

## Swiss Federal Supreme Court confirms validity of Bristol-Myers Squibb's SPC for apixaban

**Bristol-Myers Squibb successfully defended the Swiss SPC for the pharmaceutical active ingredient apixaban, used in the blockbuster anticoagulant Eliquis. The Federal Patent Court's decision upholding the SPC was confirmed by the Swiss Federal Supreme Court.**

On 26 September 2024, the Swiss Federal Supreme Court dismissed Mepha's appeal against the first-instance decision of the Swiss Federal Patent Court of 5 March 2024. Both courts confirmed the validity of the Swiss SPC C01427415/01 for the anticoagulant apixaban (see the judgment of the Swiss Federal Patent Court [here](#) and of the Swiss Federal Supreme Court [here](#) (German versions only)).

Mepha had filed a nullity action against the Swiss SPC for apixaban, challenging the validity of the Swiss part of the basic patent EP 1 427 415. The key issues were the technical effect of the invention for the assessment of inventive step and the alleged lack of validity of the priority claim.

The first-instance judgment of the Federal Patent Court, delivered by an extended panel of five judges (three of them with a scientific background), is a landmark decision as it is the first case in Switzerland to examine (i) the reliance on a purported technical effect for inventive step and (ii) priority since the decisions of the Enlarged

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Board of Appeal of the EPO in G 2/21 ("plausibility") and G1/22 and G2/22 ("entitlement to priority") were published.

Decisions of the EPO's Boards of Appeal are considered persuasive authority in Switzerland, but they are not binding on the Swiss courts.

The Federal Patent Court considered the two decisions of the Enlarged Board of Appeal and discussed them in detail in the apixaban case.

Regarding the *priority claim*, the Federal Patent Court affirmed an implied transfer of the right to claim the priority of the priority application on the basis of the evidence submitted by the parties. In particular, the Federal Patent Court took into account the vital interest of BMS Pharma and the subsequent applicant BMS Company – which both belong to the same group of companies – that the subsequent application could claim the priority of the first application US 60/324,165, as well as the fact that BMS Pharma had provided



BMS Company with the priority documents and the details of the priority declaration in the knowledge that BMS Company would need them to claim priority.

The Federal Supreme Court confirmed the assessment of the priority by the Federal Patent Court. The Supreme Court explicitly left open whether third parties who do not have allegedly better priority rights may challenge that the patent proprietor is not entitled to claim priority, or whether such challenges are reserved for parties who can claim better rights to the priority for themselves. In the consolidated cases G 1/22 / G 2/22, the Enlarged Board of Appeal of the EPO concluded that, in principle, anyone could challenge the entitlement to priority before the EPO, but that this may be different in the EPO member states (see point 117 of G 1/22 / G 2/22).

Regarding the reliance on a purported *technical effect* of the invention, the Federal Patent Court interpreted the decision G 2/21 as follows: Two criteria must be fulfilled for a technical effect to be taken into account in the assessment of inventive step: The technical effect must be (i) encompassed by the technical teaching and (ii) embodied by the originally disclosed technical teaching. The first criterion is met if the alleged technical effect, together with the claimed subject-matter, is conceptually covered by the broadest technical teaching of the application as filed. There is no need that the technical effect must be expressly disclosed in the original application. It is sufficient if the skilled person recognises, based on the common knowledge and the original application, that the technical effect is relevant to the claimed subject-matter.

According to the apixaban ruling of the Swiss Federal Patent Court, the second criterion is fulfilled if the technical effect is derivable for the skilled person from the original application, considering the general technical knowledge at the filing date. Experimental data or an explicit statement on the technical effect in the original application are not necessary. Since the purpose of this criterion is merely to prevent abusive speculative applications, the threshold for the patentee must not be set too high according to the Swiss Federal Patent Court, as otherwise inventions worthy of reward would not receive protection. In the light of the above, post-published data supporting the technical effect were taken into consideration and the Federal Patent Court acknowledged the presence of inventive step. In summary, the Federal Patent Court confirmed the validity of the basic patent and the Swiss SPC for apixaban.

The Federal Supreme Court did not have to deal with the alleged lack of the technical effect of the invention since Mepha's appeal was solely based on priority arguments.

As described above, the Federal Supreme Court dismissed Mepha's appeal, and the landmark decision of the Federal Patent Court has become final and binding. The Swiss SPC for apixaban was upheld.