the composition itself is disclosed in an enabling way but also that its suitability for the claimed treatment is **plausibly** disclosed in the application. In the case of a claim directed to a pharmaceutical composition comprising two classes of compounds which had both already been used in therapy in the prior art, there was a priori no reason to doubt that such a pharmaceutical composition could be produced; no specific functional effect had to be demonstrated. In the case of second-medical-use claims, if the claimed therapeutic effect was already known to the skilled person at the priority date, it was not necessary to demonstrate it in the application. According to **T 1616/09**, **T 609/02** does not apply to compositions but only to second-medical-use-claims (see also **T 1592/12**, which also states that it is not sufficient to show that the skilled person can apply the claimed dosage regime, points 16-17 of the Reasons).

7.2.4 Field of pharmaceutical combinations (drug-drug interactions)

See **T 391/18** above on the need in the field of pharmaceutical combinations to assess drug-drug interactions for each drug combination.

7.2.5 Medicament directed to a specific group of patients

T 1491/14 concerned a medicament whose novel feature was that it was directed to a specific group of patients. A lack of sufficiency was alleged on the basis, in particular, that the skilled person was not able to identify the group of patients. Contrary to the opponent's arguments, it was not necessary to measure a physical or chemical parameter to identify the patients. This view was confirmed by the expert declarations (standard practice for a physician to question the patient). The fact that there were no standard questionnaires for this purpose did not create an impasse (anamnesis). While there might sometimes be uncertainty, this amounted to a lack of clarity rather than a lack of sufficiency. As the technical features in question (definition of the patient group) were already present in the claims as granted, and the cause of uncertainty was not the amendment, this issue was not within the scope of the opposition appeal proceedings (see **G 3/14**).

7.3. Level of disclosure required for antibodies

In **T 431/96** the skilled person seeking to reproduce the invention would have had to produce monoclonal antibodies by routine methods and test them singly in an assay. Although this might possibly involve some tedious and time-consuming work, it was nothing out of the ordinary since the techniques for the production and selection of hybridomas were common routine techniques at the priority date of the patent in suit.

The board found that the essential issue to be considered in **T 601/05** of 2 December 2009 was whether or not the patent enabled the production of human monoclonal antibodies binding with high affinity to soluble TNF and, consequently, whether or not the skilled person could practise the invention over the whole scope of the claim (following **T 792/00**). On the evidence before the board it did not.

In **T 1466/05** the question arose whether the availability of a hybridoma producing one specific antibody together with a general description of the epitope recognised by this