest (particularly antibodies or antibody fragments) using affinity chromatography.	Board 3.3.02 considered that there were multiple selections "made at different levels of preference" and consequently there was no pointer for direct and unambiguous disclosure of a combination of features. In the claim there were multiple range features (2 x concentrations and 1 x pH). The board identified multiple (4) selections that were necessary to arrive at the subject-matter of claim 1: 1) the list of proteins of interest in the wash solution, 2) the concentration of arginine, 3) the concentration of salt, and 4) the pH. The board held that the combination amounted to added matter for the following reasons: 1) The "example" pointers that fell within the claimed ranges of arginine and salt concentrations, weren't enough to be relied on. There was no pointer that suggested the claimed ranges (which were intermediate ranges) should be selected over the most preferred ranges. 2) In relation to "preferable" pointers, the board considered that the claimed range being the broadest range didn't equate to it being the preferred range "in the context of the whole disclosure". This was despite the word "preferably" being used in the description to describe the claimed pH range. 3) In relation to the list of proteins of interest (POI) (an antibody, antibody fragment or Fc fusion protein), the board considered 2 separate passages as providing relevant disclosure. The first passage disclosed a "preferred embodiment" where the POI is an antibody, antibody fragment and other proteins that bind to the affinity matrices. The second passage disclosed a "preferred embodiment" where the POI is an antibody, antibody fragment comprising an Fc region or Fc fusion protein. Rather than viewing the list in the claim as a "shrinking" of the collective list from the 2 passages, the board viewed the claimed list as a combination of two selections: a first selection of 'antibodies and antibody fragments' from the first passage and a second selection of 'Fc fusion proteins' from the second passage.	Decision under appeal set aside and the patent revoked.	A123(2)	Method claim	Patent upheld in amended form.	Patent revoked	No	Yes
04/07/2024	T1754/22	3.3.08	OD	Claims to a process for testing a tumour sample for the presence or absence of PD-1:PD-Ligand proximity biomarker that is predictive of an anti-tumour response to treatment with a PD-1 antagonist.	This decision highlights the EPO's 2-hurdle approach to assessing the patentability of computer-implemented inventions – eligibility (A52) and inventive step (A56). PCT claim 1 was directed to a process involving: (a) obtaining an image of a tumour sample and generating a proximity score based on the presence or absence of PD-1:PD-ligand, (b) comparing the score to a threshold, and (c) classifying the tumour as biomarker positive or negative based on the score. Under A52, the examiner objected that there was no step of a technical nature in the claim since "obtaining" an image encompassed the mere act of providing an image. Amending the claim to "obtaining by imaging" overcame this. Under A56, the examiner stated that the PCT claim didn't have any additional step involving the use of the score to serve a technical purpose. Amending the claim to add a new step (d) "using the classification to predict if a subject is likely to respond to a PD-1 antagonist" satisfied this hurdle. However, the board found there was no verbatim disclosure of this step meaning the amendment added matter. They made a distinction between the claimed process and the disclosures in the application as filed which related to a composition or drug product per se. This distinction meant the SKP would not derive directly and unambiguously a process step using the classification established in step (c) to predict if a subject is likely to respond to a PD-1 antagonist.	Decision under appeal set aside and the patent revoked.	A123(2)	Method claim	Patent upheld in amended form.	Patent revoked	No	Yes