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The Swiss Federal Supreme Court Approves New Dosage Regime as Patentable Subject Matter in Swiss Type Claims under the EPC 1973

Simon Holzer (MLL Meyerlustenberger Lachenal Froriep Ltd.) · Friday, May 27th, 2011

In a very recently published decision of 4 March 2011 the Swiss Federal Supreme Court dealt with the decision of the Enlarged Board of Appeal 2/08 and approved a dosage regime for a pharmaceutical product as patentable subject matter of a Swiss type claim under the EPC 1973. According to the Supreme Court such claim is patentable subject matter and can be valid if the dosage regime is new and inventive.

The decision was preceded by the following dispute:

On 28 March 2007 the European Patent EP 1 175 904, relating to the use of alendronic acid in the treatment of osteoporosis, was granted to Merck & Co., Inc., New Jersey (**Merck**). Alendronic acid is also an active ingredient of Merck's product "Fosamax", which was first marketed for use in treatment of osteoporosis by oral administration of **10mg alendronic acid once a day**. Later, Merck brought a new form of Fosamax with a new dosage regime onto the market and had sought patent protection for this new dosage regime.

Claim 1 of the Merck patent EP '904 reads as follows: The use of alendronic acid in the manufacture of a medicament for treating osteoporosis in a human in need of such treatment, where said medicament is orally administered to said human as a unit dosage comprising **about 70mg of the aldendronate compound**, on an alendronic acid active weight basis, according to a continuous schedule having **a once-weekly dosing interval**. (Emphasis added).

On 29 March 2007 the Swiss generic companies Mepha Pharma AG and Mepha AG brought a proceeding before the Commercial Court of Zurich against Merck asserting the Swiss part of the European patent to be invalid. The Commercial Court held that the only feature likely to confer novelty on claim 1 was the dosage regime. The Commercial Court of Zurich concluded that the dosage regime was a method of therapeutic treatment and thus was excluded from patentability according to Art. 2(2)(a) of the Swiss Patent Act and Art. 52(4) EPC 1973. Unhappy with this outcome, Merck appealed the decision to the Swiss Federal Supreme Court.

Making reference to the European case law (the G 2/08 decision had been published in the meantime), the Swiss Federal Supreme Court first pointed out that Art. 53(c) EPC 2000 (= Art. 52(4) EPC 1973) clearly drew a borderline between non-patentable method claims directed to therapeutic treatments on the one hand and patentable product claims, in particular substances or

compositions for use in such methods on the other hand. Art. 54(4) EPC 2000 (= Art. 54(5) EPC 1973) has consistently been interpreted to provide that a product (substance or composition) already known *per se* may be granted patent protection, provided, said product has not yet been used for a therapeutic treatment.

The Swiss Federal Supreme Court noted that in contrast to the EPC 1973, Art. 54(5) EPC 2000 expressly allowed patent protection for substances or compositions already known as medicines. Under the EPC 1973 this lacuna was filled by the "Swiss type claims" providing patent protection for second (and subsequent) medical indications by means of claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application.

In the view of the Swiss Federal Supreme Court, Swiss type claims with new dosage regimes are patentable subject matter under the EPC 1973 even in cases where the already known active agent is used for the treatment of the same illness.

As a result, the Swiss Supreme Court reversed the decision of the Commercial Court and sent the case back for a new decision on the merits. The Commercial Court will have to assess, inter alia, novelty and inventive step of the invention.

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