responded to the treatment. The existence of a population of non-responders was also confirmed by the inventors' own results. In the board's view, the existence of these non-responders was not a reason to find the disclosure insufficient, and the treatment of non-responders did not have to be excluded or disclaimed; that a substantial proportion of patients were non-responders was a common phenomenon.

T 338/10 concerned a claim for a second therapeutic use in which the active ingredient was a "first allergen" and the therapeutic use the treatment or prevention of an allergy caused by a different, second allergen. The board found that there was no experimental data in the patent proving that a first allergen could be used to treat an allergy caused by a different allergen.

In **T 1777/12** claims 1 and 10 were medical use claims and related to the use of a PYY agonist in the manufacture of a medicament for treating a metabolic disorder in an obese or overweight subject. Clinical trials are not required to establish suitability. It may suffice that in vitro or in vivo data directly and unambiguously reflect the therapeutic effect on which the claimed therapeutic application relies or, alternatively, that there is an established relationship between the physiological activities of the compound under consideration and the disease in question. The board concluded that the disclosure in the patent demonstrated the suitability of PYY for achieving a beneficial effect in all of the claimed therapeutic applications by reducing weight or weight gain.

A post-published document reporting that no proven effective vaccine against HSV was available did not prove the non-workability of the invented vaccine, since there might have been other reasons, e.g. regulatory reasons, for not producing vaccines according to the invention. Furthermore, for compliance with the requirements of Art. 83 EPC 1973, it was not necessary to undertake and disclose clinical trials (**T 1023/02**).

For the acceptance of sufficient disclosure of a therapeutic application, it is not always necessary for results of clinical trials to be provided at the relevant date, but the patent/patent application must provide some information showing that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. Once this evidence is available from the patent/patent application, post-published evidence may be taken into account to support the disclosure in the patent application (**T 433/05**). In **T 1045/13** the board agreed with the statements made in **T 433/05** and **T 801/06**, but in case **T 1868/16** (suitability of everolismus for treating PNETs), no data or plausible technical concept was present in the patent.

7.2.3 Pharmaceutical compositions

In **T 1616/09** the board pointed out that, for the purposes of Art. 83 EPC, the level of disclosure in the application which is required for claims directed to pharmaceutical compositions or kits is not the same as that which is required for medical-use claims. For claims directed to pharmaceutical compositions or kits it is in principle sufficient that the application provides information which allows the skilled person to produce the composition or kit, and that there are no substantiated doubts that it could indeed be used in therapy. For second-medical-use claims, on the other hand, it is required not only that