

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?
02/01/2023	<a href="#">I1624/21</a>	3.3.08	ED	Claims to Ab against human 14-3-3 eta protein defined by epitope a.a. sequence and use in treatment of arthritis.	Applying a standard of proof of "absolute certainty", the ED refused the application for lack of novelty over D6 and D7 which also disclosed anti-14-3-3-eta antibodies. The patentee appealed. In its PO, the BoA criticised the ED decision saying that the correct standard of proof is based on the "balance of probabilities" (facts that are more likely to be true than not true). In view of the positive PO, no oral proceedings were held. The BoA reversed the ED decision and the case was remitted to the ED for further prosecution.	Case remitted to ED for further prosecution	A54 A111(1)	Antibody Product by epitope	Application Refused	Remitted for further prosecution.	Yes	Yes
28/03/2023	<a href="#">I0835/21</a>	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, AB3 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	<a href="#">I0654/20</a>	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
14/09/2023	<a href="#">I0885/21</a>	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 GlcNAc 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
06/12/2023	<a href="#">I1927/22</a>	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 board's 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

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
11/05/2023	I0416/20	3.3.04	OD	Claims to a set of polypeptides that target two different cell surface antigens and form a functional dimer when they are bound to them. The polypeptides comprise a targeting moiety and a fragment of a functional domain which comprises either the VL or VH domain of an antibody (i.e. such the VL domain is in one and the VH domain is in the other). The polypeptides are further not functional when not-associated.	The OD rejected opposition from two opponents and maintained the patent as amended according to AR1. The OD also considered a set of claims of a main request, that were amended compared to the claims of the patent as granted and held that the deletion of claim 14 as granted didn't contravene Rule 80, claim 18 as amended was not open to challenge under A84, and that claim 21 constituted added matter. All parties to the opposition proceedings filed an appeal. The patentee requested the patent be maintained on the basis of the main request. The two opponents requested the patent be revoked in its entirety on the grounds that claim 1 of AR1 doesn't meet the requirements of the EPC for novelty, inventive step and sufficient disclosure. The BoA PO disagreed with the OD's decision. The OD had found the invention novel over D1 stating that it 'does not disclose the [functional] "not-associated" feature of claim 1'. However, the BoA argued that since the KD values in D1 for the VL/VH interaction fell within the range disclosed in the patent, it couldn't agree that the claimed polypeptides were distinct due to the "non-associated" functional feature. In agreement with its PO, the BoA found that the claimed polypeptides were not novel over D1.	The decision under appeal was set aside and the patent was revoked.	A54	Product claim	Patent upheld in amended form.	Patent revoked	No	Yes
21/09/2023	I1515/20	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