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Switzerland: Trends & Developments

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Trends and Developments

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The Next Ten Years for the Swiss Federal Patent Court

On 1 January 2022, the Swiss Federal Patent Court had its tenth anniversary! In the Swiss Trends & Developments chapter of the 2022 Patent Litigation Global Practice Guide, we took this as an opportunity to look back and reflect upon the last ten years for a moment – and this year we want to give an outlook on how the Swiss Federal Patent Court could further establish and position itself in the second decade after its foundation. If one looks at the most recent case law of the past year, one clearly notices that the Swiss Federal Patent Court renders its judgments with both the necessary pragmatism and a sense of proportion, making it an increasingly attractive forum for any patent owner to enforce their patent rights.

In the first years after its foundation, quite a number of cases dealt with procedural questions and were decided on the basis of Swiss procedural law. Depending on whether one sympathised more with the plaintiff or the defendant, one was happy or not with the result – but a true patent litigator is jubilant only when the case is argued and decided on the merits, not when a case is won because the filing of amended patent claims after having obtained the Court's preliminary opinion is deemed too late (which is the case in Swiss proceedings and often a pain for patent owners). The possibility of still amending the patent in infringement proceedings has been unnecessarily limited in recent years by the Federal Supreme Court and should again be handled more pragmatically in the authors' view.

Like other courts, the Swiss Federal Patent Court always tries to find a compromise between time, costs and quality. It is immediately clear that these aspects are contrary to each other and that, especially in patent litigation, the highest quality can hardly be achieved quickly and, at the same time, at low cost. But since the Swiss are well-known for reaching good compromises, it seems clear that the Swiss Federal Patent Court is on a very promising path. In particular, a look at some recent decisions in summary proceedings shows that the Federal Patent Court is taking a quick and pragmatic and, at the same time, well-founded approach, which – from a neutral and restrained perspective – could be called patentee-friendly. To illustrate this rather patentee-friendly approach, this article highlight three cases which the Swiss Federal Patent Court decided last year. Some of these judgments were made in awareness of – and in contrast to – rulings in parallel proceedings by well-established courts in the United Kingdom, Germany, or the Netherlands.

The "Fingolimod Case" (S2022_002)

In a dispute spreading across numerous European countries, Novartis sought to enforce its second medical use patent EP 2 959 894 (EP 894). The patent covers a 0.5mg per day dosage of active ingredient fingolimod, which forms the basis of Novartis' drug Gilenya. The product is used to treat relapsing-remitting multiple sclerosis.

The dilemma Novartis faced was that the extended market exclusivity for Gilenya expired

in March 2022, but EP 894 had not yet been officially granted by that time. However, the patent grant was imminent, as the European Patent Office (EPO), in the form of the Board of Appeal, had already given the green light to the granting of EP 894.

In light of Article 67 of the European Patent Convention (EPC), the EPC member states have different regimes as to what rights a patent application confers. In Switzerland, injunctive relief generally requires a granted patent. The same applies, for example, in Germany.

In the meantime, some generic manufacturers in Europe took advantage of the gap between the end of Novartis's market exclusivity and the official granting of the patent to sell their own generic products in various markets. Therefore, Novartis initiated patent infringement proceedings against these generic manufacturers, including Mepha Pharma AG in Switzerland, even though Novartis did not yet have a granted patent.

Several courts, including the Düsseldorf Regional Court, dismissed Novartis's application for preliminary injunctions on the grounds that injunctive relief is only available for a granted patent while financial compensation can also be claimed based on a published patent application.

So, what did the Swiss Federal Patent Court do?

The Swiss Federal Patent Court neither dismissed nor suspended the case.

It was undisputed between the parties and acknowledged by the Court that a published European patent application does not grant the applicant the protection provided for in Article 64 of the EPC in Switzerland and that preliminary injunctive relief requires a granted patent. However, in Switzerland, it is sufficient for the issuance of preliminary measures if, at the time of the judgment, the plaintiff is entitled to a claim that has been infringed or that is likely to be infringed. If an application for a preliminary injunction is filed while the application is still pending and the patent is granted only during the course of the proceedings, this defect is deemed to be "cured" because, according to general principles of Swiss civil procedure, the facts at the time of the judgment (rather than at the time of filing) are decisive. Therefore, a patentee can file a request for preliminary measures as soon as the grant of the patent is only a question of time and the claims have been established. In the present case, the fact that the defendant was not aware of the reasoning of the EPO Board of Appeal was not considered to cause any significant disadvantage. Firstly, the applicant was not aware of the reasoning either. Secondly, and crucially, the defendant must allege and establish the lack of validity in the present proceedings and respond to the relevant counterarguments of the applicant presented in those proceedings. The Board of Appeal's reasoning is not binding on the Swiss Federal Patent Court in any case.

Likewise, the defendant's request to suspend the preliminary injunction proceedings was dismissed immediately. The Court pointed out that summary proceedings serve the purpose of granting quick and provisional legal protection if the relevant prerequisites are met. Accordingly, preliminary injunction proceedings should be suspended only with extreme caution. In the present case, the grant of the patent was foreseeable and, according to general experience, would take place before the summary proceedings were ready for judgment. If this were not the case, the judgment would have to be suspended

until the patent were granted. However, the proceedings should not be stayed immediately, as this would violate the applicant's constitutional right to have its case decided within a reasonable time.

The "Sorafenib Tosylate Case" (S2021_006)

In this case, also spreading across Europe, Bayer HealthCare sought preliminary injunctive relief against the generic product Sorafenib Zentiva of Helvepharm, the Swiss branch of Zentiva. More specifically, Bayer HealthCare sought to enforce the compound claim 12 of EP 2 305 255 B1 (EP 255), claiming the tosylate salt of sorafenib as such. Sorafenib tosylate is the active ingredient in Bayer's medicament Nexavar, which is, inter alia, authorised for the treatment of primary kidney cancer and advanced primary liver cancer.

This case has attracted attention because it was litigated simultaneously in a number of European countries. For example, EP 255 was held to be invalid in Germany, UK and in the Netherlands.

So, what did the Swiss Federal Patent Court decide?

While the Technical Judge in his written Preliminary Opinion provisionally regarded claim 12 of EP 255 as invalid due to lack of inventive step, similar to the positions taken, for example, in the UK and Germany; the applicant convinced the court to decide that claim 12 was valid and a preliminary injunction was granted accordingly.

Even though the defendant referred to the entire range of grounds for invalidity to defend itself, namely Article 123(2) of the EPC, invalid priority, lack of novelty and lack of inventive step, in the end, the case depended mainly on the assessment of inventive step.

With respect to the examination of priority, attention should be paid to one important aspect where Swiss case law might differ from the case law of other European jurisdiction. The Swiss Federal Patent Court pointed out that according to the case law of the Swiss Federal Patent Court, it was sufficient for a valid priority claim if at least one of the applicants of the earlier application and one of the applicants of the later application were identical. Since in the present case, the defendant did not dispute that at least the eight inventors/applicants for whom copies of the signed "Bayer Corporation Agreements" were filed were identical during the relevant period, the priority claim was considered valid. Thus, in a case where validity is dependent on the priority claim and where the priority claim might be disputed because not all applicants of the earlier application and the later application are identical, it could still be advisable for a patent owner to enforce the patent in Switzerland.

Regarding inventive step, the judgment discussed the questions as to whether the skilled person would have considered the tosylate salt at all as a target compound for the development of a sorafenib medicament and, if so, whether and at which stage the skilled person would have given up in view of discouraging results obtained in pre-formulation studies. The judgment of the Swiss Federal Patent Court came to the conclusion that the skilled person could not have determined promising properties of sorafenib tosylate – ie, by measuring the dissolution rate of sorafenib tosylate – with routine methods at the priority date. The Court concluded that the skilled person would not have realised that sorafenib tosylate had a surprisingly high dissolution rate, despite its low solubility.

As mentioned above, an inventive step was acknowledged by the Swiss Federal Patent Court, and a preliminary injunction was granted.

The "Deferasirox Case" (S2021_005)
In this case, Novartis and Mepha Pharma again faced each other, and Novartis AG sued Mepha Pharma AG for the alleged infringement of the Swiss parts of EP 2 964 202 (EP 202) and EP 3 124 018 (EP 018).

Both patents concern formulations of deferasirox which is an active ingredient from the group of iron chelators and used to treat iron overload caused by frequent blood transfusions.

The patents require, according to the independent claims, that deferasirox or a pharmaceutically acceptable salt thereof is present in the claimed film-coated tablet for oral administration in an amount from 45% to 60% by weight based on the total weight of the tablet. The issue in dispute was, in particular, whether the alleged infringing product "Deferasirox Mepha® 90 mg, 180 mg and 360 mg" containing deferasirox in an amount of 64.3% by weight met this essential feature. Or, in other words, the Federal Patent Court considered the question whether a tablet with a higher amount of the active ingredient – ie, a tablet containing 64.3% by weight of that active ingredient – may fall within the protective scope of a patent wherein the weight range of the active ingredient is defined as 45% to 60% by weight.

Interestingly, in a parallel case, the High Court of England and Wales recently invalidated the two patents following revocation action proceedings brought by Teva. The presiding judge found that Novartis' claim relating to the amount of deferasirox within the tablet was an obvious modification over the two previous examples of prior art. While the precise figures for Teva DFX were confidential in the UK proceedings, the judge also found that Teva did not infringe the claims of the patents.

So, what did the Swiss Federal Patent Court decide in this case?

The Swiss Federal Patent Court decided that Deferasirox Mepha® did not literally infringe the patents. So far so good. However, the Swiss Federal Patent Court also concluded that Deferasirox Mepha® 90 mg, 180 mg and 360 mg containing 64.3% Deferasirox by weight realised the feature "a Deferasirox content in the range of 45% and 60% by weight" by equivalent means.

In this case, the Court – for the first time, by the way – dealt with the question of how numerical ranges in a patent claim are to be construed, especially against the background of a product allegedly infringing the patent claim despite a feature deviating from this numerical range.

When assessing the question of infringement under the doctrine of equivalence, the Swiss Federal Patent Court basically applied the three-step-test known as "*Schneidmesser's*" (cutting knife) questions, developed by the German Federal Supreme Court (BGH, judgment X ZR 168/00 dated 12 March 2003 "Schneidmesser I"; see the Swiss decision S2013_001 of 21 March 2013, cons. 17.2 "Drospirenon I"). However, the relevant questions are not formulated completely identically by the Swiss courts, as is shown below. According to Swiss practice, the first two questions must be answered in the affirmative and the last in the negative for a patent infringement to exist.

- Does the modified feature, in combination with the other technical features of the patent

claim, objectively perform the same function as the claimed feature? Known as "same effect."
- Is the equal effect obvious to the person skilled in the art when viewed objectively, considering the teaching of the patent, if the features are interchanged? Known as "accessibility."
- Does an objective reading of the patent specification lead the skilled person to the conclusion that the patent owner has formulated the claim – for whatever reasons – so narrowly that it does not claim protection for an accessible embodiment having the same effect?

In the case at hand, the Federal Patent Court affirmed the "same effect", mainly because the tablet with 64.3% by weight of deferasirox was bioequivalent to Novartis' tablet. The bioequivalence was confirmed by the fact that the generic tablet was approved by the Swiss Agency of Therapeutic Products (Swissmedic) in a drug application procedure to which bioequivalence is a prerequisite.

The second question – ie, "accessibility" – was also answered in the affirmative for the reason that the patents did not require explicit compliance with the upper limit of the claimed range. Rather, it was allegedly clear from the patents that the intention was to increase the proportion of active ingredient in the tablet. According to the Court, an increase of the portion of the active ingredient of up to 10% would still be considered safe and effective.

In a third step, the Federal Patent Court assessed whether the skilled person when reading the patent specification would conclude that the patentee had deliberately formulated the claim so narrowly that they thereby waived protection for an embodiment with an equal technical effect that would have been accessible to the skilled person. In assessing this question, the Court particularly considered accepted tolerances for pharmaceutical formulations. In doing so, the Court took into consideration both the accepted tolerance for active ingredient weight and for the total weight of the tablet. That, in practice, much smaller deviations from the target weight can actually be achieved today than are considered acceptable by the cited references, was not relevant. What was decisive, according to the Court, was that these generous tolerances are apparently accepted in the technical field in question. Therefore, the skilled person would assume that a drug which is within these tolerances is effective and safe.

With an active ingredient content of 64.3% by weight of deferasirox, the challenged embodiments were considered to be within the tolerance generally accepted in the relevant technical field, which is 66% for the upper value of the relative active ingredient content, based on the total weight of the tablet.

As a result, the Federal Patent Court considered that Deferasirox Mepha® 90 mg, 180 mg and 360 mg containing 64.3% Deferasirox by weight fulfil the feature "a Deferasirox content in the range of 45% and 60% by weight" by equivalent means.

This case shows that even numerical ranges in patent claims, the scope of protection of which is normally strictly determined by their literal sense, are certainly amenable to the doctrine of equivalence and that differences that are much more than mere rounding differences can still fall within the scope of protection under the doctrine of equivalence.

The latter two cases – ie, the Sorafenib Tosylate Case and the Deferasirox Case – are currently being litigated in ordinary proceedings on the merits and it remains exciting to see whether the Court will confirm the preliminary rulings.

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In closing, with a look to the future, we would like to quote the President of the Federal Patent Court, Mark Schweizer. In a very recent interview, the President answered the question of where he sees the Federal Patent Court in 2032 as follows: “When I became president four years ago, I said that we wanted to become the best patent court in Europe. In ten years, that goal shall be realised.”

We think the Court is on its way to achieving this ambitious goal.

MLL Legal has an IP team that unites Switzerland's leading consultants and representatives for patent law. Led by Simon Holzer, MLL's patent team includes four partners and four associates. The firm handles an impressive amount of litigation in the Swiss life sciences and hi-tech areas and it is many global pharmaceutical originators' first choice. The team covers a wide range of industries, including pharmaceuticals, medical devices, software, telecommunications, and foodstuffs. It has also taken centre stage in Switzerland's first FRAND battle. MLL's patent team has particular expertise in the field of supplementary protection certificates and achieved two landmark Swiss Federal Supreme Court decisions on behalf of Gilead Sciences Inc. (Gilead v Mepha Pharma AG), which affirmed the validity and infringement of Gilead's SPC for the combination product Truvada. Measured by published decisions, there is no other firm that has represented as many clients before the Swiss Federal Patent Court as the MLL Legal patent team.

Authors

Simon Holzer heads MLL's patent and life sciences team. He has vast experience in all areas of IP law, with a clear focus on patent disputes and transactions. Simon is a leading figure in a wide range of industries and technologies, including pharmaceuticals, medical devices and telecommunications. In 2010, the Swiss parliament appointed him as a part-time judge of the Swiss Federal Patent Court.

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