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Patent Litigation 2022

Switzerland: Trends & Developments

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Trends and Developments

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The Swiss Federal Patent Court

On 1 January 2022, the Swiss Federal Patent Court had its tenth anniversary! This is a good reason to celebrate, but also to look over and reflect upon the last ten years for a moment.

While a practicing litigator naturally will not always agree with the Court on the merits, it can be stated without reservation that the Swiss Federal Patent Court is a success story. It has positioned itself successfully within other important patent courts in Europe and contributes decisively to the development of the law, at both the domestic and international level.

In 2021, the Swiss Federal Patent Court conducted its yearly satisfaction survey among Swiss litigators, attorneys at law and patent attorneys. The results showed that there is a very high level of satisfaction overall. In particular, there is unanimously high satisfaction with the Court's service, the duration of proceedings and the quality of judgments. However, the practitioners do not entirely agree on the question of whether the Court's rather strict case law – which is strongly influenced by procedural law – discourages parties from taking legal action in Switzerland. It remains to be seen whether the Court is willing to learn any lessons from this. Overall, however, the result of the poll is a clear sign that the Swiss patent system with the Federal Patent Court specialised in patent litigation matters is very well established and enjoys great support from the ranks of practitioners.

It would be desirable though if, in the future, Switzerland would become even more attractive as a jurisdiction for patent matters. The total number of judgments that were made publicly available in 2021, with nine decisions in ordinary proceedings and three decisions in summary proceedings, was rather low compared to the previous years. At the beginning of 2021 in particular, the number of new actions filed seemed to drop sharply, but then fortunately picked up again during the course of the year. Towards the end of the year in particular, a number of exciting cases were brought before the Swiss Federal Patent Court, some of which have already been decided.

Modernising the Swiss Patent Act

There are plans to further strengthen the Swiss patent system in the near future by modernising the Swiss Patent Act. So far, the Swiss Federal Institute of Intellectual Property (IPI) has examined Swiss patent applications merely with regard to the questions of the application's comprehensibility and clarity as well as the invention's technical character and unity. This is to be changed by introducing a Swiss patent that is, upon request, fully examined also with regard to novelty and inventive step.

The respective political motion is entitled "Towards a modern Swiss patent" and, inter alia, intends to extend the examination powers of the IPI thereby bringing its competence on a par with that of the European Patent Office. The Swiss Federal Council, being the commissioner of this initiative, hopes that a fully examined Swiss patent will become an advantageous alternative to a European patent or unitary patent, especially for SMEs and individual inventors. It is noteworthy that the motion further provides for the possibility to choose English as the language of the proceedings. This would make the Swiss patent particularly attractive for international appli-

cants and internationally operating companies. Following the acceptance of the motion by the Federal Council in May 2019, both chambers of the Swiss Parliament approved the motion (the Council of States on 4 June 2019, and the National Council on 12 December 2019). At its meeting on 14 October 2020, the Federal Council opened the public consultation on the partial revision of the Patent Act. The consultation period on the patent law revision lasted until 1 February 2021. At its meeting in August 2021, the Federal Council took note of the results of the consultation on the partial revision of the Swiss Patent Act. In the consultation, a development of the existing patent examination procedure was welcomed in principle. As a next step, the Federal Council plans to take into account some of the criticism expressed in the consultation by making changes to the content of the draft bill. It has instructed the Federal Department of Justice and Police (FDJP) to provide a draft bill on the partial revision of the Patent Act with the following key points by the end of 2022.

- Provision of fully examined Swiss patents, but adding flexibility to patent examination by making it optional to examine all patenting requirements, including novelty and inventive step.
- Waiver of the introduction of a utility model; ie, contrary to the original plans, there will be no Swiss utility model (but the possibility of a patent that will not be examined with respect to novelty and inventive step remains).
- Increase of legal certainty through mandatory searches for all patent applications.
- Abandoning the conduct of opposition proceedings before the IPI.
- Appointment of the Federal Patent Court as an appeal authority against decisions of the IPI instead of the Federal Administrative Court.

Overall, the proposed revision, together with the well-established Swiss Federal Patent Court, would provide Switzerland with an up-to-date patent system. Such a patent system would be independent from any developments on the European level, such as the upcoming Unified Patent Court (UPC), in which Switzerland as non-EU member will not participate. Against this background, the proposed creation of a fully examined independent Swiss Patent as an alternative to European or unitary patents could be a welcome development.

The Doctrine of Equivalence in Swiss Jurisprudence: The Deferasirox Case

Turning now more specifically to the case law of 2021, one highlight from the series of judgments of 2021 is a case concerning the doctrine of equivalence (judgment of the Federal Patent Court S2021_005 of December 15 December 2021, "Deferasirox"). The authors chose this judgment from 2021 for a more detailed discussion in the present article. Of course, this is a merely subjective choice, and this discussion of the case law is therefore in no way exhaustive or representative for the whole Swiss case law in patent matters of 2021.

The Deferasirox case is particularly noteworthy because it shows that, under special circumstances, a numerical range can have a quite considerable scope of equivalence.

In this case, the plaintiff Novartis AG sued the defendant Mepha Pharma AG for the alleged infringement of the Swiss parts of the European Patents EP 2 964 202 and EP 3 124 018 (patents in suit).

Both patents in suit concern formulations of Deferasirox. Deferasirox is an active ingredient from the group of iron chelators and is used to treat iron overload caused by frequent blood transfusions. The patents in suit state that due to the

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poor solubility of the active ingredient, a high dose is required to achieve the desired therapeutic effect, which can lead to side effects such as irritation of the gastrointestinal tract and renal toxicity. The low solubility of the active ingredient also leads to technical difficulties in the development of pharmaceutical formulations.

Both patents in suit 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" met this essential feature requiring the film-coated tablet to contain Deferasirox in an amount between 45% and 60% by weight.

The first issue in dispute between the parties concerned the claim construction and, more specifically, the question as to whether the content of Deferasirox referred to the tablet as a whole or to the tablet without coating. According to the defendant, Deferasirox Mepha® film-coated tablets contain 66.2% by weight of Deferasirox, based on the tablet without coating, and the plaintiff calculated a weight of 64.3% by weight based on the film-coated tablet. The defendant calculated the content of Deferasirox based on the tablet without coating, while the plaintiff based its calculations on the tablet as a whole. According to the Swiss Federal Patent Court's claim construction, the percentage content of Deferasirox according to the patents in suit referred to the entire tablet including the coating. Accordingly, the Court agreed with the plaintiff and based its further assessment of infringement on the finding that Deferasirox Mepha® 90 mg, 180 mg and 360 mg contained Deferasirox in an amount of 64.3% by weight.

Consequently, the next question to be examined was therefore whether a film-coated tablet with a Deferasirox content of 64.3% by weight falls within the scope of protection of the film-coated tablet as claimed in the patents in suit, which was defined as having a Deferasirox content in the range of 45% and 60% by weight.

Literal infringement

The plaintiff even argued literal infringement of the respective claims of the patents in suit. However, the Court did not follow plaintiff's arguments.

Although the Court acknowledged that even numerical ranges in patent claims are open to interpretation, they are not understood by the skilled person as "inferior", as the plaintiff argued. On the contrary, the skilled person generally grants such indications a lower degree of ambiguity and clarity than is the case with verbally described features of a claimed teaching. If a measured value is outside of a numerical range defined in a claim, it is no longer covered by the literal wording. Also, values within usual tolerances are no longer covered by the literal sense of the claim. According to the court, a more generous understanding of numerical indications in patent claims can only apply if there are indications in the claim itself, such as "essentially in the range of" or "approximately in the range of", or it is directly and unambiguously recognisable to the skilled person from the claim in the overall context and/or the patent description that the claimed numerical range is not strictly numerically limited.

According to the Swiss Federal Patent Court, the respective claims of the patents in suit do not give any indication – neither with regard to the individual feature alone, nor in the overall context of all features – that the numerical range is not to be given a strictly limiting effect. A relativising reference such as "approximately" or "essen-

tially" is missing. Thus, from the claim language alone it is not clear why the literal sense should also extend to embodiments outside the specifically defined numerical range. Nor is there any direct and unambiguous indication from the patent description that the range of 45–60% by weight of Deferasirox should be ready more vaguely. Although numerical indications in patent claims are, in principle, open to interpretation, in the specific case a value outside the indicated range of 45–60% by weight of active ingredient content is therefore no longer considered within the literal meaning of the claims of both patents in suit.

Consequently and not surprisingly, the Swiss Federal Patent Court decided that Deferasirox Mepha® 90 mg, 180 mg and 360 mg does not literally infringe the patents in suit.

Infringement under the doctrine of equivalence

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 in a completely identical way 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.

(1) Does the modified feature, in combination with the other technical features of the patent claim, objectively perform the same function as the claimed feature? ("Same effect".)

(2) Is the equal effect obvious to the person skilled in the art when viewed objectively, taking into account the teaching of the patent, if the features are interchanged? ("Accessibility".)

(3) Does an objective reading of the patent specification lead the skilled person to the conclusion that the patent proprietor 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 present case, the Court answered the first two questions in the affirmative, basically for the following reasons.

Same effect

The plaintiff claimed equal effect within the meaning of the first question by showing that the marketing authorisation documents of its own product, Jadenu®, which correspond to an example in the patents in suit, mention the technical effects which are also emphasised in the patents in suit; namely, swallowability, bioavailability of the active ingredient, reduced "food effect" and better tolerability. In addition, the plaintiff referred to the fact that the challenged embodiments of the defendant were approved by the Swiss Agency for Therapeutic Products (Swissmedic) in the simplified approval procedure within the meaning of Article 14, paragraph 1, littera a of the Therapeutic Products Act (HMG, SR 812.21), which is only possible if proof of bioequivalence with the approved (and patented) original preparation (in the present case, Jadenu®) has been provided. The information on the package inserts of the generic product Deferasirox Mepha® 90 mg, 180 mg and 360 mg is identical to that of the original preparation.

Furthermore, the defendant did not dispute that the challenged embodiments are bioequivalent to the claimed original preparation Jadenu®. Two drugs with the same active ingredient are

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considered bioequivalent after administration of the same molar doses if the rate of absorption (Cmax and tmax) and the extent of systemic availability (AUC) are comparable. For the evaluation of bioequivalence, the Swiss Agency for Therapeutic Products (Swissmedic) referred to the corresponding guideline of the European Medicines Agency (EMA). There it is stated that orally administered fast-release dosage forms with systemic effect are in principle bioequivalent to the reference preparation if the 90% confidence interval of the quotients of test and reference preparation for AUC and Cmax are within 80–125%. Consequently, the Court considered it plausibly established that the Deferasirox Mepha® 90 mg, 180 mg and 360 mg also achieve an AUC of Deferasirox that, as required by the patents in suit, is greater than that of conventional dispersible prior art Exjade® tablets.

Furthermore, the Court noted that it was undisputed that the challenged embodiments also fulfil the effect of being swallowable. Thus, the Court concluded that Deferasirox Mepha® 90 mg, 180 mg and 360 mg achieve the two technical effects of the patents in suit.

The fact that further effects are mentioned in the patents in suit, which the plaintiff has not succeeded in making credible, cannot be to its disadvantage, according to the Court. The defendant did not prove that the challenged embodiments do not achieve the corresponding effects either, although this would have been necessary in order to be able to claim that the modified feature does not achieve all the effects of the claimed feature.

Regarding the objection of the defendant that the regulatory approval documents do not allow the conclusion that it is just the range of the active ingredient portion that leads to the same effect, as required by the first question, it has to be said that the challenged embodiments differ only in the active ingredient portion from the literal teaching of the independent claims of the patents in suit. This allows the conclusion that the modified feature – ie, the active ingredient content of more than 60% by weight – in combination with the other technical features of the patent claim achieves the same effect as the claimed active ingredient content of 45 to 60% by weight. The Federal Patent Court concluded that the objective equal effect had thus been made plausible.

As a result, the Court acknowledged that the challenged embodiments achieved the same effects as a formulation claimed in the patents in suit.

Accessibility

With regard to accessibility within the meaning of the second question, the Federal Patent Court considered that the patents in suit consistently speak of increasing the proportion of the active ingredient. There is no indication from the patents in suit that an increase in the proportion of the active ingredient by less than 10% over the claimed range – ie, in any case up to a proportion of 64.3% Deferasirox – would result in a formulation no longer being effective and safe. The skilled person further recognises from the dimensions for the proportions of the relevant excipients that a total proportion of excipients of about 15% by weight results if the respective lower limit is used for each excipient. As a result, it is possible to use more than 80% of Deferasirox. Even if the skilled person chooses the middle of each range given in the patents in suit for each excipient, this results in a total percentage of excipients of about 35%, which still allows more than 60% by weight of Deferasirox, even taking into account a portion of about 3% for the coating. The excipients are critical to the formulation of the active ingredient as a swallowable tablet and, at first glance, allow a much higher proportion of active ingredient than that

claimed. Thus, according to the Court, the proportion in the challenged embodiment of 64.3% Deferasirox is accessible by the skilled person even if the patents in suit alone were taken as a starting point.

The defendant's assertions that it can only be verified on the basis of elaborate experiments whether the mentioned effects still occur were not convincing to the Court, since they were only submitted in general abstract terms and no concrete indications were given as to why one or more effects would no longer be achieved due to the proportion of the active ingredient being less than 10% above the claimed range.

The Federal Patent Court thus concluded that it was therefore plausibly shown by plaintiff (as the described case concerned preliminary injunction proceedings, the applicable standard of proof was "making credible" instead of proofing beyond reasonable doubt) that a content of 64.3% by weight of Deferasirox could be found in the light of the teaching of the patents in suit; ie, it is accessible, and this without an inventive step when starting from the patented technology.

Narrowness of the claim

On the third question, the plaintiff stated that it is known to the skilled person that formulations do not immediately cease to provide the desired effect above a precisely definable limit. In addition, the plaintiff pointed to a statement by the defendant's expert, who confirmed that the range selected in the patent claim is nothing special, that this range for the active ingredient simply works with the other excipients, and that this does not prevent the skilled person from increasing the proportion of Deferasirox.

The plaintiff further argued that there are accepted regulatory tolerances for the active ingredient and the total weight of a tablet manufactured for medicinal products. Citing the EMA Committee for Medicinal Products for Human Use's 1996 Note for Guidance on Manufacture of the Finished Dosage Form, the plaintiff argued that the tolerance for the active ingredient is +/- 5% by weight. For the total weight of the tablet, the tolerance is weight-dependent; for a total weight of the tablet between 80 and 250 mg, it is 7.5% by weight, and for a total weight of more than 250 mg 5% by weight (citing European Pharmacopoeia 10.0, Section 2.9.5 Uniformity of mass of single-dose preparations). Since the active ingredient percentage is defined in the patent claim as the quotient of the active ingredient weight and the total tablet weight, assuming that the active ingredient weight is at the upper end and the total tablet weight is at the lower end of the acceptable range, the result is an upper value of acceptable active ingredient percentage of 68% for the challenged embodiments with 90 mg Deferasirox and of 66% for the challenged embodiments with 180 mg Deferasirox and 360 mg Deferasirox.

The Court noted that in relation to the individual tablet, the plaintiff's calculation of the upper value for the active ingredient content, which is still within the tolerances generally accepted, is correct. Since the two tolerances for active ingredient weight and total weight must be observed independently, a tablet whose active ingredient weight is at the upper edge and whose total weight is at the lower edge of the respective range satisfies the requirements. The fact that there is another independent tolerance for the uniformity of the active ingredient distribution in the dosage form (with reference to European Pharmacopeia 5.2, Section 2.9.40. Uniformity of dosage units) does not change this. If compliance with the parameters for uniformity of active ingredient distribution were already sufficient to ensure that there is (approximately) the same amount of active ingredient in each tablet, the additional acceptance value for the

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active ingredient weight would be superfluous. It is conceivable that, in practice, much smaller deviations from the target weight can actually be achieved today than are considered acceptable by the cited sources. What is decisive, according to the Court, is that the more generous tolerances are apparently accepted in the technical field in question; ie, the person skilled in the art assumes that a drug which is within these tolerances is effective and safe. As far as the defendant claimed that the regulatory authorities would allow a maximum deviation of 2.5% from the target weight, it failed to provide any evidence for this assertion. The Court could not base its judgment on this assertion when the more generous tolerances are documented by the Note for Guidance on Manufacture of the Finished Dosage Form of the Committee for Medicinal Products for Human Use of the EMA and the European Pharmacopoeia.

With an active ingredient content of 64.3% by weight, the challenged embodiments are thus 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.

Deferasirox Mepha® 90 mg, 180 mg and 360 mg was thus considered to infringe the claims of the patents in suit.

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 examination under 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.

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MLL Meyerlustenberger Lachenal Froriep AG (MLL) has an IP team that unites Switzerland's leading consultants and representatives for patent law. Led by Simon Holzer, MLL's patent team includes five partners and nine associates. The firm handles an impressive amount of litigation in the Swiss life sciences and hi-tech spaces and it is many global pharmaceutical originators' first choice. The team covers a wide range of industries, including pharmaceuticals, medical devices, software and telecommunications. 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.

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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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