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?
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
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 1435/20	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 1,2,4 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. 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
24/10/2024	T 0810/22	3.3.07	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
12/12/2024	T 1815/22	3.3.04	ED	Claims to a composition comprising (a) an anti-IL-5 antibody and a variant of the antibody wherein residue N31 is deamidated and wherein the composition comprises 3% or less oxidised antibody variant at W52 of the heavy chain amino acid sequence, 50% or less oxidised antibody variant at M64 of the heavy chain amino acid sequence, and 20% or less deamidated antibody variants at N31 of the light chain amino sequence.	In a relatively straightforward decision, the Board of Appeal found the Examining Division's conclusion that claim 1 lacked clarity was erroneous. The claim was directed to a composition comprising (a) an anti-IL-5 Ab and (b) a variant of the anti-IL-5 Ab where residue N31 of the light chain is deamidated. Three further limitations on the amount of antibody variants in the composition were imposed: 3% or less oxidised variants at W52, 50% or less oxidised variants at M64, and 20% or less deamidated variants at N31. In their refusal of the application, the Examining Division stated that these final limitations were "unusual paramaters" with which to define an Ab to IL-5 which amounted to a lack of clarity. Further they objected that the method for determining these parameters wasn't included in the claim, even though it was present in the description. In view of a number of cited documents, the BoA flatly dismissed the EDs findings. Firstly, they suggested that the structurual characterisation presented in the claim was not uncommon for defining antibody compositions and distinguished it from definitions by means of a parameter with no meaning to the SKP. Secondly, they disagreed that the method should be incorporated into claim 1, taking the view it was commonly used in the field and not merely one of several alternative methods that might result in different measured values.	Case remitted to ED for further prosecution	A84	Pharmaceutical composition claim	Patent refused	Remitted to ED for further prosecution	Yes	Yes