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Review on terms of extension of patents for pharmaceutical and agrochemical inventions in Kazakhstan



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In this review we collected and systematized the current data on the extension of the validity period of patents for inventions in the pharmaceutical area in the countries of Central Asia and Caucasus.

The data provided in the schedules below is related to the main Central Asian Republics and Caucasus , but on your demand we can provide information for other CIS countries as well.

The team would like to express its special gratitude to colleagues-respondents from Azerbaijan, Armenia, Georgia, Uzbekistan, Tajikistan, Turkmenistan and Kyrgyzstan who participated in the project and provided valuable peer review comments during the consultation and data review period.

We hope that provided information will help you in strategic decision making on registration of pharmaceuticals, as well as in applying for a patent for invention in one of the mentioned countries.

The information is actual as for August 2017.

REPUBLIC OF KAZAKHSTAN

- Patent extension option (yes / no), term of extension of patent

validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

The Patent Law of the Republic of Kazakhstan №427 dated 16 July 1999 (with amendments and additions as of 31.10.2015).

- Normative acts regulating possibility to extend patent validity period

The Rules on extension of validity of patent for invention (Order №361 of the Ministry of Justice of the Republic of Kazakhstan dated 30.06.2015).

- Objects, for which the extension of patent validity period is allowed

Pharmaceuticals (substances, compositions), pesticide (agricultural chemical).

- Calculation of term of extension of the patent validity period

The term is extended by the time elapsed from the filing date of the patent for the invention before the date of the first authorization to use the invention with the deduction of 5 years.

- Term of submitting of application for patent extension

During the validity period of patent not exceeding 6 months from the date of obtaining the first authorization to use of the invention or the date of granting the patent depending on whether date expires first. If the first authorization is granted before 07.07.2015, the application should be filed during the patent validity period, but not later than 2 months before its expiration.

- Required list of documents and information data for patent extension

1) Copy of document on the first registration of a medical product in the Republic of Kazakhstan, (i.e. registration certificate that allows to use product as an invention); 2) Document containing information that allows the product to be classified as an independent claim (for example, extract

from the Normative Document (ND), Instructions for use, etc.); 3) Explanations, from which it follows that indicated pharmaceutical product, pesticide or agricultural chemical is characterized by appropriate independent claim; 4) Power of Attorney.

- Terms and procedure for considering an application for patent extension

Consideration in the expert organization is carried out within 1 month from the date of receipt of the application.

- Official fees for extension - US \$ 28
- Patent attorney's fees, US \$ 250
- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

Yes, it is possible, but without right to sale product before patent expiration. (Art.11 of the Order №735 of the Health Ministry of the Republic of Kazakhstan dated 18.11.2009 (with amendments as of 28.06.2016).

- Data Exclusivity regulations

There are some regulations in the legislation related to data exclusivity. It is impossible to use confidential data (such as pre-clinical, clinical trials data) of dossiers for original (new) products during 6 years since its first Marketing Authorization (Art. 71-19 of the Code of Republic of Kazakhstan "On Public Health and Health Care System").

REPUBLIC OF AZERBAIJAN

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

The Azerbaijani Law №312 "About Patent" dated 25.07.1997 (with amendments and additions dated 20.10.2009).

- Normative acts regulating possibility to extend patent validity

period

The Rules for extension the validity of a patent for invention (Decision №63 of the Cabinet Council of Azerbaijan dated 12.04.2010).

- Objects, for which the extension of patent validity period is allowed

Pharmacology and agrochemistry.

- Calculation of term of extension of the patent validity period

The term is extended by the time elapsed from the filing date of the patent for the invention before the date of the first authorization to use the invention but for no more than for 5 years.

- Term of submitting of application for patent extension

The application is filed during the patent validity period, but not later than 2 months before its expiration.

- Required list of documents and information data for patent extension

1) Copy of document on the first registration of a medical product in Azerbaijan (i.e. registration certificate that allows to use product as an invention); 2) Document containing information that allows the product to be classified as an independent claim (for example, extract from the Normative Document (ND), Instructions for use, etc.); 3) Explanations, from which it follows that indicated pharmaceutical product, pesticide or agricultural chemical is characterized by appropriate independent claim; 4) Power of Attorney.

- Terms and procedure for considering an application for patent extension

Consideration in the expert organization within 1 month from the date of receipt of the application.

- Official fees for extension - No
- Patent attorney's fees, US \$ 500
- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

There is no information.

- Data Exclusivity regulations

There is no information.

REPUBLIC OF ARMENIA

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

The Law of the Republic of Armenia "On Inventions, Utility Models and Industrial Designs" dated 01.01.2009.

- Normative acts regulating possibility to extend patent validity period

Not applicable.

- Objects, for which the extension of patent validity period is allowed

a) For all objects under force majeure conditions; b) For pharmaceuticals, substances, compositions, methods of its preparation (synthesis etc.).

- Calculation of term of extension of the patent validity period

Term of extension period is equal to the difference between the date of filing the application and the date of issue of the permission of the authorized body for introduction of object into economic turnover in the territory of Armenia, but not more than 5 years.

- Term of submitting of application for patent extension

An application for extension of patent validity period shall be filed within 6 months from the date of granting of such permission.

- Required list of documents and information data for patent extension

1) Permission of the authorized body for introduction of object into economic turnover in the territory of Armenia; 2) Power of attorney.

- Terms and procedure for considering an application for patent extension

Not indicated.

- Official fees for extension - US \$ 155
- Patent attorney's fees, US \$ 500
- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

It is possible if in addition to the active substance, there are other components for a particular type of pharmaceutical.

- Data Exclusivity regulations

Not applicable.

REPUBLIC OF GEORGIA

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

The Patent Law of Georgia №1791 dated 05.07.1999 (with amendments and additions dated 04.05.2010; 24.05.2010; 26.10.2010).

- Normative acts regulating possibility to extend patent validity period

The Rules for extension the validity of a patent on invention (Order №185 of Government of Georgia dated 03.07.2010).

- Objects, for which the extension of patent validity period is allowed

Pharmaceuticals (substances, compositions).

- Calculation of term of extension of the patent validity period

The term is extended by the time elapsed from the filing date of the patent for the invention before the date of the first authorization to use the invention with the deduction of 5 years.

- Term of submitting of application for patent extension

During patent validity period not exceeding 6 months from the date of obtaining the first permission for use of the invention or the date of granting the patent depending on whether date expires first.

- Required list of documents and information data for patent extension

Power of Attorney.

- Terms and procedure for considering an application for patent extension

Consideration in the expert organization within 1 month from the date of receipt of the application.

- Official fees for extension - US \$ 84
- Patent attorney's fees, US \$ 500
- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

Yes. It is possible (without any limitations).

- Data Exclusivity regulations

Yes. It is possible.

REPUBLIC OF TAJIKISTAN

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period

is extended

Republic of Tajikistan's Law №17 dated 28.02.2004 (with amendments and additions as of 14.11.2016).

- Normative acts regulating possibility to extend patent validity period

The Rules for extension of the validity of a patent for invention still have not been developed.

- Objects, for which the extension of patent validity period is allowed

Pharmaceuticals (substances, compositions), pesticides and agrochemicals.

- Calculation of term of extension of the patent validity period

The term is extended by the time elapsed from the filing date of the patent for the invention before the date of the first authorization to use the invention, minus 4 years, but not more than 5 years.

- Term of submitting of application for patent extension

The term of patent for invention for medicinal product or pesticide and agrochemicals where duly obtained registration certificate is required, is extended by Patent Office at the request of the holder of the title of protection if, from the date of filing the application for protection before the receipt of this certificate has passed more than 4 years.

- Required list of documents and information data for patent extension

The list of documents and information that should be attached to the application for extension is not stipulated.

- Terms and procedure for considering an application for patent extension

Terms and procedure for considering an application for patent extension is not indicated.

- Official fees for extension - Official fees for extension are not indicated.
- Patent attorney's fees, US \$ 500

- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

Information is not indicated.

- Data Exclusivity regulations

Yes. Information on medicines and medical goods that have passed state registration, at the request of legal entities or individuals carrying out state registration of these funds, may be classified as confidential if: - medicinal product or its composition is not known to persons engaged in similar activities, and the manufacturer must keep it confidential; - Confidentiality stems from its commercial significance. (Law No.861 of RT "On medicines and pharmaceutical activities" dated 03.07.2012). Term is not specified.

REPUBLIC OF TURKMENISTAN

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

Law of Turkmenistan "On Inventions and Industrial Designs" of 23.10.2008 (as amended by the Law of Turkmenistan dated 22.06.2013).

- Normative acts regulating possibility to extend patent validity period

There are no normative acts regulating the possibility to extend patent validity period.

- Objects, for which the extension of patent validity period is allowed

Pharmaceuticals, pesticides or agrochemicals.

- Calculation of term of extension of the patent validity period

The term of extension of the patent validity period is not indicated.

- Term of submitting of application for patent extension

Application can be submitted till expiration of a patent validity period.

- Required list of documents and information data for patent extension

Required list of documents and information data for patent extension is not indicated.

- Terms and procedure for considering an application for patent extension

Terms and procedure for considering an application for patent extension is not indicated.

- Official fees for extension - US \$ 56
- Patent attorney's fees, US \$ 500
- Is it possible to submit and obtain a Marketing Authorization of pharmaceutical before expiration of patent on original product?

There is no information on Marketing Authorization of pharmaceutical before expiration of patent for original product.

- Data Exclusivity regulations

There is no information on Data Exclusivity regulations.

REPUBLIC OF UZBEKISTAN

- Patent extension option (yes / no), term of extension of patent validity period

Yes, it may be extended at the request of the patent owner but not more than 5 years.

- Legislative act, in accordance with which the patent validity period is extended

The Law of the Republic of Uzbekistan № 1062-XII «On inventions, utility models and industrial designs» dated 06.05.1994 (with amendments in accordance with the Law of the Republic of Uzbekistan №ZRU-312 dated 26.12.2011).

- Normative acts regulating possibility to extend patent validity period

The Rules on extension of validity of patent for invention for utility model, industrial design and invention refer to pharmaceutical or pesticide (Order №1678 of Minister of Justice of Republic of Uzbekistan dated 05.05.2007) with amendments №1678-1 dated 30.09.2011.

- Objects, for which the extension of patent validity period is allowed

Pharmaceuticals or pesticides.

- Calculation of term of extension of the patent validity period

The term of patent for invention for medicinal product or pesticide where duly obtained registration certificate is required, is extended by the time elapsed from the filing date of the patent before the date of granting the first authorization to use the invention.

- Term of submitting of application for patent extension

During the validity period of patent not exceeding 6 months from the date of obtaining the first permission for use of the invention or the date of granting the patent depending on whether date expires first.

- Required list of documents and information data for patent extension

1) Copy of document on the first registration of a medical product in the Republic of Kazakhstan, (i.e. registration certificate that allows to use product as an invention); 2) Document containing information that allows the product to be classified as an independent claim (for example, extract from the Normative Document (ND), Instructions for use, etc.); 3) Explanations, from which it follows that indicated pharmaceutical product, pesticide or agricultural chemical is characterized by appropriate independent claim; 4) Power of Attorney.

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There are some regulations in the legislation related to data exclusivity. It is impossible to use confidential data (such as pre-clinical, clinical trials data) of dossiers for original (new) products during 6 years since its first Marketing Authorization (Art. 71-19 of the Code of Republic of Kazakhstan "On Public Health and Health Care System").