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EUROPEAN COURT OF JUSTICE

C-139/24 P

Appellant:

XY represented and defended by attorney DDr. Renate Holzeisen

Respondent:

Commission

Concerning:

Order of the Court of First Instance received on 11.12.23, T-109/23

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1. XY, in his capacity as father of minors, brought an action for annulment against, inter alia, **Commission Implementing Decision C(2022) 7342 (final)** of **10 October 2022 granting a marketing authorization for the medicinal product for human use "Comirnaty – Tozinameran"** (hereinafter "Implementing Decision") (doc. A1, T-109/23).
2. With the implementing decision, the **substance Comirnaty from Pfizer/BioNTech** (hereinafter "Comirnaty"), **which is demonstrably experimental and based on genetic engineering,** was **approved** without conditions for a period of five years **as a "vaccine" for use in children**. This is **despite the fact that** Comirnaty **corresponds to an advanced therapy medicinal product (gene therapy) in terms of its composition and mode of action**, and its **efficacy and safety** have **never been proven.**

3. The conditional marketing authorization of Comirnaty initially granted in accordance with Regulation (EC) No. 507/2006 was already granted in the most radical violation of the pharmaceutical law provisions applicable in the EU. See the **Advanced Purchase Agreement (APA) between the Commission and the manufacturer Pfizer/BioNTech** (Annex I point 4, p. 48), which was concluded four weeks before the conditional approval of Comirnaty (21.12.2020) (**Doc. A.5**): "*The Participating Member State acknowledges that the Vaccine and materials related to the Vaccine, and their* ***components and constituent materials are being rapidly developed*** *due to the emergency circumstances*

of the COVID-19 pandemic and ***will continue to be studied after provision of the Vaccine to the Participating Member States*** *under the APA. The Participating Member State further acknowledges that the* ***long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known.”***

4. Because the Commission and the Member States explicitly accepted this **contractually stipulated experimental stage**, **in which Comirnaty was (and still is) unequivocally located,** by signing the contract, the manufacturer was guaranteed **comprehensive indemnification in** the same contract (see point I.2. *Indemnification*, page 24 ff.).

5. **In 2021, it became known that Pfizer/BioNTech[1] had dissolved the control groups of its studies, despite the requirement from the conditional approval to confirm efficacy and safety through clinical studies**. The reason given for the dissolution of the control group was that it was ethically unacceptable to withhold the vaccine from the members of the control group.

6. In its plea of alleged inadmissibility of the action for annulment, the Commission claimed that the implementing decision was not a legal act in the nature of a regulation within the meaning of Art. 263 (4) TFEU.

7. In his statement, XY explained in detail why the implementing decision is indeed a legal act in the nature of a regulation within the meaning of Art. 263 (4) TFEU.

8. On 18.09.23, XY filed an application for urgent measures to ensure a fair trial due to the lack of the necessary independence and impartiality of the judge reporting in the proceedings.

[1] Doc. A.26, A.27 T-109/23

9. An essential point of the **action for annulment is the non-applicability (in application of Art. 277 TFEU, incidental review of standards) of the COMMISSION's Directive 2009/120/EC.**

   This Directive amends Directive 2001/83/EC.
   Even substances declared only formally as "vaccines against infectious diseases," contrary to the nature of their ingredients and their mode of action analogous to gene therapy drugs, were thus exempted from the much stricter regulation intended for the approval of gene therapy drugs.

10. **In 2009, the reporting judge Dr. J. Ch. Laitenberger was first Head of the Spokesperson's Service of the Commission and then Head of Cabinet of the President of that Commission, which in 2009 made this legal amendment that puts the lives and health of future generations of the EU population at risk**!
    This meant that the independence and impartiality of judges provided for in Art. 47 CFR and Art. 5 of the EU Constitution Act and a fair trial were not guaranteed!

    From 2004 to 2005, Dr. Laitenberger was a member of the cabinet of Commission President José Manuel Barroso. From 2005 to 2009, he was Spokesman and Head of the Spokesman's Service of the Commission. From 2009 to 2014, he was Head of Cabinet in the Cabinet of the President of the Commission. The cabinet under President Barroso adopted Directive 2009/120/EU.

11. By decision of 18.10.23, XY's application for the recusal of Judge Laitenberger was rejected on the following grounds: "*It must be held that none of the factors relied on by the applicant leads to the conclusion that one of the cases referred to in Article 18 of the Statute of the Court of Justice of the European Union or Article 16 of the Rules of Procedure of the General Court, in which the conditions for the removal of a judge are laid down, applies to Mr. Laitenberger ... 16 of the Rules of Procedure of the General Court, which lay down the conditions for the disqualification of a Judge, applies to Mr Laitenberger ... the fact that he held high office in an institution of the European Union*

at the time when it adopted the act whose annulment is sought, or even that he directed the services of that institution, does not in itself constitute a ground for disqualifying a Judge …".

12. **The court thus *de facto* confirmed the facts put forward by XY, but did not find them to be substantial to the existence of judicial bias.**

13. By order of the court dated 11.12.23 (**Doc. A.1**.), XY's action was dismissed as inadmissible.

I. GROUND OF APPEAL

14. Violation of the fundamental right to independent and impartial judges and to a fair trial (Art. 47 CFR, Art. 18 ECJ Statute, Art. 5 and 16 EU Constitutional Treaty)

15. Based on the facts set out in paragraphs 9 and 10 above, the **violation of XY's fundamental right to independent and impartial judges and thus to a fair trial** is **obvious**.

II. GROUND OF APPEAL

16. **Violation of Art. 263 (4), 168 and 169 AUEV, Art. 3, 35 and 38 EU Charter, Directive 2001/83/EC Art. 8, 11, 26, 54, 58, 59, 86 et seq., 101 et seq, Annex I Part I, Part III, Part IV, Regulation (EC) 726/2004 Art. 3 to 7, 10a, 12, 14-a, 20, 20a, 25a, 57, 81, 84a, UN Declaration on the Human Genome and Human Rights, Regulation (EC) 507/2006 Art. 5 and 7, Regulation (EU) 536/2014**

17. **On XY's alleged lack of interest in legal protection with regard to the implementing decision**

18. In its order, the court claims in paragraphs 36 to 41 that XY lacks interest in legal protection in relation to the implementing decision.

    The Court claims that the implementing decision is not addressed to health professionals, public health authorities, patients or persons who may be vaccinated.

    According to the court, these groups of persons in particular cannot be regarded as addressees of the annexes to the implementing decision.

    Moreover, according to the court, the implementing decision only has the effect of allowing BioNTech to place Comirnaty on the EU market and prohibiting the Member States from opposing its placing on the market.

    The resolution does not create any kind of burden or obligation for natural persons.

    The implementing decision would not change the legal position of XY or his children in a qualified manner and therefore the annulment of the decision as such could not give them any advantage.

19. **In order to be able to assess whether XY can challenge the implementing decision by way of an action for annulment, it must therefore be examined whether it constitutes an act or decision that has binding legal effects on XY**. **In doing so, the object, content, substance, scope, effects and the factual and legal context in which it stands must be taken into account and not its nature, form, designation or** medium.

    (see orders of the General Court of 8.03.12, Octopharma Pharmazeutica Produktionsgesellschaft mbH v Commission, T-573/10, para. 30, of 10.07.19, Pilatus Bank plc v European Central Bank (ECB), T-687/18, para. 16).

20. **The objective of health protection is given priority in EU drug authorization law**. Recital 13 of Regulation (EC) No. 726/2004 states: "*In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of*

*the objective scientific criteria of quality, **safety** and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations."*

21. **At the heart of the implementation is a <u>reservation of authorization</u> for the placing on the market of medicinal products. Such a reservation of authorization is standardized for the central procedure in Art. 3 para. 1 of Regulation 726/2004.**

22. **<u>The implementing decision is a legal act in the nature of a regulation.</u>**

23. As is well known, the category of decisions was included in the category of binding legal acts with the Treaty of Lisbon (Art. 288 TFEU). **Decisions can also have abstract-general effects, regardless of whether they are addressed to an addressee or not**.

24. **Although the implementing decision is formally addressed to BioNTech, it has a general validity that directly affects XY and his children in their interests, as it does not require mediatization in the form of a discretionary implementing act.**

25. **The implementing decision consists, among other things, of extensive annexes, which are essentially of general application and in some cases are even aimed directly at healthcare professionals, users in general and potential vaccinees.**

26. The European Parliamentary Research Service (EPRS) analysis "Medicinal products in the European Union – The legal framework for medicinal products for human use" (April 2015—**Doc. A.2**) shows the following**:**

"The fundamental aim of the rules for medicinal products in the EU is to safeguard public health ... is the common thread of the entire legal framework for medicinal products. …

EU pharmaceutical legislation covers the whole lifecycle of a medicinal product, from manufacture, to clinical trials, ***to marketing authorisation, to pharmacovigilance and patient information.*** *...*
The legal basis for medicinal products is Article 168 ...TFEU: 'A ***high level of human health protection*** *shall be ensured in the definition and implementation of all Union policies and activities.'*
The European Parliament and the Council shall contribute to this objective by adopting 'measures setting high ***standards of quality and safety for medicinal products*** *and devices for medical use.' ...*

The EU regulatory system for medicinal products – Medicines can only be marketed in the EU after they have been authorised – and to be authorised, they must undergo strict testing and an assessment of their quality, safety and efficacy. ... The relevant provisions are primarily laid down in Directive 2001/83/EC and Regulation (EC) No 726/2004. … Granting of the authorisation ... is proof that the medicine complies with the required standards."

27. The EPRS explains the **centralized marketing authorization procedure regulated by Regulation (EC) No. 726/2004 as** follows **(Doc. A.2)**:

"The Regulation introduces a single scientific assessment procedure of the highest standard for the medicinal products falling within its scope, with the ***aim 'to preserve the confidence of patients and the medical professions in the evaluation,' especially in the context of new emerging therapies*** *...*

The centralised procedure results in a single marketing authorisation that is valid in all Member States ...
Under the centralised procedure, a company submits its application directly to the EMA ...

After considering the opinion, the Commission can issue a <u>legally binding EU-wide</u> marketing authorisation.

Once it is granted, the marketing authorisation holder can begin to market the medicine in the EU. ...

***3.2 Paediatric medicines** ... are governed by Regulation (EC) No 1901/2006. The Regulation sets up requirements ... to ... **ensure that those medicines are ethically researched, of high quality and appropriately authorised for use in children;** ....*

*3.4 Advanced-therapy medicines. **Advanced therapy medicinal products (ATMPs) are governed by Regulation (EC) No. 1394/2007 (the ATMP Regulation)**. **ATMPs are novel biotechnology medicines based on cells and tissues. They comprise: – gene therapy medicinal products.…** In 2012, the Commission undertook a public consultation on the application and impact of the ATMP Regulation. The results were published in a report **(Doc. A.3)** in April 2014.*

It concludes that, despite the big potential benefits of these therapies for patients, there are still many unknown elements, which is why adequate controls are necessary to prevent negative consequences for public health.

4.4 Information for patients. Patients have to be properly informed about medicines.** ... 4.4.1 **Legislative approach. The regulatory basis for patient information is Directive 2001/83/EC.

***Medicinal products must be accompanied by labelling and package leaflet information that is easily legible, clearly comprehensible. .. This information must be drafted in consultation with patient groups.** ...*

Regulation (EC) No 726/2004 introduced a number of further criteria in regard to patient information, such as: – the requirement to publish a public assessment report (EPAR), including a user-friendly summary of product characteristics; – the basis for access to

information on pharmacovigilance and clinical trials; - the creation of a database on medicinal products accessible to the general public (EudraPharm).”

28. The **report of the Commission to the EU Parliament and the Council of 22.3.17 pursuant to Art. 59 (4) Directive 2001/83/EC (Doc. A.4)** states the following**:**

“2. ***Regulatory Framework –*** *The* ***summary of product characteristics*** *(SmPC) the content of which is described in Article 11 of Directive 2001/83/EC and the* ***package leaflet*** *(PL) the content of which is described in Article 59 of Directive 2001/83/EC* ***form an intrinsic and integral part of the marketing authorisation for medicinal products*** *in the Union in accordance with Article 6 of Directive 2001/83/EC and Article 3 of Regulation (EC) 726/2004.*

Article 8(3)(j) of Directive 2001/83/EC and Article 6(1) of Regulation (EC) 726/2004 require that, in order to obtain a marketing authorisation, a SmPC and a PL must be included in the marketing authorisation application. …

When the marketing authorisation is issued by the competent authorities of the Member States, the Marketing Authorisation Holder shall be informed of the SmPC as approved by them (Article 21(2) of Directive 2001/83/EC) and the national competent authority concerned shall, without delay, make publicly available the marketing authorisation together with the package leaflet and the summary of product characteristics. (Article 21(3) of Directive 2001/83/EC)

For decisions concerning centralised marketing authorisations, according to Article 10 of Regulation (EC) No 726/2004, the final Commission decision with the SmPC and the PL is addressed and notified to the Marketing Authorisation Holder **(and made available to the public** ... *see* https://ec.europa.eu/health/documents/community-register/html/) ...

After a marketing authorisation has been granted the content of the SmPC cannot be changed except with the approval of the competent authority that granted the marketing authorisation. *The SmPC is the basis of* ***information for healthcare professionals on how to use the medicinal product safely and effectively.***

... specific aspects of the treatment related to use of the medicinal product or its effects should be mentioned in the SmPC. Similarly, ... any advice specific to the concerned medicinal product should be included.

The PL ***provides a set of comprehensible information enabling the use of the medicinal product safely and appropriately. The package leaflet is primarily intended for the patient/user. If the package leaflet is well designed and clearly worded, this maximises the number of people who can use the information.*****"**

29. **Contrary to the erroneous opinion of the Court of First Instance, the content of the implementing decision is** therefore **very much aimed at healthcare professionals, public health authorities and vaccinated persons.**

30. Since the content of the package leaflet and the information for healthcare professionals is determined exclusively by Commission decision, and the content of the package leaflet and the information for healthcare professionals constitute an essential and integral part of the implementing decision, the implementing decision is *de facto* also addressed to all those groups of persons who, according to Directive 2001/83 EC, have a right to the content of the package leaflet and the information for healthcare professionals in conformity with EU law.

31. According to Art. 11 Directive 2001/83 EC, last paragraph, the following applies:

"For all medicinal products, a standard text shall be included expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national

spontaneous reporting system referred to in Article 107a(1).”

32. The pharmacovigilance requirements for vaccines are much lower than for advanced therapy medicinal products (gene therapy).

33. It is in line with the case law of the EU (see para. 19 above) **which indicates that it is not the nature, form or designation of an act or decision of an EU institution, but its object, content, substance, scope, effects and also the factual and legal context that are essential for assessing the legal effects of the act or decision of the EU institution**.

34. It is therefore not true what the General Court states in paragraph 37 of its decision, according to which the implementing decision only has the effect of allowing BioNTech to place Comirnaty on the EU market.

35. It is indisputable that the substance marketed as Comirnaty could never have been used in vaccination programs of EU Member States if it had not been approved as a “vaccine” but as an advanced therapy medicinal product (gene therapy).

36. The case law cited by the Court of First Instance in paragraph 37 of its order is irrelevant, since the arguments put forward by XY in his action for annulment and in his statement on the plea of inadmissibility of the action were not submitted to the Court of First Instance in the proceedings thus decided.

37. This is not about the mandatory Covid-19 vaccination ordered by the Italian government.

The point is **that a pharmaceutical-therapeutic classification of the substance Comirnaty as a “vaccine” instead of as a “medicinal product for advanced therapies**

(gene therapy),” which completely disregards its actual nature and mode of action, leads to Comirnaty being used en masse as a “vaccine”, demonstrably putting the health and lives of EU citizens at risk, right down to the very youngest!

38. Furthermore, in his action for annulment, XYhas **shown that the clinical trials for Comirnaty were simply discontinued for the purpose of confirming efficacy and safety.**
    Thus—contrary to the Commission’s untrue assertion—efficacy and safety have never been proven. See above under para. 5.

39. If Comirnaty had not been approved by the Commission as a “vaccine,” Italy would never have been able to include this substance in a “vaccination program.”

40. If the Commission had not stated in its decision, contrary to the truth, that proof of efficacy and safety had been provided, Comirnaty could never have been authorized for a period of five years, but would have had to be withdrawn from the market immediately in accordance with Art. 14-a of Regulation (EC) No. 726/2004!

41. This in turn would have meant that Comirnaty could no longer be used as a “vaccine” in the EU member states.

42. Therefore, contrary to the erroneous assertion of the court (see para. 40), **the declaration of nullity changes the legal position of XY and that of his children in a qualified manner**.

43. **If Comirnaty is withdrawn from the market, this substance can no longer be used in vaccination programs**.

44. The General Court’s erroneous assertion in paragraph 39 of its order that the implementing decision does not prejudge the decisions taken by the authorities at national level is thus refuted.

45. In paragraph 47 of its decision, the court displays an **absolutely unacceptable and frighteningly totalitarian attitude**.

    The Court claims **that** the **authorities of the Member States have full discretion to decide whether it is appropriate to impose the use of Comirnaty on doctors, <u>if necessary by means of coercive measures!</u>**

46. <u>This contradicts the most fundamental principles of EU law and the ECHR</u>. Imposing coercive measures on doctors to use a substance that is demonstrably experimental and based on gene therapy corresponds to the mindset of totalitarian regimes, but not to the EU treaties, the CFR and the ECHR!

47. **This one paragraph—as an *obiter dictum*—has an extremely dangerous effect and must not be allowed to stand! For if it were to remain, this would be tantamount to an obvious departure of EU jurisdiction from all fundamental principles of EU law**!

48. Since, according to the court, it would be at the discretion of the member states to use Comirnaty "*even with coercive measures*," XY and his children, as well as all EU citizens, have an unmistakable personal existing and present interest in the immediate revocation of the authorization of Comirnaty as a "vaccine."

49. It is the General Court itself which, in paragraph 47 of its decision, provides the reasons why not only XY and his children, but all EU citizens have a personal existing and present interest in the annulment of the implementing decision.

50. A further statement of the court decision ultimately shows the **abstract-general effect** of the implementing decision: according to the court, the granting of authorization for Comirnaty (an experimental substance based on genetic engineering) would "only" mean that the member states cannot oppose the placing on the market.

51. <u>On the alleged lack of standing of the XY due to alleged lack of direct concern</u>

52. The above also shows that XY and his children are directly affected.

53. The Court itself emphasizes that the Member State cannot oppose the unconditional marketing of Comirnaty as a vaccine decided by the Commission, and that the Member State can—if necessary—force the use of Comirnaty as an alleged "vaccine" on XYand his children!

54. **Following the frighteningly authoritarian logic of the court, there is hardly a more direct concern than that of the XY, its children, indeed all EU citizens, who see themselves at the mercy of the authority of their member states**, **which, according to the court, can also use coercion to apply experimental genetic engineering substances, such as Comirnaty,** to **the citizens!**

55. <u>On the alleged lack of standing to sue due to alleged lack of individual concern</u>

56. Proof of individual concern is not necessary, as the contested Commission decision is a legal act in the nature of a regulation, which has a generally abstract effect.

57. <u>On the alleged lack of standing because the contested Commission decision is allegedly not a legal act in the nature of a regulation</u>

58. The court claims that the implementing decision would only have legal effect towards the company producing Comirnaty. The fact that this is not true has already been explained in detail above.

59. In its attempt to deny XY standing, the Court even goes so far as to claim (para. 56) that the implementing decision does not classify the medicinal product Comirnaty as a vaccine, but merely grants an authorization for this medicinal product!

60. This corresponds to a disregard of the most rudimentary principles of pharmaceutical law, because **it is precisely the authorization decision that determines the pharmaceutical-therapeutic class (category) of the medicinal product with legal effect for all, and**

declares the medicinal product as belonging to this pharmaceutical-therapeutic class (in this specific case "vaccine" *versus* "advanced therapy gene therapy medicinal product") (see Art. 59 Directive 2001/83/EC)!

61. According to Art. 1 pt. 26a. Lit b) Directive 2001/83/EC, "variation and variation to the terms of the marketing authorization" means a decision or resolution to grant a marketing authorization for a medicinal product for human use, including the summary of product characteristics .... ,

"changes to the labelling or the package leaflet related to changes to the summary of the product characteristics."

62. **According to Art. 8 of Directive 2001/83/EC, the application for marketing authorization of a medicinal product must be accompanied by the following, among other things, as this must be included in the authorization decision as an essential component and thus acquires legal effect**: **Therapeutic indications, a summary of the product characteristics in accordance with Article 11)—**in this specific case, this means vaccination versus medicinal product for novel therapies (gene therapy).

63. **According to Article 11 of Directive 2001/83/EC, the summary of product characteristics (which forms an essential and integral part of the marketing authorization decision) must include the qualitative and quantitative composition of the active substances and ingredients, the indication for use and much more.**

64. When the court writes: "*Insofar as Annex I of the implementing decision states in particular that this medicinal product is an mRNA vaccine whose therapeutic indication is active immunisation in persons aged six years and over for the prevention of Covid-19*

caused by SARS-CoV-2, it must be assumed that this information is included in the summary of product characteristics and thus substantiates the authorisation granted." This is an expression of the fact that an **attempt was obviously made to deny the decision its effective content and meaning "by hook or by crook**."

This is because **a marketing authorization is not "concretized", but is granted or not granted for a medicinal product with the pharmaceutical-therapeutic properties declared in the marketing authorization** ("vaccine *versus* advanced therapy medicinal product – gene therapy)."

U. **The characteristics of the medicinal product declared in the marketing authorization have general validity, as they apply not only to the pharmaceutical company submitting the application, but also to the Member States, all authorities, healthcare professionals and vaccinees.**

65. As already explained above (para. 28), **the Commission itself states that the package leaflet is aimed at the vaccinees/users and the information for healthcare professionals**.

66. Article 59 of Directive 2001/83/EC stipulates that the package leaflet must be drawn up in accordance with the summary of product characteristics. Among other things, it must contain **the pharmaceutical-therapeutic class or mode of action** in **a form easily understood by the patient in order to identify the medicinal product.**

67. **In the package leaflet, Comirnaty is referred to as a** Covid-19 **mRNA** vaccine (nucleoside-modified)**, contrary to its actual mode of action and composition**.

68. **Both the information for healthcare professionals and the package leaflet are completely misleading in the case of Comirnaty**!

69. **Abstract-general and direct effect of the classification and approval-procedural treatment as a (conventional) "vaccine" of an experimental substance analogous to gene therapeutics in its mode of action and composition**.

70. Both in the contested implementing decision (Doc. A.1 Action for annulment) and in the annexes thereto (Doc. A.2 Action for annulment), which form an essential and integral part of the decision, **Comirnaty** is **declared to be a "vaccine."**

    This has an **abstract-general and direct effect that does not require any further implementing acts.**

71. Because **on the basis of this** (see action for annulment para. 28 ff.) **completely misleading and contrary to EU law categorization of the substance Comirnaty under pharmaceutical law, the provisions applied for market approval, the extremely reduced and completely inadequate risk management (RMP) and the absolutely inadequate pharmacovigilance to be exercised by the authorities and health personnel were based solely on the guidelines drawn up by the WHO for conventional vaccines in 2005**!

72. The disastrous, far-reaching consequences of the implementing decision have already resulted in death for at least tens of thousands of EU citizens and other serious irreversible damage for at least tens of hundreds of thousands of citizens according to the data from EudraVigilance (Doc. B.1 Statement on the objection of inadmissibility T-109/23). EudraVigilance is only fed with extremely underreported data due to exclusively passive pharmacovigilance.

73. **The implementing decision has an abstract-general effect, since it was used to bring a dangerous experimental substance based on genetic engineering, which corresponds in its mode of action to a gene therapeutic agent, onto the market as a "vaccine" for use on the entire population, right down to the smallest children, with the predicate "safe" in the Covid-19 "vaccination campaign" pushed by the Commission, bypassing all safety precautions and conditions**.

74. Apart from the fact that **not** even the clinical studies imposed in the decision of 21.12.2020 regarding the conditional authorization of Comirnaty pursuant to Art. 14-a Regulation (EC) No. 726/2004 for the purpose of confirming efficacy and safety were carried out (see action for annulment para. 116 to 134), neither **genotoxicity studies, nor carcinogenicity studies, nor mutagenicity studies (i.e. studies on the risk of DNA modification)** were **carried out.**

75. This has an abstract-general effect for the entire EU population, as a highly dangerous experimental substance based on genetic engineering has been brought onto the EU market for mass use through "vaccination campaigns."

76. In the action for annulment, XY had already stated in paragraph 54 that **the main difference between the approval procedure for a genetically engineered medicinal product and that for <u>conventional</u> vaccines is that the risk factors to be taken into account for genetically engineered products include the degree of integration of nucleic acid sequences or genes into the human genome, the long-term functionality and the oncogenicity risk.**

77. Annex I to the contested implementing decision (Doc. A.2 Action for annulment T-109/23) expressly states under point 5.3 that **neither genotoxicity nor carcinogenicity studies** were **carried out.**

78. **The assessment report on Comirnaty shows that these studies were not carried out because the EMA simply adhered to the WHO guidelines for conventional vaccines (2005)**! (see action for annulment para. 86 ff.).

79. Due to its fundamental importance, the protection of the human genome is enshrined at supranational and international level. See the Convention on Human Rights and Biomedicine of the Council of Europe of 1997, as well as the Universal Declaration on the Human Genome and Human Rights of the 29th UNESCO General Conference in November 1997.

80. **Abstract-general and direct effect due to the gross criminal deception and the fundamental prevention of informed and therefore free consent to the injection of the substance.**

81. **The fundamental right of people to not be subjected to pharmacological experiments without their free and informed consent is enshrined at EU and international level** (**Regulation (EU) No. 536/2014, Nuremberg Code,** action for annulment, para. 135 et seq.)**.**

82. **By categorizing Comirnaty as a "vaccine," which does not correspond to its actual mode of action, the population of the EU is being grossly deceived and therefore cannot freely consent to the injection of this substance**!

83. And this regardless of any Covid-19 "vaccination obligations" provided for at Member State level, which are not at issue in this case!

84. **The EU population has been and is being *de facto* subjected to a criminal pharmacological mass experiment by the implementing decision.**
This abstract-general effect does not require an implementing act, but results directly and immediately from the implementing decision.

85. The implementing decision radically violates **Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use, as well as the Nuremberg Code**.

86. **The pretense of false facts in the contested implementing decision automatically leads to mass involuntary treatment with an experimental substance**.

87. Since 27.12.20 (start of the EU-wide "vaccination campaign"), the EU population has been injected with experimental substances that correspond in their composition (nucleic acid sequence) and mode of action (genetic manipulation) to a gene therapeutic agent (action for annulment para. 28 ff.) without the population being informed about this and without the citizens having given and giving their informed and therefore free consent!

88. **The contested implementing decision has *de facto* degraded EU citizens from the position of human beings with their fundamental right to life and health and their guaranteed human dignity to laboratory animals.**

89. **Abstract-general and direct effect of the implementing decision due to the failure to revoke the conditional marketing authorization and even the granting of an unconditional five-year renewable marketing authorization**

90. The implementing decision (Doc. A.1. and A.2. Action for annulment T-109/23) also has an abstract-general direct effect with **criminal relevance because**, **despite the fact that the clinical studies required to confirm the propagated efficacy and safety (and thus the propagated positive benefit/risk ratio of Comirnaty) were never initially carried out in the implementing decision of 6.1.21** (Doc. A.5 and A.6 Action for annulment T-109/23) and the subsequent implementing decisions **were never carried out, yet unconditional marketing authorization was granted for five years (renewable).**

91. The **placebo groups were dissolved a few months after the start of the "vaccination campaign" with the cynical pretext that for ethical reasons the participants in the**

control group could not be exposed to any risk of Covid-19 disease (action for annulment para. 123 et seq.).

92. With the implementing decision, the Commission has approved Comirnaty for mass use on the EU population for five years and renewable, without conditions, in the most brutal violation of fundamental principles of EU pharmaceutical law, although the efficacy and safety of this substance have never been confirmed in clinical trials.

93. **It could hardly be more cynical and criminal, because it deceives and potentially harms around 451 million EU citizens!**

94. The implementing decision has a **clear abstract-general and direct effect**.

95. If the Commission had not treated Comirnaty like a conventional vaccine and authorized it, but treated it and declared it as what it is, namely an experimental substance based on genetic engineering:

- even conditional approval for use in the context of "vaccination campaigns" for the entire population would never have been possible,
- the mother of XY's minor children would probably never have had the idea of obtaining court authorization to subject the two minor children to this injection, even against the father's desperate objection,
- the competent courts of the member state Italy would never have given authorization for the genetic engineering and experimental treatment of healthy children, and
- more or less the entire EU population would probably not have been prepared to have this substance injected, even repeatedly, into themselves (and their children!).

96. On the basis of the above, the contested court order of 11.12.23 in Case T-109/23 must be set aside and the action for annulment declared admissible.

Bolzano, 25.02.2024

RA DDr. Renate Holzeisen

The following documents are annexed:

A.1 European Court of Justice Order of 11.12.2023 in Case T-109/23; p. 1 to p. 18; para. 13;
A.2 European Parliament – Medicinal products in the European Union – The regulatory framework for medicinal products for human use, Staff Research Service, April 2015; p. 19 to p. 51; (color print); para. 26, 27;
A.3. EU Commission report on advanced therapy medicinal products 28.3.14; p. 52 to p. 67; (color print); para. 27;
A.4. EU Commission Report COM(2017) 135 final l 22.3.2017; p. 68 to p. 78; (color print); para. 28;
A.5. APA EU Commission BioNTech Pfizer; p. 79 to p. 139; (color print); para. 3.