

## PATENT LAW

### UKRAINE

#### Implications of Missing the Newly Introduced Deadline for Supplementary Protection Application

Convention for the Protection of Human Rights and Fundamental Freedoms, Art. 6; Law of Ukraine ‘On Protection of Rights to Inventions and Utility Models’, Art. 27-1 – **ALEKENZA**

##### Headnotes by the Editorial Office

1. After new provisions on supplementary protection of rights in inventions came into force, the deadline for submitting an application for supplementary protection was effectively shortened from 19.5 years to 6 months. In the present case, the patent holder, whose right to supplementary protection arose prior to the amendments, failed to meet the newly introduced deadline.

2. This Court establishes that the amendments made to the legislation should not deprive a patent holder of the opportunity to exercise the right to supplementary protection.

3. The decisive factor is not the event of submitting an application but the moment when the patent holder’s right to supplementary protection arose.

4. Based on Art. 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms (the Convention) and the criteria of ‘a reasonable time period’ defined by the practice of the European Court of Human Rights in applying Art. 6 of the Convention, this Court concludes that the patent holder applied for supplementary protection within a time frame that falls under the concept of ‘a reasonable time period’.

#### Supreme Court, decision of 14 December 2023 – 115821573

[...]

##### 1. Summary of the claims

1.1. Chugai Seiyaku Kabushiki Kaisha (hereinafter ‘the Company’, the Plaintiff in these proceedings) filed a lawsuit against the state enterprise ‘Ukrainian Intellectual Property Institute’ (hereinafter ‘Ukrpatent’; according to the court order<sup>1</sup> of the Commercial Court of Kyiv dated 29 November 2022, its successor, the state organization

‘Ukrainian National Office for Intellectual Property and Innovations’, hereinafter ‘UANIPPIO’, the Defendant in these proceedings) in which it requests the court:

- to declare invalid and annul the refusal of Ukrpatent dated 23 November 2020 No. 22221/PIA/20 to grant supplementary protection to the rights to the invention under Ukraine patent No. 107796 [hereinafter referred to as ‘the Letter of Refusal’];
- to order Ukrpatent to implement the state registration of supplementary protection for Ukraine patent No. 107796 for the invention according to the Company’s application dated 6 November 2020 by entering the relevant information into the Ukrainian State Register of Inventions, to publish it in the official electronic bulletin of the UANIPPIO<sup>2</sup> and to issue a supplementary protection certificate.

1.2. The claims are based on the fact that the Plaintiff, as the owner of the Ukraine patent No. 107796, has a statutory right to extend the term of validity of the economic intellectual property rights to the invention under the said patent.

##### 2. Summary of the judgment of the court of first instance and the ruling of the court of appeals

2.1. The case has been heard by commercial courts on several occasions.

2.2. By judgment of the Commercial Court of Kyiv dated 28 October 2021, which was left unchanged by the ruling of the Northern Commercial Court of Appeals dated 20 June 2022, the claim was denied.

2.3. By ruling of the Supreme Court dated 4 August 2022, Chugai Seiyaku Kabushiki Kaisha’s appeal on the law was partially upheld, the judgment of the Commercial Court of Kyiv dated 28 October 2021 and the ruling of the Northern Commercial Court of Appeals dated 20 June 2022 in case No. 910/8295/21 were annulled, and the case was returned for rehearing to the Commercial Court of Kyiv.

2.4. By judgment of the Commercial Court of Kyiv dated 7 February 2023, which was left unchanged by

details. No official translation has been established so far. For the purpose of this translation, the following terms are used: *judgment* [рішення] for decisions of a court of first instance; *ruling* [постанова] for decisions of the second instance and cassation. The other two types are *court order* [ухвала] and *court resolution* [судовий наказ].

<sup>2</sup> Translator’s note: The original refers to ‘the official electronic bulletin of the NIPO’. The NIPO stands for the National Intellectual Property Office, whose functions are performed by the UANIPPIO. To enhance readability, this translation replaces ‘NIPO’ with ‘UANIPPIO’ wherever ‘NIPO’ is mentioned in the original.

<sup>1</sup> Translator’s note: According to the Civil Procedure Code of Ukraine (art 258), as well as the Commercial Procedure Code of Ukraine (art 232) four types [ухвала, рішення, постанова, судовий наказ] of judicial decisions are distinguished according to the court instance and case

the ruling of the Northern Commercial Court of Appeals dated 30 August 2023, the claim was upheld in full.

2.5. The Letter of Refusal to grant supplementary protection rights for the invention under Ukraine patent No. 107796 was declared invalid and annulled.

2.6. The UANIPIO was ordered to implement the state registration of supplementary protection for Ukraine patent No. 107796 for the invention according to Chugai Seiyaku Kabushiki Kaisha's application dated 6 November 2020 by entering relevant information into the Ukrainian State Register of Inventions, to publish it in the official electronic bulletin of the UANIPIO and to issue a supplementary protection certificate.

### 3. Summary of the claims on appeal on the law

3.1. The UANIPIO contested the decisions of the previous instances and filed an appeal on the law to the Supreme Court in which, referring to violations of the rules of procedural law and the incorrect application of the rules of substantive law by the courts, it requests the annulment of the judgment and ruling of the previous instances and the adoption of a new judgment dismissing the claim in full.

### Arguments of the parties

#### 4. Appellant's arguments

4.1. The appeal on the law is filed based on para. 1, part one of Art. 287 Commercial Procedure Code of Ukraine (hereinafter referred to as the CPC of Ukraine), taking into account the requirements of para. 5, part two of Art. 290 and para. 3, part two of Art. 287 CPC of Ukraine.

4.2. In particular, the UANIPIO, in justification of the grounds for the appeal on the law provided by para. 3, part two of Art. 287 CPC of Ukraine, points out the absence of the Supreme Court's conclusion regarding the application of Art. 27-1 Law of Ukraine 'On Protection of Rights to Inventions and Utility Models' (hereinafter Law No. 3687-XII [or 'the Patent Law']) as amended by the Law dated 21 July 2020 No. 816-IX [hereinafter referred to as 'the Amending Law'], which came into force on 16 August 2020, namely: the applicability of the terms for filing an application for supplementary protection of rights to inventions for holders of patents, the state registration of which was carried out before the new edition of the said Patent Law came into force on 16 August 2020.

4.3. In its appeal on the law, the Defendant also draws attention to the violations of procedural and substantive law rules by the first and second instance courts, which applied a law that should not have been applied due to an incorrect legal qualification of the legal relations, and the first instance court's intervention in the discretionary powers of the UANIPIO when upholding the claim for mandatory action.

#### 5. Arguments of other parties to the action

5.1. In the statement of defense to the appeal on the law, the Plaintiff contests the Defendant's arguments as being unfounded and requests that the challenged decisions be upheld, and that the appeal on the law be denied.

5.2. The Supreme Court received additional explanations regarding certain issues from the Plaintiff on 13 December 2023.

### 6. Brief statement of the facts of the case established by the first and second instance courts

6.1. Chugai Seiyaku Kabushiki Kaisha is the owner of Ukraine patent dated 25 February 2015 No. 107796 for the invention 'tetracyclic compounds' (registered based on application dated 9 June 2010 No. a201200237, as published on 25 February 2015 in the official bulletin 'Industrial Property' No. 4). The Ukraine patent was issued for 20 years.

6.2. In turn, as the Plaintiff points out, on 2 November 2018, F. Hoffmann-La Roche Ltd received Ukraine registration certificate No. UA /16997/01/01 for the medicinal product 'ALEKENZA' hard capsules 150 mg (registered in Ukraine for 5 years), issued on the basis of the Order of the Ministry of Health of Ukraine dated 31 October 2018 No. 1979.

6.3. The registration certificate in Ukraine is valid until 31 October 2023.

6.4. As follows from the case materials, namely the license, the Plaintiff company as the owner of Ukraine patent No. 107796 agreed to grant F. Hoffmann-La Roche Ltd permission to use the said invention under Ukraine patent No. 107796 for the manufacture, offering for sale, sale, import, and other placing on the civil market, and storage for these purposes of the medicinal product 'ALEKENZA'.

6.5. This license is valid until the end of the term of Ukraine patent No. 107796 and applies to relations that existed before it was issued, namely in the period from the day following the date of state registration of the invention, i.e., from 26 February 2015 (para. 3.1. section 3 of the license).

6.6. The Plaintiff states that 'ALEKENZA' is a medicinal product with the active substance alectinib, indicated as a first-line treatment for adult patients with ALK-positive advanced non-small cell lung cancer. Alectinib is the International Nonproprietary Name (INN), i.e., the internationally recognized official name of the corresponding compound.

6.7. The Plaintiff also states that the compound with the aforementioned name (9-ethyl-6,6-dimethyl-8-(4-morpholin-4-yl)piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile) is directly listed in section 6 of the invention formula under the patent – the eleventh in the list of compounds in this section.

6.8. Therefore, as the Plaintiff points out, the application of the inventions under the patent was impossible until the state registration in Ukraine of the relevant medicinal product. The state registration of the medicinal product 'ALEKENZA' on 2 November 2018 made it possible to apply the Plaintiff's inventions under patent No. 107796.

6.9. Taking the above into account, the Plaintiff filed an application to Ukrpatent dated 6 November 2020, w/o number, requesting the extension of the term of the economic intellectual property rights to patent No. 107796 and the issue of a supplementary protection certificate. The Plaintiff argued that since the application of inventions

under Patent No. 107796 was impossible before the state registration in Ukraine of a medicinal product based on a new compound or its salt or solvate according to sections 1-6 of the invention formula, which required state registration of such a medicinal product, it was the state registration on 2 November 2018 of the medicinal product 'ALEKENZA', which contains alectinib in the form of this compound's salt (alectinib hydrochloride), that first enabled the use of inventions under patent No. 107796. Meanwhile, more than five years passed between the date of patent application No. 107796 and the date of issue of the registration certificate for the medicinal product 'ALEKENZA'. The Company therefore requested Ukrpatent to issue a supplementary protection certificate for patent No. 107796 for three years, four months, and twenty-four days for such inventions, in the light of the limitations provided by para. 3, part one of Art. 27-1 of the Patent Law:

6.10. The formula of the invention for the supplementary protection certificate:

1) 9-ethyl-6,6-dimethyl-8-(4-morpholin-4-ylpiperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile or its salt or solvate.

2) A medicinal product containing as an active ingredient the compound under section 1 or its salt or solvate.

3) An anaplastic lymphoma kinase (ALK) inhibitor containing as an active ingredient the compound under section 1 or its salt or solvate.

4) A pharmaceutical drug for the prevention or treatment of cancer or cancer metastases containing as an active ingredient the compound under section 1 or its salt or solvate.

5) A pharmaceutical composition containing the compound under section 1 or its salt or solvate and a pharmaceutically acceptable carrier(s).

6.11. However, in the Letter of Refusal, Ukrpatent, following the review of the Plaintiff's application for the extension of the term of the economic intellectual property rights to patent No. 107796 and the issue of a supplementary protection certificate, stated that according to the data of the Ukrainian State Register of Inventions, the date of publication of the information about the state registration of the invention is the date of publication of the information about the issue of the patent, namely 25 February 2015, with the date of issue of the registration certificate being 2 November 2018. However, the Plaintiff's application was received on 13 November 2020, i.e., later than the deadline established by para. 1 of part three of Art. 27-1 of the Patent Law, for which reason the Plaintiff's application cannot be granted.

6.12. In justification of its claims, the Plaintiff states that the challenged decisions are illegal and unsubstantiated and violate the Plaintiff's intellectual property rights related to obtaining supplementary protection for inventions under Ukraine patent No. 107796. The Plaintiff therefore requests the court to declare invalid and annul the Letter of Refusal to grant supplementary protection of rights to the invention under Ukraine patent No. 107796 and to order the Defendant to implement the state registration of supplementary protection for Ukraine patent No. 107796 for the invention according to the Plaintiff's application dated 6 November 2020 by entering the

relevant information into the Ukrainian State Register of Inventions, to publish it in the official electronic bulletin of the UANIPIO and to issue a supplementary protection certificate.

6.13. The Defendant contests the claims and points out that the Plaintiff's application was received later than the deadline established by para. 1 of part one<sup>3</sup> of Art. 27-1 of the Patent Law, for which reason the Plaintiff's application could not be granted, and thus the Ukrainian Intellectual Property Institute acted in accordance with the current version of the Patent Law.

7. [...]

## 8. The procedure and scope of case review by the cassation court

8.1. According to part one of Art. 300 of the CPC of Ukraine, when reviewing court decisions on appeal on the law, the cassation court examines the arguments and requirements of the appeal on the law that formed the basis for opening the appeal proceedings and the established factual circumstances of the case to determine the correctness of the application of substantive and procedural rules by the court of first or second instance.

8.2. The cassation court does not have the right to establish or consider as proven facts that were not established or were dismissed in the judgment or ruling of the court, to decide on the authenticity of one or another piece of evidence, to decide on the superiority of some piece of evidence over others, to collect or consider new evidence or additionally check evidence (part two of Art. 300 of the CPC of Ukraine).

## Position of the Supreme Court

### 9. Sources of law. Assessment of the parties' arguments and the conclusions of the courts of previous instances

9.1. The Supreme Court, based on the circumstances of the case established by the previous instances, examined the arguments and requirements of the appeal on the law that formed the basis for the opening of the appeal proceedings, to determine the application of the substantive and procedural rules by the previous instances, and notes the following.

9.2. The court of first instance established that the Plaintiff filed to Ukrpatent an application dated 6 November 2020, w/o number, for the extension of the term of the economic intellectual property rights in patent No. 107796 and the issue of a supplementary protection certificate, requesting the Defendant to issue a supplementary protection certificate for patent No. 107796 for three years, four months, and 24 days, in the light of the limitations provided by para. 3 of part one of Art. 27-1 of the Patent Law.

9.3. However, by the Letter of Refusal, Ukrpatent, following the review of the Plaintiff's application for the

<sup>3</sup> Translator's note: The Law of Ukraine 'On Protection of Rights to Inventions and Utility Models' No 3687-XII establishes the said deadline in para 1 part three of art 27-1; therefore, it is probable that the original text of the ruling contains a typing error.

extension of the term of the economic intellectual property rights in patent No. 107796 and issue of a supplementary protection certificate, stated that according to the data of the Ukrainian State Register of Inventions, the date of publication of the information about the state registration of the invention is the date of publication of the information about the issue of the patent, namely 25 February 2015, with the date of issue of the registration certificate being 2 November 2018. However, the Plaintiff's application was received on 13 November 2020, i.e., later than the deadline established by para. 1 of part three of Art. 27-1 of the Patent Law, for which reason the Plaintiff's application cannot be granted.

9.4. The Plaintiff, as the owner of an invention patent, the object of which is a medicinal product ('ALEKENZA' under the registration certificate dated 2 November 2018, No. UA/16997/01/01), has the right to extend the term of the economic intellectual property rights in the patent. This right is provided by part four of Art. 6 of the Patent Law in the wording effective at the time of the grant of the patent and the registration of the medicinal product.

9.5. The procedure for submitting the application is determined by the Instruction on the Procedure for Extending the Term of a Patent for an Invention, the Object of Which is a Product Requiring Approval of a Competent Authority, approved by the Order of the Ministry of Education and Science of Ukraine of 13 May 2002 No. 298 (hereinafter 'the Instruction').

9.6. According to the provision of para. 1.5 of the Instruction, the fee for submitting the application must be paid and the application must be submitted to the State Service no later than 6 months before the end of the patent term.

9.7. Thus, according to part four of Art. 6 of the Patent Law (in the wording effective at the time of the grant of the patent and the registration of the medicinal product), the term of a patent for an invention, the object of which is a medicinal product, an animal protection product, a plant protection product etc., the use of which requires approval from the relevant competent authority, can be extended upon application by the owner of this patent for a term equal to the period between the date of the application for and the date of receipt of such approval, but not more than five years. A fee is paid for submitting the application. The procedure for submitting the application and extending the term of the patent in this case is determined by the central body of the executive power ensuring the formation of state policy in the field of intellectual property.

9.8. However, on 16 August 2020, Art. 27-1 of the Patent Law came into force under the Amending Law, which, among other things, provides that the holder of a patent for an invention, the object of which is an active pharmaceutical ingredient of a medicinal product, a process for obtaining a medicinal product, or a use of a medicinal product, an animal protection product, or a plant protection product, the introduction of which on the market in Ukraine is granted by the corresponding competent authority according to the legislation of Ukraine, has the right to extend the term of the economic intellectual property rights for such invention (supplementary protection), which is confirmed by a supplementary

protection certificate. The term of supplementary protection equals the period between the date of application to UANIPIO and the date the first permit is received by the patent holder from the competent authority, reduced by five years. The term of supplementary protection shall not exceed five years.

9.9. The revision of the current legislation of Ukraine in the field of protection of rights to inventions and utility models was driven by the necessity to ensure effective fulfilment of Ukraine's obligations under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part (hereinafter 'the Association Agreement').

9.10. The Amending Law, among other things, aimed at implementing the requirements of Arts. 219-223 of the Association Agreement.

9.11. The purpose of the adoption of the law was to ensure the fulfilment of Ukraine's obligations in the field of European integration in terms of harmonizing the requirements of the current legislation of Ukraine regarding the protection of rights to inventions and utility models with the law of the European Union.

9.12. According to Art. 6 of the Patent Law, the priority, authorship, and rights to an invention and utility model are certified by a patent.

9.13. According to Art. 465 of the Civil Code of Ukraine, the term of the exclusive economic intellectual property rights for an invention expires after twenty years counted from the date an application is filed for an invention in the manner prescribed by law. This term can be extended in the manner prescribed by law regarding an invention, the use of which requires special testing and official approval.

9.14. The right to extend the term of a patent for an invention has the same purpose both in the wording of the Law before and after 16 August 2020, namely to compensate the patent owner for a part of the effective term of the patent during which the invention under the patent could not actually be used because its use required state registration of a medicinal product, which takes a certain amount of time.

9.15. Therefore, according to the provisions of part three of Art. 465 of the Civil Code of Ukraine and the Patent Law, the total term of legal protection of an invention is 20 years with the possibility of an extension for a term not exceeding five years (with certain restrictions).

9.16. The supplementary term beyond the expected 20 years is intended to protect the interests of owners of inventions related to the pharmaceutical and agrochemical fields. This refers to supplementary protection certificates, which compensate the rights holder for the time that elapses between the filing of an application for an invention and the receipt of the permit to sell the patent-protected drug.

9.17. As the courts of previous instances established, the Plaintiff was granted the patent on 25 February 2015, and the use of inventions under the patent became possible after the state registration of the medicinal product 'ALEKENZA', which took place on 2 November 2018.

9.18. Thus, according to the provisions of Art. 27-1 of the Patent Law, the holder of a patent for an invention,

the object of which is an active pharmaceutical ingredient of a medicinal product, a process for obtaining a medicinal product, or use of a medicinal product, an animal protection product, or a plant protection product, the introduction of which onto the market in Ukraine is granted by the corresponding competent authority under the legislation of Ukraine, has the right to extend the term of the economic intellectual property rights for such invention (supplementary protection), which is confirmed by a supplementary protection certificate. The term of supplementary protection equals the period between the date of application to the Institution and the date when the first permit is received by the patent holder from the competent authority, reduced by five years. The term of supplementary protection shall not exceed five years.

9.19. However, Art. 27-1 of the Patent Law sets a specific timeframe within which an application can be made for supplementary protection – six months from the date of publication of information about the state registration of the invention or from the date of issue of the first permit by the corresponding competent authority (depending on which of these dates is later). Previously (before entry into effect of the Amending Law), this period was effectively 19.5 years – the application had to be submitted no later than six months before the expiry of the patent term.

9.20. The Law does not provide for a transitional period for the application of Art. 27-1. Nor do the Association Agreement provisions contain a specific mechanism for the realization of these rights.

9.21. Hence, the patent holders who had obtained the corresponding approval from the competent authority before 16 August 2020 but did not submit an application for the extension of the patent term are deprived of the opportunity to obtain supplementary protection, even though such right is provided by both the current wording of Amending Law as of 21 July 2020 and its previous wording.

9.22. The previous instance courts established that, based on the application dated 9 June 2010 No. a201200237, Chugai Seiyaku Kabushiki Kaisha is the owner of the Ukraine patent dated 25 February 2015 No. 107796 for the invention ‘tetracyclic compounds’. The Ukraine patent was issued for 20 years. On 2 November 2018, F. Hoffmann-La Roche Ltd obtained Ukraine registration certificate No. UA/16997/01/01 for the medicinal product ‘ALEKENZA’ hard capsules 150 mg (registered in Ukraine for five years) issued based on the Order of the Ministry of Health of Ukraine dated 31 October 2018 No. 1979. As evident from the license, the plaintiff, as the owner of Ukraine patent No. 107796, agreed to grant F. Hoffmann-La Roche Ltd permission to use the said invention under Ukraine patent No. 107796 for the manufacture, offering for sale, sale, import, and other introduction onto the civil market and storage for these purposes of the medicinal product ‘ALEKENZA’. This license is valid until the end of the term of Ukraine patent No. 107796 and applies to relations that had existed before its issue, namely from the day following the date of state registration of the invention, i.e., from 26 February 2015 (para. 3.1. section 3 of the License).

9.23. Thus, the Plaintiff’s patent and the medicinal product ‘ALEKENZA’ were registered in the manner

prescribed by Ukraine law before the Amending Law came into force on 16 August 2020, supplementing Section IV of the Patent Law with Art. 27-1 ‘Supplementary Protection of Rights to Inventions’ and deleting the provision of part four of Art. 6 of the Patent Law.

9.24. When the case was reconsidered, taking into account the principle of legal certainty, the previous instance courts established that the Plaintiff, as the patent owner, had a statutory right to extend the term of the economic intellectual property rights for inventions under the patent since all the requirements of current legislation (at the time the relevant right arose), which the Plaintiff had reasonably relied upon, were met.

9.25. The local commercial court also noted that according to Art. 27-1 of the Patent Law the last day for submitting an application for the extension of the term of the economic intellectual property rights for Ukraine patent No. 107796, and for the issue of a supplementary protection certificate was 30 April 2019. However, as of 30 April 2019, the Amending Law had not yet come into force, and the procedure for extending the term of the economic intellectual property rights defined by Art. 6 of the Patent Law and Sec. 1.5 of the Instruction, which laid down a different procedure from Art. 27-1 of the Patent Law for extending the term of the economic intellectual property rights, was in effect.

9.26. The court of first instance, with which the commercial court of appeals agreed, upheld the claim, based, among other things, on the fact that the Plaintiff was deprived of the opportunity to realize its right to extend the term of the economic intellectual property rights, which is not acceptable and is inconsistent with the Association Agreement and the General Agreement on Trade in Services dated 15 April 1994. According to these agreements, Ukraine has committed to facilitate the protection of intellectual property for nationals of any country, including the Plaintiff, since the latter is a resident of Japan, a member of the World Trade Organization. The Plaintiff’s right to supplementary protection was to be exercised according to the provisions of the Patent Law and the Instruction in the wording that was effective as of the date of registration of the patent and the medicinal product ‘ALEKENZA’. Therefore, the supplementary protection period for the inventions under Ukraine patent No. 107796 should be calculated from 10 June 2030, and the term of supplementary protection for the inventions under this patent, considering the provisions of the Association Agreement, should be three years, four months, and 24 days.

9.27. The previous instances, after analyzing the legal relationships that arose between the parties, examining the case materials, the provisions of Ukraine national legislation, and the provisions of treaties ratified by the Ukraine parliament, concluded that the Plaintiff’s claims should be upheld, as the deprivation of the right to supplementary protection is contrary to Ukraine’s obligations under the Association Agreement.

9.28. Thus, the previous instances, taking into account the principle of non-retroactive effect of civil legislation, correctly concluded that the Plaintiff should not be deprived of the right to supplementary protection by the introduction of a new mechanism for the realization of

this right according to the provisions of Art. 27-1 of the Law, which came into force on 16 August 2020, since the Plaintiff's patent and corresponding medicinal product had been registered before the entry into effect of Art. 27-1 of the Law. In the present case, the Plaintiff obtained the patent on 25 February 2015, and the use of inventions under the patent became possible after the state registration of the medicinal product 'ALEKENZA' on 2 November 2018. It was from the latter date, according to the provisions of the Law that were effective at that time, that the Plaintiff had a right to extend the term of the rights to the inventions under the patent. The mechanism for realizing this right is set forth in para. 1.5 of the Instruction, with only one limitation – no later than six months before the end of the patent term.

9.29. In this specific case, considering the established facts, the decisive factor is not the event of submitting the application but the moment when the Plaintiff's right to extend the term of the rights to the inventions under the patent arose, which occurred on 2 November 2018 with the registration of the medicinal product 'ALEKENZA'. At the time the Plaintiff's right arose, part four of Art. 6 of the Law and para. 1.5 of the Instruction were in effect, setting the deadline for the Plaintiff to submit the application.

9.30. The Defendant's reference to the impossibility of applying Art. 58 of the Constitution of Ukraine and Art. 5 of the Ukraine Civil Code to the disputed legal relations is also unjustified, as the acts regulating the disputed civil relations did not lose their effectiveness but only underwent changes according to the amendment of the Law on 16 August 2020, adding the new Art. 27-1.

9.31. The new provisions of the Patent Law, which came into effect on 16 August 2020, clarify more precisely the grounds and conditions for granting supplementary protection by extending the term of the rights to an invention, with the aim of maintaining a balance between the economic interests of the patent owner and the interests of society. Society, on the one hand, wishes to have effective and safe medicinal products, and additional administrative procedures were introduced for obtaining approval for the market launch of the product, and on the other hand, desires to eliminate the 'patent monopoly' as soon as possible.

9.32. Moreover, the absence in the amendments made to the legislation in 2020 of references to the rights of patent owners that arose prior to the entry into effect of Art. 27-1 of the Law should not deprive the Plaintiff of the opportunity to exercise his right to supplementary protection, guaranteed by the international agreements of Ukraine.

9.33. The Supreme Court is of the opinion that the absence of a specific procedure for obtaining supplementary protection for an invention during the transition period cannot indicate its unconditional nature. Thus, the specific period established by the legislator within which an application can be made for supplementary protection has its legitimate purpose.

9.34. At the same time, the holder of the patent for an invention whose object may be granted supplementary protection must, from the date of the entry into force of the Amending Law, submit a corresponding application

for supplementary protection within a reasonable time period.

9.35. As previously mentioned, the Amending Law came into effect on 16 August 2020. According to the facts established by the previous instances, the Plaintiff submitted to the Ukrainian Intellectual Property Institute an application w/o number dated 6 November 2020 for the extension of the term of the economic intellectual property rights, specifically Ukraine patent No. 107796, and the issue of a certificate of supplementary protection.

9.36. Therefore, based on Art. 6 of the Convention [for the Protection of Human Rights and Fundamental Freedoms], the Supreme Court, taking into account the above and guided by the principles and criteria of 'a reasonable time period' defined by the ECHR practice in applying Art. 6 of the Convention, concluded that in the present case the Plaintiff submitted the application within a time frame that falls under the concept of 'a reasonable time period'.

9.37. The Defendant's arguments that the previous instances, whose judicial decision was based on the 'principle of legitimate expectations according to the interpretation of the Venice Commission' and did not consider another principle - the 'principle of the rule of law' – in no way refute the correctness of the application by the previous instances of substantive legal rules regarding the principle of the rule of law, since the term allegedly overlooked by the Plaintiff was established not by law but by instruction.

9.38. In the appeal on the law, the Defendant also refers to the violation by the first instance court of the rules of procedural law through the replacement of the previous defendant, the Ukrainian Intellectual Property Institute (Ukrpatent), by UANIPIO, which, in the Defendant's opinion, was not corrected by the appeal court. However, the Supreme Court rejects this argument, taking into account the stated claims which are consistent with the provisions of the Patent Law and the Defendant's pleadings as set out in the appeal on the law.

9.39. Regarding the Defendant's argument that the first instance court violated the Defendant's discretionary powers by upholding the second claim on the obligation to take actions, the case materials show that the first instance court took into account the Recommendations of the Committee of Ministers of the Council of Europe, the Venice Commission, the positions of the Supreme Court, and the case law of the European Court of Human Rights (ECtHR), and noted that 'the discretionary powers of the defendant in making decisions must be consistent with the constitutional principle of the rule of law and its elements such as legal certainty and the prohibition of arbitrariness'.

9.40. In this part of the appeal on the law, there is no reference to the violation of the rules of substantive or procedural law, which is inconsistent with the provisions of Art. 300 of the Commercial Procedure Code, and so the Supreme Court dismisses these arguments.

9.41. Having examined the arguments presented in the appeal on the law, the Supreme Court notes that the facts concerning the incorrect application of rules of substantive law or a violation of procedural law rules were not confirmed without a conclusion of the Supreme Court on

the issue of the application of the law in the appeal-on-the-law proceedings since the arguments of the appeal on the law relate exclusively to the necessity of reassessing the evidence, and are no more than a challenge of the facts established by the previous instances during the trial, and a review of the assessment already made of evidence in the case.

9.42. The court of cassation dismisses as unfounded the Defendant's arguments about an incorrect application of rules of substantive law and a violation of procedural law in the adoption of judicial decisions in this case.

9.43. The court of cassation accepts the arguments presented in the statement of defense to the appeal on the law to the extent that they do not contradict this ruling.

9.44. Moreover, as noted in the decision of the ECtHR dated 19 February 2009 in *Khristov v. Ukraine* (application No. 24465/14), the right to a fair trial guaranteed by para. 1 of Art. 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms should be interpreted in the context of the preamble of this Convention, which, among other things, proclaims the rule of law, one of the fundamental aspects of which is the principle of legal certainty, according to which in the final resolution of a dispute by the courts, the decisions that have entered into force cannot be questioned (see also *Brumarescu v. Romania*, application No. 28342/95). The principle of legal certainty requires respect for the principle of *res judicata*, that is, respect for the final decision of the courts. According to this principle, no party can demand a review of the final and mandatory decision of the court solely with the aim of seeking a retrial and a new decision in the case. The review powers of higher courts are to be exercised to correct judicial errors and deficiencies, not for a new consideration of the case. The mere possibility of having two opinions on the subject of the dispute cannot be a basis for a new consideration of the case. A departure from this principle is possible only when it is required by relevant significant and insurmountable circumstances (case *Ryabykh v. Russia*, application No. 52854/99), the existence of which the Defendant has neither mentioned nor substantiated.

9.45. The relevant case law of the ECtHR is applied by the Commercial Cassation Court based on Art. 17 of the Law of Ukraine On the Implementation of Decisions and Application of the Practice of the ECtHR, according to which courts apply the said Convention and the relevant case law as a source of law.

9.46. Analyzing the issue of the extent of the examination of the Defendant's arguments and their reflection in the judicial decisions, and the question of the comprehensiveness of the court's conclusions, the decision of the court of cassation is based on the conclusions made by the ECtHR in *Pronina v. Ukraine* (ECtHR decision dated 18 July 2006). In particular, the ECtHR in its decision stated that para. 1 of Art. 6 of the Convention obliges courts to provide reasons for their decisions, but this cannot be perceived as a requirement to provide a detailed response to every argument. The limits of this obligation can vary depending on the nature of the decision. Furthermore, it is necessary to take into account the diversity of the arguments that a party may present in court and the differences that exist in the Member States

with regard to the provisions of the legislation, traditions, legal conclusions, presentation and formulation of decisions. Thus, the question of whether a court has fulfilled its obligation to provide reasoning stemming from Art. 6 of the Convention can only be determined in the light of the specific circumstances of the case.

9.47. In the present case, the Supreme Court reached the conclusion that the Defendant was given a comprehensive response to all significant questions arising in the determination of the disputed relations in both the substantial-legal and the procedural sense.

## 10. Conclusions based on the examination of the appeal on the law

10.1. Paragraph 3 of part one of Art. 308 of the Ukraine Commercial Procedure Code stipulates that the court of cassation, based on the results of the examination of the appeal on the law, has the right to annul decisions entirely or partially and to issue a new decision on the corresponding part or change the decision without returning the case for a new trial.

10.2. According to part four of Art. 311 of the Ukraine Commercial Procedure Code, changing a judicial decision may involve supplementing or changing its reasoning and/or operative part.

10.3. Under the given circumstances, the Supreme Court, considering that the courts of first and second instance established the facts of the case correctly, and using the powers granted by procedural law, deems it necessary to change the contested judicial decisions in the present case, presenting their reasoning in the text of this decision, and for the rest, the decisions of the courts remain unchanged.

10.4. Thus, the Supreme Court concludes that the appeal on the law by the Ukrainian National Office for Intellectual Property and Innovations is to be dismissed for the reasons mentioned above; accordingly, the reasonings of the judgment and ruling in this case are to be amended and are presented in the text of this ruling of the cassation court.

[...]

Guided by Arts. 300, 308, 311, 315 of the Ukraine Commercial Procedure Code, the Supreme Court has ruled as follows:

1. The appeal on the law by the state organization 'Ukrainian National Office for Intellectual Property and Innovations' is dismissed.
2. The decision judgment of the Commercial Court of Kyiv dated 7 February 2023 and the ruling of the Northern Commercial Court of Appeals dated 30 August 2023 in case No. 910/8295/21, shall be amended to set out the reasoning in the text of this ruling. In other parts, the judgment of the Commercial Court of Kyiv dated 7 February 2023 and the ruling of the Northern Commercial Court of Appeals dated 30 August 2023 in case No. 910/8295/21 shall remain unchanged.

The ruling shall come into effect from the moment of its adoption, is final, and is not subject to appeal.

Translated from the Ukrainian by Anastasiia Shmatko, Kyiv, Ukraine.

## Case note by Illya Novoseltsev\*

### Introduction

In the realm of patent law, particularly for patents on medicines and pharmaceuticals, patent term extension (PTE) or supplementary protection certificate (SPC) mechanisms compensate for the patent term lost during the mandatory regulatory approval process, including clinical trials. These extensions, available in various jurisdictions, aim to restore the patent lifespan spent on regulatory processes required prior to commercialization. Ukrainian patent law provides for a PTE/SPC aligning with global practices to offset the unique challenges of regulatory delays in the pharmaceutical industry. This framework is designed to foster innovation and investment by ensuring that pharmaceutical companies can enjoy a full term of market exclusivity to recoup R&D investments and profit. It acknowledges the extensive time from drug discovery to market authorization, which can significantly affect enjoyment of the standard 20-year patent protection from filing date.

### I. Legal context and facts

In case No. 910/8295/21 Chugai Seiyaku Kabushiki Kaisha (hereinafter ‘the Company’ or ‘the Plaintiff’) filed a lawsuit against the state enterprise ‘Ukrainian Intellectual Property Institute’ (hereinafter ‘Ukrpatent’), which was succeeded by the state organization ‘Ukrainian National Office for Intellectual Property and Innovations’ (hereinafter ‘UANPIO’ or ‘the Defendant’), requesting the court:

- to declare invalid and annul the refusal of Ukrpatent dated 23 November 2020 No. 22221/ПА/20 to grant supplementary protection to the rights to the invention under Ukraine patent No. 107796 (hereinafter referred to as ‘the Letter of Refusal’);
- to order Ukrpatent to implement the state registration of supplementary protection for Ukraine patent No. 107796 for the invention according to the Company’s application dated 6 November 2020 by entering the relevant information into the Ukrainian State Register of Inventions, to publish it in the official electronic bulletin of the UANPIO and to issue a supplementary protection certificate.

The Plaintiff’s claims were substantiated by the fact that the Plaintiff, as the owner of Ukraine patent No. 107796, had a statutory right to extend the term of validity of the economic intellectual property rights to the invention under the said patent.

The Company is the owner of Ukraine patent dated 25 February 2015 No. 107796 for the invention ‘tetracyclic compounds’ (registered based on application dated 9 June 2010 No. a201200237, as published on 25 February 2015 in the official bulletin ‘Industrial Property’ No. 4). The Ukraine patent was issued for 20 years. As indicated by the Company, on 2 November 2018, F. Hoffmann-La Roche Ltd received Ukraine registration certificate No. UA /16997/01/01 for the medicinal product ‘ALEKENZA’ hard capsules 150 mg (registered in Ukraine for five

years), issued on the basis of the Order of the Ministry of Health of Ukraine dated 31 October 2018 No. 1979. According to the case materials, the Plaintiff company as the owner of Ukraine patent No. 107796 agreed to grant F. Hoffmann-La Roche Ltd permission to use the said invention under Ukraine patent No. 107796 for the manufacture, offering for sale, sale, import, and other placing on the civil market, and storage for these purposes of the medicinal product ‘ALEKENZA’. This license is valid until the end of the term of Ukraine patent No. 107796 and applies to relations that existed before it was issued, namely in the period from the day following the date of state registration of the invention, i.e., from 26 February 2015.

The Company states that ‘ALEKENZA’ is a medicinal product with the active substance alectinib, indicated as a first-line treatment for adult patients with ALK-positive advanced non-small cell lung cancer. Alectinib is the International Nonproprietary Name (INN), i.e., the internationally recognized official name of the corresponding compound. The Plaintiff also states that the compound with the aforementioned name (9-ethyl-6,6-dimethyl-8-(4-morpholin-4-ylpiperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile) is directly listed in section 6 of the invention formula.

As stated by the Company, the application of the invention under the patent was impossible before the state registration in Ukraine of the relevant medicinal product based on a new compound or its salt or solvate according to sections 1-6 of the invention formula. Therefore, it was the state registration on 2 November 2018 of the medicinal product ‘ALEKENZA’, which contains alectinib in the form of this compound’s salt (alectinib hydrochloride), that first enabled the use of inventions under patent No. 107796. In the light of this, the Company filed an application to Ukrpatent dated 6 November 2020, requesting the extension of the term of the economic intellectual property rights to patent No. 107796 and the issue of a supplementary protection certificate for three years, four months, and 24 days for the invention, in the light of the limitations provided by para. 3, part one of Art. 27-1 Law of Ukraine ‘On Protection of Rights to Inventions and Utility Models’ (hereinafter ‘the Patent Law’). In the Letter of Refusal, Ukrpatent stated that the date of publication of the information about the state registration of the invention is the date of publication of the information about the issue of the patent, namely 25 February 2015, with the date of issue of the registration certificate being 2 November 2018. The Plaintiff’s application was received on 13 November 2020. Ukrpatent refused to grant the Plaintiff’s application on the grounds of non-compliance with the deadline established by para. 1 of part three of Art. 27-1 of the Patent Law.

Against this background, the Company filed a lawsuit with the above claims. The UANPIO, in opposing the Plaintiff’s claims, argued that it had acted according to the wording of the Patent Law in force on the date it issued the refusal. Since the Company’s request was received after the deadline, it could not be upheld.

### II. Analysis: Factual background and outcome of the case

The case was heard by commercial courts on several occasions. By judgment of the Commercial Court of Kyiv

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dated 7 February 2023, which was left unchanged by the ruling of the Northern Commercial Court of Appeals dated 30 August 2023, the claim was upheld in full. The Letter of Refusal to grant supplementary protection rights for the invention under Ukraine patent No. 107796 was declared invalid and annulled. The UANIPIO was ordered to implement the state registration of supplementary protection for Ukraine patent No. 107796 for the invention according to Chugai Seiyaku Kabushiki Kaisha's application dated 6 November 2020 by entering relevant information into the Ukrainian State Register of Inventions, to publish it in the official electronic bulletin of the UANIPIO and to issue a supplementary protection certificate. The UANIPIO justified its appeal on the law with the absence of a decisive ruling by the Supreme Court regarding the application of Art. 27-1 of the Patent Law. Specifically, it referred to the deadline for submitting applications for supplementary protection of rights to inventions whose state registration was completed before the new version of the Patent Law entered into force on 16 August 2020.

#### *Position of the Supreme Court*

The revision of the current legislation of Ukraine in the field of the protection of rights to inventions and utility models was driven by the need to ensure effective fulfilment of Ukraine's obligations under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part.

According to the provisions of part three of Art. 465 of the Civil Code of Ukraine and the Patent Law, the total term of legal protection for an invention is 20 years with the possibility of extending it for a maximum of five years (with certain reservations). The supplementary term beyond the expected 20 years aims to protect the interests of owners of inventions related to the pharmaceutical and agrochemical fields. This refers to supplementary protection certificates that compensate the patent rights holder for the time that elapses between filing an application for an invention and obtaining the permit to sell the patented product. As established by the previous instances, the Plaintiff obtained the patent on 25 February 2015, and the use of the invention under the patent became possible after the state registration of the medicinal product 'ALEKENZA', which took place on 2 November 2018. From the latter date, the Plaintiff was entitled to extend the term of validity of the rights to the invention under the patent.

According to the Patent Law as amended by the Law dated 21 July 2020 No. 816-IX (hereinafter 'the Amending Law'), which came into force on 16 August 2020, an application for supplementary protection must be submitted within six months from the date of publication of information about the state registration of the invention or from the date of issue of the first permit by the corresponding competent authority (depending on which of these dates is later). However, before the amendment, this deadline was effectively 19.5 years, as such an application had to be submitted no later than six months before the end of the patent term. There are no provisions regarding the establishment of a transitional period

for the application of Art. 27-1 of the Patent Law. It follows from this that patent holders who had obtained the relevant permit from the competent authority before 16 August 2020, but did not file an application for extending the patent term, were deprived of the opportunity to obtain supplementary protection, even though such a right was provided for by both the current and the previous versions of the Patent Law.

The previous instances, considering the principle of the irreversibility of civil legislation over time, correctly concluded that *the Plaintiff could not be deprived of the right to supplementary protection by the introduction of a new mechanism for exercising this right* according to the provisions of Art. 27-1 of the Patent Law, which came into force on 16 August 2020, as the Plaintiff's patent and corresponding medicinal product were registered prior to the entry into force of Art. 27-1 of the Patent Law. Based on the established circumstances, *the decisive factor was not the event of filing the application but the moment when the Plaintiff's right to extend the term of the rights to the inventions under the patent arose, which occurred on 2 November 2018* with the registration of the medicinal product 'ALEKENZA'. The Defendant's reference to the impossibility of applying Art. 58 of the Constitution of Ukraine and Art. 5 of the Civil Code of Ukraine to the disputed legal relations was also unjustified because, in this case, the acts regulating these disputed civil relations did not lose their validity but only underwent changes according to the amendment of the Law on 16 August 2020, which added the new Art. 27-1.

#### **III. Practical significance**

In the opinion of the Supreme Court, the alteration of a specific procedure for obtaining supplementary protection cannot be construed in a manner that would deprive patent holders of their corresponding right. The patent holders of inventions whose state registration was completed before the new version of the Patent Law can submit the relevant application for supplementary protection within a reasonable time period from the date of entry into force of the Amending Law. Therefore, based on Art. 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms, the Supreme Court, taking into account the principles and criteria of 'a reasonable time period' as interpreted by the European Court of Human Rights (ECtHR) in applying Art. 6 of the Convention, concluded that in this case the Plaintiff had filed the application within 'a reasonable time period'.

The principle of legal certainty requires respect of the principle of *res judicata*, i.e., respect for the final and binding court decision. According to this principle, neither party has the right to demand a review of the final and enforceable court decision solely for the purpose of a reconsideration and issuance of a new decision in the case. The review powers of higher courts are to be exercised to correct judicial errors and deficiencies, not for a new consideration of the case. The mere possibility of the existence of two opinions on the subject matter of the dispute cannot be a reason for a new consideration of the case. A departure from this principle is possible only if there are compelling and insurmountable circumstances (*Ryabikh v. Russia*, application No. 52854/99).

The relevant practice of the ECtHR is applied by the Commercial Cassation Court based on Art. 17 of the Law of Ukraine ‘On the Implementation of Decisions and Application of the Practice of the European Court of Human Rights’, according to which courts apply the said Convention and the relevant case law as a source of law.

Analyzing the issue of the scope of examination of the Defendant’s arguments and their reflection in judicial decisions, as well as the completeness of the court’s conclusions, the decision of the court of cassation was guided by the conclusions reached by the ECtHR in *Pronina v. Ukraine* (ECtHR decision dated 18 July 2006). In particular, the ECtHR noted in its decision that para. 1 of Art. 6 of the Convention obliges courts to provide reasons for their decisions, but this cannot be perceived as a requirement to provide a detailed response to every argument. The limits of this obligation can vary depending on the nature of the decision. Thus, the question of whether the court fulfilled its obligation to provide reasoning, arising from Art. 6 of the Convention, can only be determined in light of the specific circumstances of the case.

### Conclusions

The application of Art. 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms by the Supreme Court in this context highlights a significant legal precedent, particularly emphasizing the

principles and criteria of ‘a reasonable time period’ as interpreted by the ECtHR. By concluding that the Plaintiff filed the application within ‘a reasonable time period’, the court not only adheres to the established guidelines of the ECtHR *but also sets a new benchmark* in balancing individual rights against state interests. This decision, marking a first of its kind, places the interests of the investor above governmental interests, signalling a potentially transformative shift in the legal landscape. This move could be seen as a robust affirmation of the protection of individual rights, especially those of investors, against arbitrary or overly prolonged state actions, thereby strengthening the rule of law and investor confidence in the legal system’s fairness and predictability.

*Exhaustiveness of Judicial Decisions:* The Supreme Court referred to ECtHR judicial practice to determine the adequacy of judicial reasoning, emphasizing that while courts must provide reasoning, they are not obliged to address every argument in detail.

*Supreme Court Ruling:* Upon review, the Supreme Court upheld the decisions of the lower courts, but opted to modify their reasoning. Emphasizing the necessity for courts to provide comprehensive justifications for their rulings, the Supreme Court cited precedents from the ECtHR in elucidating this requirement. While acknowledging the UANIPIO’s arguments, the Supreme Court concluded that they did not justify overturning the lower courts’ decisions.