Decision 3434/2023. (X. 25.) AB

on the annulment of a judicial decision

The plenary session of the Constitutional Court, in the subject-matter of a constitutional complaint – with concurring reasoning by Justices *dr. Ágnes Czine, dr. Ildikó Hörcherné dr. Marosi* and *dr. András Patyi* – adopted the following

decision:

1. The Constitutional Court finds that the ruling No. Pfv.IV.21.464/2021/9 of the Curia, as well as the ruling No. 8.Pkf.25.537/2021/6 of the Budapest-Capital Regional Court of Appeal, as revised by foregoing, the ruling No. 3.Pk.20.224/2021/17 of the Budapest-Capital Regional Court as corrected by the ruling No. 3.Pk.20.224/2021/19, and the decision No. E15155479/11 of the National Intellectual Property Office are contrary to the Fundamental Law, and therefore annuls them.

2. The Constitutional Court finds that the ruling No. Pfv.IV.21.465/2021/10 of the Curia, as well as the ruling No. 8.Pkf.25.536/2021/6 of the Budapest-Capital Regional Court of Appeal, as revised by foregoing, the ruling No. 3.Pk.20.219/2021/16 of the Budapest-Capital Regional Court as corrected by the ruling No. 3.Pk.20.224/2021/18, and the decision No. E09734175/11 of the National Intellectual Property Office are contrary to the Fundamental Law, and therefore annuls them.

3. The Constitutional Court finds that the ruling No. Pfv.IV.21.466/2021/11 of the Curia, as well as the ruling No. 8.Pkf.25.538/2021/6 of the Budapest-Capital Regional Court of Appeal, as revised by foregoing, the ruling No. 3.Pk.20.225/2021/18 of the Budapest-Capital Regional Court as corrected by the ruling No. 3.Pk.20.225/2021/20, and the decision No. E15797205/10 of the National Intellectual Property Office are contrary to the Fundamental Law, and therefore annuls them.

Reasoning

I

[1] 1 The petitioner, a pharmaceutical company, through its legal representative (Dr. Bálint Halász, attorney-at-law), submitted three related petitions to the Constitutional Court.

[2] In its constitutional complaint pursuant to section 27 (1) of the Act CLI of 2011 on the Constitutional Court (hereinafter: ACC) of 1 September 2022, received by the Constitutional Court on 9 September 2022 (hereinafter: "Petition 1"), the petitioner asked for the declaration of a conflict with the Fundamental Law of the ruling No. Pfv.IV.21.464/2021/9 of the Curia (hereinafter: "Curia Ruling 1"), as well as the ruling No. 8.Pkf.25.537/2021/6 of the Budapest-Capital Regional Court of Appeal (hereinafter: "Second Instance Ruling 1"), as revised by foregoing, the ruling No. 3.Pk.20.224/2021/17 of the Budapest-Capital Regional Court (hereinafter: "First Instance Ruling 1") as corrected by the ruling No. 3.Pk.20.224/2021/19, and the decision No. E15155479/11 (hereinafter: "Decision 1") of the National Intellectual Property Office (NIPO), and for their annulment.

[3] In its constitutional complaint pursuant to section 27 (1) of the ACC of 8 September 2022, received by the Constitutional Court on 19 September 2022 (hereinafter: "Petition 2"), the petitioner asked for the declaration of a conflict with the Fundamental Law of the ruling No. Pfv.IV.21.465/2021/10 of the Curia (hereinafter: "Curia Ruling 2"), as well as the ruling No. 8.Pkf.25.536/2021/6 of the Budapest-Capital Regional Court of Appeal (hereinafter: "Second Instance Ruling 2"), as revised by foregoing, the ruling No. 3.Pk.20.219/2021/16 of the Budapest-Capital Regional Court (hereinafter: "First Instance Ruling 2") as corrected by the ruling No. 3.Pk.20.219/2021/18, and the decision No. E09734175/11 (hereinafter: "Decision 2") of the NIPO, and for their annulment.

[4] In its constitutional complaint pursuant to section 27 (1) of the ACC of 8 September 2022, received by the Constitutional Court on 19 September 2022 (hereinafter: "Petition 3"; Petition 1, Petition 2 and Petition 3 hereinafter collectively: "petitions" or "constitutional complaints"), the petitioner asked for the declaration of a conflict with the Fundamental Law of the ruling No. Pfv.IV.21.466/2021/11 of the Curia (hereinafter: "Curia Ruling 3"; Curia Ruling 1, Curia Ruling 2 and Curia Ruling 3 hereinafter collectively: "Curia rulings"), as well as the ruling No. 8.Pkf.25.538/2021/6 of the Budapest-Capital Regional Court of Appeal (hereinafter: "Second Instance Ruling 3"; Second Instance Ruling 1, Second Instance Ruling 2 and Second Instance Ruling 3 hereinafter collectively: "second instance rulings"), as revised by foregoing, the ruling No. 3.Pk.20.225/2021/18 of the Budapest-Capital Regional Court (hereinafter: "First Instance Ruling 3"; First Instance Ruling 1, First Instance Ruling 2 and First Instance Ruling 3 hereinafter collectively: "first instance rulings") as corrected by the ruling No. 3.Pk.20.225/2021/20, and the decision No. E15797205/10 (hereinafter: "Decision 3"; Decision 1, Decision 2 and Decision 3 hereinafter collectively: "Decisions" or "NIPO Decisions") of the NIPO, and for their annulment.

[5] The petitioner is of the opinion that in the course of the proceedings of the NIPO its right to a fair administrative procedure under Article XXIV (1) of the

Fundamental Law was violated, and in the court proceedings for the review of the decisions its right to a fair judicial procedure under Article XXVIII (1) of the Fundamental Law and its right to a remedy under Article XXVIII (7) of the Fundamental Law were violated.

[6] 2 The substance of the cases on which the constitutional complaints are based can be summarised as follows.

[7] 2.1 The petitioner is the beneficiary of the European patent No. EP2937350 registered in Hungary by the NIPO under the registration number No. E038946 (hereinafter: "Patent 1"), the European patent No. EP2268642 registered in Hungary by the NIPO under the registration number No. E025528 (hereinafter: "Patent 2") and the European patent No. EP3212174 registered in Hungary by the NIPO under registration number E039231 (hereinafter: "Patent 3"; Patent 1, Patent 2 and Patent 3 are hereinafter collectively referred to as the "Patents").

[8] The Patents protect to the product VEKLURY 100 mg concentrate for solution for infusion and VEKLURY 100 mg powder for concentrate for solution for infusion (hereinafter: Product), which was the only patent-protected Remdesivir-containing medicinal product at the time of rendering the Decisions that was fully recommended by the European Medicines Agency for use in adults and adolescents of 12 years of age and older weighing 40 kg or more with the 2019 Coronavirus Influenza Virus Disease ("COVID-19"), who have pneumonia requiring supplemental oxygen therapy - low or high flow oxygen or other non-invasive ventilation at the start of treatment.

[9] The Product has been granted marketing authorisations under numbers EU/1/20/1459/001 and EU/1/20/1459/002, the beneficiary being a company belonging to the same group of companies (hereinafter:"Company Group") as the petitioner (hereinafter: "Licensee").

[10] In the summer of 2020, the European Commission concluded a contract with the petitioner and the Company Group for the supply of the Product. Hungary was also a beneficiary of that procurement. Between 5 August 2020 and 12 October 2020, the Licensee supplied Hungary with a total of 1 797 vials of the Product.

[11] On 7 October 2020, 36 contracting parties, including the Hungarian State, signed a joint framework procurement contract with the Company Group for the supply of 500 000 therapeutic doses of the Product and for the supply of additional stocks. On 12 October 2020, the Hungarian State also independently initiated negotiations with the petitioner in order to sign an individual agreement based on the framework contract. During these negotiations, the Hungarian State indicated that it intended to order 3,500 vials of the Product by October 2020, 7,000 by November 2020 and 3,500

by December 2020, which were delivered by the petitioner on the basis of individual contracts. Further orders and deliveries took place in January and February 2021.

[12] 2.2 On 20 November 2020, one of the largest pharmaceutical companies in Hungary (hereinafter: "compulsory licence holder") filed a request for a compulsory public health licence concerning the petitioner's Patents and Products with the NIPO pursuant to section 33/B of the Act XXXIII of 1995 on the Patent Protection of Inventions (hereinafter: "Patent Act"). The compulsory licence holder attached a certificate from the National Institute of Pharmacy and Nutrition (hereinafter: "NIPN") as the state pharmaceutical administration body stating that the quantity of the Product available in Hungary is zero vials; and the quantity of the Product ordered and not yet delivered but scheduled to arrive to meet the needs in Hungary is 24,000 vials. The compulsory licence holder also referred to data obtained from the Ministry of Human Resources indicating that the approximate domestic demand for Remdesivir is 85,500 vials/month, which is 514,800 vials for 6 months. On this basis, the NIPN concluded that the demand in Hungary is higher than the amount of the Product that will be available in Hungary.

[13] By a notification dated 23 November 2020 and served on 9 December 2020, the NIPO informed the petitioner that an application for a compulsory public health licence for Patent 1 had been submitted, but the notification did not contain any details.

[14] By the Decision 1 dated 1 December 2020, received by the petitioner on 10 December 2020, the NIPO granted the compulsory licence holder a compulsory public health licence for Patent 1 for a period of 6 months to meet domestic needs.

[15] In the case of Patent 2, the notice of the opening of the procedure of the NIPO was dated 23 November 2020, was posted on 1 December 2020, and the petitioner received it on 2 December 2020. Decision 2 for Patent 2, which is identical in content to Decision 1, was dated 1 December 2020 and received by the petitioner on 10 December 2020.

[16] In the case of Patent 3, the NIPO mailed on 1 December 2020 its notice on filing the application, dated 23 November 2020, which was received by the petitioner on 2 December 2020. Decision 3, dated 1 December 2020 and received by the petitioner on 2 December 2020, also granted a compulsory public health licence to the applicant for a period of 6 months.

[17] 2.3 The petitioner brought applications for modification of the Decisions under Chapter XI of the Patent Act. In the first place, the petitioner sought the modification of the Decisions on the basis of section 100 (1) of the Patent Act and the rejection of the applications for a compulsory public health licence, in the second place,

the annulment of the Decisions on the basis of section 100 (2) (b) or (3) of the Patent Act and the ordering of the NIPO to initiate new proceedings and issue new decisions, and in the third place, the amendment of the licence fee, which application the petitioner subsequently withdrew. The applicant complained, among others, that it had not been able to express its views in the proceedings before the NIPO, that it had not been requested to provide information on its production and delivery capacity of the Product and it also stated that it had been able to satisfy demand in Hungary.

[18] By its rulings of first instance delivered in the non-litigious procedure, the Budapest-Capital Regional Court dismissed the petitioner's applications for modification, among others, on the ground that the petitioner was not a party to the compulsory public health licensing proceedings before the NIPO and was therefore not entitled to make a statement. The first-instance rulings also pointed out that the Patent Act establishes a fixed system of proof in the relevant case, whereby the NIPO is obliged to grant a compulsory public health licence if the NIPN has made a declaration. Consequently, neither the NIPO nor the court has the right to review the adequacy and veracity of the NIPN declaration, and thus the court is not entitled to consider whether the petitioner has the capacity to satisfy domestic needs itself. The Budapest-Capital Regional Court of Appeal, acting on the petitioner's appeals, upheld the first instance rulings by its second instance rulings dated 16 September 2021, agreeing with the grounds stated in the first instance rulings.

[19] 2.4 On 2 December 2021, the petitioner filed an application for review and on 17 December 2021, the petitioner also filed a constitutional complaint against the second instance rulings. The Constitutional Court dismissed these complaints with regard to the proceedings pending before the Curia by its rulings dated 10 February 2022, issued in a single-judge procedure.

[20] 2.5 The Curia upheld the second instance rulings, partly for reasons other than those stated in them. It stated that, contrary to the position of the NIPO and the ordinary courts, the petitioner qualifies as a party in the proceedings before the NIPO, but that obtaining a statement from the petitioner is unnecessary. According to the interpretation of the Curia, the petitioner was not entitled to make a statement because section 5 (1) of Act CL of 2016 on the General Administrative Procedure (hereinafter: AGAP), which states that the party may make a statement or comment at any time during the proceedings, does not apply in patent cases pursuant to Section 45 (2) of the Patent Act. In the interpretation of the Curia, section 83/I (5) of the Patent Act provides for the obligation of the NIPO to provide notification on the fact of the submission of the request for the grant of a compulsory licence within eight days of the receipt of the request, while section 83/J (1) of the Patent Act provides for the decision to be taken without a hearing, and according to this provision, the NIPO is required to communicate the decision with the applicant and only has to notify the

patent holder within eight days. The Curia found that "even these requirements were not fully met in the case at hand", as the NIPO had notified the beneficiary of the patent of the submission of a request for a compulsory licence beyond the statutory time limit. However, as the court of first instance held, it was not this procedural defect but the statutory regulations that prevented the applicant from exercising its rights as a party.

[21] With regard to the certificate of the NIPN, the Curia, agreeing with the reasoning of the ordinary courts, pointed out that, when examining whether the conditions for the grant of a compulsory licence exist, the NIPO should, without discretion, take into account only the certificate of the NIPN, in accordance with a strict system of proof, since that certificate is the only evidence of the existence of the conditions for the grant of a compulsory public health licence. Therefore, there is no possibility for a review of the merits of the certificate issued by the NIPN by the court, to examine the petitioner's ability to meet domestic needs: "Pursuant to section 45 (1) of the Patent Act, section 62 (5) of the AGAP also applies to patent matters falling within the competence [of the NIPO] allows – as an exception to the principle of free provision of evidence under section 62 (4) of the AGAP – that an Act of Parliament or Government Decree may, on compelling grounds in the public interest, make the use of a document or other evidence compulsory in specific cases. The court of first instance correctly identified that overriding reason in the public interest with the health crisis, which is also specified as one of the necessary conditions for a compulsory public health licence."

[22] 3 The constitutional complaints contain the following reasoning in relation to specific provisions of the Fundamental Law invoked.

[23] 3.1 With regard to Article XXIV (1) of the Fundamental Law, the petitions stress, on the one hand, that by ruling out the possibility of counter-proof against the certificate of the NIPN, the NIPO and the trial courts of the case have created law, because this interpretation cannot be derived from the laws. Second, the petitioner also submits that the failure to recognise its status as a party to the proceedings before the NIPO and the fact that the Curia corrected that failure but nevertheless recognised the lawfulness of the failure to obtain a statement from the petitioner led to a breach of the right to a fair hearing, since the exercise of the rights to make a statement and to inspect the documents is time-barred and the lapse of time would have made it possible to remedy the failure to exercise those rights only in a retrial. In the petitioner's view, the right to make a statement is particularly important in asymmetrical situations such as compulsory licensing proceedings, in which the applicant determines the forum, the date of commencement of the proceedings and the claim to be brought, and the patent holder can only defend itself within that framework. The petitioner further complained that the compulsory licence was granted to the compulsory licence holder by completely excluding the petitioner from the proceedings: first, because the

petitioner was not invited to make a statement and, second, because it could not voluntarily make a statement, since the NIPO had already adopted the Decisions before the petitioner had even been informed of the opening of the proceedings. The petitioner holds that this also infringed the principle of equality of arms, which, in the petitioner's view, cannot be restricted even on the ground that the examination of an application for a compulsory public health licence should indeed, in certain circumstances, be carried out within a genuinely short time-limit. In the petitioner’s view, it is also possible, under the AGAP, for the proceeding authority to lay down an expressly short time-limit, even in hours, for the submission of the party's statement.

[24] 3.2 The petitioner claims the violation of the right to a fair trial under Article XXVIII (1) of the Fundamental Law by arguing that the ordinary courts did not remedy the interpretation of the law found in the Decisions that the petitioner was not entitled to the rights of the party in the proceedings of the NIPO. This situation was not helped by the decision of the Curia, since its right to make a statement was not recognised by the Curia's rulings, despite the fact that its status as a party had otherwise been established.

[25] The petitions also interpret as a violation of the right to a fair trial the fact that the possibility of recourse to the courts has been emptied out, because the judicial review of the legality of the Decisions was limited to an examination of formal aspects. The judicial forums took the view that, in view of the system of fixed evidence, the NIPO could not deviate from the content of the NIPN certificate and therefore did not examine the merits of the arguments and documentary evidence put forward by the petitioner. The courts deviated without an express statutory provision from the main rule on the free provision of evidence in the Act CXXX of 2016 on the Civil Procedure. According to the petitioner, this leads to the conclusion that the NIPO and de facto the NIPN had unlimited or unrestricted power in the procedure for the compulsory public health licence.

[26] With regard to the infringement of the right to a fair court procedure, the applicant submits that the courts before which the case was brought failed to fulfil their obligation under Article 28 of the Fundamental Law to take account of the legislative reasoning for the laws. Indeed, according to the legislative reasoning to the Act LVIII of 2020 on transitional rules in connection with the end of the state of danger and on epidemic preparedness, which incorporates the applicable provisions of the Patent Act, a compulsory public health licence may be granted only if the patent holder is unable to satisfy the demand. However, this aspect was not addressed at all in the reasoning of the decisions.

[27] According to the petitioner, the Curia – and the ordinary courts – did not decide on the application of the laws, but created the system of fixed evidence by

interpreting the applicable laws in a manner contrary to the Fundamental Law, thus extending beyond the framework of their judicial activity, and took away the legislative power of the Parliament, in violation of the principle of the separation of powers. The principle of equality of arms in the judicial procedure was also violated by the judicial interpretation of the law creating a system of fixed evidence, since the courts considered the NIPN certificate on which the application for a compulsory licence was based as authoritative, without taking anything else into account, since they categorically refused to assess the evidence submitted by the petitioner.

[28] According to the applicant, the Curia's rulings also infringed its right to a fair hearing by failing to take account of the fact that the NIPO had failed to act impartially. According to the Curia, the fact that the NIPN which issued the certificate was involved in the authorisation and regulatory measures relating to the medical product in question is irrelevant for the purposes of assessing the evidential value of the certificate issued by the NIPN.

[29] 3.3 According to the petitioner, its right to a judicial remedy under Article XXVIII (7) of the Fundamental Law was violated because the courts did not examine the merits of the lawfulness of the granting of the compulsory public health licence, as they refrained from examining the merits of the NIPN certificate. The petitioner's right to a legal remedy was also infringed by the fact that the NIPN certificate, which was not classified as a final or preliminary statement of the competent authority, was not subject to any right of appeal, any possibility of bringing a case or making a statement.

[30] 4 In an amicus curiae brief, the Minister of Justice informed the Constitutional Court of his position on Petition 1 and his opinion on the interpretation of the relevant legislative context. The Constitutional Court held a personal hearing on the case, at which the petitioner and the compulsory licence holder, as opposing parties, presented their views.

II

[31] 1 The affected provisions of the Fundamental Law:

“Article XXIV (1) Everyone shall have the right to have his or her affairs handled impartially, fairly and within a reasonable time by the authorities. Authorities shall be obliged to state the reasons for their decisions, as provided for by an Act.”

"Article XXVIII (1) Everyone shall have the right to have any indictment brought against him or her, or his or her rights and obligations in any court action, adjudicated within a reasonable time in a fair and public trial by an independent and impartial court established by an Act.

[...]

(7)Everyone shall have the right to seek legal remedy against any court, authority or other administrative decision which violates his or her rights or legitimate interests."

[32] 2 The relevant provisions of the Patent Act:

"Section 33/B (1) The National Intellectual Property Office shall grant a compulsory public health licence (hereinafter referred to as "compulsory public health licence") for the purpose of meeting domestic demands in connection with a health emergency situation (hereinafter referred to as "health emergency situation") within the meaning of section 228 (2) of the Act CLIV of 1997 on Health Care, or for the purpose of export utilisation connected to a compulsory public health licence for the purpose of addressing a public health problem in another country (hereinafter referred to as "compulsory foreign health licence") for the utilisation of

(a) a medicinal product or active substance subject to a patent or supplementary protection, or a patented medical device (hereinafter together referred to as "health care product"); or

(b) a patented process, apparatus or device for the manufacture of a health care product."

"Section 33/C (2) The certificate pursuant to section 33/B (2) (b) and (1) (a) shall be issued by the pharmaceutical administration agency at its own discretion, based on an analysis of information on the quantity of available stocks and a risk assessment. In order to obtain additional data necessary for the issue of the certificate, the pharmaceutical administration agency may also apply to the manager of the State Health Reserve or to the ministry headed by the minister responsible for health for the provision of data."

"Section 45 (1) The National Intellectual Property Office shall act in patent matters falling within its competence, with the exceptions and additions specified in this Act, in accordance with the provisions of the Act CL of 2016 on General Administrative Procedure (hereinafter: AGAP) and the Act CCXXII of 2015 on the General Rules of Electronic Administration and Trust Services.

(2) In patent matters section 3, section 5 (1), section 13 (8), section 14 (1), section 21, section 26, section 37 (2), section 46 (2), section 48 (1) to (4), section 62 (1), section 74 (1), section 75, section 76, section 87, section 94 (2), section 97, section 127 (2) and section 130 of the AGAP are not applicable."

"Section 83/I (1) The provisions of this Act shall apply to the procedure for a compulsory public health licence, with the following exceptions:

(a) a time limit of at least fifteen but not more than thirty days shall be set for the submission of missing documents and making a statement, and an extension of the time limit may be granted only in particularly justified cases,

(b) the National Intellectual Property Office shall act out of turn."

"Section 85 (2a) An application for a modification of the decision on the granting of a compulsory public health licence shall not have suspending effect in respect of the compulsory public health licence granted."

"Section 91 (1) The applicant shall be a party to the court proceedings. The prosecutor who institutes the proceedings shall have all the rights of a party, but may not enter into any agreement, waive any right or recognise any right.

(2) If an opposing party has been involved in the proceedings before the National Intellectual Property Office, the court proceedings shall be instituted against it."

[33] 3 The relevant provisions of the AGAP:

"Section 5 [Fundamental principles concerning the party]

(1) In the course of the procedure, the party may make a statement or observation at any time.

(2) The authority shall ensure that

(a) the party and

(b) the witness, the official witness, the expert, the interpreter, the holder of the object of the inspection and the party's representative (hereinafter jointly "other participants in the procedure")

are aware of their rights and obligations and shall promote the exercise of parties' rights."

"Section 10 [The party]

(1) Party means any natural or legal person or any organisation whose rights or lawful interests are directly affected by the case, with respect to whom an official register holds data or who (which) is subjected to administrative audit."

III

[34] The petitions meet the conditions for admissibility as follows.

[35] 1 In accordance with section 30 (1) of the ACC, a constitutional complaint may be submitted within sixty days from the date of delivery of the challenged decision in a case specified in section 27 (1). The complaints meet this requirement. The petitions are also not out of time with regard to the second instance decisions that cannot be challenged by ordinary appeal, because the petitioner also filed constitutional complaints against them within the time limit, therefore the final decisions can also be examined on the basis of the petitions on which the present case is based.

[36] 2 The Curia rulings examined the merits of the applications for review and are therefore decisions delivered on the merits of the cases. No appeal lies against the ruling of the Curia as reviewing court. In the light of this, the petitions also satisfy these conditions for admissibility arising from section 27 (1) of the ACC. The petitioner was a party to the proceedings underlying the contested court decisions and therefore qualifies as a party concerned.

[37] 3 A complaint under section 27 (1) of the ACC may be based on a violation of the right of the petitioner guaranteed by the Fundamental Law.

[38] Article XXIV (1) and Article XXVIII (1) and (7) of the Fundamental Law confer rights which constitute a right guaranteed by the Fundamental Law {Decision 25/2020. (XII.2.) AB, Reasoning [32], Decision 3403/2021. (X.15.) AB, Reasoning [12], [20]}. Taking into account that the petitioner is not a natural person, it is necessary to examine under Article I (4) of the Fundamental Law whether the relevant rights granted in the Fundamental Law are also granted to the petitioner. According to the case-law of the Constitutional Court, both Article XXIV (1) and Article XXVIII (1) and (7) of the Fundamental Law confer fundamental rights on non-natural persons as well {Decision 3064/2022. (II.25.) AB, Reasoning [1], [8] to [13] and [22]}. In view of this, this condition for admission is also fulfilled.

[39] 4 Pursuant to section 52 (1b) of the ACC, only a constitutional complaint containing a definite request may be admitted, and therefore the Constitutional Court also examined whether this condition is fulfilled. The petitioner has indicated the provisions of the Fundamental Law that are alleged to be violated, the petitions contain an express request for the annulment of the challenged legislative provisions, and comply with the requirement to state reasons under section 52 (1b) (e) of the ACC {Ruling 3015/2015. (I.27.) AB, Reasoning [13]; Ruling 3119/2020. (V.8.) AB, Reasoning [7]}.

[40] 5 Pursuant to section 29 of the ACC, a constitutional complaint – which meets other statutory requirements – may be accepted if it supports the possibility of an infringement of the Fundamental Law that materially affects the judicial decision or raises a question of fundamental constitutional significance. These two conditions are of alternative character, thus the existence of either of them shall form the basis of the

Constitutional Court's procedure in the merits of the case {Decision 21/2016. (XI.30.) AB, Reasoning [20]; Decision 34/2013. (XI.22.) AB, Reasoning [18]}. It is for the Constitutional Court to assess whether these conditions are met.

[41] In the Constitutional Court's view, the fact that the petitioner could not exercise its rights as a party in the proceedings before the NIPO and that this was not remedied by the courts hearing the case raises the possibility of a violation of the right to a fair administrative procedure, which may result in a violation of the Fundamental Law that may have a material impact on the judicial decision.

[42] 6 In view of the foregoing, pursuant to section 31 (1) of the Rules of Procedure, in the light of section 56 (1) of the ACC, the panel of the Constitutional Court has granted admission to the constitutional complaints. Subsequently, in accordance with the provisions of the section 58 (2) of the ACC and section 34 (1) of the Rules of Procedure, the cases brought on the basis of Petition 2 and Petition3 were merged with the case brought on the basis of Petition 1 and the petitions were examined together.

IV

[43] 1 The petitions are well-founded.

[44] 2 The Constitutional Court first examined the petition-element relating to the right to a fair administrative procedure, as granted in Article XXIV (1) of the Fundamental Law.

[45] 2.1 In the context of Article XXIV (1) of the Fundamental Law, the petitioner complained, first of all, that the NIPO, the Regional Court and the Regional Court of Appeal did not recognise its status as a party to the case from the outset and that, although the Curia did so, it could not exercise its right to make a statement on the basis of the Curia’s conclusion derived from a joint interpretation of the Patent Act and the AGAP.

[46] As pointed out by the Constitutional Court in paragraph III/1 (Reasoning [35]), the petitioner also lodged a constitutional complaint against the final rulings of the second instance within the time limit, and therefore the examination of the Constitutional Court is not limited to the review phase of the main proceedings, but extends to the proceedings as a whole. The complex evaluation of the main cases also follows from the fact that, according to its consistent case-law, the Constitutional Court “may conduct a constitutional review of a substantive decision taken in an official procedure prior to the court proceedings if the violation of rights alleged in the petition occurred as a result of the official decision {e.g. Decision No 22/2017 (IX.11.) AB, Reasoning [26]}. However, this is subject to the condition that the court failed to

recognise the infringement of fundamental rights by the administrative decision in the review procedure." {Decision 3093/2018. (III.26.) AB, Reasoning [43]}

[47] Obviously, however, it is not enough for the court to recognise the violation of fundamental rights by the administrative decision, it is also essential for the subjective legal protection of the petitioner that the court remedies the violation of fundamental rights resulting from the administrative decision that violates the Fundamental Law. This requirement derives primarily from the right to legal remedy declared in Article XXVIII (7) of the Fundamental Law. According to the consistent case-law of the Constitutional Court, the right to legal remedy guaranteed by the Fundamental Law requires that the possibility of effective and efficient legal remedy be guaranteed. Not only can a breach of a fundamental right be established if the possibility of legal remedy has been completely excluded {see, for example, Decision No 36/2013 (XII.5.) AB, Reasoning [61]}, but also if the legal remedy otherwise provided by law cannot be actually and efficiently exercised for other reasons {Decision 10/2017. (V.5.) AB (hereinafter: CCDec1), Reasoning [67] to [68]; Decision 33/2017. (XII.6.) AB, Reasoning [113]}.

[48] At the same time, the Constitutional Court recalls that the possibility of judicial review of administrative decisions is both a safeguard of the right of access to a court under Article XXVIII (1) of the Fundamental Law and the right to a remedy under Article XXVIII (7) of the Fundamental Law. {See in particular: Decision 3102/2023. (III.14.) AB (hereinafter: CCDec2), Reasoning [77] and [97]}. Consequently, in cases of constitutional complaints against judicial decisions reviewing administrative decisions, the right of access to court under Article XXIV (1) of the Fundamental Law and the right to a remedy guaranteed by Article XXVIII (7) of the Fundamental Law are presented as being closely interrelated.

[49] 2.2 In view of the fact that the subject-matter of the present case is the conformity of judicial decisions with the Fundamental Law, the criteria developed for assessing the constitutionality of judicial decisions should be applied.

[50] In accordance with Article 24 (2) (d) of the Fundamental Law, the Constitutional Court »shall review, on the basis of a constitutional complaint, the conformity with the Fundamental Law of a judicial decision«. When assessing this, the Constitutional Court first of all examines the question of whether the court has recognised the fundamental rights implications of the case: »According to Article 28 of the Fundamental Law, in the course of the application of law, courts shall interpret the text of laws primarily in accordance with their purpose and with the Fundamental Law. This provision of the Constitutional Court lays down as a constitutional requirement for the courts in the course of the application of law to interpret the laws primarily in accordance with the Fundamental Law [...]. Based on this obligation, the courts should

identify the fundamental rights' aspects of the relevant case within the limits of interpretation provided by the laws, and they should interpret the laws applied in the judicial decisions with due account to the constitutional content of the affected fundamental right. The constitutional complaint allowing the constitutional review of judicial decisions (Section 27 of the ACC) is a legal institution that serves the purpose of enforcing Article 28 of the Fundamental Law. On the basis of such a complaint, the Constitutional Court examines the compatibility with the Fundamental Law of the interpretation of law found in the judicial decision, i.e. whether the court enforced the constitutional content of the rights granted in the Fundamental Law. If the court acts without paying due attention to the fundamental rights affected by the relevant case and if the interpretation of the law developed by the court is not compatible with the constitutional content of this right, then the adopted judicial decision is contrary to the Fundamental Law.« {Decision 3/2015. (II.2.) AB, Reasoning [17] to [18]." Decision 3298/2021. (VII.22.) AB, Reasoning [29]}.

[51] The interpretation in conformity with the Fundamental Law – as the Constitutional Court has already pointed out on several occasions – does not mean that the courts should base their decisions directly on the provisions of the Fundamental Law, but that they should take into account the relevant constitutional aspects when interpreting the applicable legal provisions and applying them to the specific facts of the case {Decision 7/2013. (III.1.) AB, Reasoning [33]; Decision 3/2015. (II.2.) AB, Reasoning [20]}.

[52] Due to the fact that the subject of the constitutional complaint cases focusing on Article XXIV (1) of the Fundamental Law, initiated on the basis of section 27 (1) of the ACC, is the decision of the court obliged to recognise the potential violation of fundamental rights by an administrative decision, the constitutionality requirements addressed to the court apply to the administrative authority as well. For this reason, in such proceedings, the Constitutional Court may not disregard the assessment of the administrative decision from the point of view of fundamental rights, since this is a necessary prerequisite for the conviction of the appropriateness of the judicial decision.

[53] 2.3 Pursuant to section 33/B (1) of the Patent Act, a compulsory public health licence may be granted only in the event of a health crisis within the meaning of section 228 (2) of Act CLIV of 1997 on Health Care. The specific feature of the cases at issue in the present proceedings is, however, that they were not simply initiated during a health emergency, which could also be declared under normal legal order, but during the special legal order announced in the period of the emergency declared as a result of the second wave of the coronavirus pandemic.

[54] In the case-law of the Constitutional Court, the judicial authorities should also take into account the grounds for imposing a special legal order in each case involving fundamental rights and must weigh the extent of the interference with fundamental rights in the light of those grounds. However, this assessment should not be formalistic and shall not be limited to a general invocation of the special legal order, but must cover all the relevant circumstances of the case {see in particular: Decision 3067/2021. (II.24.) AB, Reasoning [35] to [40]}.

[55] 2.4 On the basis of the above, the Constitutional Court shall primarily answer the question as to the extent to which the rights deriving from the status of the party, in particular the patent holder's right to be heard and the opportunity to make a statement, should prevail, pursuant to Article XXIV (1) of the Fundamental Law, in the compulsory public health licensing procedure. The second question arising from this is whether the position of the NIPO as an administrative agency in this respect was examined by the court taking into account fundamental rights aspects, and the third question – arising from Article XXVIII (7) of the Fundamental Law – is how a possible breach of fundamental rights committed in the administrative procedure relating to the status of the party can be remedied at the judicial stage. Thus, the Constitutional Court should consider the following aspects in order to assess whether there has been an interference with the rights of the petitioner as a party, which are part of his right to a fair administrative procedure, and, whether or not together with that right, with his right to a remedy (CCDec2, reasoning [97]): whether the procedure and decision of the administrative authority infringed fundamental rights; whether the court reviewing the administrative decision recognised the fundamental rights aspects of the main case and the possible infringement of fundamental rights by the administrative body; whether the court effectively and substantively remedied the established infringement of fundamental rights.

[56] 3 In order to answer the first question, the Constitutional Court reviewed the requirements and its case-law concerning the rights deriving from the status of the party, in particular the right to make a statement.

[57] 3.1 The Constitutional Court has identified several elements of guarantee of party-status which are directly linked to the right to a fair administration by the authorities enshrined in Article XXIV (1) of the Fundamental Law. The Decision 3311/2018 (X.16.) AB (hereinafter: CCDec3), which focused on the notification of the opening of proceedings, identified the right of access to documents, the right to make statements and the right to file a petition as such. In that decision, "the Constitutional Court held that the right to be notified of the opening of proceedings and the right to be acquainted with the evidence, through the right to make a statement and the right of defence, necessarily form part of the scope of the right to a fair official procedure." (Reasoning [33]).

[58] In another case concerning the constitutional framework of the imposition of fines by public authorities, the Constitutional Court held that "the subject of the fundamental right under Article XXIV (1) of the Fundamental Law is, as explained above, the party, i.e. the natural or legal person or organisation whose right or legitimate interest is directly affected by the case. [...] The public authority is the subject of this right [...]. The purpose of the fundamental right is to ensure, in a party-oriented approach, a balance between the public interest and subjective legal protection, the enforcement of substantive law and, ultimately, the lawful functioning of the public authority. In terms of its content, the right to a fair procedure by public authorities encompasses all the partial rights required to ensure the party's right to participate. Its components therefore include, inter alia, the right to make a statement and the right to an effective defence in administrative proceedings leading to the imposition of sanctions. Both presuppose the exercise of the rights of access by the party." {Decision 3223/2018. (VII.2.) AB (hereinafter: CCDec4), Reasoning [57]; quoted and reinforced in: Decision 7/2019. (III.22.) AB, Reasoning [33]; Decision 32/2019. (XI.15.) AB, Reasoning [59]}

[59] It is clear from the consisted case-law of the Constitutional Court that the right to access to documents and to make statements are guaranteed components of the party's legal status, the expression of which in the norms of specialised law – typically administrative procedural law – can be directly derived from Article XXIV (1) of the Fundamental Law, and are thus essential elements of the party's legal status and the right to a fair procedure before the authorities.

[60] This conclusion is also in line with the expression of this fundamental right in international documents as a result of recent European legal developments. For instance, according to Principle I of Council of Europe Resolution No 31 (77) on the protection of the individual with regard to acts of public authorities, "In respect of any administrative act of such nature as is likely to affect adversely his rights, liberties or interests, the person concerned may put forward facts and arguments and, in appropriate cases, call evidence which will be taken into account by the administrative authority". Similar language is used in Principle 14 of Recommendation No 7 of the Committee of Ministers of the Council of Europe (2007) on good administration: "If a public authority intends to take an individual decision that will directly and adversely affect the rights of private persons, and provided that an opportunity to express their views has not been given, such persons shall, unless this is manifestly unnecessary, have an opportunity to express their views within a reasonable time and in the manner provided for by national law, and if necessary with the assistance of a person of their choice."

[61] The substantive role of the right to make a statement in relation to the status of the party is also supported by the legal literature: "[The] right to be heard

serves a dual purpose: on the one hand, of course, it serves to protect the rights of citizens, but on the other, it ensures that the authority is in possession of the fullest possible knowledge of all the facts and circumstances which may be relevant to the case, so that the most favourable decision can be taken" (Eric Barbier de la Serre: "Procedural Justice in the European Community Case-Law Concerning the Rights of the Defence", based on PéterVáczi, The Fundamental Right to Good Administrative Procedure and its Components. Dialóg-Campus, Budapest-Pécs, 2013. pp. 130 to 131).

[62] In relation to the right to access to documents and to make statements, which is at the core of the rights of the party, the Constitutional Court emphasised that "the operation of public authorities in which the party is the »sufferer« of the public interest protection of the authority, or in which subjective legal protection is undeservedly relegated to the background, is not in accordance with the concept of the human being of the Fundamental Law. Consequently, the infringement of the statutory right of access to the file constitutes a restriction of the fundamental right to a fair procedure by the public authority in so far as it impairs the right of the party [...] to make a statement and to defend himself." (CCDec4, Reasoning [37])

[63] The principle of equality of arms, which has been recognised by the Constitutional Court as a requirement of the right to a fair hearing, is also linked to the subjective legal protection function detailed above (CCDec 1, Reasoning [60] to [65]). CCDec1 was based on an administrative case initiated on request, in which the applicant asked the authority to establish an entitlement which affected him and which adversely affected the legal position of another legal entity. In such administrative proceedings – which involve opposing parties and thus also have an adversary element – the requirement of the equality of arms, originally applicable to criminal proceedings, shall apply as appropriate. As explained by the Constitutional Court in the Decision 21/2014. (VII.15.) AB: »According to the consistent case-law of the Constitutional Court, the principle of equal arms is an essential element of fair trial, securing equal chances and possibilities, basically in criminal proceedings, for the prosecution and the defence to form their opinions and take a stand on factual and legal questions. The principle of equal arms does not entail in each case the rights of the prosecution and the defence to be completely the same; however, it requires that the rights of the defence should be of comparable weight in relation to those of the prosecution«." (CCDec1, Reasoning [61])

[64] Consequently, equality of arms shall be ensured in public authority cases involving opposing parties, so that, in relation to the type of case, the opposing party has the chance and opportunity to formulate his views and position on questions of fact and law. The principle of equal arms does not necessarily entail the rights of the applicant and the opposing party to be completely the same, but it requires at all times

that the rights of the opposing party should be of comparable weight in relation to those of the applicant.

[65] The Constitutional Court has previously pointed out that the "right to make a statement and to defend oneself, which includes the right of access to documents, may also be restricted." (CCDec4, Reasoning [58]). However, "under the right to a fair trial, certain procedural guarantees are of value, the breach or non-observance of which affects the merits of the case, whatever the outcome of the case is. A violation of the right to a fair trial may occur even if there is no causal link between the substantive procedural violation and the concrete outcome of the case, but the enforceability of the rights of the party suffers a violation that, taking into account the totality and circumstances of the proceedings, rises to the level of an infringement of fundamental rights." (DCC3., Reasoning [34])

[66] 3.2 With regard to main basic cases which are the subject of the present constitutional complaints, it can be established that the NIPO restricted the petitioner's right to a fair official procedure arising from Article XXIV (1) of the Fundamental Law by not recognising its status as a party, and thus not granting the partial rights under the above-mentioned guarantees.

[67] In order to assess the decision of the NIPO which resulted in a restriction of fundamental rights, the Constitutional Court reviewed the legal context of the compulsory licensing procedure in the field of public health.

[68] Compulsory licensing in the field of public health is an administrative procedure initiated upon request, the purpose of which is to ensure that health products subject to patent- or supplementary protection or patented processes, equipment or devices necessary for their manufacture are available primarily to satisfy domestic – and to a limited extent, even foreign – needs. The specificity of the procedure is that the compulsory public health licence is based on an overriding public interest – guaranteeing security of supply for a health product – yet the procedure is not initiated by an act of public authority but by an initiative of an entity wishing to produce the health product in question but not otherwise entitled to use the patent, typically under a licensing agreement.

[69] The competence of the NIPO to examine applications for compulsory public health licences is laid down in section 44 (5) of the Patent Act. Section 45 (1) of the Patent Act refers to the AGAP as the general background legislation to the Patent Act, declaring that in matters falling within the competence of the NIPO, the AGAP shall apply, with the exceptions and additions provided for in the Patent Act. In addition, however, the Patent Act itself contains specific provisions on compulsory public health licensing which provide for derogations from the general procedural provisions of the Patent Act. Compulsory public health licensing procedure is therefore regulated by two

pieces of legislation, but at three levels: at the most general level, the AGAP as background legislation, Chapter VII of the Patent Act for all procedures of the NIPO, and the subheading "Procedures related to compulsory public health licences" in chapter of Chapter X of the Patent Act, which applies only to compulsory public health licences as a specific type of procedure.

[70] With regard to the status and rights of the party, section 45 (2) of the Patent Act, which falls within Chapter VII, precludes in all proceedings before the NIPO the applicability of section 5 (1) of the AGAP, which grants the party the right to make statements and submit observations at any time during the official procedure. However, section 47 (3) of the Patent Act, which is included in the general procedural rules, states that the NIPO "may base its decision only on facts and evidence on which the customer has had an opportunity to make a statement; it may, however, disregard statements or evidence which the customer has not submitted in due time". Among the procedural rules specifically relating to compulsory public health licences, the law-maker provided in section 83/I (1), first, that such procedures are to be implemented out of turn and, second, in point (a), that "a time limit of at least fifteen but not more than thirty days shall be set for the submission of missing documents and making a statement, and an extension of the time limit may be granted only in particularly justified cases". Pursuant to section 83/I (5), the NIPO "shall notify the proprietor of the patent to which the application relates within eight days of receipt of the application of the fact that a request for compulsory licensing of his invention has been filed".

[71] It follows from all the above that the application of section 10 of the AGAP, which lays down the definition of party, is not precluded by the Patent Act, nor does it provide for any derogation from it. Indeed, the patent holder (in the present case: the petitioner), whose exclusive right to the exploitation of the patent is the subject of the compulsory public health licence (section 33/B of the Patent Act), is undoubtedly a legal person whose "right or legitimate interest is directly affected by the case" [section 10 (1) of the Patent Act]. As the Constitutional Court has previously pointed out, section 10 (2) of the AGAP may not be interpreted as meaning that a special Act of Parliament or government decree as *lexspecialis* could automatically, without an express statutory provision, exclude the application of the definition of party under section 10 (1) of the AGAP {Decision 3158/2020. (V.21.) AB, Reasoning [16]}. The initiation of breaking up the exclusive exploitation right, which is the essence of the patent, not only establishes the party status, but also necessarily makes the patent holder and the applicant for a compulsory public health licence opposing parties.

[72] Although by excluding the application of section 5 (1) of the AGAP, the Patent Act restricts the right to make a declaration, which is also an element of constitutional significance of the status of the party, since this right cannot be exercised "at any time". Even when read in conjunction with the obligation to notify the applicant

of the filing of a request for a compulsory licence (section 83/I (5) of the Patent Act), it does not necessarily follow that the Patent Act would have completely excluded the right of the patent holder-applicant to make a declaration. On the contrary, it follows from section 47 (3) of the Patent Act, which only allows the NIPO to take into account evidence on which the party was in a position to make a statement. This is also confirmed by section 83/I (1) of the Patent Act, which, on the one hand, makes the making of a statement subject to a time limit and, on the other hand, also – as a matter of course – applies this to support the possibility of making a statement.

[73] On the basis of a comparison of the relevant provisions of the Patent Act and the AGAP, it can be concluded that there is an interpretation of section 5 (1) of the AGAP which is in conformity with Article 28 of the Fundamental Law and which ensures the petitioner the right to make a declaration arising from its status as a party.

[74] 3.3 As concluded by the Constitutional Court in paragraph IV/3.1 of the reasoning of the present decision (Reasoning [57] et seq.), the status of the party and the fundamental rights deriving from it, including in particular the right to make a statement, are guarantees of the fundamental right to a fair administrative procedure, the restriction of which requires strong justification.

[75] Compulsory licensing in the field of public health is clearly unfavourable from the point of view of the legal position of the patent holder, since it provides an exception to the right of exploitation exercised exclusively by the patent holder. The denial of both the status of a party and the resulting right to make a statement caused the patent holder to have no opportunity in the compulsory public health licensing procedure to bring its arguments against compulsory licensing to the attention of the authority or to adduce evidence which might call into question the legal basis for compulsory licensing. The patent holder was thus deprived of the possibility of defending itself in a procedure which could have had a potentially adverse outcome for it.

[76] Given the necessary conflict of interest between the patent holder and the applicant for a compulsory public health licence, the principle of equality of arms could not be applied in the proceedings either: while the applicant for a compulsory licence could substantiate the merits of its claim in detail, the applicant had no opportunity to refute it in the absence of party status and the resulting opportunity to make a statement.

[77] 3.4 In its decisions, the NIPO did not provide any reasoning as to the grounds for the deprivation of the party's legal status and essential elements underlying the exercise of the right to a fair administrative procedure, nor did the Constitutional Court identify any such grounds in its assessment of all the relevant circumstances of the case. In this respect, the Constitutional Court paid particular

attention to the fact that the application for a compulsory public health licence and the procedure of the NIPO also took place during the period of the state of danger as a special legal order due to the coronavirus pandemic. Protection against an epidemic, and in particular access to sufficient quantities of essential health products, may be a legitimate aim of a restriction of a fundamental right which is not an absolute right, which may be justified by the right to life protected by Article II of the Fundamental Law and the right to health protected by Article XX (1) of the Fundamental Law. The speed of the compulsory public health licensing procedure can also be assessed in this context.

[78] However, the judiciary is expected to assess all the circumstances of a given case in a complex, overall manner in the context of the interpretation of the law involving a restriction of a fundamental right. In the context of compulsory licensing in the field of public health, such relevant circumstance is the fact that the procedure was initiated on application, which shows that, at least formally, it is not the State – obliged to ensure the protection of the public interest and fundamental rights by exercising its public authority – but an independent market actor is the one who grants the compulsory licence.

[79] Another such circumstance, relating to the protection of life and health and the time dimension thereof, is that the law-maker has provided for the initiation of a compulsory public health licensing procedure to be carried out without delay, which it has confirmed by setting a time-limit for the submission of a statement. Here the Constitutional Court also refers to the fact that the decision of the NIPO granting a compulsory public health licence is enforceable in advance [section 85 (2a) of the Patent Act], which prevents the patent holder from delaying the production based on the compulsory licence by filing a request for a modification. The time required to prepare for the authorisation and manufacture of medicinal products as health care products must also be taken into account. It can therefore be concluded that, in the interests of ensuring an adequate supply of medicines in sufficient quantity and speed, and thereby protecting life and health, the law-maker has introduced a number of restrictions in the compulsory licensing procedure for public health. These provisions limit the rights of the patent holder in the compulsory licensing procedure from the outset, and it is therefore not in accordance with the Fundamental Law for the law-maker to interpret the procedural rules in such a way as to restrict the rights of the patent holder beyond that.

[80] Taken all this together, it cannot be concluded that the recognition of the status of the patent holder as a party or the expressly short time-limit for the patent holder to make a declaration, as provided for in section 83/I (1)(a) of the Patent Act, would have caused a delay which would have jeopardised the effectiveness of the

epidemic defence and which would have offset the disadvantages resulting from the deprivation of the most essential guarantees of the right to a fair hearing.

[81] 3.5 On the basis of the above, the Constitutional Court found that the procedures of the NIPO and the resulting Decisions were in breach of the Fundamental Law, as the NIPO adopted an interpretation of the law that led to the deprivation of the most essential guarantees of the right to a fair public procedure and was not in line with the Fundamental Law. Furthermore, in the circumstances of the cases, no interest could be identified which would have justified the complete withdrawal of the essential elements of Article XXIV (1) of the Fundamental Law, namely the status of the party and the resulting rights of the patent holder to defend itself, in particular the right to make a statement, which give effect to the principle of equality of arms.

[82] 4 Following a finding that the decisions of the NIPO are contrary to the Fundamental Law, the Constitutional Court needs to rule on the question whether the courts hearing the main cases have fulfilled their obligation to detect the fundamental law implications of the decisions and that the decisions of the NIPO are contrary to the Fundamental Law.

[83] In the scope of examining this question, the Constitutional Court points out at the outset to the specificity of patent cases, arising from section 85 (1), section 88 and section 91 (2) of the Patent Act, that the system of appeal against decisions of the NIPO differs from the system of administrative proceedings under the general rule of judicial review of administrative decisions, as regulated by the Act I of 2017 on Administrative Procedure. The form of legal remedy against the decision of the NIPO is an application for a modification of the decision, which, if the NIPO disagrees with the content of the application, is adjudicated by a court in civil non-litigious proceedings, i.e. not in an administrative action (cf. section 88 of the Patent Act), which, by its nature, is an adversarial procedure between the patent applicant requesting the modification and the compulsory public health licence holder as opposing parties [section 91 (2) of the Patent Act]. However, even though the application for modification is not an administrative procedure and the NIPO is not even a party to it, the purpose of the non-litigious procedure before the court is to review the decisions of the NIPO. This is also clear from the title of Chapter XI of the Patent Act, which contains the cited rules – "Review of the decisions of the National Intellectual Property Office". In the light of this, the Constitutional Court considers the requirements it has developed for the judicial review of decisions of public authorities, typically administrative proceedings, to be applicable to the non-litigious proceedings brought following applications for the modification of decisions of the NIPO {see paragraph IV/2.2 of the reasoning to the decision (Reasoning [49] et seq.)}.

[84] It is clear from the judgements of first instance in the main cases that neither the regional court nor the regional court of appeal fulfilled the duty incumbent on the courts under Article XXIV (1) of the Fundamental Law. Despite the *ex parte* procedure – i.e. a procedure carried out without involving the patent holder as a party –, which was expressly challenged in the application for modification, and the invocation of the right to a fair hearing by a public authority, which is also referred to in the Fundamental Law, the court expressly refused to examine the fundamental rights aspects of the cases and also examined in a one-sided way the time factor arising from the epidemic situation, excluding the interests of the patent holder from its consideration.

[85] As the regional court of appeal upholding the first instance rulings fully shared the view of the regional court, it failed to recognise the fundamental rights aspects related to the status of the party, which the petitioner-patent-holder had repeatedly invoked in its appeal.

[86] The Curia interpreted the existence of the status of party entitling the patent-holder in the compulsory public health licensing procedure in the light of and in accordance with the relevant case-law of the Constitutional Court. However, it ignored the fact that the purpose of the party status in such cases is to ensure the possibility of the party's defence and to enforce the principle of equality of arms, which require – at least to a limited extent – the exercise of the right to have access to the case and the express right to make a statement, which is the essence of the party status {see the findings in paragraph IV/3.1 of the reasoning of the decision (Reasoning [57] et seq.) on the double justification of the right to make a statement}. Thus, – formally – granting the status of the party without its most important components is not in conformity with the right to a fair administration enshrined in Article XXIV (1) of the Fundamental Law. Therefore, the Curia has only partially fulfilled its constitutional obligation to identify the guarantee elements related to the fundamental rights aspects of the case and the decisions of the judicial authorities that infringe them.

[87] 5 Finally, the Constitutional Court must should ascertain, in the context of its examination of the conformity of a judicial decision with the Fundamental Law, whether the court has remedied the perceived infringement of the Fundamental Law by the administrative decision.

[88] Since, in the present cases, according to paragraph IV/4 of the reasoning of the decision (Reasoning [82] et seq.), the courts have not fully recognised the conflict of the NIPO's decisions with the Fundamental Law, they have not remedied it. In this context, the Constitutional Court observes that the failure to recognise the status of the party and the resulting lack of essential elements, such as the right to make a statement, in administrative proceedings are procedural violations that amount to a

breach of fundamental rights and cannot be remedied in a review procedure: they need to be ensured at the administrative procedure stage as well.

[89] 6 Based on the above, the Constitutional Court found in its decision that the petitioner's fundamental right to a fair hearing before the NIPO was violated due to the non-recognition of its client status in the proceedings before the NIPO, and that this was not recognised by the ordinary courts. Although the Curia found that the petitioner had client status, it failed to remedy the injury, because it did not recognise the petitioner's right to make a statement, thus the petitioner's right to legal remedy was violated during the court proceedings. In the light of this, the Constitutional Court annulled the decisions of the NIPO and the challenged court rulings.

[90] 7 The petitioner holds that the contested decisions of the judicial authorities also violate Article XXIV (1) of the Fundamental Law because of the system of evidence linked to the NIPN certificate, and the court orders violate Article XXVIII (7) of the Fundamental Law. In view of the fact that the Constitutional Court has found that the Curia's rulings violate the Fundamental Law as set out above, it has decided not to examine these elements of the petition.

[91] The Constitutional Court notes, however, that, as explained in paragraph IV/3.1 of the reasoning of the decision (Reasoning [57] et seq.), the only interpretation of the law which is compatible with Article XXIV(1) of the Fundamental Law is one which allows the party's defence of the case on the merits. The requirement of effective remedy can also be inferred from Article XXVIII (7), which in the present cases is closely linked to the right to a fair hearing {cf. the arguments in paragraph IV/2.1 of the reasoning of the decision (Reasoning [45] et seq.)}. The certificate issued by the NIPN is of particular importance in the compulsory public health licensing procedure. Therefore, the Constitutional Court notes that the contestability by the opposing party of the validity of a document which has a substantial influence on the outcome of an official procedure and its reviewability by the competent bodies also deserves increased attention with regard to the guarantees of the right to a fair trial.

Budapest, 10 October 2023.

Dr. Tamás Sulyok, President of the Constitutional Court

Dr. Ágnes Czine, Justice of the Constitutional Court

Dr. Tünde Handó, Justice of the Constitutional Court

Dr. Mária Ádám-Haszonicsné, Justice of the Constitutional Court

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Dr. Tamás Sulyok, President of the Constitutional Court on behalf of Justice *dr. Marcel Szabó* unable to sign

Dr. Réka Varga, Justice of the Constitutional Court