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The plausibility battleground at the EPO

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Plausibility in the context of the inventive step and sufficiency requirements can be a contentious issue before the European Patent Office. Markus Grammel of Grünecker reports.

The European Patent Office (EPO), as the central organ of the European patent system, rewards inventors or their legal successors for their technical contribution to art with patent monopolies, fostering and stimulating innovation.

It is therefore a central pillar of the EPO's practice to weed out purely speculative patents that do not make a technical contribution at the filing date.

To assess whether an invention is purely speculative, the Boards of Appeal of the EPO have developed the doctrine of "plausibility" in the context of sufficiency of disclosure/enablement as well as inventive step/non-obviousness. Plausibility is also sometimes applied when considering industrial applicability.

Under this doctrine, the EPO examines whether a technical effect that is relevant for sufficiency or inventive step is "plausibly demonstrated" in the application documents as filed.

Given the nature of the pharmaceutical and biotech industry, and academic research in this area—often requiring very early patent filings with no, little or deficient data—we often see plausibility as a contentious issue in these technical areas, in particular in relation to asserted therapeutic effects that are associated with the claimed invention.

Whether the question of plausibility arises under sufficiency of disclosure or inventive step depends on the nature of the patent claim. In general, if the technical effect in question is a feature of the claim, plausibility is dealt with under sufficiency. If the technical effect is not a feature of the claim, plausibility might be an issue under inventive step.

To provide an example, medical use claims (compound X for use in treating disease Y) which recite the therapeutic effect as a feature of the claim, require a plausible demonstration of the therapeutic effect in the application for a sufficient/enabling disclosure.

For product claims on the other hand, such as a claim directed to a chemical compound as such (compound X), which does not recite the therapeutic effect in the claim, plausibility is typically assessed in the context of inventive step.

‘Tightening the screws’ on patentees

The Boards of Appeal in principle have held that “experimental data or results in the application as filed and/or post-published evidence is not always required” for a plausible disclosure (*T578/06* [*Pancreatic cells/Ipsen Pharma*]).

But it turns out that, more often than not, the boards and the EPO’s Examining Divisions and Opposition Divisions see a need for “at least some technical evidence” to demonstrate that a technical effect is plausibly achieved (*T488/16 [Dasatinib/Bristol-Myers Squibb*]).

In particular, the latter decision was generally perceived as tightening the screws on patentees and applicants. This is because the board arrived at the conclusion that a therapeutic effect had not been plausibly demonstrated, despite the fact that the patent in question stated that the described compounds “have been tested in one or more of these assays and have shown activity”.

The board did not admit and hence did not take into account submitted post-published data demonstrating a therapeutic effect for dasatinib—the claimed compound—because of an original lack of plausibility, due to lack of original “verifiable data”.

Leeway and speculation

However, more recent developments at the Boards of Appeal seem to provide applicants again with more leeway for early filings, even with little or no data, if absolutely necessary.

In decision *T184/16*, the board acknowledged plausibility of the recited therapeutic effect despite the absence of any experimental data. The claims essentially related to small molecules for use in the treatment of diabetes-related diseases.

This decision is highly interesting for multiple reasons. First, it establishes that plausibility can be based on a document of the prior art. The question remains, however, whether the application has to cite the document for being taken into account.

In *T184/16*, the relevant prior art document was cited in the patent. Yet, in a general statement the board held that plausibility can be acknowledged "in view of the common general knowledge and the prior art", which suggests that even prior art that is not cited in the application could be used for establishing plausibility.

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Second, while in *T184/16* the therapeutic effect was corroborated by a document of the prior art, the board clearly stated, "it is enough [for plausibility to be acknowledged] if there are no prima facie serious doubts that the effect can be obtained and conversely no a priori reason and indication in the common general knowledge that the effect cannot be obtained", which would be a very low bar for applicants and patentees to demonstrate plausibility.

By this standard, the absence of evidence to the contrary would seem to be already sufficient for plausibility.

Third, decision *T184/16* is particularly relevant because it clarifies that the concepts of plausibility and obviousness are different. In contrast to plausibility, a case of obviousness requires that the claimed solution is suggested in the prior art, ie, that there is a pointer to the claimed subject matter.

In particular, the board held that the prior art that taught compounds of the same core structure made the therapeutic effect plausible, but the prior art did not suggest introducing the required substituent modifications, so as to arrive at the claimed compounds.

This clarification is highly important for patentees and applicants, since often they find themselves in a squeeze between arguing plausibility on the one hand and non-obviousness on the other.

In the end, even with this new case law, it still holds true that pure speculation with regard to a relevant technical effect, eg, therapeutic effect, is not enough. The gold standard for pharmaceutical applications is still to include solid experimental data—in vitro or in vivo—in the original application.

However, to paraphrase the board in decision *T898/05*, sometimes an "educated guess" concerning the relevant technical effect may be enough, in particular if it is based on a verifiable conclusive theoretical concept, mechanistic considerations, evidence in the prior art or the common general knowledge.

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