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Doctrine of Equivalents and Numerical Ranges

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The two patents in suit require 45% to 60% by weight of a specific active ingredient. The attacked product containing 64.3% was ultimately found not to be infringing. Patent protection for a numerical range could not be extended under the doctrine of equivalents to cover values outside that range.

Background

The dispute concerns deferasirox, an iron chelator used to treat iron overload caused by frequent blood transfusions. Novartis' compound patent for deferasirox expired in 2017 and the Swiss SPC in 2021. Novartis also holds patents covering formulations of deferasirox, including the two patents at issue for swallowable tablets. The independent claims of both patents require, inter alia, deferasirox to be present in an amount from 45% to 60% by weight based on the total weight of the tablet.

Mepha obtained marketing authorisation for its product in Switzerland in 2020. According to the product information, Mepha's product contains 64.3% by weight of deferasirox. The lowest (disputed) analytical value submitted by Novartis was 60.8%.

On 19 April 2021, Mepha filed an invalidity action against the two Novartis patents with the Swiss Federal Patent Court ("**FPC**"). Novartis counterclaimed for infringement. In parallel, Novartis filed a motion for a preliminary injunction against Mepha, which was granted on 15 December 2021 (S2021_005).

Decision of the Swiss Federal Patent Court

The FPC issued its judgment in the main proceedings on 20 April 2023 (O2021_004, O2021_005). The decision is noteworthy for several reasons, of which only infringement will be discussed in more detail.

On validity, the FPC found the two patents did not suffer from unallowable amendments and were not obvious over the prior art. On infringement, the dispute turned on the amount of deferasirox. It was not disputed that Mepha's products fulfilled the other features of the patents in suit. As noted, Novartis' patents require 45% to 60% by weight of deferasirox. Even though Mepha's product undisputedly had a deferasirox content of more than 60%, Novartis asserted literal infringement of its patents. Subsidiarily, Novartis claimed infringement by equivalent means. Mepha contended that its product did not fall within the scope of protection of the patents.

Literal Infringement

On literal infringement, the FPC held that although numerical ranges in patent claims are open to interpretation, they are not understood as "less binding" by the skilled person. Values falling outside of a claimed range are not literally covered, regardless of industry tolerances. A more lenient interpretation of numerical ranges is permissible only if there are indications in the claim itself, such as "approximately in the range of", which was not the case here. Knowing that numerical ranges are subject to measurement errors, the skilled person understands that, in the absence of other spec-

ified error limits, the maximum error for the last specified digit is determined by the rounding convention. Thus, in the case at hand, the range still within the literal scope of protection of the patents extends from ≥44.5% to <60.5%.

Consequently, Mepha's product with 64.3% by weight of deferasirox, or 60.8% according to the lowest measured value claimed by Novartis, did not literally infringe Novartis' patents.

Infringement under the Doctrine of Equivalents

The FPC then turned to infringement by equivalent means. This is assessed by a three-question test: for there to be infringement by equivalent means, the first ("same effect") and second question ("accessibility") must be answered in the affirmative and the third question ("no waiver") in the negative.

The first question asks whether the variant (modified feature), in combination with the other technical features of the patent claim, objectively fulfils the same function as the claimed feature ("same effect"). Only the desired effects of the replaced feature matter, but these must be achieved by the variant.

According to the FPC, Mepha's product achieves the same effect in terms of bioequivalence and swallowability. The first question was therefore answered in the affirmative.

The second question asks whether the same effect is obvious to the skilled person when viewed objectively, taking into account the teaching of the patent, if the features are interchanged ("accessibility"). As currently formulated by the FPC, this is an ex-post assessment, asking whether the skilled person, knowing that the feature has been replaced, would recognise that the variant fulfils the same function as the claimed feature.

The patents in suit consistently speak of increasing the proportion of deferasirox. There is no indication in the patents that an increase to 64.3% would result in the formulation no longer being effective or safe. The same effect of the variant was therefore accessible to the skilled person.

The third questions asks whether, on an objective reading of the patent, the skilled person would conclude that the patentee has formulated the claim, for whatever reason, so narrowly that it does not claim protection for an equivalent variant, i.e., an equally effective, accessible feature ("no waiver", sometimes "equal value").

Novartis essentially argued that the skilled person knew that formulations did not immediately cease to have the desired effect after a precise threshold, and that a formulation with 64.3% of deferasirox was still within generally accepted industry tolerances. There was nothing in the patents to indicate that protection for more than 60% by weight of deferasirox was waived.

Contrary to its decision on the preliminary injunction, the FPC did not follow this line of argument. The description of the patents discloses a preferred active ingredient content of 56%. The claim does not mention this exact value but rather a range of 45% to 60% around this value. The skilled person assumes that the patentee has bindingly defined the claimed range around the preferred value, i.e., has deliberately limited the invention to this range and waived protection outside it. In these circumstances, there is no room for extending the claimed range under the doctrine of equivalents. In particular, the skilled person will assume that possible tolerances have already been taken into account when defining the claimed range. If the patentee had wanted the scope of protection to cover values even further away from the preferred value, the claimed range would have had to be defined more broadly.

The FPC, therefore, found Mepha's product with a deferasirox content above the claimed range of 45% to 60% not to infringe Novartis' patents under the doctrine of equivalents either.

Decision of the Swiss Federal Supreme Court

Novartis appealed the decision to the Swiss Federal Supreme Court ("**FSC**") but no longer asserted literal infringement.

The FSC upheld the FPC's ruling in its decision of 25 September 2023 (4A_273/2023). Novartis could not convincingly explain the purpose of the precise numerical range, comprising the preferred value, other than a waiver of the values outside this range. That the preferred value was mentioned in the description rather than the patent claims was immaterial, as claims must be interpreted in light of the description. If a patentee does not wish to be limited to or exclude general tolerances beyond a specified range, the claim must be drafted accordingly. The FPC had therefore correctly rejected the third question and thus denied an equivalent infringement. The appeal was dismissed, without addressing Mepha's criticism of the FPC's reasoning on the first and second question.

Comment

A technical inventive concept often cannot be conclusively expressed in words. In general, a patentee is thus only adequately rewarded if the scope of protection of a patent extends beyond the scope of the patent claims. However, extending the scope of protection beyond literal infringement requires caution. A balance needs to be struck between adequate protection for the patentee, on the one

hand, and a reasonable degree of legal certainty for third parties, on the other hand. The three-question test is intended to do that.

As currently formulated, however, the second ("accessibility") and third question ("no waiver") for establishing equivalent infringement are rarely limiting. This results in a test that will often find in favour of the patentee if a variant fulfils the same functions as the claimed feature, i.e., if the first question ("same effect") is answered in the affirmative.

The present case is interesting because an equivalent infringement was denied on the basis of the third question only. It illustrates that there is (some) life in the third question.