7.6.1 Substantive law questions

R. 31(1)(b) EPC requires that the application as filed give such **relevant information** as is available to the applicant **on the characteristics** of the deposited biological material. Details of what is meant by "relevant information" can be found in the Guidelines (see F-III, 6 – March 2022 version).

In decision **T 418/89** (OJ 1993, 20) the characteristics of the monoclonal antibodies produced by the deposited strain were different from those mentioned in the claims. It was not possible to produce monoclonal antibodies from the deposited hybridoma using techniques recommended by the depository institution. The requirements of Art. 83 EPC 1973 were thus not met. A disclosure could not be regarded as sufficient if it was only possible to reproduce the invention after repeated requests to the depository institution and by applying techniques considerably more sophisticated than those the latter recommended. Nor could the scope of the patent be restricted to what had been deposited, as the characteristics of the deposit differed from the written disclosure in the patent. Thus a mere deposit of a hybridoma **without any corresponding written description** did not provide a sufficient disclosure. Similar conclusions were reached in decisions **T 495/89** and **T 498/94**.

R. 31(1) EPC cannot be interpreted such that there is an obligation to deposit material to facilitate the reproduction if the invention can be repeated on the basis of the written description, even if this should be a much more cumbersome way than by merely growing the deposited micro-organism (see e.g. **T 223/92**).

Similarly, in **T 412/93** the board stated that the need for a deposit cannot be introduced by reference to the concept of undue burden. This concept relates more to cases where the route that the reader is to follow is so poorly marked that success is not certain such as in **T 418/89**. If the road is certain but long and laborious, the patentee is under no obligation to assist the disclosure by making actual physical samples available. The board felt that to come to the opposite conclusion would be effectively to introduce a requirement to make the best mode immediately accessible to the public, and such a requirement is not part of the European patent system (see also **T 431/96**).

With respect to the question whether the reproducibility of specific micro-organisms (e.g. plasmids or viral strains) was assured by the written description in the absence of a deposit, the board, after careful examination of the written disclosure, held in some cases that the information provided in the application was sufficient to lead the skilled person reliably to the same micro-organisms (**T 283/86**, **T 181/87**); in other cases it was not (**T 815/90** of 20 October 1997, **T 816/90**; see **T 2542/12**, commercial fish farms in Norway – not a reliable source; also **T 1338/12**, scientific publications).

The board in **T 32/17** decided (catchword) that the deposit of a hybridoma under R. 31 EPC for compliance with the disclosure requirement of Art. 83 EPC did not in itself convey any technical information about the molecular structure of the monoclonal antibody produced by that hybridoma, such as its amino acid sequence.