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Switzerland: Trends & Developments

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Trends and Developments

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MLL Legal is a leading Swiss patent law firm. MLL Legal brings talent, expertise and solution-oriented teamwork to all IP matters. The IP team members are among the leaders in the field and have extensive experience in Swiss, EU and German law. The firm is highly recommended for patent and other IP disputes and transactions in Switzerland. MLL Legal is ranked by Chambers and Partners in Chambers Global, Europe, High Net Worth and FinTech, all as a leading firm.

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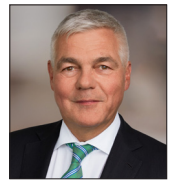

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Recent Cases in Swiss Patent Litigation

According to the statistics of the cases handled by the Swiss Federal Patent Court, 2023 was not a successful year for patent owners in Swiss patent litigation proceedings. The year 2024 was much more favourable for patentees. Particularly noticeable are the cases in which the Swiss Federal Patent Court upheld patent protection for sorafenib tosylate contained in Bayer's NEXAVAR® and for apixaban in BMS' ELIQUIS®. These patents have been the subject of litigation in many European jurisdictions, and not all national courts have reached the same conclusions.

Furthermore, the Federal Patent Court has issued some important case law on procedural matters in the past year. Especially in PI proceedings, some changes in practice have occurred, as the court intends to conduct the proceedings in a stricter, quicker and more efficient manner. Good preparation, which has always been essential for the front-loaded patent litigation system in Switzerland, will become even more important.

Below, the authors discuss in more detail four selected judgments that they believe are the highlights of Swiss patent litigation from 2024. For the sake of transparency, the authors would like to point out that MLL Legal has been involved and represented the patentees in these proceedings.

New practice in Swiss PI proceedings (S2024_008, court order of 29 October 2024)

Previously, inter partes PI proceedings in Switzerland were mini-trials in which the defendant could defend against infringement claims with arguments of non-infringement and the plea of invalidity of the asserted patent. Conversely, the plaintiff could defend the patent in a limited form with one or more auxiliary requests when filing the complaint or responding to the answer to the complaint.

This has changed. In October 2024, the Federal Patent Court changed its practice and since then the patent in suit can only be asserted in one single version in PI proceedings.

In PI proceedings S2024_008, the Federal Patent Court requested the plaintiff – contrary to the court's previous practice – to assert the patent, ie, the basic patent of the SPC in suit, in only one version after filing the complaint.

In order to prevent such a procedural restriction, the plaintiff argued that a defence including one

or more auxiliary requests is a legitimate means against a nullity plea. The principles of procedural fairness and the right to be heard require that parties in civil proceedings may submit arguments and requests (including auxiliary requests) and that the courts duly consider, examine and take them into account in their decision. However, according to the Federal Patent Court, it is neither unfair nor contrary to the right to be heard to require a plaintiff in PI proceedings to indicate in which (single) version it intends to assert the patent in suit.

The plaintiff also argued that if the proceedings had to be procedurally limited, the defendant should be ordered to present only those validity and prior art arguments that had not already been considered in opposition and appeal proceedings before the European Patent Office against the basic patent. However, according to the Federal Patent Court, this binding effect of decisions of the EPO Board of Appeal is unknown under Swiss law. The plaintiff's procedural motions were therefore rejected.

Patent owners should adapt to this new practice of the Federal Patent Court and adjust their strategy before initiating PI proceedings accordingly.

Unexpected final rejection of ex parte PI request due to protective letter (S2024_003, judgment of 10 July 2024)

A case that has gained significant attention internationally beyond the borders of Switzerland is the judgment of the Federal Patent Court in the case S2024_003 of 10 July 2024 concerning Bayer's blockbuster product XARELTO® containing the active ingredient rivaroxaban.

After the SPC for rivaroxaban having expired in Switzerland in June 2024, the first generic companies entered the market with their generic products, despite Bayer's Swiss part of EP 1 845 961 B1 (EP 961) titled "Therapy of thromboembolic disorders with Rivaroxaban", which is valid until 19 January 2026. EP 961 specifically protects the once-daily administration of rivaroxaban for the treatment of thromboembolic diseases.

The validity of EP 961 was confirmed in opposition-appeal proceedings before the EPO by the Board of Appeal and is currently the subject of numerous infringement and nullity proceedings before national courts. The results in the national proceedings are mixed and mostly not final. For example, EP 961 was considered invalid by courts in the UK, France, and South Africa, while its validity was confirmed in the Netherlands, Belgium, and according to the preliminary opinion of the German Federal Patent Court.

Since the validity of EP 961 had been confirmed by the EPO Board of Appeal, Bayer filed an ex parte PI request before the Swiss Federal Patent Court in June 2024 based on the Swiss part of the once-daily dosage patent EP 961. Previously, the defendant had filed a protective letter with the Swiss Federal Patent Court. As the judgment shows, the Federal Patent Court considered the protective letter and concluded, without the plaintiff being able to comment on the allegations made in the protective letter, that EP 961 was likely not valid due to alleged lack of inventive step. Bayer's request for an ex parte PI was thus rejected.

According to the previous practice of the Federal Patent Court, a decision on an ex parte PI request was normally issued within 1–2 days. If an ex parte request was dismissed, inter partes PI proceedings usually followed, in which both

parties could comment within the short deadlines appropriate for PI proceedings.

In the present case, the Federal Patent Court dismissed Bayer's ex parte PI request after having involved two technical judges and after a period of 14 days. No inter partes PI proceedings were conducted in this case.

It remains to be seen whether this new practice of the Federal Patent Court will prevail in Switzerland. Bayer's appeal is currently pending before the Federal Supreme Court (second and highest instance court in Switzerland). The authors will likely be able to provide an update on this matter next year. Apart from that, there are also nullity proceedings concerning EP 916 currently pending before the Federal Patent Court. The judgment of the Federal Patent Court in those proceedings is expected in Q1 2025.

Confirmation of validity of the SPC for apixaban (O2022_007, judgment of 5 March 2024)

Another case that attracted particular attention in Switzerland and beyond concerns the Swiss SPC for apixaban owned by Bristol-Myers Squibb (BMS). This is another case that was or still is litigated in several parallel national proceedings, either in PI proceedings or nullity proceedings, with mixed results on both the questions of priority and inventive step.

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. As a result, the Swiss Federal Patent Court and the Federal Supreme Court confirm the validity of the Swiss SPC for apixaban. No further appeal is possible.

In Switzerland, 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 (EP 415). The main issues were the alleged lack of validity of the priority claim and the technical effect of the invention for the assessment of inventive step (previously called "plausibility").

The first-instance judgment of the Swiss Federal Patent Court, issued 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 the reliance on a purported technical effect for inventive step and an allegedly invalid priority since the decisions of the Enlarged 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 its judgment on BMS' basic patent for the Swiss SPC for apixaban.

Regarding the priority claim, Mepha argued that BMS cannot rely on the priority document US 165 because, at the date of filing of the EP 415 application, the applicant (BMS Company, the predecessor of BMS) was not the holder of priority document US 60/324,165 (US 165). In 2001, group companies of Bristol-Myers Squibb Company ("BMS Company") acquired DuPont Pharma, which was later renamed "BMS Pharma". The inventors transferred their rights to the provisional US patent application to BMS Pharma. In 2002, BMS Company submitted an international patent application for the same

invention, claiming priority based on the original provisional US patent application. The transfer of US 165 from the holder of the priority document to the applicant of EP 415 did not take place until several years after the filing of the EP 415 application.

The Federal Patent Court confirmed 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 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 meanwhile confirmed the assessment of the Federal Patent Court. The Supreme Court explicitly left open the question of whether third parties who do not have allegedly better priority rights may even challenge that the patent proprietor is not validly entitled to claim priority, or whether this is reserved for parties who can claim better rights to the priority for themselves. In the consolidated cases G 1/22 and 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 proceedings in the EPO member states.

Regarding the 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:

- encompassed by the technical teaching; and
- 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 for the technical effect to be be expressly disclosed in the original application. It is sufficient if the skilled person recognises, based on common general knowledge and the original application, that the technical effect is necessarily relevant to the claimed subject-matter.

The second criterion is fulfilled if the technical effect is derivable for the skilled person from the original application, taking into account 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 to prevent abusive speculative applications, the hurdle 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 an inventive step.

Therefore, the validity of the Swiss SPC for apixaban was finally confirmed by the Federal Patent Court.

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 argumentation against the entitlement to priority. The Federal Supreme Court dismissed Mepha's appeal, and the landmark decision of the Federal Patent Court has become final and binding.

Confirmation of validity of the patent protecting sorafenib tosylate (O2022_006, judgment of 15 April 2024)

In this case, Bayer asserted the infringement of claim 12 of the Swiss part of EP 2 305 255 B1 (EP255). Claim 12 is directed at an aryl urea compound, which is a tosylate salt of sorafenib.

Sorafenib is a protein kinase inhibitor. Protein kinase inhibitors block certain enzymes known as protein kinases. These enzymes are located in certain receptors on the surface of cancer cells, where they are involved in the growth and spread of the cancer cells, as well as in the blood vessels that supply the tumors with blood. Sorafenib blocks these enzymes, including Raf kinase, thereby reducing the growth of cancer cells and cutting off their blood supply. Sorafenib tosylate is the active ingredient in Bayer's product NEXAVAR®.

The case of sorafenib tosylate also has an international context. Again, there were mixed results in parallel proceedings before national courts, in particular in the assessment of inventive step. For example, the patent was revoked at first instance in Germany and then upheld by the German Federal Supreme Court with amended claims. The nullity proceedings in the UK led to the revocation of the patent.

The defendant argued that EP 255 was invalid. Similar to the apixaban case discussed above, the main issues in this case were the validity of the priority claim and inventive step.

The plaintiff, the registered proprietor of EP 255, claimed priority from US 334609P. The defendant argued that the transfer of the priority right to Bayer Corporation was not proven, citing three points:

- not all inventors/applicants of the US priority were shown to be employed by Bayer Corporation;
- employment contracts were not identical; and
- contracts did not prove the transfer of the priority right.

The plaintiff stated that all 18 inventors/applicants were Bayer Corporation employees at the time of the priority application, supported by a declaration and signed copies of the "Bayer Corporation Agreements" for eight inventors/applicants. The plaintiff also showed that the employment contracts included clauses for an advance transfer of rights under US law and invoked the "hired-to-invent" doctrine.

The Federal Patent Court found that the inventors/applicants of the US priority validly assigned the priority right to Bayer Corporation, despite the absence of signed letters of assignment for some inventors/applicants.

Moreover, the Federal Patent Court pointed out that according to the standing case law of the Federal Patent Court, it is sufficient for a valid priority claim if at least one of the applicants of the previous application or their legal successor and one of the applicants of the subsequent application are identical. In the present case, the subsequent applicant is in any case the legal successor of the eight applicants of the first application, for whom copies of signed declarations of assignment are available. Therefore, priority would be validly claimed under Swiss law even if the transfer of rights for the other appli-

cants of the first filing, for whom no written declarations of assignment were submitted to the court, were not considered proven. The patent in suit EP 255 therefore validly claims its priority.

The starting point for the assessment of inventive step was a scientific article, Lyons et al 2001, describing the Raf signalling pathways and explaining why the inhibition of Raf kinase is a promising approach for the destruction of tumors. A clinical trial with an oral formulation of "BAY 43-9006" is reported in this article. The drug was well tolerated, and the dose was increased. Preliminary clinical data are encouraging, with at least 37% of patients showing stable disease progression for more than 12 weeks.

The term "BAY 43-9006" used in Lyons et al stands for sorafenib. However, the Federal Patent Court concluded that the scientific article does not directly and unambiguously disclose the tosylate salt of sorafenib nor the free base. Therefore, one cannot simply assume that the article discloses the free base or the tosylate salt of sorafenib, as this would already read an element of the solution into the starting point for the assessment of inventive step.

Ultimately, and this is probably the main reason why the Federal Patent Court arrived at an assessment that differs from that of foreign courts in parallel proceedings, the overall view must not be neglected when considering the individual steps leading to an invention. If several steps are necessary to arrive at the subject matter of the invention, this is considered a "clear indication of the existence of an inventive step", although this should not apply if each individual step is obvious from the point of view of what has been achieved and the problem still to be solved.

In order to include sorafenib tosylate as a candidate in (pre)clinical testing, the skilled person in the present case must:

- (1) include the tosylate salt in the salt screening;
- (2) despite the very low solubility of the salt, nevertheless attempt to determine its dissolution rate;
- (3) successfully determine the dissolution rate and establish that it is higher than that of other salt forms; and
- (4) consider the tosylate salt as a promising candidate despite the still low dissolution rate, that it is higher than that of other salt forms, whereby it should be noted that at least step (2) is not associated with a very high expectation of success.

There may be reasons to carry out each individual step, as the defendant has shown. However, the fact that the skilled person performs all steps without inventive step was not proven in the opinion of the Federal Patent Court. If the skilled person only makes one "wrong turn" or finds the result of the respective step insufficient to continue, the skilled person does not arrive at the subject matter of the invention. Even if the skilled person would have to assume on the basis of Lyons et al 2001 that there is a clinically effective, ie, sufficiently bioavailable, form of sorafenib, it is not obvious that this is in the tosylate salt. Based on these considerations, the Federal Patent Court acknowledged the presence of an inventive step.

Therefore, the Federal Patent Court confirmed the validity of the Swiss part of EP 255 and found EP 255 to be infringed. The judgment has not been appealed and is therefore final.

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