LIABILITY RISKS OF THE USE OF DIGITAL TECHNIQUES

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ABSTRACT

New technologies not only present new opportunities but also new legal challenges. However, it could be expected that the use of robotics and AI will steadily increase over the next few years. Liability considerations are therefore urgently required.

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I.   INTRODUCTION

In the last few years, the topic of digital technology in medicine and the legal requirements have become increasingly relevant. In particular the keywords Big Data, Artificial Intelligence (AI) or Blockchain have now taken their place in medical everyday life. As the relevance of digital technology increases, technical issues as well as ethical and legal issues arise. The following publication should be devoted exclusively to the liability law aspects.

II.   DIGITAL TECHNOLOGY

The possibilities of digital technology are also enormously diverse in the medical field, ranging from health apps to robotics to the use of artificial intelligence (AI). This paper focuses on robotics and artificial intelligence, which are gradually finding their way into everyday clinical practice. The decisive difference between the two manifestations is the ability to learn. While a robot is defined (by one of many definitions) as a "sensorimotor machine for the purpose of expanding the human ability to act consisting of mechatronic components, sensors and computer-based control and control function", there is currently no binding definition for AI.[1] This is probably due to the fact that there are already different views on what is meant by "intelligence".[2]

A. Attacks on the rise

Looking first at robotics as a facet of digital technology in medicine, one realizes that this aspect has already taken its place into everyday clinical practice for many years. For instance, robots are already being used in nursing and for medical treatment. In particular fully automatic laboratories or service robots in maintenance can be mentioned here. These should complete the work by nurses for example by entertaining seniors through guesswork or playing music.[3]

Better known and used in many clinics worldwide is the Da Vinci robot system. It assists the surgeon in the management of minimally invasive instruments, which can compensate for involuntary hand movements like the trembling of hands.[4]

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[1]   Melinda Florina Müller, *Roboter und Recht*, 5, AKTUELLE JURISTISCHE PRAXIS, 595, 596 (2014).

[2]   Andreas Wichert, *Künstliche Intelligenz*, (Apr. 02, 2019, 03:48 PM) www.Spektrum.de, https://www.spektrum.de/lexikon/neurowissenschaft/kuenstliche-intelligenz/6810.

[3]   Barbara Bückmann, *Pflege-Roboter „Pepper" wird in Senioreneinrichtung getestet*, (Apr. 02, 2019, 03:51 PM) https://www.gesundheitsstadt-berlin.de/pflege-roboter-pepper-wird-in-senioreneinrichtung-getestet-12922/.

[4]   (Apr. 02, 2019, 03:52 PM) https://www.intuitive.com/en-us, https://www.intuitive.com/en-us/products-and-services/da-vinci/instruments.

B. Artificial Intelligence (AI)

As a rule, it is possible to differentiate between weak and strong artificial intelligence. While weak AI is more like the simulation of intelligent human behavior, strong AI is understood to equal or even surpass the intelligent behavior of humans. [5]

1. Weak AI

The functionality of weak AI is essentially based on mathematical methods - especially algorithms - and applications from computer science, which allows the analysis of patterns.[6] Forms of weak AI are fundamentally geared towards solving clearly defined tasks.[7] One example of such a system is the PANTHER system (Patient-oriented Oncological Therapy Assistance).[8] By entering a variety of pre-diagnosed CT images, the system is able to create a pattern. This pattern can then be matched with new CT images. Subsequently the system can detect tumors much earlier than the radiologist.[9]

2. Strong AI

While weak AI requires a certain impulse of an input command, strong AI works on its own initiative.[10] According to the current state of knowledge, however, it has not yet been possible to develop a medical system based on strong AI. However, it is expected that this will be possible in the future. Due to that liability, considerations should be applied today, to not run the risk of the law being overtaken by technical progress.

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[5]   NILS J. NILSSON, THE QUEST FOR ARTIFICIAL INTELLIGENCE, 649, (Web Version (Print version published by Cambridge University Press), 2009).

[6]   Jay Tuck, *Künstliche Intelligenz in der Medizin*, (Apr. 02, 2019, 04:15 PM) https://www.pcwelt.de/a/kuenstliche-intelligenz-im-weissen-kittel,3387296.

[7]   Julian Moeser, *Starke KI, schwache KI – Was kann künstliche Intelligenz?*, (Apr. 02, 2019, 04:17 PM) https://jaai.de/starke-ki-schwache-ki-was-kann-kuenstliche-intelligenz-261/.

[8]   Fraunhofer Institut, *Früher gegensteuern bei unwirksamen Therapien*, (Apr. 02, 2018), https://www.mevis.fraunhofer.de/de/press-and-scicom/press-release/2018/frueher-gegensteuern-bei-unwirksamen-therapien.html.

[9]   Jay Tuck, *Künstliche Intelligenz in der Medizin*, (Apr. 02, 2019, 04:15 PM) https://www.pcwelt.de/a/kuenstliche-intelligenz-im-weissen-kittel,3387296.

[10]   Julian Moeser, *Starke KI, schwache KI – Was kann künstliche Intelligenz?*, (Mar. 11, 2019, 04:25 PM) https://jaai.de/starke-ki-schwache-ki-was-kann-kuenstliche-intelligenz-261/.

III.   LIABILITY CONSIDERATIONS

A. Robotics

1. Legal foundations

In Germany, there is currently no codified robotic law, so the liability law assessment is carried out according to existing general legal norms. Robots that are used in medicine fall in Germany and Europe under the medical device law (hereinafter MPG) as a composite of (among others) instruments and software with medical purpose.[11] Since the MPG currently does not contain a liability law standard, the German civil law (hereinafter BGB) and the German product liability law (hereinafter ProdHaftG) must be consulted.

2. Liability of the manufacturer

A patient who suffers damage to property or health through the use of a (treatment) robot initially has the option of taking legal action against the manufacturer of the robot. According to paragraph 1 ProdHaftG the manufacturer of a product is obliged to pay damages. In the context of this paragraph it is problematic which definition of manufacturer should be applied. According to the Medical Devices Act, the manufacturer is responsible for the initial placing on the market. However as per the definition of the ProdHaftG the manufacturer is the entity whose name is placed on a product or who has introduced the product into an economic area. The starting point therefore varies when different definitions of manufacturer are used. Since there is no clear regulation which definition should be used, the legal practice for patients poses the problem of who is liable.

Further requirements for liability are the defectiveness of the product, a damage in the form of a bodily injury or damage to health or damage to property as well as the causality between the product defect and the breach of legal rights.

According to the ProdHaftG, the defectiveness of the product is assumed when the product does not provide the security - including all circumstances, in particular performance, typical use or time of placing on the market - which can legitimately be expected.

3. Liability of the doctor or hospital

Since 2013, the liability relationship between doctor and patient has been based in particular on the regulations of the treatment contract of §§ 630 a ff. BGB. Other basis of claims can arise from the tort law.

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[11]   §3 Nr. 1 Medizinproduktgesetz.

a) Contractual liability

As mentioned above, robots in the medical field fall under the MPG. In the case that the use of a robot causes damage to the patient, the doctor (or hospital) will only be liable if this damage is due to a breach in the duty of care. The duty of care requirements is very diverse and arise in particular, but not exclusively, from the MPG and the Regulation about the Construction, Instigation and Use of Medical Devices (MPBetreibV). For example, the doctor's duty of care includes compliance with manufacturer warnings and safety notices, the proper checking of functions, and the observance of shelf life data.

b) Contractual liability

Taking into account the MPG, the doctor is liable under tort law only when the devices used are free of defects and fully functional or then the devices were operated incorrectly.[12]

However, a limitation of this extent of liability results from the requirement of full controllability of the risk. As a rule medical devices are regarded as fully manageable, so the practitioner has the burden of proof that the injury to the patient is not due to a wrongdoing of the physician or staff.[13]

B. AI

The administration of artificial intelligence in medicine is currently fraught with unpredictability. Among other things, the question arises who is liable in the use of artificial intelligence. In German law it is not possible that objects or software can be liable. Therefore, only the manufacturer, the doctor or the hospital can be liable. While the manufacturer could be considered a liable party due to having placed the product on the market or having developed it, the hospital could also be considered liable as the owner of the product, or the doctor as the user.

1. Weak AI

As already indicated above, the operation of weak AI requires an input command. In everyday clinical practice, this input command would be performed by a doctor - similar to the activation of another electronic device (e.g. X-ray machine). The doctor thus controls the use of weak AI and therefore assumes liability. As a consequence, the doctor is a liable party and existing liability regulations are applicable – as was the result with reference to robotics.

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[12] RÜDIGER MARTIS & MARTINA MARTIS-WINKHART, ARZTHAFTUNGSRECHT FALLGRUPPENKOMMENTAR, 1524 (5th ed. 2018).

[13] RÜDIGER MARTIS & MARTINA MARTIS-WINKHART, ARZTHAFTUNGSRECHT FALLGRUPPENKOMMENTAR, 1525 (5th ed. 2018).

2. Strong AI

In the context of strong AI, the problem arises in particular that there is the possibility of autonomous decision-making, meaning that the "if" and the "how" of the use are applied by the AI-based system and not the doctor. Since according to the current legal situation, however, objects or software cannot be considered as independent liable parties, it is also necessary in the context of strong AI to turn towards the manufacturer or the doctor as liable party.

a) Liability of the manufacturer

i.) Contractual liability

There is no contractual liability of the manufacturer as there is no contractual relationship between the patient and the manufacturer.

ii.) Tortious liability

Artificial intelligence is likely to fall under the MPG because the use of AI is a connection of apparatus, software and other operations which are subjected to a medical purpose. Therefore, the manufacturer is liable for construction errors.[14] Again, the AI's ability to learn could be problematic because it allows procedures to be modified and overwritten so that they no longer correspond to the original programming. So, the liability of the manufacturer is ruled out because the defect did not exist at the time when the product was put on the market.

Moreover, the fact that the manufacturer of a product which works with AI has given it the opportunity to learn by algorithms cannot be used as a suitable starting point, since exactly this possibility of AI is desired and intended.

b) Liability of the doctor or hospital

i.) Contractual liability

Similar to the considerations on the topic robotics, a contractual liability could result from paragraphs 630a et seq. BGB. Although AI is not yet a general form of treatment, in the future it could become the medical standard. Therefore, according to current standards of liability, its application requires careful and conscientious medical consideration of the advantages and disadvantages, considering all circumstances of the individual case

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[14] Rüdiger Martis & Martina Martis-Winkhart, Arzthaftungsrecht Fallgruppenkommentar, 1525 (5th ed. 2018).

and the well-being of the patient.[15] Furthermore with such a form of treatment, there arises higher requirements in the duty to inform the patient. Thus, the patient must be informed that this is a new method in which unknown risks cannot yet be ruled out.[16]

Mainly, however, problems should arise from who has to assume liability for any damage. In principle, in German law paragraph 280 BGB shows a refutable presumption of fault for the doctor. In a civil law process the doctor would have to prove the lack of liability for a treatment error. The requirement that somebody has to take responsibility for a damage must again conform to the provisions of paragraphs 276 and 278 BGB. According to paragraph 276 part 2 BGB, the doctor is responsible for intent and negligence. The requirements for negligent behavior presuppose that the doctor is not concerned about the objective, usual care and that the doctor could foresee the subsequent damage.[17] However, the foreseeability in particular in the use of artificial intelligence is likely to be doubtful, since strong artificial intelligence is able to learn and decide autonomously. This quality, with the further possibility of its own decision-making, allows us to rule out the foreseeability of the doctor. Therefore, paragraph 276 subparagraph 2 BGB cannot be applied when using strong artificial intelligence.

Equally an attribution of liability according to paragraph 278 BGB is not possible. It would be conceivable to see artificial intelligence as a vicarious agent, under whose operation the doctor would have to accept a fault as his own fault. However, the application of paragraph 278 BGB does not come into consideration for two possible reasons. First, the provision only applies to individuals. Even if one could navigate this problem, however, the following problem arises that paragraph 278 BGB assumes a fault of the vicarious agent. However, a blame can only exist if there is also cognitive faculty, which means the ability to recognize the dangerous nature of actions and to be aware of the responsibility.[18] It is undeniable that artificial intelligence does not possess such an insight.

In summary, it can be seen that contractual liability on the basis of legal regulations is withdrawn when a patient is injured by the use of AI. Of course, a different evaluation should arise when individual contractual arrangements between doctor and patient are made.

ii.) Tortious liability

Suitable infringing action within the meaning of paragraph 823 BGB could be, for instance, the use or the omission of the timely shutdown of a system which features strong

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[15]   BGH (German Federal Supreme Court), VERSICHERUNGSRECHT, 1142,1143 (2017).

[16]   BGH (German Federal Supreme Court, VERSICHERUNGSRECHT, 1073 (2006).

[17]   BGH (German Federal Supreme Court), NEUE JURISTISCHE WOCHENSCHRIFT RECHTSPRECHUNGSRE-PORT, 965 (2006).

[18]   BGH (German Federal Supreme Court), NEUE JURISTISCHE WOCHENSCHRIFT, 354 (2005).

AI. Problems arise here in the context of causality as to whether the misconduct of AI can be attributed to the doctor. According to the equivalence theory, there would be a context for attribution because the doctor would have contributed to the breach of legal rights through the use of AI. However, the equivalence theory is limited on a second level by the adequacy theory. Assuming that the learning ability of AI systems represents an unpredictability, a context for attribution should not be given, since the adequacy theory excludes completely unlikely causal trajectories.[19] Using teleological considerations, however, this result is likely to be paradoxical, since learning is an essential feature of AI systems.

Under the premise that the context for attribution is broken due to the adequacy theory, there would however be room for an analogous application of paragraph 831 BGB.[20] According to paragraph 831 BGB, the principal is liable for damages that the vicarious agent unlawfully caused in the performance of the action. Since the human agent is characterized by the transfer of instructions as well as by the limits of these instructions,[21] there are definitely starting points for an analogous application. In contrast to paragraph 278 it does not depend on a fault of the agent. Here both the fault of the principal in the selection and monitoring of the agent is supposed as well as the causality for the damage.[22] Thus the doctor is responsible for the proof of exculpatory evidence.

Since the doctor who uses an AI system to help in principle must have to enter into a written liability insurance (as well as all practicing doctors in Germany), on the other hand the patient can neither understand the technical nor medical processes of AI systems so the proof of the exculpatory evidence cannot be offered by him (especially since access to it should be excluded), such a burden of proof should also be appropriate. The presumption of negligence would also mean that the regulatory gap would be closed, since the issue of the autonomy of AI is only relevant in the context of the exculpatory evidence. Similarly, the situation of interests may argue for an analogy because paragraph 831 BGB creates the possibility of confronting the creditor with a liquid debtor.[23] Furthermore, the principal also bears the liability risk for human vicarious agents. Reasons why this distribution of risk should move to the patients' burden when AI was used by a doctor is currently not apparent. At most, an absolute total failure of an AI system with the result of exceeding all programmed technical limits, should omit a context for an attribution to the doctor.[24]

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[19] Dr. Christian Grüneberg, Vorbemerkung zu § 249, *in:* Palandt BGB, Rn. 25 (Otto Palandt, 77th ed., 2018).

[20] Michael Denga, *Deliktische Haftung für künstliche Intelligenz*, 10, COMPUTER UND RECHT, 69, 75 (2018).

[21] Hartwig Sprau, § 831, *in:* Palandt BGB, Rn. 1 (Otto Palandt, 77th ed., 2018).

[22] Hartwig Sprau, § 831, *in:* Palandt BGB, Rn. 1 (Otto Palandt, 77th ed., 2018).

[23] Prof. Dr. Gerhard Wagner, LL.M., § 831, *in:* Münchener Kommentar zum Bürgerlichen Gesetzbuch: BGB Band 5, § 831, Rn. 4, (Franz Jürgen Säcker, 7th ed., 2017)

[24] Michael Denga, *Deliktische Haftung für künstliche Intelligenz*, 10, COMPUTER UND RECHT, 69, 75 (2018)

C. Robotics linked to AI

In the future, it should not be rare that robotics and especially strong AI are connected. In this case, due to the ability to learn or the possibility of autonomous decision making by AI, the working method of robotics could be overridden, with the consequence that the liability considerations of AI would be applied.

IV.   CONCLUSION

In summary, it should be noted that the liability valuation of medical use robots can be based on general liability standards.

The current legal situation makes it possible to apply existing liability standards in the context of weak AI, because the liability is linked to the doctor who uses AI. In contrast, the use of strong AI currently presents liability problems, because both the liability of the manufacturer is eliminated, as well as the contractual liability of the doctor. Equally the tortious liability of the doctor or hospital is only possible via an analogy of paragraph 831 BGB.

Therefore, it should be necessary in the future to create a codified AI law, also due to the fact that the use of AI is constantly gaining in importance. Our current legal system is not (yet) up to this.