Registry of the Enlarged Board of Appeal  
European Patent Office  
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Attn.: Mr. Wiek Crasborn

Brussels, 25 September 2019

EFPIA Amicus Curiae Brief for European Patent Office Enlarged Board of Appeal Referral G 1-19  
(patentability of computer simulations)

Dear Chairman and Members of the Enlarged Board of Appeal,

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 39 leading pharmaceutical companies, EFPIA’s mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Our vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

In decision T489/14, the Board of Appeal has referred three questions to the Enlarged Board of Appeal relating to the patentability of inventions involving computer-implemented simulation. The referral mainly stems from the Board of Appeal’s disagreement with the reasoning applied in T1227/05. According to T1227/05, the computer-implemented simulation of an adequately defined class of
technical items, such as an electronic circuit subject to 1/f noise, serves a technical purpose and constitutes in itself a technical effect.

The current practice of the EPO, and the case law of the EPO’s Boards of Appeal, follow the principles of T1227/05 (cf. Guidelines for Examination in the EPO G-II 3.3.2 and decisions cited therein).

In the decision underlying the present referral, the Board of Appeal deviates from this principle and considers that the presence of a technical effect requires at least a direct link to physical reality, such as a change in or a measurement of a physical entity. As such direct links are absent from computer-implemented simulations of technical systems or processes claimed “as such”, the board holds that they do not solve a technical problem going beyond the computer-implementation.

The pharmaceutical industry, among other industries, needs ongoing consistency in Europe regarding the patentability of inventions involving computer-implemented technology in general, and computer-implemented simulations specifically. Development of new medicines today frequently relies on computer-implemented modelling and simulation of physical systems, such as biological systems, molecules, and their interactions. Examples include model-based drug development, physiologically-based pharmacokinetic modelling and simulation or molecular dynamics simulations. Modelling and simulation are also frequently used when developing improved production methods or when developing medical devices delivering drugs. Many of such inventions make use of machine learning (ML) and artificial intelligence technologies (AI), being tightly related to computer-implemented inventions. Hence, EFPIA is concerned that a potential inconsistency in the application of law could affect other areas of computer-implemented inventions and create hurdles for the progress of those technologies, in particular, as it applies to drug research and development.

EFPIA therefore supports the approach set out in T1227/05 and the significant body of case law which has subsequently followed this approach, and which focused on the technical purpose of a claimed computer simulation to determine whether it had technical character.

Based on this and as explained below in more detail, EFPIA respectfully submits that the three questions referred to the Enlarged Board should be answered as follows:

Question (1) – “In the assessment of inventive step, can the computer-implemented simulation of a technical system or process solve a technical problem by producing a technical effect which goes
beyond the simulation’s implementation on a computer, if the computer-implemented simulation is claimed as such? “

In T489/14, the Board of Appeal intends to deviate from the well-established practice set out in T1227/05 namely for two reasons:

"First, although a computer-implemented simulation of a circuit or environment is a tool that can perform a function "typical of modern engineering work", it assists the engineer only in the cognitive process of verifying the design of the circuit or environment, i.e. of studying the behaviour of the virtual circuit or environment designed. The circuit or environment, when realised, may be a technical object, but the cognitive process of theoretically verifying its design appears to be fundamentally non-technical.

Second, the decision appears to rely on the greater speed of the computer-implemented method as an argument for finding technicality. But any algorithmically specified procedure that can be carried out mentally can be carried out more quickly if implemented on a computer, and it is not the case that the implementation of a non-technical method on a computer necessarily results in a process providing a technical contribution going beyond its computer implementation."

Regarding the first statement, namely that “the cognitive process of theoretically verifying its design appears to be fundamentally non-technical", T1227/05 states on this issue (reasons 3.2.1) that: "while the invention may be preceded by a mental or mathematical act, the claimed result must not be equated with this act. The present claims relate to a simulation method that cannot be performed by purely mental or mathematical means, not to the thought process that led to that simulation method.” We agree with this point of view, and it follows that a computer-implemented simulation method is not a purely mental act (or “cognitive process” as argued in T489/14).

Regarding the second statement from T489/14 quoted above, according to which T1227/05 relies on "the greater speed of the computer-implemented method as an argument for finding technicality), we believe that this is a misinterpretation of T1227/05. A technical purpose is attributed to the simulation method of T1227/05 on the basis that an "adequately defined class of technical items" is simulated including "a circuit with input channels, noise input channels and output channels whose performance is described by differential equations" (cf. reasons 3.1.1).
T1227/05 even explicitly states under reason 3.2.5 that "a mere speed comparison is not a suitable criterion for distinguishing between technical and non-technical procedural steps".

For these reasons, we think the doubts expressed in T489/14 regarding T1227/05 are not supported by the detailed reasoning provided in T1227/05.

We would also like to comment on the proposed reintroduction of the requirement of a "direct link with physical reality" (cf. reasons 11 and 23 of T489/14). The application of such a criterion is in contradiction with the current EPO practice, with the case law of the Boards of Appeal and also with opinion G03/08, where the Enlarged Board of Appeal had confirmed the “any technical means” approach established by T258/03 (cf. headnote 1).

EFPIA is concerned that the application of such a requirement could de facto lead to an exclusion from patentability of many inventions related to digital technologies beyond computer-implemented simulations and is therefore opposed to the reintroduction of such a requirement.

Based on the foregoing, question 1 should be answered as “Yes, a computer-implemented simulation of a technical system or process can solve a technical problem by producing a technical effect which goes beyond the simulation’s implementation on a computer, if the computer-implemented simulation is claimed as such”.

Question (2) – “If the answer to the first question is yes, what are the relevant criteria for assessing whether a computer-implemented simulation claimed as such solves a technical problem? In particular, is it a sufficient condition that the simulation is based, at least in part, on technical principles underlying the simulated system or process?”

Regarding the 1st part of this question, the relevant criteria for assessing whether a claim to a computer-implemented simulation solves a technical problem should be the same as for any computer-implemented method. Any additional guidance from the Enlarged Board of Appeal on these criteria for computer-implemented methods in general, and computer-implemented simulations in particular, would be highly appreciated.
Regarding the second part of the question, based on the foregoing and in line with T1227/05, this should be answered “Yes, it is a sufficient condition that the simulation is based, at least in part, on technical principles underlying the simulated system or process”.

**Question (3) – “What are the answers to the first and second questions if the computer-implemented simulation is claimed as part of a design process, in particular for verifying a design?”**

Question 3 should be answered as “The answers to the first and second questions are yes, even if the computer-implemented simulation is claimed as part of a design process, in particular for verifying a design”. We cannot see any justifiable reason why a patentable simulation process that solves a technical problem could or should no longer be patentable when such is claimed in the context of a verification of a design.

Yours faithfully,

Kristine Peers
General Counsel