medical use. In order to meet the requirement of sufficiency of disclosure of Art. 83 EPC, the therapeutic efficacy of the composition and dosage regime for the claimed therapeutic indication must therefore be credible (principle reiterated in e.g. **T 421/14** (dosage regime involving twice-daily treatment – multiple sclerosis), where the claims related to a further medical use).

The decision in **T 1959/15**, in which granted claim 1 was a second medical use claim in the format of a purpose-restricted product claim pursuant to Art. 54(5) EPC, also helpfully summarises the applicable notions and reasoning (point 4.2 of the Reasons): According to Art. 54(5) EPC, patentability is not excluded for substances or compositions comprised in the state of the art for a specific use in a method referred to in Art. 53(c) EPC, provided that such use is not comprised in the state of the art. When a technical effect (which, in the case of a second medical use claim, is the therapeutic effect) is a feature of a claim, whether this effect is achieved by substantially all embodiments covered by the claim is a question of sufficiency of disclosure. Hence, because the subject-matter of second medical use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, it is usually only necessary that the patent renders it plausible that the known therapeutic agent (i.e. the product) is suitable for the claimed therapeutic application (i.e. the purpose: the technical effect).

T 1868/16 also stated that it is established jurisprudence of the boards of appeal that, for Art. 83 EPC to be complied with, unless this is already known to the skilled person at the priority date, the application must disclose the suitability for the claimed therapeutic use (see **T 609/02**, point 9 of the Reasons; **T 433/05**, point 28 of the Reasons; **T 801/06**, point 25 of the Reasons). Clinical data are not always required. Mere verbal statements are however not enough. The patent application must provide some information in the form of, for example, experimental tests to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. In vitro examples may be sufficient, if for the skilled person they directly and unambiguously reflect the therapeutic application. Post-published evidence may be taken into account, but only to back-up the findings in the application (cf. **T 609/02**, point 9 of the Reasons).

In **T 609/02** the board pointed out that where a therapeutic application is claimed in the form allowed by the Enlarged Board of Appeal in **G 5/83** (OJ 1985, 64), i.e. in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim (see **G 2/88**, OJ 1990, 93, and **G 6/88**, OJ 1990 114, for non-medical applications). As a consequence, under Art. 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application (summaries of the points established by these decisions as regards claimed therapeutic effects can be found in, for example, **T 2571/12**, point 5.2 of the Reasons; **T 1437/07**, reported below, point 37 of the Reasons; **T 421/14**, point 2.3 of the Reasons; **T 2015/20**, which contains some very detailed and instructive findings on the point; **T 395/18**, point 4.3. of the Reasons; and **T 899/14**, points 2.4 and 2.5 of the Reasons). In decisions such as **T 2181/08**, **T 338/10**, **T 1685/10**, **T 943/13** and **T 2059/13**, the boards have cited the approach taken in **T 433/05** and **T 609/02** and applied it to the specific cases before them.