EJPLT

European Journal of Privacy Law & Technologies • 2020/2 • ISSN 2704-8012

Model of liability for harm caused to the patient by the use of bioprinting technologies: view into the future[1]

DMITRY E. BOGDANOV[2]
Professor at the Kutafin Moscow State Law University (Russia)

Abstract

The rapid development of bioprinting technology creates serious challenges for the legal system, which is lagging behind scientific and technological progress in its development. Lawmakers and the judicial system will soon be forced to answer the questions posed by the new technological revolution. The main area of legal regulation that bioprinting will have a serious impact on is tort liability, since the use of this technology will be associated with harm to the health of patients.

There is a question about the rules that will need to be followed when compensating for harm to the patient. The article considers various models of liability for harm to the patient caused by the use of bioprinting technologies. It is concluded that the patient's voluntary informed consent to treatment using bioprinting technologies can be qualified as the patient's acceptance of the risk of possible adverse consequences that are beyond the control of the medical organization. Such consent may be qualified as a circumstance that is the basis for releasing a hospital from liability for harm caused to a patient when using bioprinting technologies.

Keywords: 3D printing technology - Three-dimensional bioprinting - Tort – Harm - Product liability - Fault liability - Non-fault liability.

Summary: Introduction. – 1. Current practice of compensation for damage caused by 3D medical products. – 2. Modern approaches to determining the model of liability for harm caused to the patient by the use of bioprinting technologies. – 3. Prognostic view of the model of liability for harm caused to the patient by the use of bioprinting technologies. – 4. Concluding remarks and future perspectives.

Introduction

Currently, the world is facing the rapidly developing 3D printing technology designated in scientific literature as an example of additive technology[3]. This technology is based on the connectivity method, which essence lies in the fact that a 3D printer through serial connection and layering of "ingredients" (powders, metal, polymers, etc.) ensures layer-by-layer printing of a new three-dimensional object. 3D printer operation is controlled by a

[1] This study was financially supported by the Russian Foundation for Basic Research within the framework of the Scientific Project No. 18-29-14027 mk "Concept of legal regulation of relations for conducting genomic research in creation and use of bioprinted human organs".

[2] Doctor of Law, Professor, Department of Civil Law, Kutafin Moscow State Law University (MSAL) 9, Sadovaya-Kudrinskaya st., Moscow, 125933, Russia
ORCID: 0000-0002-9740-9923
ResearcherID: P-9117-2015
E-mail: Bogdanov.de@yandex.ru

[3] E. J. Kennedy and A. Giampetro-Meyer, 'Gearing Up for the Next Industrial Revolution: 3D Printing, Home-Based Factories, and Modes of Social Contro'l, 46 (4) Loyola University Chicago Law Journal, 955-988 (2015).

computer with appropriate software; however, the printing itself is preceded by creation of a computer-aided model (prototype) of the future three-dimensional object (Computer Aided Design files or CAD files), which could be obtained, for example, by means of three-dimensional scanning.

3D printing technology development leads to "digitalization" of the material world objects, boundaries between the physical world and the digital space are being erased, since distinction between a computer-aided prototype and its material embodiment is thinned to one click[4]. As noted by Lucas Osbourne, 3D printing is becoming the reason for overlaying worlds of atoms and bits on each other. With the spread and improvement in 3D printing technology, three-dimensional computer-aided templates for many products would become equivalent to their physical counterparts. Regulating relations associated with such files would appear to be a major challenge for the legal system seeking to adapt to the world of 3D printing[5].

If three-dimensional printing (3D printing) digitalizes objects of the material world, which relates not only to high-tech products (for example, components and parts of spacecraft or aircraft), but also to everyday goods (for example, dishes or shoes), then bioprinting starts to digitalize a person and his body. Subsequently, this could lead to a kind of digitalizing the very existence of a person[6], since it would directly depend on its digital embodiment in the corresponding CAD files, i.e. electronic templates both of the entire human body, as well as of its separate parts, individual tissues and organs.

Currently, 3D printing technology is already actively introduced in the area connected to a person "digitalization" for health purposes. Thus, a number of corporations (for example, Organovo, Aspect Biosystems, TeVido Biodevices) are successfully developing the bioprinting technology for liver tissue and other human organs in order to provide toxicological testing of new medical preparations, which helps to reduce risks of harm, as well as time required for testing new medical prescriptions and expenses related with this. 3D printing is actively used in patients' recreation after suffering serious injuries, since this technology makes it possible to print individual prostheses and implants that consider individual physiological characteristics of each patient. Three-dimensional printing also makes it possible to restore the patient's appearance, as it is already actively used in face surgery. 3D printing is used in many leading medical centers before complex operations, which technique was initially practiced on a 3D model of the corresponding organ, for example, before transplantation[7]. Back in 2018, Roscosmos State Corporation, INVITRO and 3D Bioprinting Solutions announced successful completion of the first stage of the Magnetic 3D-Bioprinter space experiment conducted on board the International Space Station (ISS). For the first time in space, human cartilaginous tissue and thyroid gland of a rodent were printed.

But most importantly, bioprinting is aimed at creating a new medical paradigm that would ensure overcoming the deficit of human organs and tissues in transplantology. Since, the global problem is the constant increase in the number of patients requiring spare-part surgery and the acute shortage of donor organs necessary for transplantation.

Legal literature is trying to formulate definition of this technology; thus, Jasper Tran

[4] D. H. Brean, 'Patent Enforcement in Cyberterritories', 40 (6) Cardozo Law Review, 2549-2596 (2019).
[5] L. Osborn, 'Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms', 51 San Diego Law Review, 553-621 (2014).
[6] J. Tran, 'To Bioprint or Not to Bioprint', 17 (1) North Carolina Journal of Law and Technology, 123-178 (2015).
[7] M. Varkey and A. Atala, 'Organ Bioprinting: A Closer Look at Ethics and Policies', Wake Forest Journal of Law & Policy, 5 (2), 275-298 (2015).

indicates that bioprinting is production or manufacture of a living organism using the ink made from living cells[8].

Serious challenge to bioprinting technology is advanced by creating a replica of the human organ "frame" repeating complex architecture, on which several types of living human cells would be layered during the three-dimensional bioprinting. Thus, human organ frame creation (3D printing) is of utmost importance for bioprinting, since growth and division of living human cells would be taking place on it.

Bioprinting technology is able to revolutionize medicine, but this technology also poses serious risks[9], as we still are unable to imagine the entire picture of consequences and problems that will arise in connection with active introduction of this technology[10].

If harm to the patient's life or health is caused by drawbacks of computer-aided design in creating a digital model (replica) of a human organ or of this organ frame, the question arises on the rules that should be followed when compensating the patient for harm. Scientific literature directly indicates that tort liability is one of the main areas of legal regulation, which would be seriously influenced by 3D printing[11]. This predestinates the need in special studies aimed at determining models of liability for harm caused in the additive technologies.

1. Current practice of compensation for damage caused by 3D medical products.

As of today, court practice related to the issues of compensation for harm caused to the patients' life or health when using bioprinting technology is missing, since this is a technology of future, but of the near future. According to forecasts, human heart effective bioprinting is expected in the next 15-20 years. At present, bioprinting of individual human tissues, blood vessels, etc. is already underway.

However, there is already certain court practice on issues related to compensation for harm caused by defective medical devices, implants, etc., made using the 3D printing (additive technologies). Thus, judgement in the Buckley v. Align Tech., Inc.[12] case examined a patient's lawsuit against the dental mouthguard producer, the device was individually manufactured using the 3D printing technology. The patient was not in direct contractual relationship with the producer of this medical product. It was manufactured by the dentist order to eliminate occlusion. The patient was referring to the fact that producer advertising his medical products manufactured using the 3D printing technology misled her and other consumers that his product could eliminate occlusion.

The court rejected the lawsuit basing on the intermediary liability doctrine (intermediary doctrine). Plaintiff's arguments that producer was obliged to carry out medical analysis of the dental prints for individual medical product 3D printing and, therefore, was obliged to warn the patient about consequences of using the dental mouthguard. Based on the intermediary doctrine, the court indicated that medical product was prescribed by a dentist and was manufactured to order by the producer, who was not a medical expert. The defendant was obliged to warn the dentist of any dangerous side effect, but he did not have a similar obligation with respect to the plaintiff.

Thus, the patient was rejected in this case with the suit for compensation for health harm

---

[8] J. Tran, n 6 above, 125.

[9] M. H. Park, 'For a New Heart, Just Click Print: The Effect on Medical and Product Liability from 3D Printing Organ', 4 University of Illinois Journal of Law, Technology & Policy, 187-199 (2015).

[10] E. Lindenfeld, '3D Printing of Medical Devices: CAD Designers as the Most Realistic Target for Strict, Product Liability Lawsuits', 85 (1) University of Missouri-Kansas City Law Review, 79-103 (2016).

[11] G.Howells and C. Twigg-Flesner and C. Willett, 'Protecting the Values of Consumer Law in the Digital Economy: The Case of 3D-Printing', in A. De Franceschi and R. Schulze (eds), Digital Revolution - Challenges for Law (Beck, 2019), 214-244 .

[12] Buckley v. Align Tech., Inc., No. 5:13-CV-02812-EJD, 2015 WL 5698751 (N.D. Cal. Sept 29, 2015)

caused by a medical product made using the 3D printing technology. Motives for lawsuit rejection reflect the peculiar approaches in tort law characteristic for the Common Law countries. It looks like rejection of the lawsuit, even for the American law, is far-fetched in spite of using the intermediary doctrine. Since harm was caused by a medical product that should be safe for any end-user, regardless of whether such user was in a contractual relationship with product manufacturer. The fact that there was an intermediary between producer and consumer in the form of a doctor (medical organization) does not deprive a damaged person of the right to be compensated for harm under such circumstances.

It should be noted that the rules of Product Liability Directive 85/374/EEC[13], the Civil Code of Russia and the Tort Liability Law of the PRC allow in similar situations to impose liability for harm compensation on the medical device producer.

Given this decision, several authors believe that 3D printing connected to using individual computer-aided data (CAD files) obtained by scanning patients for the three-dimensional printing of medical devices blurs the boundaries between professional medical services (treatment) and individualized production creating the basis for the intermediary liability doctrine[14].

In another case (Cristian v. Minn Mining & Mfg. Co[15]), involving compensation for harm by defects in a breast implant, the court indicated that the person, who developed the breast implant model, could not be held strictly liable for harm caused by the product, because he did not participate in the production process. Thus, the court limited the product liability for defective goods establishing that only the direct manufacturer should bear strict responsibility for the defective goods, but not the developer (designer, planner) of the given product model.

Richard Rubenstein in this regard points out that the US case law establishes that strict liability rules for structural defects in regard to implantable medical devices are not applicable due to legal policy reasons. He asks a question about fairness of complete prohibition on application of rules governing strict liability for design (engineering) defects in regard to the 3D printed implants, where the process of computer-aided model design (CAD files) makes it possible to change the product structure for each individual patient. However, the author himself points out inability to answer this question, as the modern system of legal regulation is designed to regulate relations connected to mass production of traditional medical devices[16].

Examples provided from law enforcement practices indicate a problem in determining the model of liability for harm caused by additive technologies, in general, and bioprinting, in particular.

2. Modern approaches to determining the model of liability for harm caused to the patient by the use of bioprinting technologies.

Modern literature is already taking attempts to elaborate a scientific response to new technological challenges forcing to rethink the tort liability concept. So, Jamil Ammar thinks

---

[13] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L 210.

[14] J.M. Beck and M.D. Jacobson, '3D Printing: What Could Happen to Products Liability When Users (and Everyone Else in Between) Become Manufacturers', 18 Minnesota Journal of Law, Science & Technology, 143-205 (2017).

[15] Cristian v. Minn Mining & Mfg. Co 126 F. Supp. 2d 951, 959 (D. Md. 2d 1096, 1117 (D. Ariz. 2003)

[16] R.H. Rubenstein, '3D Printed Medical Implants: Should Laws and Regulations Be Revolutionized to Address This Revolutionary Customized Technology', 7 (349) NATIONAL LAW REVIEW, (2017) available at https://www.natlawreview.com/article/3d-printed-medical-implants-should-laws-and-regulations-be-revolutionized-to-address (last visited 10 June 2020)

that in order to compensate for harm to a patient health caused by using the bioprinting technologies, it is possible to use three theories (approaches) in the liability area:

1) medical malpractice based on a guilt special delict;
2) violation of the contract warranty;
3) strict liability imposed regardless of the delinquent non-fault liability[17].

However, as the indicated author points out, none of these theories completely suits the situations involving harm due to drawbacks in computer-aided design of the human organ three-dimensional models (CAD-Files)[18].

Thus, strict liability imposed regardless of the delinquent guilt in American law is possible only in case of compensation for harm caused by defective goods (product liability)[19].

Scientific literature notes that over the latest time a global trend in product liability is establishment of strict (non-fault) standard for such liability[20]. Therefore, non-fault strict standard of liability for harm caused by defective goods is provided, for example, in Article 1 Product Liability Directive 85/374/EEC, Article 1095 of the Civil Code of Russia, Article 41 of the PRC Tort Liability Law 2010[21].

However, the literature indicates that mass tragedies are becoming the trigger for development of legislation in product liability. It was the lack of effective remedies in situations of massive harm to the health of exposed people by a particular product that led to establishment of strict non-fault liability for harm caused by low-quality goods. Thus, Kristie Thomas claims that it was the "melamine scandal" that provoked inclusion in the new PRC Tort Liability Law rules detailing strict manufacturer liability for harm caused by defective goods. This scandal reminds of the crisis situation in product liability that occurred in Europe in 1960-1970 as a result of the so-called "thalidomide catastrophe", which subsequently affected adoption of the Product Liability Directive 85/374/EEC[22].

It also appears of interest that the US courts are following similar logic, as a rule, applying the rules on strict liability only in situations of causing harm by mass product torts[23]. Despite the fact that the "mass character" indicator is not provided as a prerequisite for establishing strict liability in the Restatement (Second) of Torts, scientific literature indicates creation of incentives for ensuring safety and distribution of risks as goals for such liability[24].

The literature also notes that the US courts are reluctant to extend the scope of strict liability upon defective products (product liability) to software (computer programs), since software is generally considered as a service, but not a product[25]. For comparison, the standard of strict non-fault liability in Russian law covers harm caused not only by defective goods, but also by works and services (Article 1095 of the Civil Code of the Russian Federation).

To illustrate the US court approach, judgement in the Sanders v. Acclaim Entm't case[26]

---

[17] J. Ammar, 'Defective Computer-Aided Design Software Liability in 3D Bioprinted Human Organ Equivalents', 35 (3) Santa Clara High Technology Law Journal, 37-67 (2019).
[18] Ibid 39-42.
[19] N. D. Berkowitz, 'Strict Liability for Individuals? The Impact of 3-D Printing on Products Liability Law', 92 (4) Washington University Law Review, 1019-1053 (2015).
[20] G. Brüggemeier, *Modernizing Civil Liability Law in Europe, China, Brazil and Russia: Texts and Commentaries* (Cambridge University Press 2011) 10.
[21] K. Thomas, 'The Product Liability System in China: Recent Changes and Prospects', 63 (3) International & Comparative Law Quarterly, 755-775 (2014).
[22] Ibid 757-762.
[23] J.K. Gable, 'An Overview of the Legal Liabilities Facing Manufactures of Medical Information Systems', 5 Quinnipiac Health Law Journal, 127-147 (2001)
[24] E. Lindenfeld, n 10 above, 82-85.
[25] J. Ammar, n 14 above, 42-43.
[26] Sanders v. Acclaim Entm't, 188 F.Supp.2d 1264 (D. Colo. 2002)

could be considered, in which the court indicated that computer games were not a "product" for the product liability purposes. Similar conclusion was made by the court in the judgment in the Wilson v. Midway Games Inc. case[27] considering the virtual reality technology. It is worth examining court position in the James v. Meow Media, Inc. case[28], where the court took a differentiated approach indicating that software could be considered as tangible property for tax purposes and as a product in relation to the Uniform Commercial Code (UCC) objectives, but this did not mean that intangible thoughts, ideas and messages contained in computer video games, video files or online materials should be considered as products for the purpose of imposing strict liability. Thus, activities of software developers and website operators are not connected to "products".

It could be stated that North American courts are taking conservative approach in regard to the "product" definition relating to the question of admissibility of imposing the non-fault liability according to the product liability model.

It is of interest that the Australian law belonging together with the North American law to the Common Law system considers software as a "product" for the purpose of imposing strict non-fault liability under the defective product liability model[29].

Similarly, the US law enforcement practice addresses the problem of liability for harm caused by provision of medical services. Given that patients are receiving treatment services in hospitals, and activities of medical organizations, as a rule, are not connected to selling the products, the courts refuse to compensate harm caused to the patient according to the strict non-fault liability model (Perlmutter v. Beth David Hospital[30]). Product liability model for harm caused by a defective product does not cover such relations[31]; compensation for harm is carried out according to the model of special guilty tort (medical malpractice). It is noted in practice that any arguments in favor of establishing a strict standard of responsibility for medical organizations are outweighed by the generally useful nature of their activities related to saving lives and human health (Cafazzo v. Cent. Med. Health Servs., Inc.[32]) Thus, in one case, the court indicated that medical services are often experimental in nature, and when provided, certainty in result is missing, since it depends on factors beyond the control of a professional. Medical services are necessary for society and should be accessible for people (Hoven v. Kelble[33]).

Jamil Ammar in this regard indicates that the bioprinting specificity is associated with combining "products" and "services", it is difficult in this area to differentiate activities of developers specializing in software used to create digital models (CAD files) of human organ analogues, as well as activities of medical organizations and manufacturers of medical devices. Taking into consideration that computer-aided design plays a key role in bioprinting, the author believes that it is easier and cheaper to prevent harm to the patient health even at the stage of creating a human organ digital model imposing strict non-fault liability on the person performing such computer-aided design of a human organ. In this case, it is necessary to differentiate two groups of tortfeasors: first, medical organizations independently carrying out activities in bioprinting and controlling the process of human organs bioprinting; second, developers of software for creating computer-aided models of human organs (CAD files)

---

27 Wilson v. Midway Games, Inc., 198 F.Supp.2d 167, 173 (D. Conn. 2002)

28 James v. Meow Media, Inc., 90 F.Supp.2d 798, 810 (W.D. Ky. 2000)

29 J. Nielsen and L. Griggs, 'Allocating risk and liability for defective 3D printed products: product safety, negligence or something new?', 42 (3) Monash University Law Review,712-739 (2017).

30 Perlmutter v. Beth David Hospital, 123 N. E. 2d 792, 795 (N.Y. 1954)

31 J. Ammar, n 14 above, 46-47.

32 Cafazzo v. Cent. Medical Health Services, 668 A.2d 521 (Pa. 1995)

33 Hoven v. Kelble, 256 N.W.2d 379 (Wis. 1977)

used in bioprinting[34].

It should be noted that earlier Eric Lindenfeld also pointed out the need to differentiate liability of developers of human organs computer-aided models (CAD files), who should be strictly liable regardless of their guilt and of responsibility of medical organizations and 3D printers manufacturers, which, in his opinion, should be liable according to the culpable standard[35].

Another point to be made here is that in the US law enforcement practice the germs of a new approach are already visible allowing software qualification as a product in order to impose strict (non-fault) liability on its developers. Thus, judgement in the Corley v. Stryker Corp. case[36] is of interest for our study, as it addressed the issue of manufacturing a surgical disposable cutting guide, which was subsequently used in operating the patient. This guide was created using software based on a three-dimensional model (3D model) taking into account the patient individual anatomy. In this case, the court agreed with the plaintiff's claim that the software was defective, because in its design the cutting guide used during the operation was "unreasonably dangerous due to alleged software defects".

However, Jamil Ammar points out that introducing strict non-fault liability could be avoided by using the unavoidably unsafe product defense rule, which could possibly be applied to liability in bioprinting[37].

This rule is provided for in Paragraph 402A of the Restatement (Second) of Torts, which states that certain products may not be completely safe in their intended or normal use. The seller of such products is not strictly (non-fault) liable for their use adverse consequences. It is noted in literature that this rule is usually not applied to production, but to design drawbacks of a product, when a safer product design solution is missing[38].

As a result of studying the North American experience in tort liability, Jamil Ammar concluded that the standard of strict non-fault liability and the guilty standard are not fully applicable to torts in bioprinting, since the strict liability standard for developers of software used to create computer-aided models of human organs (CAD-Files) could increase security of such software, but reduce its effectiveness. The liability guilty standard is complicated by the need to prove the tortfeasor negligent delinquency. Therefore, the author proposes a third approach imposing liability on developers of defective software used in computer-aided modeling of human organs. This approach is based not on artificial distinction between products and services, but on differentiating the services rendered into administrative (technical) and proper medical services. Accordingly, strict non-fault liability should be assigned only for harm caused in provision of technical services. However, the author is not proposing criteria for separating these services; he believes that the nature of a service should be determined by the court in each specific dispute, i.e. ad-hoc differentiation. In his opinion, imposing strict non-fault liability on software developers and persons engaged in the development of computer-aided models of human organs (CAD files) is economically justified, because it makes it possible to prevent tort in bioprinting at the initial technological stage and at minimal cost[39].

The source of inspiration for Jamil Ammar in elaborating the approach based on differentiating services between "technical" and proper "medical" services was to separate court decisions, where, in order to impose non-fault liability on a medical organization, the

---

[34] J. Ammar, n 14 above, 37-67.
[35] E. Lindenfeld, n 10 above, 79-103.
[36] Corley v. Stryker Corp., 2014 WL 3375596 *1 (W.D. La. May 27, 2014)
[37] J. Ammar, n 14 above, 37-67.
[38] K. Thomas, n 19 above, 755-775.
[39] J. Ammar, n 14 above, 37-67.

court indicated a different (non-medical) nature of the service provided (Johnson v. Sears, Roebuck & Co.[40]).

Of course, disadvantage of this approach lies in the lack of a clear criterion for differentiating services between medical and technical. For example, there appears a question, whether technical or medical service would include processing data obtained on the basis of a patient computer tomography followed by its subsequent use in creating a three-dimensional model of a human organ and directly in the bioprinting. According to the author's logic, the court would have to answer this question, each time separately assessing circumstances on the case.

Scientific position is of interest, according to which developers of computer-aided models of medical devices (computer-aided designers) should be imposed with strict non-fault liability, and medical organizations should only be liable, if there is fault (negligence); this idea was also presented by other scientists. Moreover, Eric Lindenfeld expressly points out that even a minor mistake in the computer-aided design of medical devices could lead to fatal consequences; therefore, computer-aided model developers should be held liable regardless of their fault[41].

It is obvious that computer-aided design of a three-dimensional model of the bioprinted organ, as a rule, would be carried out not by the third-party companies, but directly by those medical organizations obtaining appropriate equipment and qualified personnel. Therefore, if the indicated scientific position is followed, there appears the need to differentiate the liability model of a medical organization depending on its type of activity, i.e. technical (computer-aided) preparation to bioprinting and proper medical activity connected to patient treatment using the bioprinted organ transplantation. If any defect is identified in the bioprinted organ computer-aided design, i.e. in the computer-aided replica content (CAD files) of the bioprinted organ, liability for the harm caused should occur regardless of the medical organization fault.

With regard to elaborating the medical organization liability model for harm caused to the patients' life or health, including that associated with using the bioprinting technology, the Chinese experience could be interesting, since the PRC legislation differentiates legal regulation of relations in product liability and in liability for medical malpractice.

As noted in the scientific literature, the PRC Tort Liability Law 2010 provides for three models, by which a medical organization could be held liable: guilty model, guilt liability model with presumptive guilt and strict (non-fault) liability model[42].

The most acceptable standard of liability is established in regard to medical organization activities related to the patient diagnostics and treatment (Art. 54 TTL). It is of interest that Chinese lawmaker, as grounds for exempting medical organization from liability, indicated inappropriate behavior of the patient (his close relative), who avoids cooperation with the medical institution in accordance with relevant procedures and standards, as well as complexity of treatment and diagnosis, taking into account the current level of medicine (Art. 60 TTL).

Medical organization fault is presumed in case of violating information obligations; for example, medical risks and alternative medical treatment plans were not explained to the patient; patient's written consent was not obtained (Art. 55 TTL); if a medical professional did not fulfill diagnostic and treatment responsibilities in accordance with the established standard (Art. 57 TTL).

If the patient was harmed due to any defective medical product, medical instrument or

[40] Johnson v. Sears, Roebuck & Co., 355 F. Supp. 1065 (E.D. Wis. 1973).
[41] E. Lindenfeld, n 10 above, 79-103.
[42] L. Xiang and J. Jigang, *Concise Chinese Torts Law* (Springer 2014), 96-97.

transfusion of low-quality blood, the patient is entitled to demand compensation from manufacturer or institution that provided the blood, or demand compensation from the medical institution (Art. 59 TTL). In such circumstances, liability is imposed according to the strict (non-fault) standard, a characteristic feature of product liability.

Thus, legislation of the PRC, when elaborating the medical organization model liability, took into account the generally useful nature of medical activity connected to saving lives and health of people, as well as the legal nature of emerging relationship. Since medical services are often of experimental character, certainty or guaranteed result is missing, when they are provided, because it depends on many factors, including those not controlled by medical personnel. Therefore, as a basis for exemption from liability, it is indicated that difficulties in the patient diagnostics and treatment could be conditioned by the general level of medicine at the moment.

Considering the general level of medicine, as the basis for exemption from liability, recalls the rule provided for in Article 7 (e) of the Product Liability Directive 85/374/EEC that, manufacturer in order to be exempted from liability could prove that the state of scientific and technical knowledge during introduction of goods in circulation did not allow to identify this defect in the product (Development Risk Defense). Scientific literature notes that the purpose of this clause is to balance the interests of consumers in obtaining compensation for harm and the interests of manufacturers in relation to the possibility of innovative development[43].

This logic could be extended to liability for harm caused to the patient in using the bioprinting technologies. The following factors indicate the need to establish a guilt liability standard: 1) positive result is not guaranteed to a patient in case of transplanting a bioprinted organ, since the result depends on factors not controlled by a medical organization; 2) experimental nature of the bioprinting technology; 3) socially beneficial effect of technology capable of saving many lives.

3. Prognostic view of the model of liability for harm caused to the patient by the use of bioprinting technologies.

The question remains open, whether strict differentiation of the medical organization liability model is required depending on the type of its activity, i.e. technical (computer-aided) preparation to bioprinting and proper medical activity associated with patient treatment through the bioprinted organ transplantation. Is strict (non-fault) liability necessary for harm caused by a defect in the bioprinted organ computer-aided design, i.e. in the "computer-aided replica" content of a bioprinted organ (CAD files)?

It appears that such an artificial division of stages in bioprinting in order to elaborate separate liability models is inappropriate. Bioprinting is not just kind of mass production of medical devices, this technology would always be aimed at bioprinting a unique human organ for a particular patient taking into account individual characteristics of his organism. In our opinion, scientific position of Jamil Ammar, according to which it is necessary to differentiate liability of a medical organization in bioprinting by setting the liability non-fault standard for harm associated with drawbacks in computer-aided design when creating a computer-aided replica of a bioprinted organ (CAD files)[44] is controversial. The indicated author used the approach developed by other authors for the purpose of establishing a model of liability for harm caused by defects in designing the computer-aided models (CAD files) of medical

[43] L. Sterrett, 'Product Liability: Advancements in European Union Product Liability Law and a Comparison between the EU and U.S. Regime', 23 (3) Michigan State International Law Review, 885-925 (2015).
[44] J. Ammar, n 14 above, 37-67.

devices[45].

However, computer-aided design of medical devices manufactured using additive technologies based on inanimate nature materials, for example, of an individual joint endoprosthesis made of titanium and polymers, or a dental mouthguard made of thermophilic plastic, is not similar in complexity to computer-aided modeling of human heart, liver or kidney. Despite the fact that each dental mouthguard is being printed using thermophilic plastic based on a computer-aided model designed taking into consideration individual characteristics of a particular patient teeth and jaw structure, this is still massive, relatively simple and stream-fed technology.

Therefore, approach proposed by a number of authors setting the liability non-fault standard for harm caused as a result of drawbacks in computer-aided design and defectiveness of computer-aided models (CAD files) is justified in the 3D printing of medical devices, but is not applicable in bioprinting of human organs.

Bioprinting is a new, breakthrough technology that could save millions of lives. This technology is more complex compared to three-dimensional printing of medical products made from inanimate nature materials. In our opinion, if harm to the patient's health was caused by the presence of defects in the computer-aided model of a bioprinted organ, presumptive guilt model, which could be refuted by a tortfeasor, should be used. This model of guilt liability is basic for the Russian civil law, because according to Clause 2 of Article 1064 of the Civil Code of the Russian Federation, the person, who caused harm, is exempted from compensation for harm, if he proves that harm was caused not through his fault. The law may also provide for compensation for harm even, if the fault in causing harm is missing.

Thus, general rule in the Russian law is a model of tort liability with presumptive guilt, in which the burden of proving innocence rests with the person, who caused the harm. Guilt of causing harm is always assumed until proved otherwise. This distinguishes Russian law from the German law, since guilt in the Civil Code of Germany is presumed only in contractual, but not in the tort liability.

It should be noted that one of the main arguments provided by Jamil Ammar in favor of the liability strict non-fault standard for harm caused by defects in computer-aided design of a bioprinted organ model was a difficulty in proving the negligence (guilt) of the tortfeasor[46]. This argument is determined by specifics of the Anglo-Saxon tort law, in particular, by its basic tort based on guilt (negligence) of the tortfeasor (tort in negligence). To be held liable for such a tort, it is necessary to establish the tortfeasor duty to take care of the damaged physically person (duty of care), violation of such a duty, existence of harm and causal relationship between harm and duty violation[47]. However, these arguments are not working, if the liability model used is based on the tortfeasor presumed guilt.

In the prognostic aspect and in elaborating a fair model of liability for harm caused to a patient in connection with the use of bioprinting technologies, court position is of interest, which was expressed in judgement in the Wilkes v DePuy International Ltd case[48]; English literature pays serious attention to it[49].

In this case, the damaged physically patient was subjected to surgery to replace the hip joint. Artificial joint (implant) was manufactured by the defendant. Three years after the joint

---

45 E. Lindenfeld, n 10 above, 79-103. See also: E. Lindenfeld and J. Tran, 'Strict Liability and 3D-Printed Medical Devices', 17 Yale Journal of Law and Technology Online, (2015) available at SSRN: https://ssrn.com/abstract=2697245 (last visited 10 June 2020)

46 J. Ammar, n 14 above, 37-67.

47 D. Nolan, 'Deconstructing the Duty of Care',129 Law Quarterly Review 559-588 (2013).

48 Wilkes v DePuy International Limited [2016] EWHC 3096 (QB)

49 D. Nolan, 'Strict Product Liability for Design Defects', 134 Law Quarterly Review, 176-181 (2018).

replacement operation, the implant structural element broke due to "material fatigue". On this basis, the patient filed a lawsuit grounded both on the defendant tort in negligence and on the statutory rules of the Consumer Protection Act 1987 establishing strict (non-fault) liability standard. The judge in this case indicated that security is a relative category. Since, no product was absolutely safe; therefore, determination of the safety acceptable level was carried out taking into consideration the risk-benefit analysis. The court took into account that there was no evidence of a production defect in the implant and rejected the plaintiff's arguments that simple structural solutions could eliminate the risk of the implant early failure, since the alternative design proposed by the plaintiff had itself drawbacks, and the implant would become less convenient and more expensive. The damaged physically person was informed about the risk of the prosthesis destruction, as well as about dangerous factors increasing the risk level. The court pointed out that when assigning liability, it should be borne in mind that such consequences could be eliminated through the implant replacement operation and noted that it was necessary to take into consideration potential benefits for a particular patient from the use of medical goods and the risks that appeared with this patient.

However, Donal Nolan criticized position of the court and stressed that it was necessary to take into account benefits and risks not only for the individual patient, but also the "global" benefits, as well as those risks that generally arise, when using these products[50].

Thus, it is proposed to take into consideration not only the risks posed by certain products and technologies, but also their benefits on the general social scale, as well as the fact that in order to obtain any beneficial effect, the patient could voluntarily assume those risks that arise, when using one or another product or technology in the course of treatment.

Australian authors also point out from this position and indicate voluntariness in accepting the risk of harm by the damaged physically person as the basis for exempting the tortfeasor of liability for harm caused by using additive technologies. Such voluntary risk acceptance is only possible, if the damaged physically person was provided with full understanding of the existing risks, and he directly or indirectly expressed the waiver of his right for protection in case of harm[51].

In relation to the Russian law, rule of Paragraph 3 of Article 1064 of the Civil Code of Russia could be pointed out, according to which compensation for harm may be refused, if the harm was caused at the request of or with consent of the damaged physically person, and actions of the harm tortfeasor were not violating the moral principles of society.

4. Concluding remarks and future perspectives.

It looks like this norm would probably be of significant importance in resolving issues of liability for harm caused to a patient in connection to using the bioprinting technologies in treatment. Since the fact the patient is giving his voluntary informed consent to treatment using the bioprinting technologies could be qualified as taking by a patient the risk of possible adverse consequences beyond the medical organization control, for example, rejection of the bioprinted organ by the patient's organism. Such consent could be qualified as a circumstance that eliminates unlawfulness of causing harm and creates the basis for exempting a medical organization from liability for harm caused to the patient when using the bioprinting technologies.

[50] D. Nolan, n 38 above, 176-181.
[51] J. Nielsen and L. Griggs, n 24 above, 712-739.