

Integrative Review on the Ethical Perspectives in 3D Printing: Imperatives on Nursing Science



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Abstract

3d printing has its advantages and wonders, but this technology also has its dark side. Sometimes, the object will simply be a copy of an existing commercial product. Likewise, there are few reports on the ethical considerations regarding 3d printing, especially in the Philippines where piracy or illegal copying is rampant. Thus, the ethical perspective of this venture was taken into consideration. Integrative review combining meta-analysis and synthesis as a research design for this study was facilitated through a literature and study review using PRISMA. Studies on the ethical perspectives of 3D printing were searched through the electronic databases ProQuest, Elsevier, CINAHL, PubMed, Medline Plus, and Ebsco. The search for studies harvested 186 articles of which were searched through the mentioned databases. Out of these articles, 62 studies met the inclusion criteria. The data provided by these studies were compiled, organized by themes noting similarities and differences. After a more and thorough review, 8 studies exactly and completely fit all the protocols and findings needed to be included in this study. Findings revealed issues on the protocol development in the ethical conduct of 3D printing in particular to prototyping and rapid manufacturing; research on the ethical conduct of 3D printing are also lacking and post-evaluation on the conduct of 3D printing as applied to the its purpose were not considered in the existing laws and regulations. All the 8 studies on the ethical perspective on 3D printing are unique in their methods, sampling, data treatment, results and more importantly, findings but their focus is shared. More so, the study suggests further looking at the impact of certain amendments on the laws and policies in 3D printing to its ethics components and relating this to policy formulation that protects all stakeholders' interests in this emerging technological industry. Users and manufacturers of 3D printers and 3D printed objects will encounter issues involving patents, trademarks, copyrights, and other IP rights is a reality in the future.

Keywords: 3D Printing, Nursing Science, Ethical Policies, Protocols development, Data treatment, Technological industry.

Introduction

3D printing is now being widely used as a rapid prototyping and manufacturing method. 3d printers allow us to create parts of any design. Although 3d printing has its advantages and wonders, this technology also has its dark side

Naturally, every object produced in a 3D printer will not be the result of the printing individual's own creativity and ingenuity. As mentioned, sometimes the object will be downloaded and print

ed from another person's original design. However, sometimes the object will simply be a copy of an existing commercial product. Thus, the ethical perspective of this venture was into consideration.

No matter the source of the file, copying existing commercial objects will draw the attention of the object's original manufacturers. Although the proliferation of 3D printing will undoubtedly create opportunities for manufacturers

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(such as vastly reduced distribution costs and the ability to allow customers to customize objects), it will also disrupt existing business models and put risks into reality as it may endanger the ethical value of a certain product. Depending on the type of object copied, manufacturers may turn to several different forms of intellectual property protection for relief (Vincent, 2014).

One of the main issues related to 3D printing is piracy. Because files can be easily copied, users have the ability to reproduce products as long as they have access to a 3D printer. Nowadays, torrent websites offer copyrighted files such as music and movies. In the future, these websites will be capable of providing instructions to print objects.

While this technology is a clear scientific and medical breakthrough, it is also widely controversial. Similar to the cloning of animals – and possibly humans, in the future – the printing of organs produces significant ethical issues. Many associate this topic to religion, debating that only God should be able to produce live beings – or parts of them. Furthermore, this development would possibly give way to a new industry: the selling of cloned (copied and then printed) organs. Though this would be somewhat similar to organ donations, its artificial nature makes it debatable.

Likewise, as the prices of 3D printing falls, the producing companies' profit is going to fall too. As it happens today with music, many people are going to pursue the cheaper, faster way of getting products rather than buying them to the companies. Although companies could encrypt the files containing the information for 3D printing of products, they would not be able to fully prevent their illegal distribution. People would, therefore be able to download illegal copies of MP3, watches, tools, and many other things. This is a factor that might discourage producers to take advantage of the 3D printing technology.

In the Philippines and other countries, the dark side of 3d printing is that 3d printers will allow people to easily copy and print patented designs. People can easily print weapons and use these to harm others, and misuse can do more harm than good (esp. in health applications).

With all the above-mentioned issues and scenarios, 3d printing is at its stake on how deliberate be operated on the perspectives of ethically sound and delivered.

Further, Dodds (2015) shared that one major concern about the development of personalized medicine is the cost of treatments. Until recently, it has been thought that advances in personalized medicine go hand-in-hand with increasing disparities in health between rich and poor. Should these treatments only be available to those who can pay the additional cost? If so, then those patients who lack financial resources may not receive effective treatments that others can access for a range of serious conditions. Personalized medicine is most closely associated with research in genomics and stem cell therapies.

Likewise, advantages of personalizing medicine are most obvious in cases where the condition affects patients in very different ways and standardized treatments offer imperfect benefits. For example, conditions affecting the growing bones of children are among those where personalizing treatments, if these can be adapted to the rapidly changing bodies of children, can make a very big difference in the child's comfort and capacity to participate in ordinary childhood activities and play.

Until recently, the cost and time required to provide a series of customized prostheses of different sizes for a child who has lost a leg to cancer, for example, has been prohibitive for many patients. 3D printing will bring down the time and cost of customizing and producing prosthetic legs. In cases like that of Ben Chandler, printers can also be used for implants, which might avoid the need to amputate the original limb, even where significant bone loss has occurred.

The capacity to use 3D printing technology to substantially reduce the cost of prosthetics, or orthopedic surgery to restore lost bone structures means that this area of personalized medicine can avoid the criticism that personalized medicine inevitably increases the cost of health care and puts effective personalized treatments out of the reach of many patients.

Second ethical concern about any new treatment, including the use of 3D printing, is how we can test that the treatment is safe and effective before it is offered as a clinical treatment. In the case of 3D printing to replace bone, the materials used – for example titanium – are those already used for orthopedic surgery and have been tested for safety over a long pe-

riod and with many patients, so it is unlikely that there are new risks from the materials. In the future, 3D printing may be used in combination with stem cell-derived cell lines. This could lead to the development of printed functioning organs that can replace a patient's damaged organ, but without the risk or rejection associated with donor organs, because it uses that patient's own cells.

How can we know in advance that these treatments are safe? Unlike the case of developing a new drug, a stem cell therapy can't be tested on a sizable number of healthy people prior to being tested on patients and then, finally, being made available as a standard treatment. The point of using a patient's own stem cells is to tailor the treatment quite specifically to that patient, and not to develop a treatment that can be tested on anybody else. Researchers combining 3D printing with personalized stem cell therapies beyond the experimental stage will need to develop new models for testing their treatments for safety and effectiveness.

Regulatory bodies that give approval for new treatments, such as Australia's Therapeutic Goods Administration (TGA), will also need to establish new standards of testing for regulatory approval before these treatments can become readily available. This means that even if researchers were ready to print a functioning prosthetic organ, it will be quite some time before patients with kidney disease should expect to be offered a 3D printed prosthetic kidney that uses their stem cells as a routine treatment.

The third issue is whether or not we should use 3D printing for human enhancement. If the technology can be used to develop replacement organs and bones, couldn't it also be used to develop human capacities beyond what is normal for human beings? For example, should we consider replacing our existing bones with artificial ones that are stronger and more flexible, less likely to break; or improving muscle tissue so that it is more resilient and less likely to become fatigued, or implanting new lungs that oxygenate blood more efficiently, even in a more polluted environment?

The debate about human enhancement is familiar to the context of elite sport where athletes have sought to use medical technology to extend

their speed, strength or endurance beyond what is 'natural', or what they are able to achieve without drugs or supplements. In that context use of performance-enhancing drugs is considered to cheat other athletes, unbalancing the level playing field.

In the case of 3D bioprinting, the enhancement of human capacities could be associated with the military use of the technology and the idea that it would be an advantage if our soldiers were less susceptible to being wounded, fatigued or harmed in battle. While it is clear that it would be preferable for military personnel to be less vulnerable to physical harm, the history of military technology suggests that 3D printing could lead to a new kind of arms race. Increasing the defenses that soldiers have in the face of battle would lead to increasing the destructive power of weapons to overcome those defenses. And in so doing, increasing the harm to which civilians are exposed.

In this way 3D printing may open up a new gap in the vulnerabilities of "enhanced" combatants and civilians, at a time when the traditional moral rules concerning warfare and legitimate targets is muddled by terrorism and insurgency.

These three points might just be scratching the surface of new, deeper ethical and social issues that will emerge as the technology progresses. The future of 3D bioprinting applications holds the promise of better treatment while challenging communities to address emerging ethical questions.

This study explores the different ways 3D printing is used and will discuss the ethical considerations for each application. The current laws on Intellectual Property Rights pertaining to 3D printing will also be considered.

This study provided a platform to a thorough review of the literature on how the 3D printing be perceived in its ethical perspectives. Findings served inputs on how ethical undertaking be explained in the aspect of prototyping and rapid manufacturing.

This study sought answers the following questions:

1. How may the ethical perspective of 3D printing be perceived in terms of a review of literature and studies?
2. How may analysis of the existing laws regarding intellectual property rights in the Philippines be described in terms of its implementation and enforcement?
3. What is the implication of this study in the

current law on Intellectual Property Rights printing considering the ethical perspectives of 3rd printing?

Methodology

This study used an integrative approach in the review of studies. The review of literature is the methodology (integrative review) that provides synthesis of knowledge and applicability of results of significant studies to practice. It is also a review method that summarizes past empirical or theoretical literature to provide a more comprehensive understanding of a particular phenomenon or healthcare problem (Grant and Booth, 2009). Integrative reviews, thus, have the potential to build engineering sciences, health

and medicine, nursing science, informing research, practice, teacher education, business and data analytics and policy initiatives. Well-done integrative reviews present the state of the science, contribute to theory development, and have direct applicability to practice and policy.

The objective of this methodology is to present the phases of an integrative review and the relevant aspects to be taken into account when using this methodological resource. As known to many, the integrative literature review is a form of research that reviews, critiques, and synthesizes representative literature on a topic in an integrated way such that new frameworks and perspectives on the topic are generated.

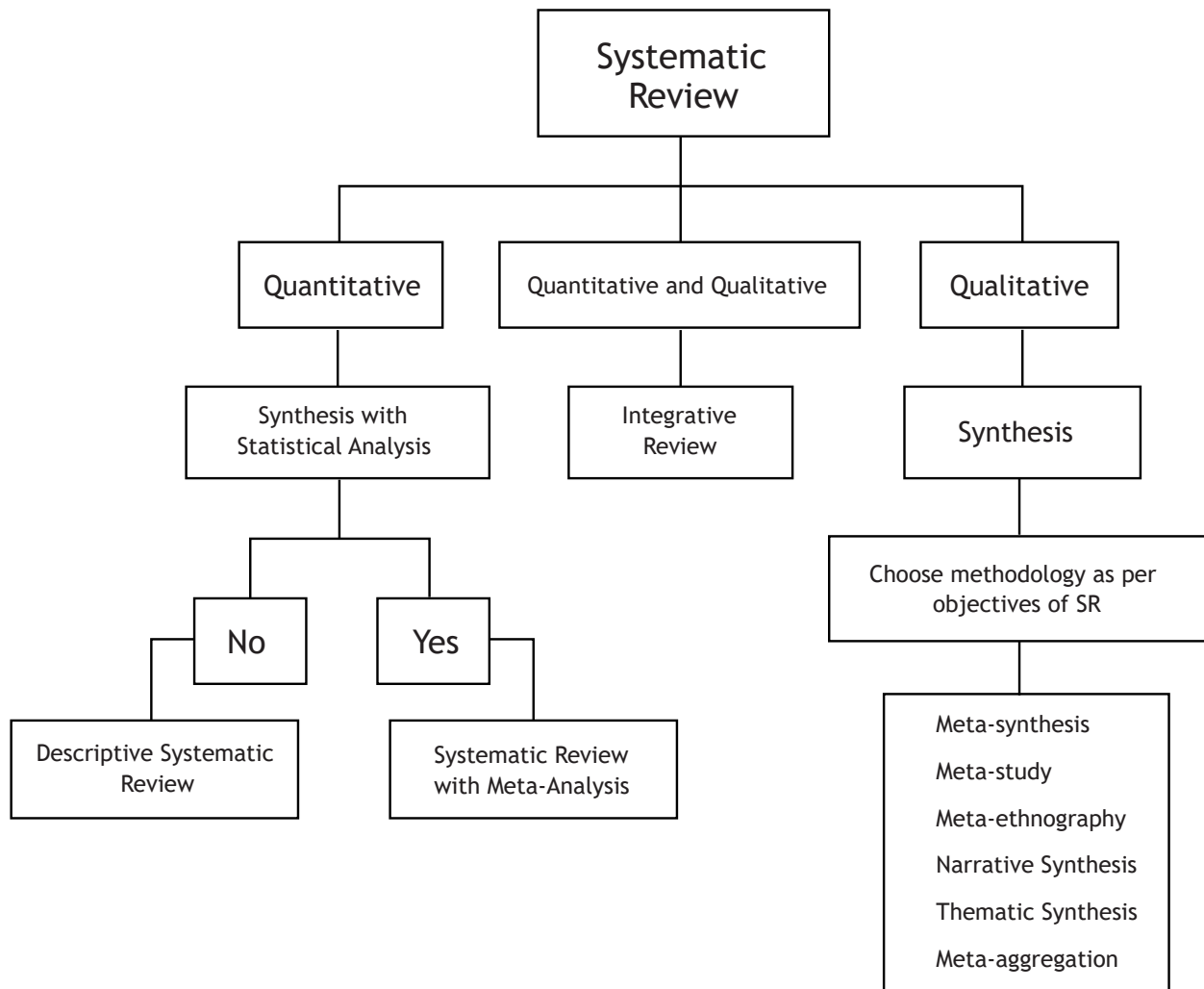


Figure 1.
Methodologies for synthesizing Scientific Evidence, According to qualitative and quantitative approach-Sao Paulo - 2010

Likewise, this is at far from meta-analysis because a systematic review answers a defined research question by collecting and summarizing all empirical evidence that fits pre-specified eligibility criteria. A meta-analysis is the use of statistical methods to summarize the results of these studies. Limitations of the integrative literature review is the combination and complexity of incorporating diverse methodologies can contribute to lack of rigor, inaccuracy, and bias. Methods of analysis, synthesis, and conclusion-drawing remain poorly formulated. Issues related to combining empirical and theoretical reports (Whittemore, and Knafl, 2005).

Figure 1 presents the methodologies for synthesizing scientific nursing evidence by Souza, et.al in 2010 to fully understand the difference of a systematic review to an integrative review. The study explored the ethical perspectives of 3d printing through review of literature and studies. There are few reports on the ethical considerations regarding 3d printing, especially in the Philippines, where piracy or illegal copying is rampant. A literature and study review using PRISMA. PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.

Integrative review combining meta-analysis and synthesis as a research design for this study was facilitated through a literature and study review using PRISMA. Studies on the ethical perspectives of 3D printing were searched through the electronic databases Proquest, Elsevier, Hindawi, CINAHL, PubMed, Medline Plus, Ebsco. The descriptors that were used to locate articles include "3D Printing", "Ethics in 3D Printing", "Ethics in Prototyping", "Ethics in Rapid Manufacturing" and were limited to English text only and publications since 2010. Issues related to combining empirical and theoretical reports were framed according to Whittemore, and Knafl in 2005. Likewise, documentary analysis served accordingly including

policy review. Focus Group Discussion (FGD) and Round Table Discussions were also employed in relating it to the current law on Intellectual Property Rights printing considering the ethical perspectives of 3rd printing. A rubric was adopted based also on the matrix and need of the selection criteria of the experts/validators of review of studies. Said experts were chosen because of their seasoned expertise in this kind of technological researches. Consent were taken into consideration also among authors of those articles included in the selection criteria of this study.

Results and Discussions

I. Ethical perspective of 3d printing be perceived in terms of review of literature and studies.

The search for studies harvested 186 articles of which were searched through the mentioned databases. Out of these articles, 62 studies met the inclusion criteria. The data provided by these studies were compiled, and organized by themes noting similarities and differences. After a more and thorough review, 8 studies exactly and completely fit all the protocols and findings needed to be included in this study. These studies, reports and cases were derived from different countries: Belgium, New Zealand, Poland, Australia, the United Kingdom and the United States of America.

All the 8 studies on ethical perspective on 3D printing are unique in their methods, sampling, data treatment, results and more importantly findings but their focus is shared. They all discussed the different outcomes as well as laws and policies that exist within each state and country where these studies were adopted from. Each study was read and re-read, synthesize and checked for accuracy to determine if it discussed the topic at hand. Thus, the study resulted to visualize the bigger picture of ethical perspectives on 3D printing are very limited and few researches are being published on its ethical undertaking. Relative to this, policies and guidelines on the ethical protocol in the operation of prototyping and rapid manufacturing are lacking.

Stage of Review	Illustrations an Descriptions
Problem Identification	3D printing has been a practice in the field community of Additive Manufacturing and Prototyping for so many years now, however, it still remained on issue of whose jurisdiction it is. Is it the law, that has the power to uphold or remove ones civil rights or science that has the knowledge to determine when the mind does not function anymore as required by society. Though the increase incidence of poor ethical conduct of 3D printing which are universal phenomena that impact the life and wellbeing of the affected person, family and even the community at large, geographically and politically, some factors draw the line between whose authority to control one’s freedom and whose intelligence can decide whether someone is unable to exist to enjoy that freedom. Therefore, literatures, theories, proven and well tested studies, laws, policies, jurisprudence, statutes, records, databases and all sources available to explain the ethical perspectives of 3D printing to a person should be sought together with the underlying laws being mandated to some states, countries and territories on this issue.
Literature Search	With a focus in mind on the concept of ethical perspective of 3D printing especially on its outcomes to a person, the keywords “3D Printing”, “Ethics in 3D Printing”, “Ethics in Prototyping”, “Ethics in Rapid Manufacturing” were searched from known 3D Printing studies databases such as Proquest, Elsevier Hindawi, CINAHL, PubMed, Medline Plus, Ebsco covering the years 2010-2020 procuring as much as latest studies as possible. Initially, 186 studies were searched and downloaded using the keywords mentioned and with available complete study. After a more thorough review of the studies and articles while bearing in mind the specific focus of the search, it was cut down to 62 studies and eventually to 8 studies upon a more critical review of them
Data Evaluation	The 8 studies downloaded that completely suit the needs of this integrative review were carefully read, checked for further fitness, determined its comparison and contrast to each other without going further away from the main problem of this integrative review.
Data Analysis	All the 8 studies on 3D printing and its ethical undertaking are unique in their methods, sampling, data treatment, results and more importantly findings but their focus is shared. They all discussed the different outcomes as well as laws and policies that exist within each state and country where these studies were adopted from. These countries are the Belgium, New Zealand, Poland, Australia, United Kingdome and United States of America. Each study was read and re-read, synthesize and checked for accuracy to determine if it discussed the topic at hand. Other quality checks for validity and reliability were implemented as well by comparing it to other existing studies and articles that discusses the same context but do not provide needed findings as required by this present integrative review.
Presentation	A synopsis of each study was explained in narrative form in this integrative review so to present diverse practices and implemented laws of different countries on 3D printing. More so, ensures better professional practice on rapid manufacturing and prototyping.

Table 1: Stages of Review

Analysis and synthesis of data extraction base on the classified articles be described using the Whittermore and Knalf approach (2005) of integrative review.

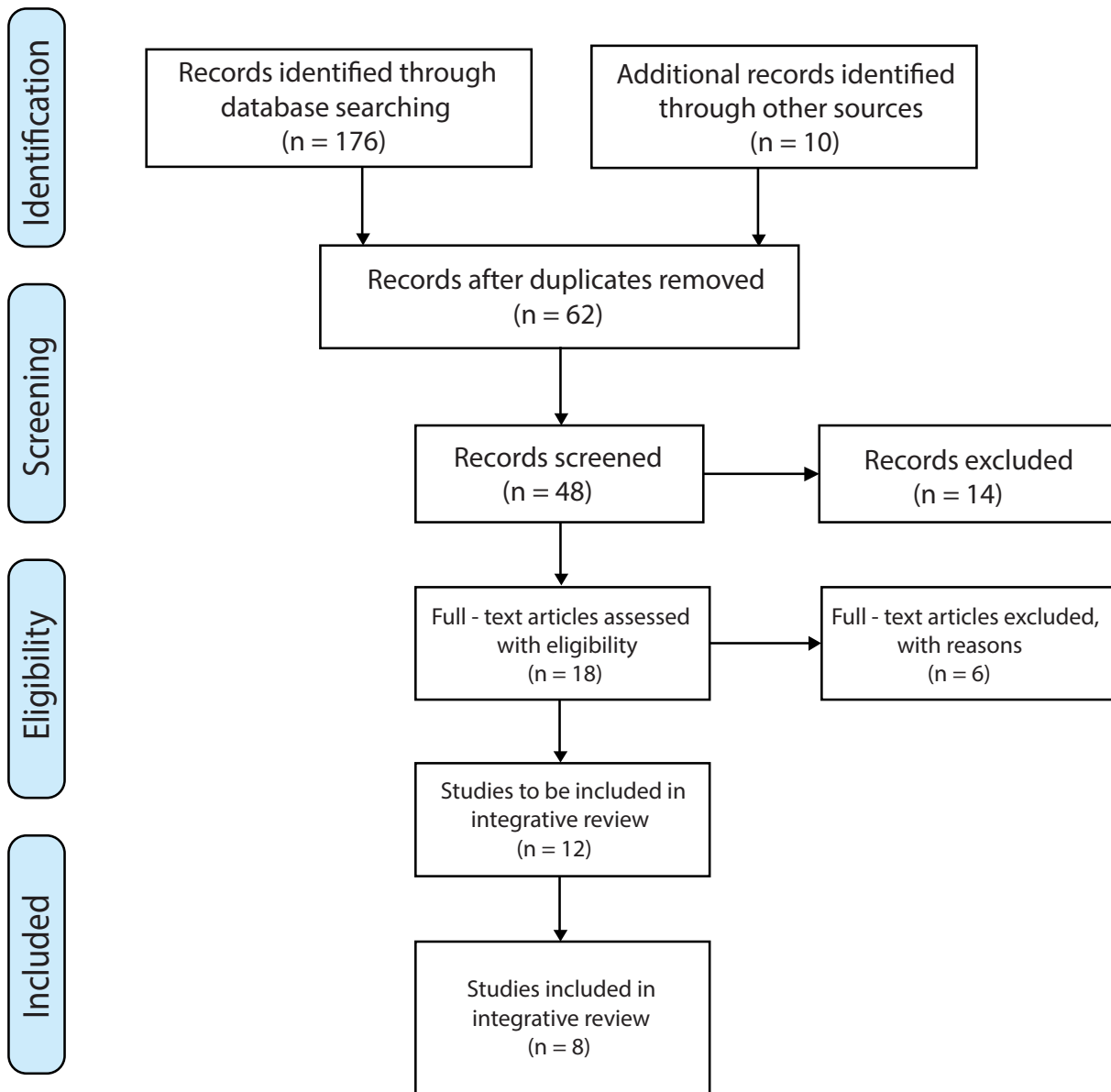


Figure 2:
Search Flow Process (Mother, 2009).

More so, the study suggests to further look at the impact of certain policies in 3D printing in particular to its ethics components and relate this to policy formulation that protect the interests of all stakeholders in this emerging technological industry. On the other hand, the reviewed studies are testimonies that researches on 3D printing are really wanting to address all issues and strengthen the strategies to ensure quality applications of outputs using this new modality of prototyping and rapid manufacturing.

II. Analysis on the existing laws regarding intellectual property rights in the Philippines as described in terms of its implementation and enforcement.

The aggressive effort of the Department of Science and Technology (DOST) to promote the establishment of an additive manufacturing industry in the country pushed initiatives to open doors to previously unimaginable possibilities to unfold more innovations. Two 3-D printing research facilities were launched in the first quarter

Author, Year, Site	Purpose, Sampling and Instrument	Design, Treatment of Data	Significant Findings
Mihalis Kritikos, 2018, Belgium	The aim of this In-depth Analysis is to illustrate the different ways in which the current EU legislative framework may be affected by the emergence of 3D printing for medical and enhancement purposes and the respective technological trends. Data Samples. Review of literature and Studies.	In-depth Analysis, Qualitative Data thru situational profiling	This analysis also provides a series of overarching recommendations that EU actors may wish to take into account when dealing with 3D bio-printing, resulting from an examination of the multiple ethical and legal challenges associated with this emerging technology has been performed, along with a scan of current legislation
Jon Cornwall, 2016, New Zealand	There is currently little information available on the ethical issues of 3D printing of body parts for use in anatomy education and research. Convenience Sampling. Interview Guided Questions.	Concept Analysis, Qualitative Data thru experts interviews	Examination and discussion around the issue of what may be deemed “responsible and ethical practice” will ensure that the benefits of body donation programmes are maintained while protecting those individuals who so selflessly donate their bodies to medical science. In line with this, perhaps a sensible default position should include the acquisition of informed consent in current donor forms if there is the possibility that the body may be copied using 3D printing, until evidence

**Table 2:
Profile of the Studies (n=8)**

Table 2. Continue...

			emerges to support a different position.
Jan Witowski · Mateusz Sitkowski · Tomasz Zuzak · Jasmine Coles-Black · Jason Chuen · Piotr Major · Michał Pędziwiatr1, 2018, Poland	<p>Although high costs are often cited as the main limitation of 3D printing (3DP) in the medical field, current lack of clinical evidence is asserting itself as an impost as the field begins to mature. The aim is to review clinical trials in the field of 3DP, an area of research which has grown dramatically in recent years.</p> <p>Surveyed clinical trials registered in 15 primary registries worldwide, including ClinicalTrials.gov. All trials which utilized 3DP in a clinical setting were included in this review. Our search was performed on December 15, 2017. Data regarding the purpose of the study, inclusion criteria, number of patients enrolled, primary outcomes, centers, start and estimated completion dates were extracted.</p>	Clinical Trials, Experimental	After several years of case reports, feasibility studies and technical reports in the field, larger-scale studies are beginning to emerge. There are almost no international register entries. Although there are new emerging areas of study in disciplines that may benefit from 3DP, it is likely to remain limited to very specific applications.
Slaviana Pavlovich, 2016, United Kingdom	My aim is to discover moral and ethical sides of 3D printing which is a new technology and, paradoxically, a new phenomenon of the twenty-first century, Interview Guided	Situational Analysis, Qualitative Approach	Particularly, 3D bioprinted organs and tissues is a controversial issue, because this technological advancement may be viewed by society as a servant or it can

Table 2. Continue...

	Questions. Data Samples		<p>even potentially become its master. For example, in the health care system, doctors may change their attitude to patients by using 3D bioprinted organs and tissues whenever it is needed, also, taking away responsibility from patients. Thus, there can be great social and psychological consequences from 3D bioprinting in a long term. Furthermore, Pete Basiliere, an analyst in a world's leading information technology research company, suggests that 3D printing can also bring economic consequences, resulting in the loss of at least \$100 billion in intellectual property theft per year by 2018 globally. By analysing the economic, psychological and social impact of the 3D printing technologies, I want to research whether anyone is going be responsible for the 3D printing production and who is going to give a right to 3D bioprint.</p>
ROSHNI KHUNTI, 2018, United Kingdom	The author investigates the ethical implications of the three replicas of the arch made by	Historical Analysis	This paper concludes that the reconstructed arch failed to meet these expectations in four key ways. First,

Table 2. Continue...

	<p>IDA in New York, London, and Dubai after the original was destroyed in the Syrian Civil War. Historical Data.</p>		<p>it does not address the human loss in Palmyra and the contribution of the Assad regime to its destruction. Second, despite an ostensible commitment to reproduction, the reconstructed arch is inaccurate in material and scale. Third, the arch is patented by the IDA and has had limited public and digital access. Finally, the reconstruction promotes a potentially irresponsible culture of quickly reconstructing destroyed heritage without respect for the context or current needs of the respective people. Through delving into Pandora's Box, this article aims to highlight ethical issues specific to digital reconstructions of heritage that need to be addressed in formal codes of ethics concerning the preservation of heritage represented by historical objects and sites.</p>
<p>Matthew Walker, Joseph Banks, 2018, London</p>	<p>Our aim is to showcase the potential that 3D printing offers in terms of improved experimental techniques, greater</p>	<p>In-depth analysis</p>	<p>By taking a general overview of studies using the technique from fields across the broad range of Ecology and Evolution, we show</p>

Table 2. Continue...

	flexibility, reduced costs and promoting open science, while also discussing its limitations. Review of Literature.		the flexibility of 3D printing technology and aim to inspire the next generation of discoveries.
Niki Vermeulen, Gill Haddow, Tirion Seymour, Alan Faulkner-Jones, Wenmiao Shu, 2015, United Kingdom	In this article, we review the extant social science and ethical literature on three-dimensional (3D) bioprinting. 3D bioprinting has the potential to be a ‘game-changer’, printing human organs on demand, no longer necessitating the need for living or deceased human donation or animal transplantation.	Systematic Review	Despite a lack of current socioethical engagement with the consequences of the technology, we outline what we see as some preliminary practical, ethical and regulatory issues that need tackling. These relate to managing public expectations and the continuing reliance on technoscientific solutions to diseases that affect highincome countries. Avoiding prescribing a course of action for the way forward in terms of research agendas, we do briefly outline one possible ethical framework ‘Responsible Research Innovation’ as an oversight model should 3D bioprinting promises are ever realised. 3D bioprinting has a lot to offer in the course of time should it move beyond a conceptual therapy, but is an area that requires ethical oversight and regulation and

Table 2. Continue...

			debate, in the here and now. The purpose of this article is to begin that discussion.
Erica L. Neely, USA, 2016	Using current US law as an example, I argue that consumers are not capable of fully assessing all relevant risks and thus continue to require protection; any regulation will likely apply to plans, however, not physical objects. Second, there are intellectual property issues	Situational Analysis	In combination with a 3D scanner, it is now possible to scan items and print copies; many items are not protected from this by current intellectual property laws. I argue that these laws are ethically sufficient. Patent exists to protect what is innovative; the rest is properly not protected. Intellectual property rests on the notion of creativity, but what counts as creative changes with the rise of new technologies.

of 2019. The inauguration of the Bataan Peninsula State University (BPSU) Additive Manufacturing Research Laboratory- a state of the art 3-D printing research facility equipped with the latest machines in additive manufacturing and the ground breaking ceremony of the construction of the Additive Manufacturing Center (AMCen) at the Metals Industry Research and Development Center (MIRDC) which aspires to be the country’s leading research in innovative 3-D printing technologies, processes and materials. Philippine Council for Industry, Energy and Emerging Technology Research and Development (PCIEERD) Director Enrico Paringit emphasized that the two research laboratories would hopefully leapfrog the Philippines in additive manufacturing capability among ASEAN neighbors like Singapore, Thailand, Indonesia and Malaysia. Issues concerning many legal questions for and

3D printing manufacturers and their customers and intellectual property owners are at hand. The technology brings with it a host of legal questions that revolve around intellectual property, product liability, regulatory and other practice areas. Questions on how 3D printing would impact the intellectual property perspectives and challenges, specifically on patent infringement need to be addressed. The existing Intellectual Property Code of the Philippines (RA 8293) contains only the general provisions which can be applied to patent infringement on 3D printing technology as outlined below based on a 2014 Special Report of the Asian Patent Attorneys Association (APAA). A 2014 Special Topic Report to the Emerging IP Rights Committee Meeting by the Asian Patent Attorneys Association (APAA) Group of the Philippines held in Penang Malaysia (Issues on 3D Printing Technology) noted the following:

Issues	Challenges
1) Patentability of 3D data	The 3D Data created by the 3D scanner or CAD program is not considered an invention under Philippine patent Law. Under Philippine Law, a patentable invention refers to any technical solution of a problem in any field of human which is novel, involves an inventive step and is industrially applicable, shall be patentable. The 3D data do not fall under what are considered as patentable inventions.
2) Exclusivity of patent rights	The one who produces 3D data does not possess an exclusive patent right based on # 1 (patentability).
3) Ownership of copyright	Producers of 3D data do not own copyrights over 3D Data. Section 172 of the Philippine IP Code confers upon literary and artistic works that are original creations in the literary and artistic domain. 3D data may not be considered as original creations in the literary and artistic domain.
4) 3D data generated by objects which belong to the producer of 3D data	It does not matter. The 3d data will still not be considered as either as an invention or a copyrightable subject
5) Infringement of a patent regarding transfer of 3 D data of a patented object	As already stated, 3 D data are not considered as patentable inventions. However, that 3D data are patentable inventions, transfer of 3D data of patented object maybe considered as a form of infringement if such transfer was unauthorized by the patentee.
6) Infringement of patent rights to manufacture the products using 3D data	It is not considered as infringement of patent rights since 3D data are not considered as patentable inventions.
7) Infringement due to repair or replacement of parts of a patented object for business	Sub-section 71.1(a) of the Philippine IP Code provides that where the subject matter of a patent is a product, a patent confers on its owner the exclusive rights of restraining, prohibiting and preventing any unauthorized person or entity from making, using, offering for sale, selling or importing that product. Thus, if the repair or replacement of the patented product is for business purposes, i.e., offering for sale or selling the repaired patented object containing replaced parts, is considered as infringement of patent rights
8) Infringement of Trademark rights or Design rights for generating 3D data of somebody else's trademark or design	It is considered as an infringement of somebody else's registered trademark or design when a) used in commerce in connection with sale, distribution, advertising of any goods or services, as said data maybe considered as a reproduction, copy of colourable imitation of a registered mark or a dominant portion of said mark, or b) reproduced, copied or colorably imitated a registered mark or a dominant portion of said mark, and such

Table 3.

Table 3. Continue...

	reproduction copy or colourable imitation are applied to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce. It is also applicable industrial designs based on Sub-section 71.1 of the IP Code of the Philippines
9) Infringement due to Transfer of 3D data of of somebody else's trademark or design	Transfer of 3D data of somebody else's trademark or design is also considered an infringement of rights
10) Awareness of public on 3D printing technology	The public is aware of the 3D printing technology
11) Knowledge of IP practitioners on 3D printing technology	IP practitioners are somewhat knowledgeable of 3D printing technology
12) Any plan or policy of the government or professional organizations regarding legislation to recognize, protect or control 3D printing	None, so far as of APAA 2014 report.

A study conducted by Reyes and Ngo (20170, De La Salle University Legal Management students focused on how 3D printing would impact the Intellectual property perspectives and challenges specifically on patent infringement. To delve deeper into the legal matters particularly on the Intellectual Property infringement on patent rights, a comparative study was also conducted between the laws of identified IP hubs in Asia- Philippines, Hong Kong and Singapore related to patent infringement in 3D printing business. The data shows how the Philippines fare with other IP hubs in Asia in terms of laws and legal frameworks that would address intellectual property issues on 3D printing. Issues noted by the De La Salle researchers included the following:

1) Whether or not one become liable for patent infringement under RA 8293 with regards to 3D printing by creating a Computer Aided Design (CAD) file of a protected invention- In the present law, it is just the making, selling, using of the patent that makes one liable for infringement. On the other hand, a CAD file is not making, selling or using the patent. It is simply a three-dimensional design file which is created for the purpose

of copying an existing patent and can used to 3-D print it. It is a computerized data of matching specifications for the instructions to blueprint to the 3-D printer. Therefore, it is not a liability for infringement.

2) Whether or not the extent of the liability of a patent infringement under RA 8293 should be only those who act in bad faith. – If a third party did not ask permission and created a CAD file of an existing patent, the third party would be held liable. The extent of the liability should be on those only done in bad faith, or in cases they claim patent, copyright or infringement as their own despite being an invention of another person. Those in good faith or without any knowledge should not be held liable.

3) Whether or not there is a need to amend the law, RA 8293 to cover infringement in the case of 3-D printing as to patient- Jefferson Ferrer of Bengson, Negre and Untalan Intellectual Property Law Firm mentioned that "The IP Code is too broad to cover the topic of 3-D printing in terms of Intellectual Property." Since the technology is new and developing, there is a need to meet the current demands of the time and adapt to the changes prevalent in the society. In other

Factors to be considered	Philippines	Hong Kong	Singapore
1 Laws specifically pertaining to 3D printing (patent infringing)	None General provision of infringement in RA 8293 (IP Code) applies Sec. 76 Civil Action for Infringement Sec. 84 Criminal Action for Repetition of Infringement	Patent Ordinance (Cap 514) Trademark Ordinance (Cap 559) Copyright Ordinance (Cap 528)	Singapore Registered Design Act Trademark Act Copyright Act
2 Government Agency	None specifically for 3D printing industry and technology Intellectual Property Office of the Philippines Few programs are from DOST, TESDA and DTI	Hong Kong Productivity Council (HKPC) Hong Kong Plastics Industry Council Intellectual Property Office	SPRING Singapore under Ministry of Trade and Industry Print and Media Association IPOS (Intellectual Property Office of Singapore)
3 Government Support	None specifically on 3D printing industry and business	Series of training programs for innovators and continuous review of IP Laws and policies of the industry that is relevant to 3D printing	Singapore Economic Development Board Funded \$500 M for the five-year development plan on 3D printing industry Singapore National Research Foundation Funding Nanyang Technological University \$42 M for 3D printing studies and operation
4 3D Printing Regulatory Framework	None	Yes	Yes
5 Penalties specifically for crimes committed using 3D printing	Sec. 84. Criminal Action for Repetition of Infringement with regards patent infringement (general provision only)	2 Remedies for Patent Infringement in 3 D printing Injunction Awarding of Damages Awarding of damages mainly a matter of the	Possession of dangerous and harmful 3D printing products such as 3D printed guns, knives and sharp objects are illegal on highest degree of penalty of death

Table 4.

Table 4 Continue...

		amount and degree of loss of the patent holder	Arms and Explosive Act for anyone to use a 3D printer to manufacture any arms
6 Non-government agencies promoting 3D printing	Groups of Young 3D printing Entrepreneurs	Hong Kong 3D Association Hong Kong Plastics Manufacturers Association	Establishment of National Additive Manufacturing Innovation Cluster
7 Initiatives and Programs for 3 D Printing	3 D Printing Seminar conducted by several IP Lawyers and Law Firms TESDA courses on Computer Aided Designs, Auto-CAD Designs and CAD Drafting only on 4 places (within Luzon)	Establishment of 3D Printing Center and Hubs in various cities Promotion of 3D Printing companies nationwide and partnerships with various universities for research and development Hosting and participation on 3 D Printing Conferences (Local and International)	Universities funding 3 D Printing technology for further research and development Establishment of a “3D center” in top universities in the country Hosting and participation on 3 D Printing Conferences (Local and International)

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words, there is an need to amend the existing law (RA 8293) to answer the needs and demands of the rising industry and, promote the industry and at the same time, create a strong and solid platform where it can efficiently utilize its potential.

As 3-D printing opens doors to new possibilities for more innovations, the researchers compared the laws of other countries developing the art of 3-D printing such as Hong Kong and Singapore with the Philippine Laws related to 3-D printing business. The data presented what is lacking in our present law and address how the two countries developed legal frameworks and laws that would be able to cater needs in 3-D printing technology. Important Highlights of Similarities and Differences Between Philippines, Hong Kong

and Singapore on 3D printing Laws and Legal Frameworks (Reyes & Ngo 2017)*

III. Implications of 3D Printing to Intellectual Property Laws

3D printing makes it technically possible to copy almost any object, with or without the authorization of the patent or copyright owners. Thus, issues were raised on the protection of an object being printed in 3D without authorization. Copyright will protect the originality of a work and the creator’s right to reproduce. This means that if copies of an original object are 3D printed without authorization, the creator can obtain relief under copyright law. Similarly, industrial design rights protect an object’s ornamental and aesthetic appearance-shape and form, while a patent pro-

protects its technical function, and a three-dimensional trademark allows creators to distinguish their products from those of their competitors.

There are a number of intellectual property rights which concern 3D printing. These include: design that protects the appearance of a product both registered and unregistered, copyrights which protect various elements of the 3D printing process, including the code of the CAD file, the design contained within the file, and the physical object to be printed. Trademark refers to any unique device that distinguishes a product from others, which could be a word, phrase or symbol on the 3D printed item, or even the shape of the item itself. Lastly, patents provide protection over new inventions, which can include a product, safeguarding the owner's product against those who try to use it without permission.

If the printed object is protected by a patent, Intellectual Property Code of France (Article L 613-4) prohibit supplying or offering to supply the means to use an invention without authorization. Thus, patent owners can seek redress from third parties for supplying or offering to supply 3D print files on the grounds that these are an "essential element of the invention covered by the patent".

In the area of copyright, the rights granted to authors "shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder" (Article 13 of the TRIPS Agreement). Thus, some countries have established a "right to private copying" authorizing a person to reproduce a work for private use. To compensate any losses incurred by the rights holder, some countries are exploring the idea of levying fee to offset private copying. On the other hand, some lawmakers considered it not appropriate to extend such fee to 3D printing as this would possible cause a brake on the development and uptake of 3d printing.

A study on the copyright implications by Li, et. al (2014) focused on the design and manufacture of 3D chocolate products such as copyright consequences of reproducing two-dimensional works in three dimensions, the requirement of originality for the subsistence of copyright along with the problems posed by substantial taking from existing works, copyright implications of con-

sumer/user co-creation of the chocolate designs and liability for authorization of infringement of copyright. 3D chocolate printing technology revolutionizes the way in which chocolate producers can engage consumers in creating artistic and personalized chocolate designs and products through the process chain from design to product based on existing Intellectual Property Laws in Europe.

1) A two-dimensional artistic work in three dimensions is a reproduction for the purpose of copyright infringement. Thus, if anyone makes a reproduction of the artistic work without the consent of the owner(s), that infringes copyright.

2) For copyright to subsist, there must be the appropriate creative effort or originality present in the artistic work.

3) if a substantial part of another work is taken, then the copyright in that first work will be infringed since another requirement for originality is that a work must not be copied from another.

4) Co-creators of chocolate designs should have collaborated in the execution of the work-design for the chocolate product.

Rajam and Jha (2018) examined the solutions to the possible problems that 3D printing can cause while seeking to reframe certain legislations in the Indian context in order to keep up with this technology. While 3D printing affects a number of industries, its impact is particularly significant in the field of medicine such as the manufacture of hearing aids in the United States through 3D printers. However, neither in the National Policy, nor in the Draft Pharmaceutical Policy, does one find any mention of 3D printed drugs or prosthetics or other devices, thus it would require initiatives for public discourse on additive manufacturing in order to address these medical concerns. The following concerns were identified:

1) Patent concerns with 3D printing- replication of patented products and getting patents for 3D printed products and processes

2) Using 3D printed Products/Process to Obtain Patents – Under Indian context, the law prohibits patents in "plants" and "animal in whole or in any part thereof"

Thus, with the revolution of 3D printing, India's patent scheme may need to re-mould itself to avoid anachronism.

Recommendations

The growth of 3D printing makes product blueprints to be easily accessible or copied in the internet without the knowledge of the rights holder. So, this raises issues of patent and copyright infringement, at least. But, infringement becomes difficult due to the "democratization" of manufacturing through 3D printing. Often, rights holders will not know when others are printing copies of their products making enforcement of infringement futile. Therefore, the issue lies on the enforcement of laws and IP rights holders suffer losses due to indiscriminate 3D printing. Further, the commercialization of 3D printing-with an increase in small-scale manufacturers-makes policing IP complex because each printed copy of an invention represents the loss of a potential sale to its patent holder. Moreover, with a 3D printer, anyone can pirate design files and turn them into tangible objects without owning the IP.

Hence, with these developments in 3D printing, there is a need to amend and update the current Intellectual Property Law of the Philippines in order to cater the legal issues that may arise in 3D printing cases such as infringement. Although IP Law in its current form, appears to be sufficient to effectively protect both 3D files and those using 3D printing technologies for non-commercial purposes, there are a number of questions which need to be answered and addressed. One aspect is the ownership of an object when it is first conceived by one individual, digitally modelled by another and printed by a third. Can the person who designed the work and the person who digitally modelled it be considered authors of a collaborative work under copyright law? What if the object qualifies for a patent, would the same individual be considered co-inventors?

How about the type of protection that can be given to 3D printer owners since their financial investments enables the creation of an object and therefore might qualify for the same type of related rights protection as those enjoyed by music producers as investors in the creation of sound recordings. Another question is on the digitization of a pre-existing object, if it can be considered an act of infringement simply because it is printed or its base file is loaded onto an online sharing platform for downloading. Since the initiatives of the Philippine government with regards to 3D printing are now being

introduced, there is an evident gap on the regulatory framework or policies in the Philippines particularly that involves 3D Printing technology.

With these initiatives getting popular focusing on research and development, would it not be appropriate to come up with new and updated Intellectual Property Code and amend RA 9283 to comply and work along with the 3D printing industry. There is also a need to formulate initiatives to that will broaden awareness on 3D printing and its commercial implications taking into consideration the legal matters associated with 3D printed objects.

The Intellectual Property Office of the Philippines can look up to the initiatives undertaken by its neighboring countries like Singapore, Hong Kong, Malaysia and Thailand and Indonesia which are already into additive manufacturing. From them, we can come up with regulatory frameworks similar to these countries and adapted to address the pressing concerns of the 3D printing industry. Undeniably, 3D printing technologies have life-enhancing, even revolutionary applications, from regenerative medicine to prosthetics and from complex airplane components to food and fashion and so 3D printing becomes embedded in our lives.

Thus, information gathered from various situations regarding intellectual property issues would serve as tools to study the strengths, weaknesses, opportunities and threats that each of those initiatives may bring and serves as guide for legislators to see the need for amending the law or formulating a policy that would assist the 3D printing industry as they develop further as well as protection from possible infringement. Users and manufacturers of 3D printers and 3D printed objects will encounter issues involving patents, trademarks, copyrights and other IP rights is a reality in the future. Therefore, as the technology plunges society into constant dynamism, it is up to the legal regime to rise up to the challenge of 3D printing.

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