

Author:

Pamela Lönnqvist

PhD Student at the University of Helsinki, Faculty of Law

E-mail: pamela.lonnqvist@helsinki.fi

Title:

Fairness, Patents and Plausibility

Abstract:

Plausibility has recently become increasingly prominent in European patent law. The emergence of plausibility as an additional test in the assessment of sufficiency of disclosure, inventive step and industrial applicability of life science inventions, represents a significant legal development in European patent law. Critics argue that the concept of plausibility lacks legal basis and is incompatible with the European Patent Convention and the TRIPS Agreement. However, plausibility is not a separate invalidation ground, but a threshold test used as a gatekeeper against (a) unduly broad claims and (b) speculative claims, where the claimed technical contribution is based upon mere assumptions. It is particularly relevant for second medical use claims requiring plausible experimental support for the claimed therapeutic effect, and broad claims to classes of chemical compounds and so-called reach-through claims.

The concept of plausibility goes to the very heart of the patent law. It is a basic underlying principle of patent law that the scope of the exclusive right must be fair and proportionate in relation to the contribution made to the state of the art. Following the patent bargain theory, exclusive rights can only be granted in exchange for a full disclosure of the invention to the public.

This paper addresses recent European developments concerning the interpretation and application of the “plausibility test” vis-à-vis life science inventions in the assessment of sufficiency of disclosure, inventive step and industrial applicability. Scrutinizing the European regulatory framework, and case law from the EPO and national courts, this paper elaborates on which qualities an invention should have, what kind of evidence must be included in application as filed and to what extent post-published evidence can be used to meet the plausibility threshold.