Katarzyna Wałdoch
Department of Civil Law
Faculty of Law and Administration
University of Gdańsk

CIVIL LIABILITY FOR DAMAGE CAUSED BY THE APPLICATION OF ARTIFICIAL INTELLIGENCE IN MEDICINE

SUMMARY

The dissertation considers issue of civil liability for damages resulting from the use of artificial intelligence in medicine. Problems related to AI are more important in the field of tort liability. In practice claims are also more often based on tort grounds, hence dissertation is limited only to issues related to this type of liability, omitting contractual liability.

The dissertation is consists of six chapters. The first chapter analyze definition of artificial intelligence, problem of black box medicine, possibility of giving AI legal personality, and the issue of obtaining informed consent for diagnostic and treatment activities using artificial intelligence systems. The chapter presents the specificity of SI systems - its complexity, opacity and non-linearity. Examples of medical artificial intelligence systems in medicine are also presented. This chapter presents the lack of terminological coherence, and possible solutions to resolve this problem.

The second chapter indicates that medical artificial intelligence is a medical device under the MDR Regulation and presents difficulties resulting from this fact, including product classification. The rest of the chapter presents the EU legal framework on safety and liability and assessing their adaptation to the issues of artificial intelligence. In particular, the draft of artificial intelligence act and the draft of directive on artificial intelligence liability are analysed.

The third chapter considers liability for defective products as a grounds for compensation claims for damage caused by medical artificial intelligence systems. The analysis covers the issues of AI as a defective product, the issue of product defects, entities liable for damage and situation when liability arise. The considerations include currently applicable regulations and amendments at the EU level, in particular the draft of new directive on liability for defective products. The chapter indicates doubts about the possibility of qualifying AI systems as a defective product, resulting from

the lack of material nature of the software. Attention was drawn to the lack of regulation of the liability of all entities controlling the AI systems during its life cycle, including entities updating the systems. The analysis led to the formulation of de lege ferenda postulates taking into account the specificity of AI systems.

The fourth chapter includes considerations regarding the grounds and scope of civil liability of a doctor using a medical device equipped with artificial intelligence. The conditions for the liability of a doctor using artificial intelligence were analyzed, in particular the objective and subjective elements of fault. The considerations led to the construction of new types of medical error, not yet distinguished in the literature, named supervision error and verification error. The chapter also presents the issue of demonstrating a causal relationship between the damage and the doctor's action and a proposal to solve various evidentiary issues related to establishing a causal relationship in the draft of AI liability directive. The advantages and disadvantages of the proposed regulation were highlighted. In particular, reference was made to a new legal institution, named order to disclose evidence. The purpose of this institution is to make easier for the injured party to pursue claims in civil proceedings.

The fifth chapter discusses the issue of civil liability of a medical entity providing medical services using tools equipped with AI. These entities are liable for their own fault in the form of the so-called organizational fault, which is expressed primarily in the use of defective medical products, checking the efficiency of medical equipment, and purchasing equipment that does not meet quality requirements. The chapter also indicates the risks resulting from replacing the registration employee with a voicebot (virtual assistant). The issue of fault in selection and liability for a subordinate is presented in the context of the specificity of artificial intelligence systems. In the next step, the possibility of incurring liability of the medical entity instead of the manufacturer of the defective AI is considered. The application of art. 435 CC to the liability of the medical entity is criticized.

The last chapter considers the possibility of applying the current regulations to the "acts" of AI systems by analogy. The possibility of assigning liability to a physician for fault during supervision is analyzed and the possibility of applying art. 431 CC to establish liability for artificial intelligence is described.

The dissertation ends with conclusions, presenting the author's own assessment of current and planned legal regulations. The analysis led to the formulation of over twenty research conclusions and several de lege ferenda postulates taking into account the specificity of AI systems.