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ARE SECOND MEDICAL USE CLAIMS MEDICAL TREATMENT METHODS? EVALUATION OF A RECENT TURKISH IP COURT DECISION

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Turkey has been a member of European Patent Convention ("EPC") since 1 November 2000. European Patents, granted by European Patent Office, are validated in Turkey without further examination and protected as a national patent.

The competence of EPO in patentability assessment is also respected by Turkish Supreme Court and it has been the case law to take the patentability assessment of the EPO into consideration during national invalidation cases, not only related to European Patents, but also for patents, entered into national phase via PCT.

Within this atmosphere, in a case, based on a "Swiss-type" European Patent, the Turkish court decided that the patent was a "medical treatment method," which should not have been registered in accordance with Article 52/(4) of EPC 1973 and therefore it was null and void.

The European patent, subject to the decision, was registered by EPO on 21 September 2005, i.e. before EPC 2000 entry into force and related to a second medical use patent, disclosing a specific dosage regime.

The court stated that the European patent was violating the EPC 1973 provisions, and therefore it was null and void and there is no need to consider the criteria of novelty, inventive step and industrial applicability.

The reasoned decision of the local court stated that the European Patent, including a second medical use claim in "Swiss-type claim format, was essentially related to a medical treatment method, and methods for treatment are not patentable inventions according to Article 52(4) of EPC 1973, however, EPO had granted patents to such medical treatment methods relying on G5/83 decision of EBA, established by by-passing the provisions of EPC. According to the court, EBA decisions were not binding for Turkey. Therefore the European Patent in question was considered to be related to a "medical treatment method" and declared null and void in Turkey.

The court evaluated that Article 54/(4) and (5) of EPC 2000, constituted an exception to Article 52(4) of EPC 1973 and opined that after EPC 2000 revisions, it had become possible to patent such "medical treatment methods".

Article 52(4) of EPC 1973, titled "Patentable Inventions," and Article 53(c) of EPC 2000 titled "Exceptions to Patentability" rule that "the methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body" could not be patented.

Similarly, EPC 1973 and EPC 2000, rule that "*This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.*" Provided that novelty, inventive step and industrial applicability conditions are met, the use of a substance or composition in the methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body should be patented.

Considering there were no differences between EPC 1973 and EPC 2000 with respect to patentable inventions and that second medical use claims were not exempted from patentability in EPC 1973, the evaluation of the court, that an invention, which was not patentable before EPC 2000 revisions, had become patentable with the amendment, does not seem correct.

After EPC 2000 revisions, a sub paragraph was added to the "Novelty" clause of Article 54 and it was ruled in Article 54(5) that "a specific use" of a substance or composition in a method for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body possess novelty, if this specific use itself is not a part of the state of the art.

The Turkish court, stated that such claims were medical treatment methods and therefore their protection through a patent was prohibited depending on the lack of any clear rules in EPC 1973 about second (or further) medical use claims. However, the local court did not discuss if any use of a substance or composition is not deemed as a medical treatment method, could a specific use thereof be seen as medical treatment method.

In fact in EBA G5/83 decision, it has been stated that the Board did not deduce any intention from the terms of the EPC 1973 or from the legislative history of Articles 52(4) and 54(5) to exclude second (and further) medical indications from patent protection.

In my opinion, deeming the second medical use inventions, related to dosage regimes, as a restriction introduced to the freedom of treatment of the physician, means ignorance of novelty, inventive step and industrial applicability criteria in entirety with respect to the patents, related to such inventions. However, the inventive step in such claims lies in the use of a drug in a certain manner for a treatment of an illness, for a purpose-limited objective. Indeed, it is more difficult to prove the inventive step in a dosage regimen claim in comparison to the inventive step in conventional claims. This difficulty must be presented by the applicant with evidence or strong teaching away.

The appeal filed against the decision of the Turkish Court has been accepted and the decision has been overruled due to the deficiencies/misinterpretations on merits. The reasoned decision of the Court of Appeal has not been received yet.

I hope that the decision of the reasoning of the CoA removes the approach against legal certainty and vested right principles. However, unfortunately, this approach creates uncertainty for the European Patent owners having a second medical use claim granted by EPC 1973 in Turkey, as they may not be sure if their registered patents will be deemed in compliance with EPC by local court(s) and if they will be able to enforce their patent rights at all.

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