



## PROTECTION OF SECOND MEDICAL USE PATENTS IN TURKEY

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### ➤ Introduction

It is commonly known that pharmaceutical patents cover the substance or the composition itself (*molecule patents*) and the use of this substance or composition in the treatment of a disease (*indication patents*).

In pharmaceutical patents, **the new and non-obvious use** of a known substance or composition for the manufacture of a medicament in the treatment of a specific disease is called as second or further medical use patents. The simplest example that can be mentioned for the second medical use patents is the patenting of an invention when a medicament with an active substance X known to be effective in the treatment of hypertension is also found to be effective in the treatment of common cold upon the further researches conducted.

### 1- Status of Second Medical Use in Turkey

In accordance with Transitional Article 4 of Decree Law No. 551 on the Protection of Patents (Decree Law No. 551), the protection pertaining to pharmaceutical products within the scope of this Decree Law commenced on January 1, 1999.

On the other hand Turkey signed the 1973 dated European Patent Convention (EPC 1973) on October 5, 1973, which provided protection for pharmaceutical patents. Although Turkey was one of the first states that signed the EPC 1973, this convention entered into force much later upon the publication of the law for accession to the convention and its annexes in the Official Gazette dated July 12, 2000.<sup>1</sup>

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<sup>1</sup> Official Gazette No. 24107 dated July 2, 2000:

<http://www.resmigazete.gov.tr/main.aspx?home=http://www.resmigazete.gov.tr/eskiler/2000/07/20000712m1.htm&main=http://www.resmigazete.gov.tr/eskiler/2000/07/20000712m1.htm>

The act revising EPC 1973 was signed as a result of the diplomatic conference held in November 2000.<sup>2</sup> This revision act is called **EPC 2000**. Turkey attended this diplomatic conference and signed the Revision Act. EPC 2000 which came into force on December 13, 2007; 2 years after the 15<sup>th</sup> contracting state deposited its instrument of ratification to the German Government.

Article 54/5 added to the convention by the EPC 2000 revision, explicitly states that specific use in any method referred to in Art. 53(c) provided that such use is not comprised in the state of the art, is patentable. According to this provision the use of a prior art substance and composition in the treatment of a new disease has become possible.

Despite the lack of a provision stating explicitly the patentability of second medical use patents in EPC 1973; it has been decided that the use of a known substance or composition for the manufacture of a medicament for a specific new and inventive therapeutic application is patentable by the **G5/83** decision of the EPO Enlarged Board of Appeal.<sup>3</sup>

There have been opinions claiming that the G5/83 decision of the Enlarged Board of Appeal is not binding for the contracting states of the EPC and that the second medical use patents granted before December 13, 2007 - i.e before EPC 2000 came into force - are invalid.<sup>4</sup>

**Contrary to the mentioned opinions, the authors of this article believe that, as far as Turkey is concerned, the decisions and opinions of the Enlarged Board of Appeal are the inseparable parts of the EPC 1973 because the Turkish Parliament acknowledged the developments with regard to the European Patent Convention since 1973 and approved the accession to the EPC 1973 on January 29, 2000 by ratifying it without any reservations. EPC 1973 and the decisions of the Enlarged Board of Appeal have been published together, in their entirety, in the Official Gazette. The fact that the Parliament acknowledged and voted the EPC 1973 together with the decisions of the Enlarged Board of Appeal without reservations; renders unquestionable the will of the Parliament to afford protection to patents covering second and further medical use on the basis of the international legislation of which Turkey is signatory and which has thus become national rule by Act of Parliament.**

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<sup>2</sup> ACT REVISING THE CONVENTION ON THE GRANT OF EUROPEAN PATENTS:  
[http://documents.epo.org/projects/babylon/eponet.nsf/0/879B3BBE83D923B0C12572AE004FE772/\\$File/act\\_revising\\_epc\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/879B3BBE83D923B0C12572AE004FE772/$File/act_revising_epc_en.pdf)

<sup>3</sup> European Patent Office Official Journal, 1985, p. 060: G1/83 German, G5/83 English, G6/83 French  
[http://documents.epo.org/projects/babylon/eponet.nsf/0/5891FCEDA0C96A07C12572C8006C5110/\\$File/g830001.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/5891FCEDA0C96A07C12572C8006C5110/$File/g830001.pdf)

<sup>4</sup> Hazal Zengingül, Ankara 2012, Fikri Mülkiyet Hukuku Yıllığı 2011, İkinci Tıbbi Kullanım Patentleri (Second Medical Use Patents), 447

Av. Ece Sarıca, Nisan 2015, İstanbul Barosu Dergisi Mart – Nisan 2015, Türkiye’de İkinci Tıbbi Kullanımın Patentlenmesi ve Korunması (Patenting and Protection of Second Medical Use in Turkey), 392

## 2- Evaluation of Second Medical Use Patents According to Decree Law No. 551 on the Protection of Patents:

Decree Law No.551 remains silent since second medical use patents are not accepted as "patentable" or "non-patentable". Neither there is a provision stating that second medical use patents are not subject to protection nor there is a distinction between first and second medical use patents in the Decree Law No. 551. Hence, in its practices, the Turkish Patent Institute grants second medical use patents provided that they meet the patentability criteria.

## 3- Evaluation of Second Medical Use Patents According to the TRIPs Agreement:

TRIPs does not indicate any prohibition for the protection of second medical use patents.

## 4- Evaluation of Second Medical Use Patents According to EPC 1973:

There is no provision in EPC 1973 that restricts patentability of inventions on second medical use.

According to Article **52 (1)** of EPC 1973 titled “**Patentable Inventions**” “*European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.*”

Paragraph 2 of the same article states that “the following in particular shall not be regarded as inventions:

“(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

- (a) discoveries, scientific theories and mathematical methods;(b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4)\* Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

**Ref: Art. 54, 56, 57, 100, 138**

\*See decisions of the Enlarged Board of Appeal [G 1/83](#), [G 5/83](#), [G 6/83](#), [G 1/98](#), [G 1/03](#), [G 2/03](#)(Annex I)..”

As understood from Article **52/4** above, this provision shall not be applied to methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. **This provision excludes the medical use of a substance or composition from non-patentable subject matters. There are no distinctions between first and second medical use patents.**

In **Article 53** titled “**Exceptions to patentability**” of **EPC 1973** the subjects which shall not be patented are listed as follows:

#### “**Article 53- Exceptions to patentability**”

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

**Ref: Art. 100, 138, 167\*”**

As shall be understood in the provisions of the article above, second medical use and medical use in general have not been listed among subjects that shall not be patented. **Thus, there are no provisions stating that inventions subject to second medical use will not be protected in the scope of EPC 1973.**

**Article 54** of EPC 1973 titled “**Novelty**” reads:

#### “**Article 54 - Novelty**”

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.

(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

**Ref: Art. 52, 55, 56, 80, 85, 89, 100, 138, 158, Rules 27, 44, 87**

\* See decisions/opinions of the Enlarged Board of Appeal G 1/83, G 5/83, G 6/83, G 2/88, G 6/88, G 1/92, G 3/93 (Annex I).”

Paragraph 5 of this article explicitly accepts the use of a known substance or composition in a therapeutic application on the condition that it is new and inventive.

**The G5/83 decision of the EPO Enlarged Board of Appeal is referenced in articles 52 and 54 of the EPC 1973.**

The G5/83 decision is listed in the “**Index of decisions and opinions of the Enlarged Board of Appeal published in the Official Journal of the EPO**”. The index of decisions and opinions is published as Annex-I of the EPC 1973 in the Official Gazette no. 24107 dated July 12, 2000. The index, relates the decision and opinion of the Enlarged Board of Appeal to the articles of the EPC 1973. The respective part of the index of decisions is quoted below:

<b>Index of Decisions and Opinions of the Enlarged Board of Appeal Published in the Official Journal of the EPO</b>		
<b>Case number, date, publication</b>	<b>Title/Subject</b>	<b>Article no., Rule no.</b>
G 5/83 05.12.1984 European Patent Office Official Journal 1985, 64	“Second medical indication/EISAI” Interpretation of EPC/Vienna Convention – use claims regarding treatment	Art. 52(1), 52(4), 54(5), 57 Articles 31, 32 of the Vienna Convention

The G5/83 decision of the EPO Enlarged Board of Appeal explains in detail how to interpret Articles 52 (4) and 54 (5) of the EPC 1973 and that a claim for the use of a known substance or composition in the manufacture of a medicament for a new therapeutic application is patentable.

The Turkish Parliament accepted the accession of Turkey to the EPC 1973 by the Act dated January 27, 2000 and No.: 4504. EPC 1973 entered into force upon its publication in the Official Gazette no. 24107 dated July 12, 2000.

It is obvious that the lawmaker namely the Parliament by the Act January 27, 2000 dates accepts the interpretation of the articles of EPC 1973 with the decisions and opinions of the Enlarged Board of Appeal which are published as inseparable annexes to the convention in the Turkish Official Gazette<sup>5</sup>. The aim of the lawmaker is that the interpretation of Articles 52 and 54 should be made in the light of the G5/83 decision which is an obvious annex of the Agreement to which Turkey is a party.

A contrary approach to EPC 1973, will be against the national legislation of Turkey and the provisions of the international conventions entered into force in Turkey and against Article 90/5<sup>6</sup> of the Constitution and Article 4<sup>7</sup> of the Decree Law No. 551.

## ➤ Conclusion

As far as Turkey is concerned, the decisions and opinions of the Enlarged Board of Appeal are the inseparable parts of the EPC 1973 because the Turkish lawmaker observed the developments with regard to the European Patent Convention since 1973 approved and voted the accession to the EPC 1973 on January 29, 2000 by ratifying it without any reservations and publishing it in the Official Gazette in their entirety together with the Enlarged Board of Appeal decisions. Therefore second medical use patents should be protected in Turkey.

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<sup>5</sup> See footnote 1.

<sup>6</sup> Article **90/5 of the 1982 Constitution of the Republic of Turkey**: International agreements duly put into effect have the force of law. No appeal to the Constitutional Court shall be made with regard to these agreements, on the grounds that they are unconstitutional. In the case of a conflict between international agreements, duly put into effect, concerning fundamental rights and freedoms and the laws due to differences in provisions on the same matter, the provisions of international agreements shall prevail.

<sup>7</sup> **Article 4 of Decree Law No. 551**: Where International Agreements having entered into force according to the laws of the Republic of Turkey, contain provisions which are preferential/more favorable to those of this present Decree-Law, the persons referred to in Article 2 may request to benefit from such preferential/more favorable provisions.