2.1.2 Scope of exception under Rule 28(d) EPC

R. 28(d) EPC (R. 23d(d) EPC 1973) provides that European patents should not be granted in respect of processes for modifying the genetic identity of animals which were likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

One of the most important cases dealing with interpretation not only of R. 23d EPC 1973, but also of Art. 53(a) EPC, concerned a patent relating to **transgenic animals having an increased probability of developing cancer**. The application resulted in two groundbreaking board decisions: **T 19/90** (OJ 1990, 476, see below), in which the matter was remitted to the department of first instance, and **T 315/03** (OJ 2006, 15), in which a patent was granted on the basis of new claims.

Having addressed the relationship between R. 23d EPC 1973 (R. 28 EPC) and Art. 53(a) EPC (see also in this chapter I.B.2.), the board in **T 315/03** turned to the test under R. 23d(d) EPC 1973 (R. 28(d) EPC). This test required **only** three matters to be considered: animal suffering, medical benefit and the necessary correspondence between the two in terms of the animals in question. The board observed that the test was to be applied to ensure that a patent extended only to those animals whose suffering was balanced by a medical benefit. The level of proof was the same for both animal suffering and substantial medical benefit, namely likelihood (see also **T 1262/04** of 13 July 2012).

In **T 1553/15** the board held that contrary to the transgenic mouse of **T 19/90**, which opened up new research avenues in the field of oncology at the cost of the suffering of a limited number of animals, the board considered that the benefit to mankind brought by the present invention was not such as to weigh up against the suffering of animals which was necessary to produce the claimed pharmaceutical composition. The new pharmaceutical composition did not open up new avenues in the treatment of the claimed diseases, and animal suffering was not limited to a given number of animals needed for testing but rather was always present and involved a considerable number of animals every time the composition was produced. There were also alternatives to the claimed pharmaceutical composition available.

2.1.3 Test date

In **T 315/03**, the board observed that the relevant date for applying the test under R. 23d EPC 1973 (R. 28 EPC) was, as for all patentability criteria, the date of filing or priority. Nevertheless, evidence becoming available later could be taken into account, provided it related to the situation on that date.

In **G 2/06**, the Enlarged Board arrived at the same basic result. When assessing whether a claim contravenes R. 28(c) EPC, technical developments which became publicly available only after the filing date cannot be taken into consideration. Any other conclusion would lead to legal uncertainty, and risk being to the detriment of any third party who later provided an innocuous way to carry out the invention. The Enlarged Board thus concluded in the case before it that it is irrelevant that, after the filing date, the same products could