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INTELLECTUAL PROPERTY RIGHTS FOR 3D BIOPRINTING IN MALAYSIA

[1]Siti Suraya Abd Razak & [2]Saiful Izwan Abd Razak
[1]Faculty of Management, Universiti Teknologi Malaysia, Malaysia
[1]College of Business Administration,
University of Business and Technology, Saudi Arabia
[2]Faculty of Electrical Engineering, Universiti Teknologi Malaysia, Malaysia

[1]Corresponding author: sitisuraya@utm.my

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ABSTRACT

Additive manufacturing in the field of tissue engineering has evolved rapidly over the past few decades. 3D bioprinting is an extended application of additive manufacturing that involves the building of tissue or organ in a layer-by-layer manner using a bioprinter via instructions from computer graphic software. 3D bioprinting technology offers promise in the transformation of healthcare sectors. Consequently, disputes regarding commercial use of 3D bioprinting, in particular on intellectual property rights will arise. Patent ownership and registration of bioprinting products and processes pose issues of ethics. The copyrighted works of 3D bioprinting software pose risks of copyright infringement. Besides, there is also a question of whether the marks and brand of 3D bioprinters can be protected as

trademarks. The main objective of this study is to analyse how existing intellectual property laws in Malaysia can be utilized to protect 3D bioprinting technology intellectual property rights. The qualitative method is employed in this study, in particular, content analysis of journal articles, books, international conventions, directives, statutes and court cases. Semi-structured interviews with two respondents from relevant ministries were conducted to achieve the objectives of this study. Additionally, a comparative study of legal frameworks in the United States and Europe is adopted to examine intellectual property rights on the international stage. The study revealed that 3D bioprinting products and processes are patentable under the Patents Act 1983; however, ethical and morality issues are challenges in granting protection. Apart from that, copyright can protect computer-aided bioprinting design software and programs under the Copyright Act 1987 and the marks and brand of 3D bioprinting products can be protected under the Trademark Act 2019. The findings of this study will expose the potential in commercialization of 3D bioprinting among industry players and propose improvements to the current regulatory framework of 3D bioprinting related to intellectual property rights.

Keywords: Intellectual property, additive manufacturing, 3D Bioprinting, copyright, patent, trademark.

INTRODUCTION

The World Intellectual Property Organization (WIPO) has named additive manufacturing as one of the frontier technologies which has the potential to boost future economic growth, apart from robotics, Internet of Things (IoT) and cloud computing (World Intellectual Property Organization, 2015). Additive manufacturing is the latest technology that builds a three-dimensional (3D) object by combining materials layer-by-layer through digital computer-aided design (CAD) modelling. The application of additive manufacturing or 3D printing technology can be seen in various sectors such as agriculture, food, construction, automotive and medical industry. 3D bioprinting is one type of additive manufacturing that is beneficial to the future of healthcare sectors in Malaysia (Wahab et al., 2020). 3D bioprinting can be used as an engineering method for printing human organs and cells by adopting a layer-by-layer approach using living cells (Ventola, 2014). Research has been actively conducted on 3D bioprinting

technology application in healthcare sectors involving the production of artificial cartilage and skin that can treat an injured knee, create an outer ear and repair a broken nose due to injury (Mori et al., 2018). The advancement of 3D bioprinting technology can solve the issue of shortages of donor organs for patients in organ transplantation procedures and directly solve the issue of organ trading between countries. A study has been done on forming organs such as kidney and human heart through the use of 3D bioprinting (Bauermeister, 2016). Shahrubudin et al. (2020) stated that 3D bioprinting holds great potential as it assists researchers in conducting experiments relating to cancer research and medical research. The application of 3D bioprinting in the Malaysian healthcare sector began in 2015, when Malaysian surgeons carried out facial implant using 3D bioprinting for a patient involved in a car accident. Majid (2018) observed that the development of 3D bioprinting technology in Malaysia will benefit society, particularly in terms of replacing internal organs, skin, and broken bones. The National Policy on Industry4WRD identifies additive manufacturing as a technology that can drive the country's growth and transformation via digitalization. In 2020, the Malaysian government approved 51 projects involving additive manufacturing in healthcare sectors in the form of 3D bioprinting with RM 6.1 billion total investment, creating 11,409 job opportunities (Malaysian Investment Development Authority, 2021).

Economists view intellectual property rights as a tool to ensure market efficiency and competitiveness in the expansion of innovative and creative activity. Intellectual property rights grant the owner or inventor an exclusive right to a product. Examples of intellectual property rights are copyrights, patents, trademarks, geographical indications, industrial designs and confidential information. In the Industrial Revolution 4.0 era, intellectual property protection, awareness, and practical use of intellectual property assets are an integral component of business strategy. Due to the rise of 3D bioprinting application, manufacturers in the healthcare sector are confronted with the risk of infringement issues as the 3D bioprinting process has made it easier for anyone to replicate human organs and cells through its production (Shahrubudin et al., 2020). The usage of living cells as part of the printing process raises ethical and morality issues of patent ownership of human organs. The 3D bioprinting software used in the process also poses risks of copyright if it is not registered. On the other hand, counterfeiting of 3D bioprinters is causing a huge economic drain.

The issue of piracy and infringement is a significant downside to the technological development of 3D bioprinting. Therefore, these issues must be dealt with to cope with the changing nature of medical technology. The main objective of this study is to analyse how existing intellectual property laws in Malaysia can be utilized to protect 3D bioprinting technology intellectual property rights.

This article begins by explaining the concept and process involved in 3D bioprinting. Next, this study illustrates the definition of intellectual property rights and the intellectual property rights regulatory framework at the international stage and explains the intellectual property protection mechanisms in Malaysia. Thereafter, it specifically concentrates and analyses the protection and ownership of 3D bioprinting intellectual property rights in the current legal framework scenario. The final part of this article provides the theoretical contribution of this study into the field of 3D bioprinting and intellectual property rights area. Additionally, the practical contribution of this study to the Malaysian policy development on 3D bioprinting technology and how it can benefit the industry players are discussed.

METHODOLOGY

Qualitative analysis method in the form of content analysis is adopted in this study. Content analysis is a systematic study of contents in a particular subject area with the aim of drawing inferences about the contexts, meanings and intentions (Reis & Melao, 2019). Content analysis is applicable in this study as it allows the researcher to compress a large amount of text into a smaller number of content categories based on clear coding criteria. Furthermore, this method assists the researcher in analysing a large volume of data in a systematic way (Salehijam, 2018). Content analysis is applied to the textual content of parliamentary statutes and case law. A careful process of selection from 833 Malaysian parliamentary statutes is conducted. The selection criteria of statutes for this study are acts that explain intellectual property rights, in particular the laws relating to copyright and patent. Three documents fit the criteria, the Copyright Act 1987, Patents Act 1983 and Trademarks Act 2019. Apart from that, this study also analyses content from secondary sources. Journal articles are selected from library databases with keywords of additive

manufacturing, 3D bioprinting and intellectual property rights. The articles are then filtered according to a range of time period between 2019 and 2023. As a result, a total of 25 relevant articles are retrieved and examined. Additionally, this study found relevant information in nine books written by prominent authors in the field of intellectual property rights, five websites, one working paper and two conference papers for the purpose of content analysis. These sources of information are analysed to understand the theoretical framework of intellectual property rights for 3D bioprinting. Apart from that, to achieve the research objectives of this study, interviews are conducted with officers from relevant ministries in Malaysia to get their perspectives on the intellectual property protection for 3D bioprinting.

Semi-structured interviews are an effective method to collect qualitative data and to explore respondent thoughts and beliefs on a particular issue (Croxson et al., 2017). Semi-structured interview is suitable for achieving the objective in this study as it allows the research to collect open-ended data through follow-up questions, probes and comments on the issue of intellectual property rights in 3D bioprinting in Malaysia. Five respondents were involved in the interviews. The respondents are directors and senior officers of department in healthcare innovations of the ministries and they were selected to share their views on the intellectual property rights issues in the development of 3D bioprinting technology in Malaysia. The identities of the respondents are withheld in this research for ethical and confidential considerations. In analysing the data, the respondents are coded for easy reference and discussion.

LITERATURE REVIEW

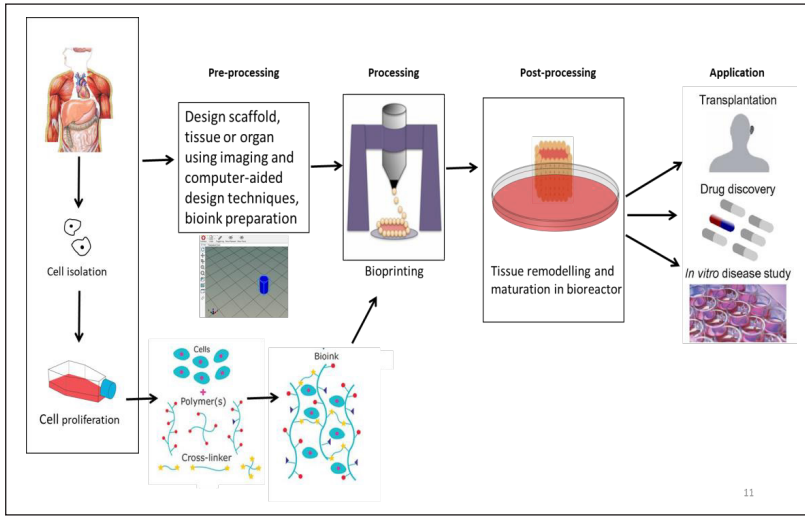
3D Bioprinting Defined

3D printing is also known as an additive manufacturing process that involves joining thin layers of materials to form a solid 3D object (Murphy & Atala, 2014). 3D printing has facilitated large-scale manufacturing and proven to be a cost-effective process in various industries. 3D bioprinting is a form of 3D printing process that can facilitate the formation of complex tissue architecture. It involves the process of using hydrogel-based scaffolds to bind living cells together

and to form individual components of the tissue or organ (Mironov et al., 2009). According to Guillemot et al. (2009), 3D bioprinting is a fabrication of biological constructs that involves addition of material layering on a scaffold to form 3D tissue with assistance from a computer-aided design (CAD) file. Therefore, this process allows tissue constructs to be fabricated by altering the CAD file before printing (Marga et al., 2012). There are three stages in 3D bioprinting: these are the pre-printing stage, printing stage and post-printing stage. The first step involves performing the imaging of the target tissue and CAD software is used to develop a model based on the imaging input. Next, the biomaterial scaffolds and cells are chosen and followed by printing tissue using a bioprinter. It also involves a post bioprinting maturation stage where the bioprinted tissue is allowed to mature (Vischerr et al., 2016). A schematic diagram of the bioprinting process is explained in Figure 1.

Figure 1

Schematic Diagram of Bioprinting Process



The application of 3D bioprinting is critical in the area of tissue engineering as it assists in restoration of anatomic defects caused by trauma, congenital disease and cancer. The restoration and reconstruction processes therefore require 3D bioprinting to produce functional nerves, vessels, muscles, ligaments, cartilage, bone, lymph

nodes and glands (Chia & Wu, 2015). 3D bioprinting application is desired as it can be used for implants, prostheses, surgical guides or tissues that require customized design (Bechthold et al., 2015). 3D bioprinting technology has assisted in producing bioprinted skin for a burn reconstruction procedure (Varkey, 2019). Furthermore, risk of tissue rejection can be reduced when using patient's autologous cells in the process of generating repair tissues and organs (Li & Faulkner, 2017). Bioprinting products produced through additive manufacturing allow researchers in the medical fields to produce or design novel products for commercial or personal use (Mertz, 2013). According to Hussain et al. (2017), the software that is used to print the 3D tissue can be shared in an open source database which gives opportunities for researchers to download the software and produce an exact model or replica of the product. Therefore, due to the various technical aspects in 3D bioprinting and its potential for commercialisation, it is important to identify intellectual properties in the field of 3D bioprinting and how to protect the rights of ownership of the said invention. Yoo (2015) observes that 3D bioprinting may cast patenting opportunities for medical researchers and industries. In the context of this study, 3D bioprinting refers to an additive manufacturing technology that uses living cells to produce human organs through a layer-by-layer approach printing method.

Intellectual Property Protection for 3D Bioprinting

Intellectual property is defined as the novel products of human intellectual endeavour (MacQueen et al., 2011). This definition is supported by Nordin and Bakar (2012) as they describe a property that is directly linked to a person's creativity is known as intellectual property. According to Stim (2001), intellectual property is a creation of the human mind; when it is reduced to material form it is regarded as a tangible asset and deserves ownership. Expressions of ideas created by human beings can be transformed into material forms such as designs, inventions, drawings, music and other various forms (Colston, 1999). When the expression is further developed and commercialised, without proper legal protection, the expression is exposed to exploitation due to competition in industry. Therefore, intellectual property law is important in protecting the creations of human intellect from being exploited without the owner's consent. The intellectual property protection serves two functions: firstly, it provides an exclusive right to the owner of the expression to prevent other

persons from using, dealing or tampering with the product without the consent of the creator. Secondly, it allows the owner to give licence to other persons to use the registered product and gain financial benefits. Intellectual property is a crucial tool for safeguarding the outputs of technology and, inadvertently, encouraging greater creativity among inventors to develop and produce new practical technologies that will benefit the society (Manap & Ahamat, 2019). Intellectual property rights are first and foremost property rights, but they are also property rights over intangibles, and they protect and promote creative and inventive work (Torremans, 2016). The types of intellectual property that are protected under the intellectual property law, among others are: patents, trademarks, copyrights, industrial designs, geographical indications, layout-designs (topographies) of integrated circuits and protection of undisclosed information.

International legal frameworks provide standards and guidelines for intellectual property protection. The World Intellectual Property Organization (WIPO) is an agency of the United Nations and was formed in 1967. WIPO plays the role of leading the development of a balanced and effective international intellectual property system that enables innovation and creativity among the member states. The Paris Convention for the Protection of Industrial Property (Paris Convention) is one of the outcomes of WIPO and was adopted in 1883. It is the first international agreement between member states of WIPO that provides protection for patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications and the repression of unfair competition. The Berne Convention was subsequently introduced by WIPO in 1886, dealing with the protection of works and the rights of their authors. It provides creators such as authors, musicians, poets, and painters with the means to control how their works are used, by whom, and on what terms (WIPO, 2022). Besides that, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was enforced in 1995 to protect intellectual property. According to the preamble of the TRIPS Agreement, the agreement was introduced to reduce the distortions and impediments to international trade, taking into consideration the need to promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights will not become barriers to legitimate trade (World Intellectual Property Organization, 2022). Member countries of the TRIPS Agreement are required to

establish the minimum intellectual property protection standards as specified in the agreement. Malaysia is a member of the WIPO and a signatory to the Paris Convention, Berne Convention and TRIPS Agreement. In Malaysia, intellectual property is protected in the form of legislation. Among the statutes that protect intellectual property rights in Malaysia are the Patent Act 1983, the Copyright Act 1987 and the Trademarks Act 2019. The Intellectual Property Corporation of Malaysia (MyIPO) is a statutory entity responsible for managing the rights associated with intellectual property in Malaysia.

According to Majid (2020), the application of 3D bioprinting in the Malaysian healthcare sector is still in its early stage and not as advanced as in the United States and United Kingdom as these countries are more developed in their technologies with clear intellectual property rights regulatory frameworks. Respondent A stated:

> "*We are still exploring the usage of 3D bioprinting in healthcare and medicine area. For instance, tissues have been produced through 3D bioprinting for the purpose of face reconstruction and for burn and accident victims."*

Additionally, a respondent B who specialises in intellectual property stated that:

> "*The usage of 3D bioprinting in Malaysia is in early stage which mainly used for experiment purpose and not for commercialisation. Currently, there is no patent registered for 3D bioprinters in Malaysia. Most of 3D bioprinters are imported from other countries."*

It can be observed that in Malaysia, the current application of 3D bioprinting is mainly in developing tissues for cosmetic purposes and not fully functional tissues and organs. Besides, the manufacturing of 3D bioprinters is lacking in Malaysia and thus has stunted the growth of 3D bioprinting in the healthcare and medical areas.

According to Shahrubudin et al. (2020), intellectual property in 3D bioprinting is vital and needs to be protected. 3D bioprinting industries must be protected for reasons of consumer interests, economics and morality. Illegal sharing of CAD files among the community is a threat to intellectual property protection of 3D bioprinting as

it causes economic loss to the owner of the CAD files (Gao et al., 2015). The issue of copying the creativity of others for financial gain has persisted throughout history. The act of copying someone else's creative work is frequently viewed as unfair by the original creator as it is natural for a person to own their creation. Therefore, the question arises on whether CAD files in 3D bioprinting can be protected under the existing Malaysian copyright law. Issues also arise on the patentability of 3D bioprinting products in Malaysian patent protection law as 3D bioprinting inventions produce a genetically altered micro-organism product. In the question of patent ownership, claiming to be the owner of bioproducts such as human organs and tissue raises the issue of ethics and morality. Bioprinter symbols and signs used by the manufacturers also pose the question of whether they can be protected under Malaysian trademark law. Hence, this study examines the extent of intellectual property protection for 3D bioprinting in the Malaysian intellectual property law context.

ANALYSIS AND DISCUSSION

Patent Protection for 3D Bioprinting

Among all intellectual property rights, patent plays a major role in investments and technology development (Yoo, 2015). A patent is a grant by the government to an inventor for their new invention. It is a right granted to the inventor to control the commercial exploitation of the invention for a period of time (San, 2020). The concept of patent is explained by Philip W. Grubb (2004) as follows:

> *"The consideration for the granting of patents, in general, is the benefit which results to the state by technological progress as represented by the commercialization of inventions. The connection between the granting of patents and the commercialization of inventions is simply that the existence of patents rights removes part of the risk involved in investment in a new development. Who, after all, would be willing to invest large sums of money in a new project if he knew that an imitator could copy his product as soon as it was marketed, without incurring any research costs? The justification for the patent system is that it provides an incentive for*

> *investment in new ideas, without which technological development would be much slower and more difficult."*

Article 5 of the TRIPS Agreement requires member countries to ensure patent protection for inventions in their countries. In Malaysia, the Patents Act 1983 regulates patent registration and protection. According to the Patents Act 1983, invention is defined as "*an idea of an inventor which permits in practice the solution to a specific problem in the field of technology*". An invention may be in the form of a product or process. Product patent refers to a patent that is in a tangible form, and includes any *"apparatus, article, device, equipment, handicraft, implement, machine, substance and composition while a process patent refers to a patent that relates to process, an art and or method"*. There are three requirements to be fulfilled before any invention can be registered under patent. Firstly, the invention must be new, second, the invention involves an inventive step and third, the invention must be relevant in industry. The patentability of the invention also depends on certain categories. An invention that is successfully registered for a patent will be protected for 20 years from the date of filing of the patent application. Section 13(1) of the Patents Act 1983 provides the list of matters which are excluded from patentability as:

> "*(a) discoveries, scientific theories and mathematical methods;*
> *(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;*
> *(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;*
> *(d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body*."

In the context of this study, the question arises on whether a 3D bioprinting product which is in the form of human living cell, tissue and organ is patentable under Malaysian law? It is observed that a 3D bioprinting product is patentable under the Patents Act 1983. This is because the nature of a 3D bioprinting product can be said to fall under the excluded category of non-patentable invention under Section 13(1)

in which the provision states "*…plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, microbiological processes and the products of such micro-organism processes...".* As the 3D bioprinting method brings cells, biomolecules and tissue into a three-dimensional structure product with biological function, it is regarded as a microbiological process and it produces a microbiological product. Therefore, based on the said provision, the 3D bioprinting product is eligible for patent protection under the Patents Act 1983. Apart from 3D bioprinting products, the 3D bioprinting process is also eligible for patent protection. Section 3 defines a "process" as including an art or a method. The pre-printing, printing and post-printing process involved in 3D bioprinting is thus protected under the Patents Act 1983. In the Malaysian case of Aventis Farma SA (M) Sdn Bhd & Anor v Rohibul Sabri bin Abas @ Megat (t/a Dabur Enterprise) & Anor [2008] 2 AMR 66, it was stated that a process patent would entail protecting the product that was directly obtained from the patented process. It is the exclusive rights of the owner of a process patent including the doing of specified acts in respect of a product obtained directly by means of the process (Section 36(3)(b)(ii) of the Patents Act 1983). Similarly, applying the principle as outlined by the court in the previous case, a product that is formed directly through the 3D bioprinting process can be automatically protected under the Patents Act 1983. Despite the provision, proving a 3D bioprinting product as a living man-made micro-organism remains unclear. The challenge lies in proving that the 3D bioprinting product is non-naturally occurring (Ebrahim, 2017). This is due to the outcome of the 3D bioprinting process that produces a replica which has a similar design to the human living organs and tissues, additionally on the factor that materials used in the 3D bioprinting process originated from real cells, tissues and organs. Hsiao (2018) argued that a 3D bioprinting product is just a duplication of natural organs without any distinctive different characteristics. To date, there is no decided case law in Malaysian courts regarding the patentability of 3D bioprinting products and processes. Therefore, further discussion of this article involves an analysis of the regulatory framework and judicial decisions of patent protection in the United States and European countries in relation to 3D bioproducts in the form of man-made living micro-organisms.

The United States is one of the earliest countries to develop the technology of 3D bioprinting and is currently active in filing

intellectual property protection for 3D bioprinting technology (World Intellectual Property Organization, 2015). Section 101 of the United States Patents Act provides that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title". This provision shows that the scope of patent protection is wide in the United States. However, in the case of American Wood Paper Co. v. Fiber Disintegrating Co 1 F. Cas. 728, 3 Fish. Pat. Cas. 362; 6 Blatchf. 27 (1868), it was held that a nature-related invention in not patentable. The patentability of living man-made micro-organisms was reversed in the case of Diamond v Chakrabarty 447 US 303 (1980). The Supreme Court held that living man-made micro-organisms, that is genetically altered micro-organisms, are qualified for patent protection under United States patent law. The judge outlined two tests to prove the invention can be patented. Firstly, it is a product ingenuity and second, it is non-naturally occurring. Therefore, applying the tests to this case, the court held that that oil-eating bacteria are patent-eligible subject matter because such bacteria were man-made and could not be found in nature. Patent eligibility test in the case of Diamond v Chakrabarty 447 US 303 (1980) was applied in the case of Association for Molecular Pathology v. Myriad Genetics, Inc- 569 U.S. 576, 133 S. Ct. 2017(2013). In this case, Myriad Genetics discovered gene mutations which could increase the risk of breast and ovarian cancers. These findings will assist medical tests in cancer research. However, applying the two tests, the court held that a naturally occurring DNA segment was a product of nature and lacks human ingenuity and therefore it was not patentable. In the case of Roslin, it was stated that the copies (clones) of a sheep were not patentable as it was "*an exact genetic replica of another sheep*" and did not possess "*marked different characteristics from any farm animals found in nature*" (Re Roslin, 2014). In dealing with this issue, the United States Patent and Trademark Office released a guideline known as the Revised Patent Subject Matter Eligibility Guidelines which provide a nature exclusion test for patent eligibility of a product of nature. According to the guideline, if the product is related to one of the statutory categories of subject matters, related to a law of nature or natural phenomenon and it recites additional elements that amount to significantly more than the judicial exceptions, then the product is patentable. Applying the Diamond v Chakrabarty 447 US 303 (1980) eligibility test to 3D bioprinting products, it infers

that a 3D bioprinting product can only be patentable if it can be proved that the product involves alteration or re-designation from the human living tissue to fulfil the non-naturally occurring element. Minssenn and Mimler (2017) stated that the 3D bioprinting product patentability depends on the level of human originality and the ability to prove its distinctions from its natural equivalent. This is supported by a study by Agarwal and Agarwal (2020) which stated that a 3D bioprinting product is patentable as there is some essential feature in the natural product that is not printable. It can be concluded that a 3D bioprinting product can be patentable if it is derived from non-natural "intermediate precursors" or if the product combines natural and non-natural materials (Xin, 2016).

The discussion on patentability of man-made living micro-organisms can also be observed in the European patent system. According to the European Patent Convention, for an invention to be patentable in Europe, the invention must be in the field of technology, concerning a technical problem and consists of technical features. Article 53 of the European Patent Convention states that microbiological processes or the products of plants or animals are patentable. Additionally, the European Patent Office also refers to the Biotechnology Directive of the European Community in its practice. A directive is a legal text drafted by the European Community and links the member states, however, allows the member state the freedom to implement the recommendation. The second chapter of the European Biotechnology Directive (Article 3(2)) states that in determining patentability criteria, biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. This is further supported by the European Parliament and Council Directive which states that an invention directed to an element isolated from the human body such as genes is patent-eligible (European Parliament and and Council Directive, 2016). The analysis of different provisions from different jurisdictions on the patentability of man-made living micro-organism suggests that the criteria for 3D bioprinting patent protection in Europe are less stringent compared to 3D bioprinting patent protection in the United States. The Malaysian Patents Act 1983's provision on patentable categories is similar to the European Patent Convention where it states that a living man-made micro-organism product is patentable. Therefore, it can be inferred that 3D bioprinting products in the form of organs and tissues are eligible

for patent protection in Malaysia. Nevertheless, it is suggested that the interpretation of invention should be revisited to improve the protection in 3D bioprinting technologies (Althabhawi & Zainol, 2022).

Copyright Protection for 3D Bioprinting

Copyright protects the creative products of the mind that are embodied in some tangible forms (San, 2020). The copyright owner is given the right to make copies of the work, perform or play the work to the public or rent out the work to the public for profit. Anyone who uses the works of the copyright owner without permission may be liable for copyright infringement. Article 1 of the TRIPS Agreement requires member countries to provide copyright and related rights protection for works, performers, producers of phonograms and broadcasting organisations. According to Bentley et al. (2018), computer program is protected as literary works and define computer program includes source code, assembly code, and object code. In the Malaysian case of Polygram Records Ltd & 11 Ors v Asia Amusements (Malaysia) Sdn Bhd [1998] AMEJ 0135, the judge stated that copyright protection was an essential foundation to the creation of a creative society. According to the Copyright Act 1987, to be eligible for copyright protection, a work must comply with some requirements. The requirements are: firstly, the work must be original; second, the work must have been written down, recorded or reduced to material form; thirdly, it fulfils the requirements under Section 10 of the Copyright Act 1987. Once these requirements are fulfilled, the produced work is qualified for copyright protection. Additionally, the Copyright Act 1987 does not define the term "original", however according to the judge in the case of Radion Trading Sdn Bhd v Sin Besteam Equipment Sdn Bhd & 2 Ors [2010] 9 MLJ 648, *"the word original does not demand the work to be inventive thought but it requires that the work originate from the author."*

Section 7(3)(a) states that "a literary, musical or artistic work shall not be eligible for copyright unless sufficient effort has been expended to make the work original in character". This principle is as applied by the court in the case of Mohamad Bin S Ahmad & 3 Ors (Trading as Darul Fikir) v Lembaga Pengelola Dewan Bahasa dan Pustaka [2019] 1 AMR 268. Additionally, another important element is on proving that the work is in material form. Section 3 defines material form as

any form of storage (whether visible or not) from which the work or a substantial part of it can be reproduced. Therefore, storage in the form of a thumb drive, compact disc, DVD or software is sufficient to constitute as material form. Another criterion to be satisfied can be found under Section 10 where it states that for a work to enjoy copyright protection in Malaysia, it is necessary for the author to be a qualified person (Malaysian citizen, or permanent resident in Malaysia or a body corporate established in Malaysia). Secondly, the work is first published in Malaysia or in any countries to which the Copyright Act 1987 has been extended. Thirdly, the work is made in Malaysia.

Additionally, for the work to be copyright protected, the work must also fall within any one of the types of works specified under the copyright law. The types of works that are protected under the Copyright Act 1987 are books, paintings, music and computer programs. Section 3 provides that computer programs are protected as literary works. The word "computer program" is defined in Section 2 as:

> "*an expression, in any language, code or notation, of a set of instructions (whether with or without related information) intended to cause a device having an information processing capability to perform a particular function either directly or after either or both of conversion to another language, code or notation or reproduction in a different material form*".

This definition was supported by the court in the case of Petraware Solutions Sdn Bhd & Anor v Readsoft Aktiebolag & Anor [2014] 1 AMCR 112 where it was stated that a computer program is protected by copyright as it is a set of instructions consisting of expressions, notations or codes in whatever language embodied in the disc format or in any other material form of the program. The issue arises as to whether software programs used in 3D bioprinting can be protected under copyright? Computer-aided design (CAD) software is a type of software to assist in design processes. It is used by engineers to create two-dimensional or three-dimensional models. In 3D bioprinting, CAD is capable of designing the human cells for 3D bioprinting. According to Xin et al. (2018), CAD has been used to create customised bone constructs for specific patients. CAD falls under the category of literary works and therefore is eligible for copyright protection. In 1997, a Malaysian court recognised the protection of

computer software in the case of Creative Purpose Sdn Bhd & Anor v Integrated Trans Corp Sdn Bhd & Ors [1997] 2 MLJ 429 where the court stated that "software programs are protected by section 3 which should be read broadly to include all manifestation of that set of instructions which can be read by a computer in whatever converted form". Additionally, a claim on copyright infringement of CAD data and CAD drawings has been recognised by the court in the Malaysian case of HSL Plastics Sdn Bhd & Ors v Lim Kai Meng & Anor [2019] MLJU 305.

Trademark Protection for 3D Bioprinting

Another type of intellectual property that can be protected in 3D bioprinting technologies is in the form of trademark. In Malaysia, trademark registration is governed under the Trademarks Act 2019. For a trademark to be registrable, it must fulfil the elements under Section 3(1) of the Trademarks Act 2019 which states that a trademark must possess the characteristic of a sign, capable of being represented graphically and capable of distinguishing goods or services of one undertaking from those of other undertakings. The word "sign" is defined in Section 2(1) of the Trademarks Act 2019 as to include any letter, word, name, signature, numeral, device, brand, heading, label, ticket, shape of goods or their packaging, colour, sound, scent, hologram positioning, sequence of motion or any combination thereof. In the United Kingdom case of Philips Electronics NV v Remington Consumer Products Ltd [1998] RPC 283 it was stated that the definition of sign is very wide as to mean anything that could convey information. In the context of 3D bioprinting, the name or brand of the 3D bioprinting product can be registered for trademark protection as long as it fulfills the elements under Section 3. Trademark protection in 3D bioprinting products was recognised by the court in the United States case of Advanced Solutions Life Sciences, LLC v BioBiots Inc. 2017 WL2114969 where the court stated that Advanced Solutions owned the trademark "Bioassemblybot" for 3D bioprinting and tissue fabrication. In Malaysia, 3D printers have been developed and a number of trademarks are registered by manufacturers. However, in the area of 3D bioprinting, there is yet a registered trademark for 3D bioprinter as most of the bioprinters are imported from other countries and they are used for the purpose of experiment and research in healthcare sectors and not commercialised. In strengthening the government's policy on the development of 3D bioprinting in healthcare sectors

and encouraging the adoption of 3D bioprinting technology among medical practitioners, a clear guideline for trademark registration is important to guide the public and private sectors in protecting their trademark for the bioprinters.

Based on the above discussions, it is observed that Malaysia has an adequate intellectual property protection mechanism to protect the application of 3D bioprinting. This is because the patent, copyright and trademark protections for 3D bioprinting technology are in line with the TRIPS Agreement and this makes Malaysia as a TRIPS Agreement compliant country.

Ownership Issues in 3D Bioprinting Technology

Morality Test in Patent Ownership

The act of patenting a 3D bioprinting process is a controversial issue as it is touches upon social or religious taboos in society. According to Li (2014), patent protection should not be accorded if the 3D bioprinting process is against social standards of morality in the community. This is because the manipulation and use of human or animal cells as bio-ink in the 3D bioprinting process is against the religious and ethics principle that living beings are the creation of God and cannot be owned by human beings through patent rights. It has been a tenet of UK patent law since the statute of monopolies in 1624 that inventions that violate the law or morality are not protected (Aplin et al., 2013). Considering these morality issues, Article 53(a) of the European Patent Convention provides that 3D printed tissues and organs must pass the "morality test" for them to be patentable. The European Patent Office Technical Board of Appeal in the case of Plant Genetic Systems v Greenpeace [1995] EPOR 123 in its decision stated that the concept of morality is related to the belief that inventions that not are in conformity with the culture and contrary to morality are to be excluded from patentability. Similarly, Malaysia adopted this principle in Section 31 of the Patents Act 1983 where it states that the grant of patent shall be refused if the act would be contrary to public order or morality. According to Kwan (2010), morality is one of the conflicting issues in biotechnology fields. Given the multi-cultural and multi-religious background of Malaysia, the issue of morality in patenting 3D bioprinting processes and products are indeed challenging in determining patent protection.

Copyright Ownership

The question arises as to who is eligible for the ownership and authorship in 3D bioprinting CAD software and programs? Referring to the copyright law in Europe, the Copyright, Designs and Patents Act 1988 provides that the author is the person by whom the arrangements necessary for the creation of the work are undertaken. The law states that the author of a literary work is the person who provides the detailed contents of the work. However, the Malaysian Patents Act 1983 is currently silent on the authorship in CAD software. Therefore, it is observed that the authorship of CAD software falls under Section 2(g) which states that "*in relation to any other cases, means the persons by whom the work has made*". In 3D bioprinting, the person who makes the arrangement to create the CAD software is the author and initially they own the right to obtain copyright protection of the software. However, if the CAD software is created while the author is in the course of employment, therefore, the copyright shall vest in the employer (Section 26(2) of the Copyright Act 1987). The owner of the copyright is entitled to assign or licence the right. The duration of copyright in software programs which is under the category of literary works is provided under Section 17 which states that copyright will be granted to the owner during the life of the author and shall continue to subsist until the expiry period of 50 years after his death.

Trademark Ownership

Section 2 of the TRIPS Agreement stipulates the needs for member countries to provide protection for trademark. 3D bioprinters used in the 3D bioprinting technology can be filed for trademark. Section 17 of the Trademarks Act 2019 states that:

> "*any person who claims to be the owner of the trademark may apply for the registration of the trademark if the person is using or intends to use the trademark in the course of trade or the person has authorized or intends to authorize another person to use the trademark in the course of trade."*

Any individual and body corporate claiming to be the proprietor of the mark may apply for registration of its trade mark, provided that they are either using the mark already or propose to use it.

The trademark owner will have the exclusive right to use the sign registered. Trademark infringement in 3D bioprinting can happen when the mark of a 3D bioprinter is used without authorization of the owner and in conjunction with a sale and is likely to cause misunderstanding, deceit, or mistake about the source of the goods or service. Trademark infringement of 3D bioprinters can confuse the industries and consumer and in turn, damage the business and reputation of the trademark holder. An aggrieved person can apply to court to cancel and expunge the registration of trademark (Section 47 of the Trademarks Act 2019). The High Court in the case of Qi Sheng Sdn Bhd v Foong Yit Meng [2021] MLJU 269 explains that to prove the party is an aggrieved person, it must show a genuine and present intention to use his trademark in the course of trade and/or his trademark may be deemed identical or similar to the registered trademark sought for cancellation.

Theoretical and Practical Contributions

This study provides a clearer framework for intellectual property protection for 3D bioprinting inventors in Malaysia as it explains the patentability of 3D bioprinting products and processes according to the Patents Act 1983. Patent agents would benefit from this study as it provides a clearer standard in examining the patent claims and reduce claim rejections in relation to 3D bioprinting applications. In the commercialisation aspect, this research will provide more clarity concerning the patent, copyright and trademark for the investors to commercialise 3D bioprinting technologies. Althabawi and Zainol (2022) proposed a clear 3D bioprinting framework that incorporates both mechanical and biological inventions to adapt to additive manufacturing emerging technologies. Besides that, the advancement of 3D bioprinting coupled with intellectual property rights will benefit the development of the organ transplantation field and prevent illegal organ trading activities and help burn victims recovering from their injuries. In the judicial aspect, as there is no case on 3D bioprinting claims yet to be heard in the Malaysian court, this article highlights the relevant provisions under the Copyright Act 1987, Patents Act 1983 and Trademarks Act 2019 on 3D bioprinting and the applicability of the subject matter to the current laws. A legal approach is sought as a long-term fix for recognising fundamental technology coupled with international agreements (Khong & Mon, 2023). Discussions on the experiences from the United States and Europe in solving the

intellectual property issues in 3D bioprinting will assist the courts in making decision on intellectual property disputes. Additionally, this study will promote healthcare innovations and increase potential commercialisation in the area of 3D bioprinting. Overall, this study contributes to the intellectual property research area and contributes to the nation policy on 3D bioprinting development.

CONCLUSION

As a conclusion, the field of 3D bioprinting is continuing to advance especially in the healthcare and medicine fields. This technology disruption requires the existing legal framework to accommodate the 3D bioprinting landscape to ensure its sustainability. Highlighting the intellectual property legal framework for 3D bioprinting in Malaysia will promote clearer intellectual property protection for the invention and lead to more commercialisation for rapid growth of the 3D bioprinting industry in Malaysia. It is recommended that morality issues on patent protection for 3D bioprinting products and processes be cleared and the manner of determining the issue is detailed in the legal framework so as to avoid the uncertainty in granting patent rights for the inventor.

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