Editorial

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Pharmaceutical Patent Analyst

Second medical use in Turkey

“...second (or further) medical use are not explicitly allowed or prohibited in Turkish law.”

Turkish patent legislation complies with European Patent Convention (EPC) 1973 and EPC 2000, but does not have a corresponding provision. This triggers a debate in Turkish Law, where no regulations address protection of second (or subsequent) use. Turkish validations of European patents concerning second medical uses that have been granted within the scope of EPC 2000. However, the approach to national patent applications and patents entered to Turkey through Patent Cooperation Treaty is still questionable since the Patent Decree Law is not offering an explicit protection to second medical use and European Board of Appeal decisions (especially G5/83) are not binding for Turkish authorities. This article overviews the current approach of the Turkish legal system to second medical use patents.

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Patent law in Turkey is regulated through the Decree Law on the Protection of Patent Rights no: 551 (Patent Decree Law). Turkey signed the European Patent Convention ([EPC] 1973) on 5 October 1973. According to the Turkish Constitution, the ratification of treaties concluded with foreign states and international organizations on behalf of the Republic of Turkey shall be subject to adoption by the Grand National Assembly of Turkey by a law approving the ratification, and international agreements duly put into effect have the force of law. Meaning, once an international agreement is ratified by the Grand National Assembly of Turkey, the provisions of the international agreement is enforced as a duly issued national law. Turkey ratified the EPC 1973 on 1 November 2000. After that the revised text of the EPC (EPC 2000) has been accepted and came into force on 13 December 2007 [1]. Accordingly, EPC 2000 is part of Turkish Law and is legally binding.

According to the Patent Decree Law, patent protection can be granted to inventions, which are novel, involve an inventive step and are applicable to industry. The following cannot be protected by patents because by their nature they cannot be described as an invention:

- Discoveries, scientific theories and mathematical methods;
- Plans, methods, schemes/rules for performing mental acts, for conducting business/trading activity and for playing games;
- Literary and artistic works, scientific works, creations having an aesthetic characteristic and computer programs;
- Methods for collecting, arranging, offering/presenting and transmitting information/data that involve no technical aspect;

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- Methods of diagnosis, therapy and surgery applying to humans or animals. However, Turkish law allows products, compositions and processes regarding these products or compositions used in connection with human or animal health to be patented [2].

To this point, Turkish patent legislation complies with EPC 1973 and EPC 2000. However, neither Article 54/5 of EPC 1973, nor Articles 54/4 and 5, have corresponding provisions in the Patent Decree Law. Therefore, second (or further) medical use are not explicitly allowed or prohibited in Turkish law [3].

According to Article 4 of Patent Decree Law, where international agreements having entered into force according to the laws of the Republic of Turkey, contain provisions that are preferential or more favorable to those of the present Decree Law, the persons referred to in Article 2 may request to benefit from the more advantageous provisions. Consequently, it is clear for Turkish validations of European Patents concerning second medical uses that have been granted within the scope of EPC 2000, that they are granted protection considering the explicit regulation protecting second medical use. However, what will be the approach to the Turkish validations of European Patents on second medical use granted within the scope of EPC 1973 (in the form of Swiss claims), national patent applications and patents entered to Turkey through Patent Cooperation Treaty (PCT), considering the issues that EPC 1973 and Patent Decree Law did not offer explicit protection to second medical use and European Board of Appeal (EBA) decisions (especially G5/83) are not binding for Turkish authorities?

Second medical use describes new therapeutic uses for known active ingredients. For example, a known active ingredient used as a pain killer may turn out to be an effective ingredient also for the treatment of hypertension. Second medical use also covers the uses where the novelty resided solely in a new dosage regime or other form of administration of a known substance.

EPC 1973 did not provide the legal basis for patentability for use of a substance or compound, included in the state of the art, used for the treatment of another disease [4]. Although the discussions were pending regarding protection of second medical use, the EBA decided (decision numbered G5/83) [5] that second and subsequent medical uses of a known substance or compound could be patented, as long as it is novel, involves inventive step and applicable to the industry through using the artificial 'Swiss-type' claim. This claim read, 'Use of product X for the manufacture of a medicament for treatment of Y.' In these claims, what

is protected is the new use of a known substance itself and not the treatment method.

In order to put an end to the debatable status of second medical use patents and ensure the unified practice in contracting states, EPC 2000 directly adapted Article 54/5. The article explicitly protects second or subsequent use. Purpose limited product claims have been accepted in this system, different to Swiss-type claims: 'substance X for use in a method for treating medical condition Y.'

Contradictions have been resolved in the legal grounds of the EPC. However, the debate seems to continue in Turkish Law, where no regulations (for or against) address protection of second (or subsequent) use. In our opinion, since it was not expressly prohibited, second medical use can also be protected by Turkish Patent Law with broad interpretation of novelty [6]. If novelty is narrowly interpreted, the conclusion results that since the substance or compound is previously disclosed, the invention regarding the second medical use cannot be deemed novel and, therefore, the second or subsequent medical use cannot be protected. Yet, the new use of a known substance or compound can be interpreted as novel according to the Turkish Patent Law.

As to the practice of the Turkish Patent Institute, it is known that patent protection is granted for patent applications through PCT and also for the national applications. In this case, whether the Turkish Courts invalidate second medical use patents depends on their interpretation of novelty. However, there is no established practice.

As to the status of the previously granted EP patents during the period in which EPC 1973 was in force, there has been a relatively recent decision [7], which did not acknowledge their validity. An EP patent granted prior to EPC 2000 was found null and void by first Intellectual and Industrial Rights Civil Court of Istanbul. In the dispute, the plaintiff filed an infringement action based on its patent, which was granted in 2005 (before EPC 2000 was in force in Turkey) and disclosed a new dosage regime. The defendant filed a counteraction and requested invalidation of the plaintiff's patent on the basis that it does not meet the patentability criteria. The first instance court ruled that the subject of the patent was a 'treatment method' and, therefore, should not have been registered in the first place, without examining the novelty or inventive step. The court also noted that EBA decisions were not binding on Turkish Courts. Therefore, the understanding of the EBA decision numbered G5/83 of the Swiss-type claims, was not adapted by the Turkish court. The decision was appealed, and the Court of Appeal reversed the first instance court's decision. It noted that the general

patentability criteria should be applied considering the lack of any provisions in Turkish Law allowing or prohibiting the second medical use claims. Accordingly, it ruled that the novelty and inventive step criteria should have been examined by an expert committee. If the experts interpret the novelty criteria broadly and accept the new dosage regime set forth by the subject patent involves novelty and an inventive step, a precedent for the second medical use patents may be established once these proceedings are finalized.

However, currently no such precedent exists in Turkey, which causes legal insecurity for second medical patent holders. Therefore, the need for a legal provision granting protection for second and subsequent medical use for the harmonization of Turkish Law with EPC 2000 continues. Such a provision will end the legal insecurity and vagueness for second medical use patents, whether they are national, through PCT or granted prior to EPC 2000. In practice, although it is not settled, the Turkish Patent Institute should accept the EPO's approach to data developed after the filing date, as long as it complies with the current patent examination procedure.

Although the problems caused by the lack of any provisions regarding the second and subsequent uses

are raised by the jurists, patent holders and nongovernmental organizations, the law makers seem to be remaining silent on the topic: a new draft industrial rights law has been published, yet no article that clearly allows second or subsequent uses can be observed. Now, the draft law is open for comment and can be examined on the Turkish Patent Institute. However, the draft may be amended by various parliamentary subcommissions, which may result with the specific regulations on second medical use. Even if no regulations are provided, the current situation will continue with a more established practice both from the courts and Turkish Patent Institute and a modern understanding of novelty, according to which second or subsequent uses are interpreted as novel.

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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