3-D BIOPRINTING LAW REGULATION PERSPECTIVES

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ABSTRACT

Introduction. Achieved level of technical progress moves us closer and closer to practical use of 3-d bioprinting technologies in real life. Such perspective raise a wide variety of crucial legal issues from the acceptable model of regulation of the science and its' societal effects to problems of the commercialization of the technology and potential restrictions of its use. Some key points on concept of legal regulation of abovementioned sphere is a base of this study.

Material and Methods. Scientific discussion on 3-D bioprinting, European Union`s and US experience in patenting of 3-D bioprinting technologies, European Medicine Agency (EMA) or the US Food and Drug Administration (FDA) regulations, European Medical Technology Industry Association (EUCOMED) Acts. Article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

Discussion. General debate of last few years comes down to an attempt to resolve hesitation between legal attempts for regulation of 3-D biobrinting and concept of complete prohibition of such activities. An adequate response to the mentioned challenge is a reasonable position between some aspects of prohibition and self-regulation, resulting in a moderate number of regulations and standards for developing and marketing. Such regulations may concern an intellectual property (IP) rights, regulation of distribution, premarket restrictions, control mechanism etc.

Conclusion. Scientific approach and regulatory settlement of 3-D bioprinting sphere must unite to achieve a fair balance between the interests of humanity and of individuals - on the one hand, and development of science and business benefits for stakeholders – on the other. The main instruments for this must be balanced regulation of intellectual property (IP) rights, regulation of access and distribution, premarket restrictions, control mechanism etc.

KEY WORDS: 3-D bioprinting, bioprinting technologies, patenting, law regulation of 3-D bioprinting.

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INTRODUCTION

Today's level of scientific and technical progress moves us closer and closer to practical use of 3-d bioprinting technologies in real life. Such perspective raise a wide variety of crucial legal issues from the acceptable model of regulation of the science and its' societal effects to problems of the commercialization of the technology and potential restrictions of its use. Leaving behind sociotechnical problematic, commercialization aspects that must be addressed at first concerns the question of what types of products and uses should be regarded as protectable subject matter under the relevant legal frameworks.

New horizons are opened. Researchers in 3-D bioprinting uniting their activities with biopharmaceutical companies to develop, design, build, and validate in vitro tissues, that can be helpful in experiments with disease modelling etc., opportunity to test drugs on functional human tissues before a living person, to create functional, three-dimensional tissues that can be implanted or delivered into the human body to improve, repair or replace damaged or diseased tissues [1].

MATERIAL AND METODS

Scientific discussion on 3-D bioprinting, European Union`s and US experience in patenting of 3-D bioprinting technologies, European Medicine Agency (EMA) or the US Food and Drug Administration (FDA) regulations, European Medical Technology Industry Association (EUCOMED) Acts. Article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

DISCUSSION

Bioprinting is an emerging field of technology that is part of the wider field of tissue engineering and uses 3D printing technology[2].

The technologies for potential 3-D printing of live tissues, including skin and organs are developing rapidly. When this technology becomes widely available, the ethical issues, such as extension of lifespan or even immortality [3, 4], must've been already addressed. Recent studies shows a tendency stakeholders to use similar model of regulation for 3-D printing as with the use of biological and non-biological materials, arguing for technical similarity of these procedures. However, these problems should not be too simplified in theory and practice because of sensibility of described sphere, bearing in mind that further research will only generate new political, legal and ethical debates, especially in terms of the possibility of using material for bioprinting from humans.

General debate of last few years comes down to an attempt to resolve hesitation between legal attempts for regulation of 3-D biobrinting and concept of complete prohibition of

such activities. Off course, the "ban" is the easiest way out, but such approach will inevitably stop or at least limit the progress of science and technology efforts. "Regulation" approach poses a complex challenge in developing of key principles for 3-D bioprinting because regulatory level of existing synthetic biology is not as comprehensive to give us the answer; it is surely not ready for spreading of unique scientific products to the market, making them available almost for everyone. Therefore, an adequate response to the mentioned challenge is a reasonable position between some aspects of prohibition and self-regulation, resulting in a moderate number of regulations and standards for developing and marketing. Such regulations may concern an intellectual property (IP) rights, regulation of distribution, premarket restrictions, control mechanism etc.

Providing intellectual property rights to the technology of 3-D bioprinting. Stimulating innovation and R & D investment by providing intellectual property rights allow investors to recoup costs incurred and save the progress of technology and access to research results, while saving scientific resources. [5] "Considering that the availability IP rights is one of the factors that might have a great impact on where the greatest investments and scientific efforts in this technology will be made, this is an utterly important question. In addition to trade secrets, copyrights, trademarks and other IPR-related rights, patents will most likely play a major role in that respect..." [5, p. 2]

The downside of such measures will be increasing the cost of 3-D bioprinting technology that will limit for some extent the accessibility and extension for potential consumers of such technology. Moreover, patent protection will be complicated by the fact that intellectual property rights can potentially protect only the "printing method" and not the "object", because the "object" (such as the human organ) is a "gift of nature" and thus cannot be "protected" as such [6]. But, as an example, software of such 3-D bioprinters could be special object of IP, as was described in previous papers. [7, 8] Popularity and high level of interest in described sphere is confirmed by obvious huge rise of patenting activity [9].

The most typical patents claims can be grouped in three main sectors:

- bioprinting design stage (R&D – machines, technique in designing, methods – US patent No. 8579620),
- bioprinting production stage (industrial-making – bioink, biopaper, hydrogel etc. – US patent No. 8143055),
- post-printing stage (biochemical and biophysical methods to accelerate tissue maturation – "bioreactors" – US patent No. 8747880).

Such high patenting activity define some key markets (USA, EU) and market leaders, but existing predefined and IP protected technologies is not enough and some engineering components are missing, thus opening "the road" for new "players" and new patent claims. Moreover, before the first functional bioprinted organ can be created and approved (by European Medicine Agency (EMA) or the US Food and Drug Administration (FDA), many of existing patents will expire. National law of most "involved" in bioprinting regions (EU and US) already has an exemption of non-infringement when it comes to research and/or experimental use of patented technology. Such practice leaves "the door to bioprinting market" wide open for variety of new stakeholders, but less developed and developing countries will most likely stay aside of this process.

Ban for sales of results of 3-D bioprinting. The availability of the results of 3-D bioprinting must not be dependent on commercial interests of main stakeholders since such a trend would obviously have unscientific perspective, which, combined with the already high unscientific debate based on moral, religious and technofobical grounds, will inevitably complicate real-life implementation of such technologies.

Wide discussion on "undue barriers" to health [10, p.9] (negotiations of the TRIPS Agreement, for example) makes some sense, proposing controversy but innovative model of "crowdfunding" donation-based way to access to 3-D bioprinting technology. While such concept could potentially be misused, in general, it stands on human- and social- oriented grounds thus being acceptable. Compulsing with described above general prohibition it will effect positively and will consider the interests of developing and less developed states [11, p 565].

Creating a model for supervising of activities in 3-D bioprinting sphere. It is difficult to choose a final model of such control mechanism, because such supervising functions may be assigned to existing bodies (such as the FDA, HHS US) or to newly created institutions. More complicated problem is a matter of body composition in terms of balance between medical, law and social professionals stuff. [12] On the one hand, task of such body and its administrative activities has more legal/political than medical nature, however, maintaining the significant level of "ethical and moral" component.

Higher levels of scientific and technical knowledge in the 3-D bioprinting area, significally higher level of public trust in terms of health issues, the ability to objectively assess the balance between the development of technology and needs of humanity and individual "adding some points" in favor of medical stuff [13]. But regulational specific, procedure aspects and communication with Government also rises value of administrative officials as a part of such bodies.

Access for individuals to 3-D bioprinting. Regulation model includes matters not only of availability of 3-D bioprinting equipment (3-D printers, its parts etc.) but availability/accessibility of related materials (raw materials, biomaterials, charts, drawings) to perform 3-D bioprinting and achieve appropriate results [14]. The complexity of this question based not only on global trend of availability/non-availability of bioprinting for private use, but also on problematic of technique used.

The final concept will depend on whether 3-D bioprinting is performed by using the printer, designed for conventional 3-D printing (as in such case, restrictions will be quite controversial – this technology is already available for anyone interested and restriction will hurt existing rights of persons), or involves the use of specialized equipment. And the access to such equipment must be limited to legally defined scope of persons who meet specified requirements.

Some access restrictions to the "raw materials" will also be essential part of regulation, given that such raw materials will include hazardous chemicals (that already limited to use), and human biological material (regulation to use of which is a gap for now). Some key terms must be defined for regulation of availability of drawings, schemes for 3-D bioprinting. The model depends on whether such drawings genetically dependent (and thus almost useless for secondary use or Unlawful distribution) or not (poses some risks for patented rights). The right way, from our point of view, is that accessibility to non-genetically dependent drawings must be restricted, which (including the dissemination via online services) require protection by establishing a single user license for preventing unlawful use.

The abovementioned is only the "tip of the iceberg" of problematic in 3-D bioprinting, specific issues are certainly in need of specialized studies. However, scientific and regulatory approach in the field of 3-D bioprinting must firstly be based on fair balance between the interests of humanity and of individuals - on the one hand, and development of science and business benefits - on the other. The main concept of regulation in 3-D bioprinting, from our stand, is patenting. However, patenting is weighed down with ethical/morality issues; "patentability" of biotechnological innovations is also a complex problem (considering current regulations in EU/US national law). It is obvious, that main stakeholders on the market will continue their tension in that direction – achievement of widening the scope of patented objects. Some kind of intricacy will come from contraversive nature of commercial (existing) and private (potential) 3-D bioprinting, which also must be resolved to provide effective settlement of appropriate legal relations.

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