document, allegedly supporting such an effect inter alia for bipolar disorders, likewise could not been taken into account for the assessment of sufficiency of disclosure.

In **T 1045/13**, concerning a second medical use claim worded in accordance with Art. 54(5) EPC, the board stated that the application as filed did not provide any indication of the principle underlying the relationship between the activity of the pharmaceutically active agent, i.e. the NGF, and the therapeutic effect, i.e. the alleviation of the symptoms of the psychological conditions claimed. The description did not provide any information on the mechanism of action of NGF. No background references were cited that linked NGF to the therapeutic effects to be obtained, and no in vitro assays were provided to illustrate any such effect. In the complete absence of such information, the experimental evidence on file was of decisive importance. But the evidence in the application as filed did not constitute a sufficient disclosure. Indeed the experimental evidence consisted of eleven examples relating to various conditions but did not cover all the conditions defined in claim 1; each example related to a single patient only, contrary to the common practice in order to allow statistical analysis of the results. Also, in the absence of a control group, placebo effects could not be excluded. The post-published evidence might be taken into account, but only to back up the findings in the patent application. Post-published evidence could not establish sufficiency of disclosure on its own. They did not need therefore to be discussed. For sufficiency of disclosure, it is not relevant what the respondent (patent proprietor) was aware of, but decided not to disclose.

d) Whether opponents can cite post-published documents

See, in this chapter II.C.7.3, the decision in **T 1872/16**, in which the board stated that opponents were free to use whatever evidence they chose to substantiate their serious doubts. This also applied to the date on which the evidence was generated.

e) Types of evidence of a therapeutic effect and consideration of clinical trials

In **T 2218/16** (gene therapy of motor neuron disorders – scAAV9 vector), the board summarised that, according to the established case law, the provision of evidence in the patent application for a claimed effect was not a prerequisite for patentability, if, based on the data in the patent application/patent, or on common general knowledge, it was plausible that a product (here: scAAV9) was suitable for the claimed therapeutic applications (the decision also contains a detailed summary of the case law on the burden of proof; see the full point 32 of the Reasons).

All kinds of experimental data have been accepted by the boards. It has also been repeatedly emphasised that "it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported" (**T 1273/09** citing **T 609/02**).

In **T 421/14** (dosage regime involving twice-daily treatment – multiple sclerosis), the claims related to a further medical use. All objections raised by the appellants (opponents) concerned the credibility of the alleged therapeutic efficacy. The respondent relied on the data and analysis of a clinical trial. It was known that only a proportion of patients