

As part of the 2000 EPC revision, for greater clarity and consistency, R. 27a, 28 and 28a EPC 1973 were restructured, trimmed and incorporated (as R. 30 to 34 EPC) into the chapter on biotechnological inventions (see OJ SE 1/2003, 164, OJ SE 5/2007, 44, and 54). New R. 31 EPC deals with the deposit of biological material, new R. 32 EPC with the expert solution to availability and new R. 33 EPC with the availability of the deposited biological material as from the date of application of the European patent application (OJ SE 5/2007, 46; see also OJ 2017, A55 (CA/D 3/17), OJ 2017, A60 and A61 (notice)). The term "micro-organism" was replaced by "biological material" in 1996 (see OJ 1996, 390) – see R. 26(3) EPC for the definition of "biological material".

In T 1045/16 the board recalled that together with Art. 83 EPC, special provision is made in R. 31 EPC for inventions which involve the use of or concern biological material which is not available to the public and which cannot be described in the European patent application. In the case at hand, it was not in dispute that there was no deposit of such material with a recognised depositary institution as set out in R. 31(1)(a) EPC. The board explained that a deposit according to the Budapest Treaty was necessary under R. 31(1)(a) EPC only in cases where the relevant biological material was not available to the public. It had to be determined whether or not the relevant biological material in question had been made available to the public. According to G 2/93, R. 28(1) EPC 1973 (R. 31(1) EPC 2000) refers to Art. 83 EPC and serves to substantiate and to supplement the general requirements of that Article for a specific group of inventions for which a mere written description is not sufficient. Therefore, the board found that the provisions of R. 28(1) EPC 1973 were **subordinate to the requirements of Art. 83 EPC**. The requirements of Art. 83 EPC are **not time limited**. Thus, to be considered "available to the public" in the sense of R. 31(1) EPC, a biological material must be available in a manner that allows the skilled person to be certain that they can obtain it at least over the term of the patent. Deposit with a **non-Budapest Treaty institution** cannot ensure availability to the public. In the case at hand, the availability of plants of the accession PI313970 from the US National Plant Germplasm System was not sufficient. Further, the mention of the biological material in a scientific publication did not per se establish that said material was available to the public in the sense of R. 31(1) EPC. The claimed invention did not meet the requirements of Art. 83 EPC.

In T 1338/12 the board held, contrary to the examining division, that the application at issue was subject to the EPC 1973, specifically R. 28 EPC 1973 on depositing biological material. The board referred to the boards' established case law (see T 2068/11). What had to be established in the case in hand was whether the requirement in R. 28(3) EPC 1973 (corresponding to R. 33(1) EPC) had in fact been met, i.e. whether the *T. thermophilus* strain, variant GY1211, in question had been unreservedly and unrestrictedly available to the skilled person or the public on the relevant date. The board considered that the mere fact that this strain had been disclosed in two **scientific publications** was not enough by itself to meet that requirement. While the editors of a scientific journal could require that the authors of an article make the biological material publicly available, they could not be sure that they had always done so. Any request for a sample of the biological material had to be addressed directly to the authors themselves, so it was always left ultimately to their discretion whether to issue it.