The Research on ownership of cell therapy products

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1. Issues concerning ownership of cell therapy products

Regarding the issue of ownership interests, American Medical Association(AMA)has pointed out in 2016 that using human tissues to develop commercially available products raises question about who holds property rights in human biological materials[1]. In United States, there have been several disputes concern the issue of the whether the donor of the cell therapy can claim ownership of the product, including Moore v. Regents of University of California(1990)[2], Greenberg v. Miami Children's Hospital Research Institute(2003)[3], and Washington University v. Catalona(2007)[4]. The courts tend to hold that since cells and tissues were donated voluntarily, the donors had already lost their property rights of their cells and tissues at the time of the donation. In Moore case, even if the researchers used Moore's cells to obtain commercial benefits in an involuntary situation, the court still held that the property rights of removed cells were not suitable to be claimed by their donor, so as to avoid the burden for researcher to clarify whether the use of cells violates the wishes of the donors and therefore decrease the legal risk for R&D activities. United Kingdom Medical Research Council(MRC)also noted in 2019 that the donated human material is usually described as 'gifts', and donors of samples are not usually regarded as having ownership or property rights in these[5]. Accordingly, both USA and UK tends to believe that it is not suitable for cell donors to claim ownership.

2. The ownership of cell therapy products in the lens of Taiwan's Civil Code

In Taiwan, Article 766 of Civil Code stipulated: "Unless otherwise provided by the Act, the component parts of a thing and the natural profits thereof, belong, even after their separation from the thing, to the owner of the thing." Accordingly, many scholars believe that the ownership of separated body parts of the human body belong to the person whom the parts were separated from. Therefore, it should be considered that the ownership of the cells obtained from the donor still belongs to the donor. In addition, since it is stipulated in Article 406 of Civil Code that "A gift is a contract whereby the parties agree that one of the parties delivers his property gratuitously to another party and the latter agrees to accept it.", if the act of donation can be considered as a gift relationship, then the ownership of the cells has been delivered from donor to other party who accept it accordingly.

However, in the different versions of Regenerative Medicine Biologics Regulation (draft) proposed by Taiwan legislators, some of which replace the term "donor" with "provider". Therefore, for cell providers, instead of cell donors, after providing cells, whether they can claim ownership of cell therapy product still needs further discussion.

According to Article 69 of the Civil Code, it is stipulated that "Natural profits are products of the earth, animals, and other products which are produced from another thing without diminution of its substance." In addition, Article 766 of the Civil Code stipulated that "Unless otherwise provided by the Act, the component parts of a thing and the natural profits thereof, belong, even after their separation from the thing, to the owner of the thing." Thus, many scholars believe that when the product is organic, original substance and the natural profits thereof are all belong to the owner of the original substance. For example, when proteins are produced from isolated cells, the proteins can be deemed as natural profits and the ownership of proteins and isolated cells all belong to the owner of the cells[6].

Nevertheless, according to Article 814 of the Civil Code, it is stipulated that "When a person has contributed work to a personal property belonging to another, the ownership of the personal property upon which the work is done belongs to the owner of the material thereof.

However, if the value of the contributing work obviously exceeds the value of the material, the ownership of the personal property upon which the work is done belongs to the contributing person." Thus, scholar believes that since regenerative medical technology, which induces cell differentiation, involves quite complex biotechnology technology, and should be deemed as contributing work. Therefore, the ownership of cell products after contributing work should belongs to the contributing person[7]. Thus, if the provider provides the cells to the researcher, after complex biotechnology contributing work, the original ownership of the cells should be deemed to have been eliminated, and there is no basis for providers to claim ownership.

However, since the development of cell therapy products involves a series of R&D activities, it still need to be clarified that who is entitled to the ownership of the final cell therapy products. According to Taiwan's Civil Code, the ownership of product after contributing work should belongs to the contributing person. However, when there are numerous contributing persons, which person should the ownership belong to, might be determined on a case-by-case basis.

3. Conclusion

The biggest difference between cell therapy products and all other small molecule drugs or biologics is that original cell materials are provided by donors or providers, and the whole development process involves numerous contributing persons. Hence, ownership disputes are prone to arise.

In addition to the above-discussed disputes, United Kingdom Co-ordinating Committee on Cancer Research(UKCCCR)also noted that there is a long list of people and organizations who might lay claim to the ownership of specimens and their derivatives, including the donor and relatives, the surgeon and pathologist, the hospital authority where the sample was taken, the scientists engaged in the research, the institution where the research work was carried out, the funding organization supporting the research and any collaborating commercial company. Thus, the ultimate control of subsequent ownership and patent rights will need to be negotiated[8].

Since the same issues might also occur in Taiwan, while developing cell therapy products, carefully clarifying the ownership between stakeholders is necessary for avoiding possible dispute.

[1]American Medical Association [AMA], *Commercial Use of Human Biological Materials,* Code of Medical Ethics Opinion 7.3.9, Nov. 14, 2016, https://www.ama-assn.org/delivering-care/ethics/commercial-use-human-biological-materials (last visited Jan. 3, 2021).

[2]*Moore v. Regents of University of California,* 793 P.2d 479 (Cal. 1990)

[3]*Greenberg v. Miami Children's Hospital Research Institute,* 264 F. Suppl. 2d, 1064 (SD Fl. 2003)

[4]*Washington University v. Catalona,* 490 F 3d 667 (8th Cir. 2007)

[5]Medical Research Council [MRC], *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines,* 2019, https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/ (last visited Jan. 3, 2021).

[6]Wen-Hui Chiu, *The legal entitlement of human body, tissue and derivatives in civil law,* Angle Publishing, 2016, at 327.

[7]*id*, at 341.

[8]Okano, M., Takebayashi, S., Okumura, K., Li, E., Gaudray, P., Carle, G. F., & Bliek, J. *UKCCCR guidelines for the use of cell lines in cancer research.* Cytogenetic and Genome Research, 86(3-4), 1999, https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC2363383&blobtype=pdf (last visited Jan. 3, 2021).

Links

- Commercial Use of Human Biological Materials
- Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines

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- UKCCCR guidelines for the use of cell lines in cancer research [fcgi?accid=PMC2363383&blobtype=pdf]

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