In **T 391/18** Claim 1 of the main request was directed to a combination of active ingredients (TMC278 and a NRTI (nucleoside or nucleotide reverse transcriptase inhibitor)) for treating HIV infection in a regime of once-daily administration. The patent did not contain any evidence on combinations of TMC278 with NRTIs. The **initial plausibility** – in view of the common general knowledge – could **not be equated with** meeting the requirement of Art. 83 EPC, but nevertheless allowed the board to consider post-published evidence. Post-published document D26 (report with clinical trials for authorisation) was then considered but appeared insufficient to make credible that every possible combination of TMC278 with NRTIs that were therapeutically effective by once-daily administration would be suitable for treating HIV in a once-daily dosage regime. To find suitable combinations and their corresponding doses among all the possibilities covered by claim 1, carrying out an undue amount of research was needed. In the **field of pharmaceutical combinations**, **drug-drug interactions** need to be assessed for each drug combination to find whether and at which dose the combination is therapeutically effective. Such an assessment involves clinical studies which cannot be considered routine tests. Even if, as argued by the respondent (patent proprietor), the number of NRTIs suitable for once-daily administration were not particularly high, the research required would go far beyond what may be seen as routine testing. Therefore, there existed serious doubts substantiated by verifiable facts. But claim 1 of auxiliary request 24, limited to encompass the combination tested in D26 met Art. 83 EPC.

In ex parte case **T 2015/20** the examining division found that it was not plausible that aclidinium bromide was suitable for treatment of asthma. The application only presented experimental results concerning treatment of COPD (chronic obstructive pulmonary disease), whereas it was part of the common knowledge, as presented by D5, that COPD and asthma were distinct diseases with different mechanisms involved. The board observed that the information in D5 did not cast doubt on the statement in the application about the effectiveness of treatment. Concerning the post-published document D6, it merely warned that the use of "Duakllir Genuair" in asthma had not been officially authorised, which was per se not a ground for any serious doubts regarding the claimed utility of aclidinium in the treatment of asthma. In conclusion, no serious doubts could support the objection of lack of sufficient disclosure. Neither **T 609/02** nor the later jurisprudence signalled a deviation from the established jurisprudence, in particular with respect to the precondition of serious doubts for a convincing argument of lack of sufficiency. The board took the view that in the present case the defined utility of aclidinium in treatment of asthma did not go against any prevailing opinion in the prior art. In this context the board considered the statement in the application, that the treatment of respiratory disorders, particularly asthma and COPD, with aclidinium was most effective upon administration by inhalation in a dosage of about 400 µg metered nominal dose to represent a significant technical teaching, which was far from an invitation to perform a research programme and which did not prima facie lack plausibility. This teaching was as such **falsifiable**, in the sense that it was open to challenge, and was therefore considered to represent information in the form of a specific technical contribution which went beyond some insufficient verbal statement. The board held that sufficiency was therefore not to be denied following its assessment that no serious doubts had come about with respect to the defined utility. The board turned to the examination of inventive step itself, considering in this respect also the question of plausibility.