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MIKOŁAJ DEPTALSKI*, PIOTR DZIEWAŁTOWSKI-GINTOWT**

TORTIOUS LIABILITY REGIME FOR MEDICAL DEVICES USING ARTIFICIAL INTELLIGENCE. ANALYSIS OF CURRENT SOLUTIONS[1]

I. INTRODUCTION AND STRUCTURE

The concept of Artificial Intelligence (hereinafter: AI) has recently been increasingly discussed not only in scientific[2] or popular science literature[3], but also in legal literature[4]. A particular area of research in broadly understood science and law is the application of artificial intelligence in medicine[5]. This, in turn, is generating keen

* *Author is a student at Jagiellonian University in Krakow. ORCID: 0009-0002-6895-9202.*
** *Author is a student at Jagiellonian University in Krakow. ORCID: 0009-0004-3818-6602.*

[1] The paper takes into account the legal position as of 21 May 2024.

[2] R. van de Schoot, J. de Bruin, R. Schram *et al.*: *An open source machine learning framework for efficient and transparent systematic reviews*, Nat. Mach. Intell. 2021, 3, pp. 125–133, https://doi.org/10.1038/s42256-020-00287-7 (access: 29.12.2023).

[3] N. Hatalska: *Wiek paradoksów. Czy technologia nas ocali?*, Kraków 2021; J. Kaplan: *Sztuczna inteligencja. Co każdy powinien wiedzieć*, Warszawa 2019; H. Frey: *Hello world. Jak być człowiekiem w epoce maszyn*, Kraków 2019.

[4] *Prawo sztucznej inteligencji*, eds. L. Lai, M. Świerczyński, Warszawa 2020; P. Księżak: *My, Naród? Konstytucjonalizacja sztucznej inteligencji, czyli o potrzebie przemodelowania założeń ustrojowych*, Przegląd Sejmowy 2021, No. 4, pp. 65–88; D. Szostek: *Wprowadzenie* (in:) *Prawo sztucznej inteligencji i nowych technologii*, eds. B. Fischer, A. Pązik, M. Świerczyński, Warszawa 2022; R. Stefanicki: *Sztuczna inteligencja tworzona przez człowieka, ukierunkowana na osobę ludzką i przez nią kontrolowana*, PPH 2023, No. 1, pp. 4–15.

[5] M. Michelson, T. Chow, NA. Martin, M. Ross, A. Tee Qiao Ying, S. Minton: *Artificial Intelligence for Rapid Meta-Analysis: Case Study on Ocular Toxicity of Hydroxychloroquine*, J. Med. Internet Res. 2020, 22(8); P. Visaggi, B. Barberio, D. Gregori *et al.*: *Systematic review with meta-analysis: artificial intelligence in the diagnosis of oesophageal diseases*, Aliment. Pharmacol. Ther. 2022, No. 55, pp. 528–540.

interest among lawyers not only in regulatory issues, i.e., the status of AI itself, but also in questions of liability[6] for AI[7].

The use of AI in various types of medical devices[8] has become crucial. Its application can be found, in particular, in diagnosing diseases, performing surgery, medical assistance, or rehabilitation and measuring devices[9]. In the language of the law, all of these devices can be collectively referred to as medical devices using artificial intelligence or, if we consider software alone, being artificial intelligence themselves.

The widespread use of AI in medical devices raises particular legal issues and risks. Specifically, the AI machine learning may be based on incorrect, incomplete or discriminatory data. Further risks are the lack of full explainability, possible lack of the informed patient consent and the superiority of AI over the doctor[10]. All of these factors open new questions concerning civil liability. Only unpredictability, however, remains the new, inherent and mostly associated with an AI risk which the existing liability regimes may not be prepared for[11]. This is because both AI may be considered as acting autonomously after it was exposed to its environment and due to opacity of its code which makes it likely impossible to determine what caused its specific behaviour[12].

These concerns have not gone unnoticed by the European lawmaker. In October 2020 the European Parliament adopted its resolution in which it directly proposed the new strict liability standard for AI-caused damage put onto both the system's frontend and backend operator[13]. On this basis, in September 2022 European Commission has delivered its own proposal for a directive called "on adapting non-contractual civil liability rules to artificial intelligence (AI Liability

[6] In this paper by "liable" we mean "legally responsible", "bears a tort/contractual liability", "who has been declared liable by courts".

[7] K. Thomasen: *AI and Tort,* Law, Artificial Intelligence and the Law in Canada, eds. F. Martin-Bariteau, T. Scass, Toronto 2021; G. Sartor, K. Branting: *Judicial Applications of Artificial Intelligence*, Dordrecht 1998, *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, eds. L. DiMatteo, C. Poncibò, M. Cannars, Cambridge 2022, pp. 87–160.

[8] As defined in the Regulation (EU) 2017/745.

[9] The widespread and comprehensive application of AI in healthcare is indicated by major research centres and public and private healthcare stakeholders, see: *Artificial intelligence in health care. Applications, risks, and ethical and societal impacts*, European Parliamentary research Service (EPRS), 2022. https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729512/EPRS_STU(2022)729512_EN.pdf (access: 6.03.2023), *10 Promising AI Applications in Health Care*, Harvard Business Review, 2018, https://hbr.org/2018/05/10-promising-ai-applications-in-health-care (access: 6.03.2023).

[10] P. Księżak: *Sztuczna inteligencja i roboty autonomiczne w* medycynie (in:) *System prawa medycznego*, t. 3, eds. D. Bach-Golecka, R. Stankiewicz, Warszawa 2020, pp. 1185–1208.

[11] B. Soyer, A. Tettenborn: *Artificial intelligence and civil liability — do we need a new regime?*, International Journal of Law and Information Technology 2022, No. 30, p. 386.

[12] C. Wendehorst: *Liability for Artificial Intelligence*, Cambridge University Press 2022, p. 195.

[13] European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). See also: B. Soyer, A. Tettenborn: *Artificial…*, *op. cit.*, p. 388; C. Wendehorst: *Liability…*, *op. cit.*, pp. 201–202.

Directive)"[14]. Work on the directive is, however, still ongoing and it is unclear when to expect the new law. The proposed AI Liability Directive would also likely impose strict liability on the so-called "high-risk" AI systems only[15]. Furthermore, the European Commission proposed a directive to deliver a minimum harmonisation approach, allowing claimants to seek redress under existing national laws, should they appear to be more favourable[16]. Therefore, the national liability standards remain today the only legal remedies for the damages caused by AI systems and will prevail also under the AI Liability Directive regime, whenever it is enacted. For this reason, it is important to determine how the existing Polish liability standards are effective in giving rise to appropriate remedies. In other words, the question posed for this paper is whether the current Polish regulations guarantee a sufficient level of protection by restitution of the damage in the event that it is caused when using an AI-based medical device.

In the first section, terminological issues will be presented, with an emphasis on differences in legal acts and jurisprudence. Following this, the various regimes of civil liability for a medical device using AI will be analysed. Finally, a conclusion will be presented outlining the primary possible directions of the AI medical device liability claim in Polish law.

II. TERMINOLOGY

In order to accurately identify legal problems related to the application of AI in medical devices it is necessary to clarify the terminology. First, a distinction between the language of the law and the legal language should be made[17]. The former describes the language found in normative acts and the latter describes the language used by lawyers and courts. The introduction of this theoretical-legal division aims to highlight the challenges in interpreting concepts pertaining to the liability for AI in medicine. Nevertheless, this division is not the main point of this paper, but rather a useful tool to clarify the presented concepts. Within this catalogue of concepts, key elements include medical device, software, and artificial intelligence.

[14] Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive).

[15] *Ibidem*, Article 1(1)(a); C. Wendehorst: *Liability…*, *op. cit.*, p. 201. The limitation of the liability to the "high-risk" AI systems would be directly linked to premises set forward in the proposed AI Regulation (Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts). In accordance with its Article 6, the "high-risk" AI systems would be indicated by Annex III thereto and updated by the European Commission on a regular basis.

[16] Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), recital 14.

[17] B. Wróblewski: *Język prawny i prawniczy*, Kraków 1948.

1. ARTIFICIAL INTELLIGENCE

There is no legal definition of AI[18]. Consequently, there is no normative criterion for assigning meaning to the term, and thus, there are also no specific definitions for types of artificial intelligence, such as "deep learning" or "machine learning". Legal definitions of other terms like "software" or "artificial intelligence system"[19], may provide interpretative guidance. The former appears in Directive 2009/24/EC of the European Parliament and of the Council[20], while the latter is found in the Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence[21]. The second term will be discussed in later sections of this paper.

However, they can only be seen as substantial (not normative) indications, because (1) one cannot interpret having the same (or nearly the same) meaning differently[22] and (2) the AI Regulation is not a binding legal act yet[23]. As a result, it leaves wide interpretation possibilities. Another guidance in interpreting a normative meaning of AI is the application of the definition of AI System[24].

On the other hand, legal jurisprudence takes over definitions of artificial intelligence from those formulated in philosophy, engineering and cognitive sciences[25]. Several proposals for defining AI may be indicated, bearing in mind that there is no single, universally accepted definition of AI in legal language[26]:

(i) a dictionary definition[27] aligned with everyday language — a branch of computer science that studies the rules governing human mental behaviour and creates computer programmes or systems that simulate human thinking[28],

[18] See point II.4 of this paper.

[19] See point II.2 and II.4 of this paper.

[20] Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (Codified version) (OJ EU. L. 2009 No. 111, p. 16); Z. Okoń: *Ochrona programów komputerowych w prawie autorskim Stanów Zjednoczonych* (in:) *Prawnoautorska ochrona programów komputerowych*, Warszawa 2022, p. 43.

[21] Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), https://data.consilium.europa.eu/doc/document/PE-24-2024-INIT/en/pdf (access: 21.05.2024).

[22] M. Pach, R. Michalczuk: *Zakazy wykładni synonimicznej i homonimicznej* (in:) M. Florczak-Wątor, A. Grabowski *et al.*: *Argumenty i rozumowania prawnicze w konstytucyjnym państwie prawa. Komentarz*, Kraków 2021, pp. 510–526.

[23] Despite coming into force, the AI Act provisions will not be applied immediately, but gradually: 6, 12, 24, and at a minimum also 36 months after publication accordingly with article 113 of the AI Act.

[24] See point II.4 of this paper.

[25] J. Kaplan: *Sztuczna inteligencja…*, *op. cit.*, p. 15; J. McCarthy, M.L. Minsky, N. Rochester, C.E. Shannon: *A Proposal for the Dartmouth Summer Research Project on Artificial Intelligence*, 1955.

[26] K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem sztucznej inteligencji w medycynie*, Przegląd Prawa Medycznego 2021, vol. 8, No. 3–4, p. 5.

[27] M. Zieliński: *Wykładnia prawa. Zasady, reguły, wskazówki*, Warszawa, p. 295.

[28] *Słownik języka polskiego PWN*, https://sjp.pwn.pl/szukaj/sztuczna%20inteligencja.html (access: 14.02. 2023).

(ii) a definition which suggests that artificial intelligence should simulate human intelligence and decision-making processes[29],

(iii) a sociological definition posits that AI is a technical solution (computer programme) that performs activities that are usually the domain of humans and require the use of intellect. It is therefore the ability of a machine to imitate human intelligence — a system that allows the performance of tasks that require a process of learning and taking into account new circumstances when solving a given type of problem[30],

(iv) an IT definition — a computer system that analyses large amounts of data (so-called big data) and then, based on this data, makes decisions, and solves tasks[31],

(v) a mechanism-based definition[32] — this is the most precise definition indicating the various computing methods used in AI design, including (1) machine learning, (2) machine reasoning, (3) deep learning mechanism, (4) cyber-physical systems[33],

(vi) no definition. This is the approach represented in both Polish and foreign legal science[34]. The authors point out that AI is such an advanced, developing, and diverse branch of science/technology that it is impossible to come up with a single satisfactory definition. Moreover, it is also not advisable to construct a legal definition of AI for the same reasons. However, the authors representing this view propose a solution to the AI definition problem. Namely, they propose to introduce a legal definition of the concept of artificial intelligence system/s[35].

It seems that, from a legal point of view, the most accurate definition is the mechanism-based one (point V of the abovementioned enumeration). Not only does it indicate the specific information systems that can be treated, but it is also an exemplary definition based on the already existing divisions. Furthermore, this corresponds with the enumeration of functions, as defined by the AI system contained in EU law. But it might also be the case that we do not need legal definition of AI. Just as we do not need one of law, human, animal, or any other vague term. Broad enough concept of AI system, proposed in EU law, could suffice.

[29] H. Ming-Hui, R. Rust, V. Maksimovic: *The feeling economy: Managing in the next generation of artificial intelligence (AI)*, California Management Review, No. 61(4), pp. 43–65.

[30] K. Bączyk-Rozwadowska: *Odpowiedzialność…*, *op. cit.*, p. 6; A. Kisielewicz: *Sztuczna inteligencja i logika. Podsumowanie przedsięwzięcia naukowego*, Warszawa 2011, p. 76.

[31] K. Bączyk-Rozwadowska: *Odpowiedzialność…*, *op. cit.*, p. 6; T. Zalewski (in:) *Prawo sztucznej inteligencji*, eds. L. Lai, M. Świerczyński, Warszawa 2020.

[32] The definition proposed by the authors of this paper.

[33] UNESCO. First version of a draft text of a recommendation on the ethics of artificial intelligence, 2020, https://unesdoc.unesco.org/ark: /48223/pf0000373434 (access: 12.03.2023).

[34] M. Nowakowski: *O moralnej odpowiedzialności HAL-a 9000, czyli etyka sztucznej inteligencji w praktyce. Czy potrzebujemy definicji sztucznej inteligencji?*, Prawo Mediów Elektronicznych 2022, No. 1, p. 4; J. Schuett: *A Legal Definition of AI*, https://www.researchgate.net/publication/335600149_A_Legal_Definition_of_AI (access: 12.03.2023).

[35] M. Nowakowski: *O moralnej…*, *op. cit.*, pp. 5–8; J. Schuett: *A Legal Definition…*, *op. cit.*, p. 8.

2. SOFTWARE

As in the case of the term of artificial intelligence, there is no legal definition of software. However, as M. Porzeżyński points out, this should not be regarded as a defect, but rather as a well-thought-out action of the legislator not to introduce into the legal system a rigid definition of a concept which, due to technological development, changes faster and more dynamically than other legally defined concepts[36]. It is also important to point out the difference that exists between software and a computer program.

The concept of a computer program appears in Directive 2009/24/EC on the legal protection of computer programs[37], according to which a computer program is any program, including a program integrated into hardware. The question, therefore, arises as to whether software, functioning in legal language as undefined, should be interpreted differently from a computer program. From the perspective of interpretation directives[38], the different concepts should be interpreted non-synonymously, but there are authors who seem to treat these concepts interchangeably[39]. While others point out the overlapping of these concepts, in which a computer program is the narrower concept, while software is the broader one, understood as a combination of multiple computer programs.

This problem is not merely theoretical. As it will become apparent later, software (also not defined in Regulation 2017/745) can be considered as a medical device according to the legal definition. However, the concept of a computer program does not appear in the same definition.

3. MEDICAL DEVICE

Article 2(1) of Regulation 2017/745 of the European Parliament and of the Council[40] (MDR) legally defines a medical device. At this point, it is worth to emphasise the two most important elements of the abovementioned definition that raise questions of interpretation[41]: (1) the manufacturer's intention and (2) the fact

[36] M. Porzeżyński: *Zdolność patentowa programów komputerowych*, Warszawa 2017, pp. 3–7.

[37] Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (Codified version) (OJ EU L 2009 No. 111, p. 16).

[38] M. Zieliński: *Wykładnia prawa…, op. cit.*, pp. 290–303; L. Morawski: *Zasady wykładni prawa*, Toruń 2010, pp. 117–119.

[39] Z. Okoń: *Raport CONTU i Computer Software Copyright Act* (in:) *Prawnoautorska ochrona programów komputerowych*, Warszawa 2022.

[40] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as 'Regulation 2017/745').

[41] M. Kupis: *Stosowanie przepisów Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 do sztucznej inteligencji*, Przegląd Prawa Medycznego 2022, 4(1), pp. 95–114.

that a medical device can be both an apparatus and an instrument. Followingly, an instrument should be understood as either tangible object or intangible software. These elements are important for the reason that the manufacturer's intention may determine the fact of treating the thing (or software) in question as a medical device and thus the possibility of holding it liable, and because of the difficulty of attributing liability for damage caused by an intangible good such as software[42].

4. ARTIFICIAL INTELLIGENCE SYSTEM

The European Commission did establish the Regulation of the European Parliament and of The Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)[43] (AI Act or AIA). And in accordance with Article 3(1) of the AI Act, an Artificial Intelligence System is:

"a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments"[44].

It is important to note that the definition in this section is not applicable yet. This is due to the fact that the definition of AI system contained in Chapter I shall apply six months from the date of entry into force of the AI Act[45]. Despite this, already the definition can be seen as part of legal language expression and as part of the normative system in the near future.

Definitions and terminological distinctions made by jurisprudence are definitely richer and more nuanced when it comes to defining artificial intelligence and its types ("machine learning"[46], "deep learning")[47] as well as computer software[48].

[42] The relationship between software and artificial intelligence will be outlined later.

[43] https://data.consilium.europa.eu/doc/document/PE-24-2024-INIT/en/pdf (access: 27.05.2024).

[44] https://data.consilium.europa.eu/doc/document/PE-24-2024-INIT/en/pdf (access: 27.05.2024).

[45] In accordance with article 113 (a) of the AI Act.

[46] *Machine Learning means that a computer program's performance improves with experience with respect to some class of tasks and performance measures*, M.I. Jordan, T.M. Mitchell: *Machine learning: Trends, perspectives, and prospects*, Science 2015, 349(6245), pp. 255–260, https://doi.org/10.1126/science.aaa8415 (access: 14.02. 2023).

[47] *Deep neural networks typically consist of more than one hidden layer, organized in deeply nested network architectures. Furthermore, they usually contain advanced neurons in contrast to simple ANNs*, C. Janiesch, P. Zschech, H. Kai: *Machine learning and deep learning*, 2021, p. 2, https://doi.org/10.1007/s12525-021-00475-2 (access: 14.02.2023).

[48] The difference between a robot in traditional sense and an autonomic robot, see: L. Bosek: *Perspektywy rozwoju odpowiedzialności cywilnej za inteligentne roboty*, Forum Prawnicze 2019.

III. EXAMPLES OF AI APPLICATION IN MEDICINE

Before highlighting the primary legal challenges linked to civil liability for damages caused by medical devices using artificial intelligence, it is valuable to clarify the practical extent of the issue at hand. This entails elucidating the scenarios within the medical domain where discussions about artificial intelligence's application take place.

As P. Księżak points out, this is mainly about medical robots and AI itself operating in medicine[49]. Examples of both such robots and software include Interrogative Biology — a program capable of examining 14 trillion data points in a single tissue sample. BERG LLC (acquired in January 2023 by BPGbio Inc.) extracted biological data from over 1,000 patients' healthy and cancerous tissue samples[50]. Likewise, BenevolentBio, a company focusing on research in amyotrophic lateral sclerosis, relies on a Judgement Correlation System (JACS) for reviewing and assessing relationships between millions of scientific research papers and abstracts to generate novel hypotheses, which researchers then evaluate[51].

In a general overview of the use of AI-based tools, official European Union documents indicate: (1) clinical practice, (2) biomedical research, (3) public health, and (4) health administration[52].

In Polish legal literature on health care as one of the economic sectors in which AI can play a significant role, several possible applications of AI-based devices are highlighted[53]. The cited literature points out, among others applications, the following: (1) better diagnosis and clinical decision support, (2) time savings for HCPs (Healthcare Professionals), (3) clinical trials and R&D (Research and Development) work, (4) faster detection of epidemic threats. In all these applications, medical devices using AI will play a significant role.

In the report published by Dentons law firm on the significant impact that AI has on the healthcare system, we can read about the relationship between AI and healthcare among the 8 AI trends in 2023 worth watching for. It was estimated that in 2021, the global market for AI in healthcare was valued at 11 billion US dollars, and it is expected that by 2030, the total amount will rise to 188 billion US dollars[54].

[49] P. Księżak (in:) *System prawa medycznego*, t. 3, ed. E. Bagińska, 2020, pp. 1205–1207.

[50] L. Tsang, D.A. Kracov, J. Mulryne, L. Strom, N. Perkins, R. Dickinson, V.M. Wallace, B. Jones: *The Impact of Artificial Intelligence*, Intellectual Property & Technology Law Journal 2017, p. 1.

[51] *Ibidem*.

[52] Artificial intelligence in healthcare. Applications, risks and ethical societal impacts. Study, Panel for the Future of Science and Technology, European Parliamentary Research Service, Scientific Foresight Unit (STOA), PE 729.512, June 2022, https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729512/EPRS_STU(2022)729512_EN.pdf (access: 25.03.2024).

[53] White Paper on AI in clinical practice. Using AI when providing health care services. June 2022, pp. 16–32, https://aiwzdrowiu.pl/wp-content/uploads/2022/11/15.11_HIPERL_ANGIELSKA_BIALA-KSIEGA_AI-W-ZDROWIU_2022.pdf (access: 23.03.2023).

[54] https://www.dentons.com/en/insights/articles/2023/january/20/ai-in-2023-key-trends-and-developments (access: 3.03.2023).

IV. LIABILITY FOR DEFECTIVE PRODUCT[55]

As one of the basic regimes of tortious liability in the context of medical devices using AI, the regime of liability for damage inflicted by unsafe product (Article 449[1] et seq. of the Polish Civil Code) is indicated. This approach is also endorsed in the literature. In order to clearly present the legal problems related to this form of tort liability, its most important prerequisites will be now discussed. Liable persons are the producer and other persons liable in the same way as the producer (quasi-producers) and importers[56]. Those types of persons are liable for a product which is dangerous (unsafe). These three elements: (1) producer or quasi-producer or importer, (2) product, (3) dangerous (unsafe) product constitute basic elements of liability based on article 449(1) of the Polish Civil Code.

1. PRODUCER

Under the strict product liability regime, a producer is defined in legal language as one who manufactures within the scope of his or her business activity (article 449(1) of the Civil Code) and, in legal language, as the producer of a product, who is an entrepreneur within the meaning of Article 43(1) of the Civil Code, regardless of the form in which he or she carries out his or her business activity, with a broad understanding of economic activity (production)[57]. A manufacturer under this provision is exclusively the producer of the final product — fit for use without any additions or changes thereto. In this respect, Polish regulations have not fully implemented the definition of a producer from Article 3(1) of Directive 85/374/EEC, dividing its provisions between the notions of a producer and entities treated as a producer.

However, the concept of a producer defined in this way is problematic. As pointed out in the literature, in the context of AI, it is difficult to identify (determine) the entity obliged to compensate for damage caused by a dangerous product if the producer is more than one entity (software developer, hardware manufacturer). This is because in the case of a complex system such as an AI medical device, it is difficult to speak of a single producer. There are usually numerous entities involved in the manufacturing process. In such a case, the producer within the meaning of

[55] It is also translated as: Liability for damage inflicted by unsafe product. See: https://sip.lex.pl/#/act-translation/1459620497 (access: 23.03.2023). Terms 'liability for defective product' and 'liability for damage inflicted by unsafe product' will be used interchangeably.

[56] We use this expression based on: E. Bagińska (in:) *European Product Liability: An Analysis of the State of the Art in the Era of New Technologies. Principles of European Tort Law*, ed. P. Machnikowski, Intersentia 2016, p. 387.

[57] Art. 449[1]: *Kodeks cywilny. Komentarz*, t. II, ed. M. Gutowski, 2022; E. Bagińska (in:) *European…*, *op. cit.*, ed. P. Machnikowski, p. 398.

Art. 449[1](1) of the Polish Civil Code will be those entities that have marketed the product as a whole — both hardware and software. The legal qualification of the responsible entity is additionally more difficult in the situation when the production process is extended in time or it is possible to compose the final product from elements coming from various producers[58].

In the case outlined above, it would be appropriate to consider joint and several liability for all entities involved on the part of the manufacturer. The doctrine also points to the use of Anglo-Saxon solutions in the form of joint and several liability towards the injured party (market share liability), although the issue of joint and several liability seems to be resolved by the Polish Act in Article 449[5] of the Polish Civil Code, introducing a category of entities liable according to the same principles as the manufacturer, which are not the manufacturer at the same time.

In the field of medical law, jurisprudence has clarified that a hospital which is not the manufacturer of medical equipment, but only its user in the process of diagnosis and treatment of a patient, cannot be considered a manufacturer within the meaning of Article 3 of Directive 85/374/EEC even if it has used faulty equipment[59]. It is then necessary to show that the damage was caused by the hospital. Consequently, such an entity cannot be regarded as a manufacturer under Article 449[1] et seq. of the Polish Civil Code either[60]. However, the hospital may be liable under other tort liability provisions[61].

2. PRODUCT

The biggest problem when considering the issue of liability for damage caused by the use of a medical device using AI as liability under Article 449[1] et seq. of the Polish Civil Code is the concept of a product. Under Article 449[1](2) of the Polish Civil Code a product is only a movable thing, animal or electricity. The same definition can be found in Article 2 of Directive 85/374/EEC. In relation to Article 45 of the Polish Civil Code, to which the definition of a dangerous product under the Polish Act refers, a product within the meaning of Article 449[1](2) of the Polish Civil Code is exclusively material goods, i.e. goods which are part of nature in their original or processed state[62]. According to this definition, a personal property and

[58] M. Jagielska: *Odpowiedzialność za sztuczną inteligencję* (in:) *Prawo sztucznej inteligencji*, ed. L. Lai, M. Świerczyński, Warszawa 2020, pp. 69–75.

[59] Judgement of the Court of Justice of 21.12.2011, C-495/10, Centre Hospitalier Universitaire De Besançon V. Thomas Dutrueux, Caisse Primaire D'assurance Maladie Du Jura, Zotsis 2011, No. 12c, item I–14155.

[60] E. Bagińska (in:) *System prawa medycznego*, t. V, ed. E. Bagińska, Warszawa 2021, p. 76.

[61] See points 6 and 7 of this paper.

[62] Art. 45: *Kodeks cywilny. Komentarz*, t. I, *Część ogólna, cz. 1 (art. 1–55(4))*, ed. J. Gudowski, Warszawa 2021.

an intangible property, such as a computer program, are not a movable thing, and consequently a dangerous product[63].

The legal definition of a product reveals the biggest problem in the field of AI — whether we are talking about a medical device that is software within the meaning of Regulation 2017/745 or an AI or Artificial Intelligence System, neither of them is tangible and thus is not a product. On the basis of a linguistic interpretation, it is therefore not possible to hold the manufacturer of a software medical device liable for a dangerous product, as the product premise is not fulfilled. Such a possibility arises only if the manufacturer is the creator of a tangible carrier (hardware) that is operated by software (within the meaning of Regulation 2017/745) or a computer program (within the meaning of Article 1(2)(1) of the Copyright and Related Rights Act.

Thus, national and EU legislation contains a legal loophole — on the one hand, the EU legislator directly determines that software may, after fulfilling other prerequisites, be a medical device. On the other hand, however, for such a medical device, the manufacturer will not be liable under product liability regime because software does not fall within the definition of a product. Such a conclusion can be drawn on the basis of a literal interpretation.

However, there are positions in the Polish scholarship which reflect an expansive (dynamic) interpretation of the product definition, proposing to also include intangible goods in the product category. The main argument put forward in favour of such a position is the purpose of the regulation of liability for a dangerous product, which is to protect the injured[64]. In this aspect, Joanna Kuźmicka-Sulikowska elaborates on this issue by adding the diverse views of the doctrine[65]:

(1) Intangible goods cannot be qualified as a product even if they are recorded on a tangible medium, as they will still not have a tangible form[66],
(2) An intangible good may be construed as a product for the purposes of liability for a dangerous product if it is integrated into a certain thing[67],
(3) An intangible good may be understood as a product with an expanded understanding of this concept. However, only software intended for mass use can be understood as a product. An intangible good prepared for the needs of a specific entity does not fall within the scope of a product[68].

[63] Art. 45: *Kodeks cywilny. Komentarz*, ed. K. Osajda, Warszawa 2022.

[64] C. Czech-Śmiałkowski: *Dobra intelektualne jako produkt niebezpieczny*, Radca Prawny 2006, No. 6, pp. 96–97.

[65] J. Kuźmicka-Sulikowska: *Pojęcie produktu niebezpiecznego na gruncie przepisów kodeksu cywilnego dot. odpowiedzialności za szkodę wyrządzona przez ten produkt*, Biblioteka cyfrowa Uniwersytetu Wrocławskiego http://www.bibliotekacyfrowa.pl/Content/42758/23_Joanna_Kuzmicka_Sulikowska.pdf (access: 3.03.2023).

[66] E. Gniewek, P. Machnikowski: *Kodeks cywilny. Komentarz*, Article 449[1], p. 827.

[67] J. Rajski: *Odpowiedzialność za produkt w świetle nowych przepisów kodeksu cywilnego*, Przegląd Prawa Handlowego 2001, No. 100, p. 25.

[68] M. Jagielska: *Odpowiedzialność za produkt*, Kraków 1999, p. 139 (see also: M. Jagielska: *Odpowiedzialność za produkt*, Warszawa 2009).

In addition, Księżak submits that the exclusion of AI from the scope of dangerous products seems discursive[69]. He argues that the key issue in assessing AI liability in the context of dangerous product liability is not the question of AI's embodiment but the autonomous operation of an AI-using robot (medical device), which, as hardware according to the literal wording of the product, falls within the scope of the concept. The author also points out that it is difficult to imagine working AI completely unembodied in any mobile thing[70]. However, Księżak does not consider the situation where the manufacturer of the AI (software) is a different entity than the manufacturer of the robot/medical device (hardware) in which the AI is embodied. Referring to the previous section of this paper on the notion of a producer, this seems to be a significant problem, as the notion of a producer defines the subjective scope of liability under Article 449^1(1)(1) of the Polish Civil Code. Therefore, if the producers of given software and hardware are different entities, only the producer of the hardware will be liable for the product, assuming that the product may only be a movable item. It will not matter that the AI is embodied in a movable thing, as the provision on an attached thing (article 46 of the Polish Civil Code) will not apply here. There are views in the doctrine suggesting that AI embodied in a tangible object could be treated as a "specific attached thing"[71]. To summarise this point, several problematic issues can be identified. The first one is that *de lege lata*, a product should only be understood as a movable thing, animals and electricity. AI is therefore not a product within the meaning of Article 449^1(2) of the Polish Civil Code. Consequently and secondly, on the basis of the current law, the recognition of AI as a product is only possible if an expansive interpretation is applied for reasons of purposeful protection of injured parties. Thirdly, even when applying a purposive interpretation, not every type of AI will be treated as a product, although this is not a widely held view. Finally, when considering the problem of AI embodied in a movable object, it remains problematic to determine the responsible party, which can only be considered to be the hardware manufacturer.

3. DANGEROUS PRODUCT

The last premise of the described liability is the qualification of a product as dangerous (Article 449^1(3) of the Polish Civil Code). This issue should be considered with the prior assumption that AI may be treated as a product under Polish law. In order to consider a product dangerous, the following conditions must be met:

(1) Failure to ensure the safety that can be expected, taking into account the normal use of the product (Art. 449^1(3) first sentence of the Polish Civil Code),

[69] P. Księżak (in:) *System prawa medycznego…*, *op. cit.*, p. 1212.
[70] *Ibidem*.
[71] J. Rajski: *Odpowiedzialność za produkt…*, *op. cit.*, p. 25.

(2) Placing on the market (Art. 449[1](3) second sentence of the Polish Civil Code).

As M. Jagielska points out, the concept of failure to ensure safety can be understood in such a way that the fact causing the damage is most often considered to be: (1) Producing an item with defects, (2) the marketing of an item with defects, (3) producing or marketing an unsafe item, (4) producing a dangerously defective good, (5) placing a dangerously defective thing on the market[72].

Thus, in general terms, the failure to ensure the safe use of a product can be understood as a defectiveness of the thing in different ways. The defectiveness of a product must be assessed from the perspective of expectation and normal use, and therefore by criteria that are relativised to each product, its specificities and the expectations of the average consumer[73]. As far as the normal use of the product is concerned, the literature indicates that it includes not only the typical use of the product, but also the probable possibility of its improper use[74], which is foreseeable and justified by the circumstances[75]. In Polish jurisprudence, the concept of normal use is further defined by, for example, technical approval of the use of a material[76]. Furthermore, according to CJEU jurisprudence, a finding of a potential defect in products belonging to the same group or series of products should also be considered a dangerous product, without the need to find this defect in a specific product[77]. However, it is essential that the risk of defect in a series of products is of sufficient severity. Indeed, a defect in a piece in a whole series of products cannot, apart from the nature of the defect, be regarded as a circumstance demonstrating a potential defect in the whole series[78].

In the context of the premise of "placing on the market", it is assumed to mean the first instance of putting a product into circulation or the first placing on the consumer market[79], which means the first sale of a product to a consumer or intermediary[80]. The majority view can be considered to be the one that suggests that the placing on the market takes place at the time of the transfer of the individual

[72] M. Jagielska: *Odpowiedzialność za produkt*, pp. 39–40. It is also translated as 'putting a product into circulation', see: E. Bagińska (in:) ed. P. Machnikowski: *European…*, *op. cit.*, p. 386.

[73] J. Kuźmicka-Sulikowska: *Pojęcie produktu niebezpiecznego…*, *op. cit.*, p. 259.

[74] *Ibidem*.

[75] B. Gnela: *Odpowiedzialność przedsiębiorców za szkody wyrządzone przez produkt niebezpieczny* (in:) *Odpowiedzialność cywilnoprawna w obrocie gospodarczym*, ed. A. Śmieja, Wrocław 2011, pp. 44–45.

[76] Judgement of the District Court in Poznań of 19.01.2021, XII C 1291/17, LEX No. 3120525; P. Modrzejewski: *Czy pianka poliuretanowa może być produktem niebezpiecznym? Glosa do wyroku s. okręg. z dnia 19 stycznia 2021 r., XII C 1291/17*, Glosa 2021, No. 2, pp. 93–99.

[77] Judgement of the Court of Justice of 5.03.2015, C-503/13, Boston Scientific Medizintechnik Gmbh V. Aok Sachsen-Anhalt — Die Gesundheitskasse I Betriebskrankenkasse Rwe, Zotsis 2015, No. 3, item I–148.

[78] A. Jabłonowska: *Potencjalna wada produktów należących do tej samej grupy lub serii a odpowiedzialność odszkodowawcza producenta. Glosa do wyroku TS z dnia 5 marca 2015 r., C-503/13 i C-504/13*, Glosa 2016, No. 3, pp. 78–85.

[79] B. Gnela: *Odpowiedzialność za produkt*, Państwo i Prawo 2009, No. 9, pp. 33–47.

[80] M. Jagielska: *Odpowiedzialność…*, *op. cit.*, p. 127.

good and not, as some authors believe, only after the delivery of the entire class of products[81].

According to CJEU case law, placing on the market or on the consumer market means that the product leaves the production process carried out by the manufacturer and enters the commercial process in which it is offered to the public for use or consumption. At the same time, it is irrelevant whether the product is sold directly by the manufacturer or in a larger distribution chain[82].

The specificity of medical devices using AI necessitates considering the category of liability for bad software when examining the premise of product defectiveness[83]. L. Bosek writes that the question arises whether the "autonomy of the robot", i.e. the possibility to choose an action that was not included in the original algorithm, can determine its qualification as dangerous[84]. This is relevant to the premise of the existence of a product defect at the time of marketing. Indeed, if an AI-based, machine-learning robot causes harm, it will not be obvious or even possible for the manufacturer to meet the premise of software defectiveness at the time of marketing due to the nature of machine learning associated with some (but not complete) decision-making autonomy of the robot. Bosek goes on to point out that the normal use of an autonomous robot can be the marketing of the robot by the manufacturer with its indication of the autonomy of its product, which would be expected to meet the statutory requirements of quality parameters[85].

An interpretative guideline indicated not only by Bosek, but also by other authors[86], may be the already cited CJEU ruling in cases C-503/13 and C-504/13[87]. In this context, P. Księżak is of the opinion that the unpredictability associated with the decision-making autonomy of AI (in medical devices in the form of robots in particular) will result in its recognition as a potentially dangerous product. In view of the above ruling, it will be possible to consider not only a single medical device, but also a whole series of medical devices as a potentially dangerous product, especially as in the context of medical devices, reference is made to legal goods of particular value in the form of health and life, which is to justify an interpretation that increases the standard of protection of the injured[88]. On the basis of these doctrinal statements, it can therefore be considered that the manufacturer would be liable for a medical device using AI due to its defectiveness in the form of the unpredictability of decisions related to the autonomy of such a device. Such defective-

[81] *Ibidem*, p. 128.

[82] Judgment of the Court of Justice of 9.02.2006, C-127/04, Declan O'byrne V. Sanofi Pasteur Msad Ltd, Sanofi Pasteur Sa, Zotsis 2006, No. 2a, Item I–1313.

[83] K.M. Goertzel: *Legal Liability for Bad Software*, CrossTalk 2016, Vol. 29, No. 5.

[84] L. Bosek: *Perspektywy…*, *op. cit.*, p. 8.

[85] *Ibidem*, p. 9.

[86] P. Księżak: *Sztuczna inteligencja…*, *op. cit.*, pp. 1212–1214.

[87] Judgement of the Court of Justice of 5.03.2015, C-503/13, Boston Scientific Medizintechnik Gmbh V. Aok Sachsen-Anhalt — Die Gesundheitskasse I Betriebskrankenkasse Rwe, Zotsis 2015, No. 3, Item I–148.

[88] P. Księżak: *Sztuczna inteligencja…*, *op. cit.*, pp. 1212–1214.

ness would already exist at the time the product, which by its very nature would be a machine learning-based product, was placed on the market, which is considered a potential defectiveness of the entire product series.

IV. FAULT-BASED LIABILITY

Classical tort liability could be the field on which controversy related to AI is best outlined. Virtually any country recognises the standard dichotomy of fault-based and risk-based tort liability, and the Polish legal system is no exception. In contrast to the latter one, fault-based liability requires both fault on the part of the damage perpetrator as well as a causal link between its action and a damage. Meanwhile, the self-correcting phenomenon of artificial intelligence appears to be independent of anyone's interference. Therefore, demonstrating any causal link between a specific person and a damage caused while using AI-embodied medical device could be challenging to say the least.

AI is not sufficiently developed to be equated with humans either from a cognitive or legal point of view. Therefore, both scholars[89] and public institutions in the form of the European Parliament[90] accept that it is unjustified and premature to attribute legal capacity to artificial intelligence, let alone holding it tortiously liable. Responsibility for some time yet will have to be attributed to a human being. Having established that our laws still regulate humans' actions only, what remains unclear is choosing one specific human, who by stepping into contact with an AI-embedded machine can be held liable for the damage effectuated by its usage. Two main possibilities come into play. The responsible party may be the manufacturer who, by violating any relevant standards, led to the creation of a robot with a high probability of causing harm to its users or any other third parties. On the other hand, it may be the operator of the robot, i.e. the person directly managing its functions. Therefore, in the case of medical devices, it could be either a qualified worker or the doctor herself who did not take the required care and failed to notice the harmful self-correction within the AI code. Within the scope of such person's duty would lie the initiation and subsequent termination of the software's work, observation of the actions performed by the robot in general and the capability to maintain control over it with a range of available commands[91]. Although depending on the circumstances any person, not even the manufacturer or operator who were described above, could

[89] D. Kaczan: *Odpowiedzialność odszkodowawcza za funkcjonowanie sztucznej inteligencji w medycynie*, Studia de Cultura 2022, No. 14(2), p. 150.

[90] European Parliament Resolution of 16 February 2017 making recommendations to the Commission on civil law provisions on robotics (2015/2103(INL)), OJ EU C 252/239, point 56.

[91] D. Kaczan: *Odpowiedzialność…*, *op. cit.*, p. 151; M. Wałachowska: *Sztuczna inteligencja a zasady odpowiedzialności cywilnej* (in:) *Prawo sztucznej inteligencji*, eds. L. Lai, M. Świerczyński, Warszawa 2000, p. 61.

be considered liable for AI-caused damage, these are still the two pivotal areas of occupation in which the probability of being ascribed such responsibility is the highest. At this stage two questions arise. Firstly, which would be on average the best strategy for a plaintiff — to sue the manufacturer or the operator? Secondly, what are the overall chances of using the fault-based type of tortious liability to successfully assert one's claims after AI-caused damage?

The prerequisites for classic tort liability based on fault are the act, the damage, the causal link, the unlawfulness, and the fault itself, which may be intentional or unintentional[92]. The issue of damage itself and its description within the topic of AI is not the subject matter of this paper, therefore for the sake of the following examination its occurrence would be presumed. This approach would be shared with the concept of illegality, therefore any breach of statutory or customary rules, such as violation of an obligation imposed either by law or by rules of social conduct[93]. For instance, a breach of such an obligation would occur if specific standards for production, training or the use of artificial intelligence were not observed[94]. At the time of compliance with the duty, the damage caused could not be regarded as a result of someone's fault, but as a work of chance, which is not a basis for liability[95]. Therefore, an injury caused by a medical device incorporating AI in a situation where both the manufacturer and the operator have complied with all prescribed safety standards would be nothing more than an accident through no fault of anyone. Such a scenario would be hardly acceptable to the plaintiff and so the latter aspect deserves a broader insight.

The source of the doctor's general legal duties is to be derived from Article 4 of the Medical Profession Act ("MPA")[96], which expects from her to make a final professional assessment of the medical situation with due care and to consider current medical knowledge and principles of professional ethics. Under specific circumstances it would be thus conceivable to even require a doctor to operate an AI-embodied medical device, should such an action be considered as "taking into account current medical knowledge". On the other hand, this general scope of duty is obviously not to be interpreted as expecting a herculean effort from a specialist in each and every case or, in other words, requiring impossible actions which would turn the doctor's scope of liability into hidden risk-based[97]. The rather undisputed position is that the doctor's general duty of care is to be of a "good professional"

[92] J. Gudowski, G. Bieniek (in:) *Kodeks cywilny. Komentarz*, t. III, *Zobowiązania. Część ogólna*, ed. J. Gudowski, Warszawa 2018, Article 415, paras. 2, 4, 118.

[93] L. Bosek: *Perspektywy…*, *op. cit.*, p. 11; M. Sośniak: *Bezprawność zachowania jako przesłanka odpowiedzialności cywilnej za czyny niedozwolone*, Kraków 1959, pp. 137–138.

[94] L. Bosek: *Perspektywy…*, *op. cit.*, p. 11.

[95] *Ibidem*.

[96] Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty (Journal of Laws 2022, item 1731, as amended).

[97] Judgment of the Court of Appeal in Warsaw of 3.03.1998, I ACa 14/98, Wokanda 1998, No. 10, item 44.

(Polish: *dobry fachowiec*) standard, therefore setting the duty of care threshold at the "medium high" level[98]. Additional selected statutory duties of doctors in the Polish legal realm are the following:

(i) compulsory training upon return to work — Art. 10 MPA,
(ii) compulsory professional development — Art. 18(1) MPA,
(iii) disclosure duties concerning medical experiments — Art. 24 MPA,
(iv) the general obligation to provide medical assistance alongside the overall information duty — Art. 30 and 31 MPA,
(v) the duty of confidentiality together with the duty to maintain the professional documentation about patient's health — Art. 40 and 41 MPA,

On the other hand, the obligation of the appropriate usage of medical devices, including the use of the provided instructions, is contained in Article 63 of the Medical Devices Act ("MDA")[99]. In turn, the general statutory obligations incumbent on manufacturers, importers and suppliers of medical devices are regulated in Article 16 MDA.

The probability of proving fault on the part of the operator, whether a mere technician or a doctor, is all the greater, as a higher standard of care is required of these persons by virtue of their professionalisation on the basis of Article 355(2) of the Polish Civil Code[100]. The responsibility of the operator of an AI machine should not differ from the traditionally accepted high standard of care. It requires the use during treatment of apparatus and tools free from defects and faults and for their intended purpose by persons with appropriate skills[101]. It will, however, be inhibited by the scope of the manufacturer's instructions and requirements depending, in turn, on the type of device and the chance, examined *in casu*, of preventing harmful self-correction of the software[102].

Together with the principally heightened standard of care on the doctor's part on most occasions, a breach of relevant regulations amounting to the illegality of the act would equal an unintentional fault itself. Consequently, proving the fault of a doctor or even a mere operator of a medical device would primarily depend on their conformity with instructions of this device and general standards of care.

On the other hand, the manufacturers of medical devices are subject to a number of legal constraints, following from both general and specific codes of

[98] M. Nesterowicz: *Glosa do wyroku SN z dnia 1 grudnia 1998 r., III CKN 741/98*, PiM 2000, No. 6–7, p. 163. Similarly in the judgment of the Court of Appeal in Poznan from 5.03.2014, I ACa 1274/13, LEX No. 1439257.

[99] Ustawa z dnia 7 kwietnia 2022 r. o wyrobach medycznych (Journal of Laws 2022 item 974).

[100] E. Bagińska, K. Bączyk-Rozwadowska: *Modele odpowiedzialności za niewłaściwe leczenie i inne zdarzenia medyczne na tle porównawczym — między winą a ryzykiem* (in:) *System prawa medycznego*, t. 5, ed. E. Bagińska, Warszawa 2021, pp. 122–123.

[101] *Ibidem*, pp. 437–438; M. Nesterowicz: *Odpowiedzialność cywilna lekarza i zakładu leczniczego*, Warszawa 1978, p. 50.

[102] D. Kaczan: *Odpowiedzialność…*, *op. cit.*, p. 155; M. Jagielska: *Odpowiedzialność za sztuczną…*, *op. cit.*, p. 58.

procedures for placing products in the EU market. The general obligations for manufacturers of almost any products can hardly be surprising, as the legislator primarily requires them to make their products safe[103]. This "safety standard" may be the subject of comprehensive interpretation in line with the dangerous product liability already described. It is, however, the specific line of obligations enacted directly for medical devices that deserves the front-and-centre approach. EU Regulation no. 2017/745 imposes on the manufacturer of medical devices not only the obligation to conform with the general safety and performance requirements[104] as specified in detail in one of its annexes, but also to take necessary corrective measures, including the withdrawal or recall of the devices which would not follow these directives[105]. The manufacturer is also placed under the obligation to establish and follow a specific risk management[106] and quality management system[107]. Comprehensively regulating the manufacturer's statutory duties may seem as increasing the aggrieved party's chances of proving their breach; however, the more detailed the legal requirements, the harder — if not impossible — it would be for an inexperienced consumer to disclose it. This will be especially the case with the second group of statutory preconditions for marketing medical devices, which is the positive completion of a set of conformity assessments and clinical evaluations[108] undertaken by credited institutions and eventually affirmed by public officials.

This precaution means that possibly the only chance of proving the manufacturer's illegality is assuming the subsequent failure of specific devices, therefore the one which may happen already after being granted all relevant official permits. In case, however, of a technical failure that would occur to a medical device at the manufacturing stage, access to such information would be notoriously limited. Taking into account the self-correction of AI embodied in a medical device, the only plausible way of determining the manufacturer's fault would be proving its neglectful approach towards generally accepted standards of AI production. As a result, considering a typical situation, establishing illegality, let alone fault on the manufacturer part, is rather elusive for a customer.

Finally, as it is theoretically possible to identify a causal link to both the operator and the manufacturer, the question about the best strategy for a plaintiff already concerns practice. Generally, the applied standard of causality requires the link between an illegal action and a damage to be direct, which means it would

[103] Article 10 ustawa z 10 grudnia 2003 r. o ogólnym bezpieczeństwie produktów (Journal of Laws 2021, item 222).

[104] Article 5(2) together with Article 10(1) Regulation 2017/745.

[105] Article 10(12) Regulation 2017/745.

[106] Article 10(2) Regulation 2017/745.

[107] Article 10(9) Regulation 2017/745.

[108] *Ibidem*, Article 52(1) and 61.

ordinarily take place under normal circumstances[109]. This standard is therefore generally more difficult to establish in comparison to the case of *casus mixtus*, which encompasses all events for which the illegal action was a necessary cause (*conditio sine qua non*)[110]. Therefore, the possibility of proving a causal link between the damage and the manufacturer of an AI product remains only theoretically possible, but practically almost impossible[111].

The initially posed questions thus require the following answers. Firstly, it is the operator of AI medical devices who is more likely to be successfully attributed fault for the damage caused. This notion, however, depends on provable violations of specific rules of conduct and the device's instructions. However, in most cases where the damage would be a matter of malfunction of the AI code itself, both chances of proving illegality with fault and causality at the same time against both operator and manufacturer would remain unreachable.

V. ORGANISATIONAL FAULT OF THE HEALTH CARE FACILITY

Determining fault with a single individual involved in medical AI services is a challenging task. The complexity of programme alterations occurring autonomously makes it all the more difficult to expect from a given individual up-to-date knowledge and skills while operating highly developed machines. For these reasons it may be beneficial to seek remuneration not from a single medic, but from the entire collective of the health care facility instead under the "organisational fault" standard.

Organisational fault is the specified standard of general fault-based liability developed for health care facilities[112]. This makes it not a free-floating standard, but strongly anchored within Polish provisions regulating fault-based liability[113]. Therefore, its application would not change liability's premises — making the fault and the causation the two essential hurdles in finding a culprit for AI-resulted damage

[109] L. Bosek: *Perspektywy…*, *op. cit.*, p. 12; Resolution of the Supreme Court of Poland from 8.10.2010, III CZP 35/10, OSNC 2011, No. 2, Item 13.

[110] M. Kaliński: *Odpowiedzialność odszkodowawcza* (in:) *System prawa prywatnego*, t. 6, ed. A. Olejniczak, Warszawa 2018, pp. 130, 132; A. Koch: *Związek przyczynowy jako podstawa odpowiedzialności w prawie cywilnym*, Warszawa 1975, pp. 132, 137.

[111] D. Kaczan: *Odpowiedzialność…*, *op. cit.*, pp. 154–155.

[112] M. Bieszczad: *Znaczenie koncepcji winy organizacyjnej i winy anonimowej przy dochodzeniu roszczeń cywilnoprawnych przez pacjentów*, Palestra 2019, No. 6, p. 57; M. Nesterowicz: *Cywilne prawo — czyny niedozwolone — odpowiedzialność publicznego zakładu opieki zdrowotnej — wina organizacyjna. Glosa do wyroku SN z dnia 13 maja 2005 r., I CK 662/04*, OSP 2009, No. 12, p. 134.

[113] In the case of health care facilities and other legal persons, the relevant legal ground for their fault-based liability in Polish law is Article 416 of the Polish Civil Code. Its only significant difference from the general standard is that the fault needs to be attributed to the specific organs of a legal person.

once more. What differentiates organisational fault from the general liability standard is its particularisation to the case of health care facilities. Its role was established numerous times in the case law[114] as allowing to attribute fault to a health care facility even in the case of little direct evidence for its fault or causation[115]. What suffices for organisational fault to be proven is the generally deficient organisation of the health care facility[116].

Over the years, Polish jurisprudence has included numerous cases of general faulty behaviour that led to the entire medical facility being held liable for a patient's damage. These included the cases of (1) lack of the appropriate number of qualified doctors[117], (2) delay in providing medical assistance[118], (3) negligence in the organisation of safety, hygiene and care of a patient[119], (4) failure to provide adequate treatment conditions[120] and, most importantly for these deliberations, (5) the use of faulty medical equipment[121].

Organisational fault has enhanced patients' chances of obtaining compensation for the damage endured in a medical facility for almost a century. Attributing fault to the hospital instead of the individual seems to objectify the fault and thus is a tempting solution to the AI dilemma analysed in this paper. Such an approach would, however, be illusory, as it still depends on demonstrating the defectiveness of the AI encoded in the device. On the one hand, a machine with AI may prove to be fundamentally defective. For instance, if the diagnoses made by AI or the surgical steps are even half wrong, it is not necessary to resort to the casuistic requirements for medical devices to conclude that the machine is not performing its function. Thus, its maintenance by the hospital is fundamentally flawed and may easily lead

[114] See e.g. judgment of the Supreme Court of 19.11.1969, II CR 294/69, OSP 1970, No. 12, item 249 and judgment of the Supreme Court of 14.12.1973, II CR 692/73, OSNC 1974, No. 10, item 176. Both of these judgments are exemplary for organisational fault, where the Supreme Court found hospitals responsible for poor organisation standards and bad care that resulted in damage on the part of patients.

[115] M. Bieszczad: *Znaczenie…*, *op. cit.*, pp. 57–58.

[116] K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu — zarys wykładu*, http://www.orawarszawa.com.pl/images/uploaded/Odpowiedzialno%C2%B6%C4%87%20cywilna%20za%20szkody%20wyrz%C2%B1dzone%20przy%20leczeniu_1.pdf (access: 12.02.2023), pp. 9–13; A. Górski, A. Górski: *Podstawy odpowiedzialności deliktowej publicznego zakładu opieki zdrowotnej za szkody medyczne — po wyroku Trybunału Konstytucyjnego z 4 grudnia 2001 r.*, Palestra 2002, No. 46/11–12, pp. 47–48; Judgment of the Court of Appeal in Rzeszow of 12.10.2006, I ACa 377/06, PiM 2009, No. 3, item 145–151; M. Nesterowicz: *Cywilne prawo…*, *op. cit.*, p. 134,

[117] Judgment of the Court of Appeal in Cracow of April 18, 2002, I ACa 214/02, not published; Judgment of the District Court of Świdnica of 2.02.2017, II Ca 627/16, LEX No. 2244998.

[118] K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu…*, *op. cit.*, pp. 10–11.

[119] Judgment of the Supreme Court of 19.11.1969, II CR 294/69, OSP 1970, No. 12, item 249; Judgment of the Supreme Court of 14.12.1973, II CR 692/73, OSNC 1974, No. 10, item 176; Judgment of the Supreme Court of 10.07.1998, I CKN 786/97, LEX No. 50228.

[120] Judgment of the Supreme Court of 27.10.1983, II KR 219/83, OSNKW 1984, No. 5–6, item 54; Judgment of the Court of Appeal in Cracow of 15.06.2020, I ACa 53/20, LEX No. 3044757.

[121] Judgment of the Supreme Court of 11.05.1983, IV CR 118/83, OSNC 1983, No. 12, item 201; Judgment of the Court of Appeal in Gdansk of 23.10.2013, I ACa 866/11, LEX No. 1396851.

to its organisational fault. This would be especially the case when a doctor, after they trusted the diagnosis rendered by a flawed device, inadvertently applies harmful treatment to a patient[122].

However, the above situation does not reflect the key risk associated with AI — its unpredictability. In case of a sudden change of the AI algorithm, it becomes impossible to establish fault of the hospital by simply accusing it of the purchase and maintenance of such a device, particularly if the device had been operating correctly until the damage occurred. Therefore, even in the case of a more liberal approach under the organisational fault standard, it may be fundamentally difficult, if not impossible, to prove the fault of a health care facility for its utilisation of an AI-embedded medical device.

VI. OTHER STRICT LIABILITY STANDARDS

Considering the limited chances of claiming damages on the fault basis, strict liability possibly remains the only legal remedy for AI-inherent risks. This makes dangerous product liability (see point 4 above) one of the most promising ways of attributing liability for damage resulting from an AI-embedded medical device. However, Polish tort law recognises two other strict liability standards which may lead to parallel remedies in the analysed field. These are liability for subordinate's acts (point 7.1 below) and liability of an enterprise owner for the damage occurred on the premises of that enterprise (point 7.2 below).

1. LIABILITY FOR SUBORDINATE'S ACTS

Liability for subordinate's acts may arise either under Article 430 of the Polish Civil Code or Article 120 of the Polish Labour Code, which regulates liability for damage caused by an employee. Although characterised as strict liability, these regulations require pedantry in proving fault, and only make it possible to obtain compensation from entities that are organisationally managerial — and therefore also financially more secure. Moreover, there may be cases when, although no doubts arise as to the fulfilment of the premise of fault by a subordinate, evidentiary diffi-

[122] A similar scenario was analysed in the case of the Court of Appeal in Gdansk of 23.10.2013, I ACa 866/11, LEX No. 1396851. There, the court had to determine whether to attribute damages to a claimant against both a hospital and a particular doctor. The claimant's damage consisted in his partial disability, which was undisputedly due to incorrectly stimulating his natural birth instead of undertaking a Caesarean section. The doctor claimed, however, that the decision on how to proceed with the claimant's birth was correct given the data obtained from prenatal tests. Ultimately, the court agreed that the doctor's actions were correct, putting all the fault on the hospital alone for allowing the use of faulty ultrasound equipment.

culties arise at the stage of establishing the actual perpetrator. In such a case, the negligence on the part of an employee may be relatively easy to prove but given the number of people involved in a medical service, it will become difficult to establish the direct culprit[123]. To address this problem, case law and doctrine have created the concept of anonymous fault[124]. Under Article 430 of the Polish Civil Code, anonymous fault consists in attributing liability to a health care facility due to the obvious fault of some of its subordinates (doctors, nurses or other employees) even if it is impossible to determine the specific individual who caused the damage[125].

Application of anonymous fault, however, would be not enough to confront the risks addressed in this paper. This is because, firstly, its adoption is dogmatically restricted to health care facilities and therefore does not extend to other possible culprits, such as producers and operators. Secondly, anonymous fault, although simpler to prove than the fault of an individual employee, is again merely a fault, and still highly unlikely to be linked with any human behaviour should the damage come from the unpredictable alteration in the AI code.

2. LIABILITY OF AN ENTERPRISE OWNER

Another possible solution is offered by Article 435 of the Polish Civil Code, the application of which could hold a facility providing medical services liable solely on the grounds that the damage occurred on its premises. However, the possibility of using this standard is debated by scholars and the basic problem turns out to be the inclusion of an establishment providing medical services in the concept of an enterprise powered by the forces of nature (steam, gas, electricity, liquid fuels etc.).

Whether a health care facility may be treated as an enterprise powered by the forces of nature should be assessed *in casu*[126]. It is further argued that fulfilment of the above premise requires that an enterprise depends entirely on the use of these

[123] M. Nesterowicz: *Cywilne prawo — zobowiązania — odpowiedzialność deliktowa za podwładnego — wina anonimowa. Glosa do wyroku s.apel. w Łodzi z dnia 8 lipca 2015 r., I ACa 63/15*, OSP 2016, No. 11, p. 109.

[124] Waclaw Zylber is considered the forerunner of this concept, see: W. Zylber: *Wynagrodzenie szkód spowodowanych przez działalność władz publicznych według prawa polskiego*, Warszawa 1934, p. 95, after: M. Nesterowicz: *op. cit.*

[125] P. Modrzejewski: *Odpowiedzialność cywilna za szkody wyrządzone przez niebezpieczny produkt medyczny*, Warszawa 2023, p. 272; M. Bieszczad: *Znaczenie…*, *op. cit.*, p. 59; Judgment of the Supreme Court of 26.01.2011, IV CSK 308/10, OSNC 2011, No. 10, item 116; Judgment of the Court of Appeal in Łódź of 8.07.2015, I ACa 63/15, LEX No. 1808661, Judgment of the Supreme Court of 26.03.2003, II CKN 1374/00, LEX No. 78829; Judgment of the Supreme Court of 28.05.1997, III CKN 82/97, OSNC 1997, No. 11, item 178; K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone przy leczeniu — zarys wykładu*, Toruń, 2013, pp. 9–13; A. Górski, A. Górski: *Podstawy…*, *op. cit.*, pp. 47–48.

[126] K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem…*, *op. cit.*, p. 21; L. Bosek: *Perspektywy…*, *op. cit.*, p. 14.

forces. In other words, the use of natural forces must be a necessary condition of the enterprise's activities[127]. This would not be met should the machines used in the enterprise not be of considerable importance to fulfilling this enterprise's main goal[128]. The second condition that must be met is the scale of transformation of these forces into the work of the enterprise. For this, it is necessary to demonstrate three factors: whether this processing generates a higher-than-average accepted danger, whether the technique used is at an above-average level of complexity and, finally, whether the overall level of technique used was necessary to achieve the enterprise's goal[129]. This second condition is especially required, as it is accurately argued that compared to 1964, when the present Civil Code was published, today there are hardly any enterprises not relying on natural forces[130].

According to scholars' prevailing opinion, these prerequisites are not met regarding health care facilities. This stems from two reasons. Firstly, the purpose of hospitals and other facilities is not dependent on natural forces, as the machines they use are not obligatory for the healthcare mission itself[131]. Secondly, and more convincingly, such a consideration would amount to a major change in today's legal practice, where hospitals are not found liable under Article 435 of the Polish Civil Code. Given this prevailing approach, the task of assigning strict liability to health care facilities should be assigned to the legislator in order not to provoke legal uncertainty[132]. This view also dominates in Polish jurisprudence[133].

VII. CONCLUSIONS

After the recent boom in artificial intelligence technology, it is high time the law caught up with it. Until then, with no specific provisions aiming to regulate both responsibility for AI products in general and for AI medical devices in particular only the old, traditional regime of fault-based tortious liability can be applied. In Polish law they are: risk-based liability for dangerous product, risk-based liability

[127] L. Jantowski (in:) *Kodeks cywilny. Komentarz*, eds. M. Balwicka-Szczyrba, A. Sylwestrzak, Warszawa 2022, Article 435.

[128] M. Wałachowska, M.P. Ziemiak (in:) *Kodeks cywilny. Komentarz*, t. III, *Zobowiązania. Część ogólna (artykuły 353–534)*, eds. M. Fras, M. Habdas, Warszawa 2018, Article 435; Judgment of the Supreme Court of 21.09.2017, I PK 272/16, LEX No. 2358813.

[129] Judgment of the Supreme Court of 27.09.2018, III PK 77/17, LEX No. 2566510; Judgment of the Supreme Court of 29.01.2008, I PK 258/07, LEX No. 865914; Resolution of the Supreme Court of 12.07.1977, IV CR 216/77, OSNC 1978, No. 4, item 73.

[130] M. Zelek: *O kryteriach kwalifikacji przedsiębiorstwa lub zakładu jako wprawianego w ruch za pomocą sił przyrody (art. 435 § 1 k.c.)*, Przegląd Sądowy 2019, No. 3, p. 81.

[131] K. Bączyk-Rozwadowska: *Odpowiedzialność cywilna za szkody wyrządzone w związku z zastosowaniem…*, *op. cit.*, p. 21; L. Bosek: *Perspektywy…*, *op. cit.*, p. 14.

[132] L. Bosek: *Perspektywy…*, *op. cit.*

[133] Judgment of the Supreme Court of 21.09.2017, I PK 272/16, LEX No. 2358813; cf. Judgment of the Court of Appeal in Gdansk of 28.12.2015, III APa 14/15, LEX No. 1994455.

for an injury caused by the enterprise and traditional fault-based responsibility both individual and corporate.

The current provisions of the Polish Civil Code on tortious liability appear, in their literal interpretation, to be insufficient in terms of tort liability for damage caused by a medical device using AI. However, a non-literal interpretation (dynamic interpretation) of the Polish Civil Code tortious liability provisions indicated in this paper remains problematic due to various possible paths this dynamic interpretation can take.

By comparing these standards, it becomes evident that none of them offers the best outline of protection against damage caused by AI medical devices. In this regard, AI seems to outmanoeuvre each and every traditional method of responsibility attribution. Fault-based liability remains unpragmatically focused on the causal link, mostly impossible to trace down. Although risk-based liability seems to be the best solution to blurred individual responsibility, it also requires a strict definition of its boundaries. With no legal provision directly regulating risk-based liability in the AI scenario, this standard of responsibility also falls short of being appropriate for this occasion. It seems that tortious liability for a dangerous product is the most suitable civil liability in tort regime for the damage caused by a medical device using AI. However, it should be emphasised that liability for damage inflicted by an unsafe product is not a flawless regime. Nevertheless, *de lege lata*, this regime remains the most suitable for the sphere of AI tools, for two main reasons. The first one is the regime of objective (not fault-based) tortious liability, which is independent of fault demonstration and, in fact, facilitates the entire procedure. The second one is consumer protection under this regime because of the shift of the burden of tortious liability to the producer. Taking into account the complexity and risks of AI-based tools and medical devices and the need to protect the patient or the user of medical devices using AI, these two aforementioned arguments lead to the conclusion that the tortious liability for a dangerous product regime under the Polish Civil Code best meets the challenges of tortious liability for medical devices using AI in healthcare.

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Słowa kluczowe: sztuczna inteligencja, wyrób medyczny, prawo medyczne, odpowiedzialność odszkodowawcza, delikt, produkt niebezpieczny, software, maszyna z wbudowaną SI, wina organizacyjna, prawo polskie.

MIKOŁAJ DEPTALSKI, PIOTR DZIEWAŁTOWSKI-GINTOWT

TORTIOUS LIABILITY REGIME FOR MEDICAL DEVICES USING ARTIFICIAL INTELLIGENCE. ANALYSIS OF CURRENT SOLUTIONS

Summary

Artificial intelligence is an increasingly popular tool in the field of healthcare and medicine, especially in medical devices. On the other hand, the possible unpredictability of its actions due to the so-called self-correction of software or the issue of predictability of the results of *machine learning* and *deep learning* raises questions about the basis and scope of legal liability. From the perspective of civil liability, the authors of this article analyze three other types of liability operating in the Polish legal system: (1) liability for a dangerous product, (2) liability based on fault, and (3) liability based on strict liability. Of these, the claim for compensation for damage caused by an AI-equipped medical device seems to be the most justified under the liability for dangerous products. However, even this standard does not cover all systems of damage caused by the operation of AI, especially in the case of AI that operates only as software and thus in isolation from a material object. In the absence of a unified legal regulation in the Polish legal system, some of the damage caused by AI will remain uncovered.

Key words: artificial intelligence, medical device, medical law, liability for damages, tort, tort law, dangerous product, software, AI-embedded machine, organizational fault, Polish law.