Patent Eligibility Analysis of Bioprint Technology

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ABSTRACT

Bioprint is an umbrella term covering a new branch of biotechnology with an extraordinary ability to artificially synthesize human tissues and organs. With this feature, many are hoping that the Bioprint Technology could address the current complications in the organ transplantation procedures. Displaying a great magnitude of capabilities, for-profit firms and private institutions are eager to quickly obtain IP protections and monopoly rights to this valuable piece of technology.

In spite of Bioprint many abilities, the legal system have been slow to keep up with the rapid development of the Bioprint Technology. Even though patent law was created to especially protect and promote technological invention such as this. However, eligibility and validity issues still plagued biotechnology related inventions with past examples such as: *Diamond v. Chakrabarty*, *AMP v. Myriad* or *Mayo v. Prometheus*. For this reason, the issue of Bioprint Technology patent eligibility still remains highly disputed. Adding to this dilemma, the modern patent landscapes have shown that having obtained a fully granted patent from the USPTO does not necessary guarantee the true validity of the invention itself. Under these conditions, the question of validity of the Bioprint Technology still requires the judiciary branch to examine and clarify.

Seeing the problem at hand, this analysis report is aimed to provide the readers with broad overview of the Bioprint Technology. Then, proceed to analyze the patent eligibility of the technology by using various tests from past US court cases. Lastly, analyzing with scope of the Bioprint Technology within the patentable subject matter of the Leahy-Smith America Invents Act.

Keywords: Bioprint Technology, Patent Eligibility, Biotechnology, Intellectual Property Law.

I. Introduction

New technologies and innovative creations have always been in the domain of intellectual property law (IP Law), the long arm of IP law stretches far and wide from patent to trademark to copyright. While the modern trademark and copyright protections may prove to be useful for Bioprint Technology but patent protection is currently the most useful legal tool that the modern intellectual property framework has to offer. There are two folds to the patent system: (1) to protect new creative inventions from exploitation and (2) to provide encouragement for empowering future development.[1] With this being said, patent framework can protect various parts of the Bioprint Technology, ranging from Bioprinter, Bioink, to the Bioprinted products (organic tissues/organs).[2] [3] [4] Trademark can protect the mark/brand of the Bioprint Technology. Whereas, the software that will be used in conjunction with the Bioprint Technology can be placed under copyright protection. Despite the obvious compatibility between Bioprint Technology and patent protection, there are aspects of the technology that will likely cause legal issues. Furthermore, statistics have shown that the filing pf Bioprint related patents are increasing quickly with some already granted and many still pending. For this reason, the question of validity for these patents will soon become an important matter for scholars and experts to analyze.[5]

Very much different from the olden days, the patent landscape has been rapidly evolving. The rapid technological advancement of the modern era had made patents more diverse and complex. As the scope of patentable subject matter continuing to expand, by obtaining granted patent no longer prove the true validity of the invention itself. Past evidences and cases have shown that the USPTO granted patents can later become invalid. The modern technology landscape has become so complex and extremely diverse where both extensive scientific and legal knowledge are required to appropriately analyze the scope of these new inventions. As such, it has become the duty of both the judiciary branch and experts to define the true validity of new technology, while also providing new foundation of understanding. Consequently, It is crucial that appropriate legal interpretations and frameworks be develop to allow the Bioprint Technology to properly thrive and become a viable technology for real-world application.

To appropriately determine the patent eligibility of the Bioprint Technology, this report will use a three-level assessments strategy to analyze the patentability of this technology. First, the report will dive into the hidden philosophy that played a critical role in both creating and governing the US Patent Act for the purpose of identifying the compatibility of the Bioprint Technology within the US patentable subject matter scope. Second, the Bioprint Technology will be subjected to the "two prong test" used in the

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1 Edmund W. Kitch, The Nature and Function of the Patent System, 20 The Journal of Law and Economics 265–290, 265-290 (1977), http://www-law-nyu-309756845.us-east-1.elb.amazonaws.com/sites/default/files/upload_documents/Kitch.pdf (last visited May 23, 2017).

2 Pallab Datta, Bugra Ayan & Ibrahim T. Ozbolat, *Bioprinting for vascular and vascularized tissue biofabrication*, 51 ACTA BIOMATERIALIA 1–20, 1-20 (2017).

3 Wei Long Ng et al., *Skin Bioprinting: Impending Reality or Fantasy?*, 34 TRENDS IN BIOTECHNOLOGY 689–699, 689-699 (2016).

4 S. Vijayavenkataraman, W.f. Lu & J.y.h. Fuh, *3D bioprinting – An Ethical, Legal and Social Aspects (ELSA) framework*, 1-2 BIOPRINTING 11–21, 11-21 (2016).

5 Id at 4

past by the US courts to provide clues to the patent eligibility of controversial inventions. Lastly, this report will attempt to analyze the "human organism" restriction prescribed in the Leahy-Smith America Invents Act (AIA) and identify whether the Bioprint Technology can be exempt from this restriction. By using these three assessment criteria, it will be possible to logically establish the patent eligibility of Bioprint Technology in accordance to the patent framework of the United States.

II. Jefferson Philosophy

The US patent system was believed to be created under the philosophy of Thomas Jefferson. As one of America's founding father and writer of Untied States Declaration of Dependency, it has been said that Jefferson realized the importance of scientific knowledge and technology to the advancement of human civilization.[6] For this, he embedded within the United States Constitution (Art. I, § 8, cl. 8) the power for congress to promote the progress of science and useful arts, while also providing incentives for further development. The line reads:

"The Congress shall have Power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries".[7]

The Jefferson Philosophy was first formally referenced during the case of Graham v. John Deere. William T. Graham designed a shock absorber mechanism for chisel plows where the plow shanks is attached to spring clamps for reducing shockwave. These spring clamps provides plow flexibility for reducing structural damages while in use. In 1950, Graham applied and received a granted U.S. Patent 2,493,811 (patent 811). After having obtained his first patent, Graham made an improvement to his original invention by moving the hinge to a location below the shanks. The adjustment was to further improve the shockwave absorption rate. For this improvement, Graham was later granted a U.S. Patent 2,627,798 (patent 798). Meanwhile, John Deere Co. invented and commercialized plows with similar mechanism. Consequentially, Graham sued John Deere Co. for patent infringements. For the first deliberation, the United States District Court for the Western District of Missouri concluded Graham's patents to be valid. The United States Court of Appeals for the Fifth Circuit held the original ruling, explaining that the improved invention (patent 798) yielded better absorption rate. Therefore, Graham's patents were valid and infringements were obvious. However, the United States Court of Appeals for the Eighth Circuit viewed that patent 798 had zero non-obvious improvement. Thus, reversed the previous two rulings. The unfavorable rulings left Graham unsatisfied. As a result, he petitioned for certiorari where the Supreme Court agrees to hear the case to resolve the conflict.[8]

During the trial, the Supreme Court looked back to the core principle of the Patent Act and philosophy of the man whom was believed to be the forefather of U.S. intellectual property concepts. As a result, the court proceed to examine and quote

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[6] Adam Mossoff, *Who Cares What Thomas Jefferson Thought about Patents – Reevaluating the Patent Privilege in Historical Context*, 92 Cornell L. Rev. 953 (2007), http://scholarship.law.cornell.edu/clr/vol92/iss5/2 (last visited May 23, 2017).

[7] U.S. Const. art. I, § 8, cl. 8

[8] *Graham v. John Deere Co.*, 383 U.S. 1 (1966)

Jefferson's 1813 letter written to one Isaac MacPherson. In this letter, the court have chosen to emphasize one main passage, it reads:

"Stable ownership is the gift of social law, and is given late in the progress of society. It would be curious then, if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody".[9]

Since then, the passage had been recited and researched countless times by both legal scholars and constitutional historians. Interpreting from this passage, the Supreme Court viewed that patents and exceptional ideas behind it should qualified as a form of legal rights granted to the inventors. Thus, began the concept of intellectual property rights. These rights would serve to promote human knowledge and further the growth of social and economic landscapes of America. Under this interpretation, the Supreme Court anointed the Jefferson rules, in which will be used to measure all inventions under the patentable subject matter. Upon the ruling of Graham v. John Deere, Justice Clark cited the Patent Act of 1790 and underlying Jefferson philosophy. He stated that under the Jefferson rules the patent law was based on utilitarian economic applications for promoting technological inventions and ideas. It was clear that Jefferson only intended to grant limited monopoly rights to exceptional inventions that were new, useful and promote technological development. Even though, Graham had received granted patents for his original invention (patent 811) and improvement patent (patent 798) but after having applied the Jefferson rules the court ruled that the second patent was invalid (patent 798) for failing the Jefferson rules. In his opinion, Justice Clark commented that Graham improvement patent does not contain any new nor inventive elements. Hence, it did little to the advance the knowledge within the field. Second, the improvement patent was mainly used to extend Graham's monopoly rights. These factors violated the core philosophy of the Patent Act, therefore, patent 798 was deemed invalid.[10]

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9 Thomas Jefferson to Isaac McPherson, ARTICLE 1, SECTION 8, CLAUSE 8: THOMAS JEFFERSON TO ISAAC MCPHERSON, http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html (last visited May 23, 2017).

10 Supra note 8

The second time that the United States Supreme Court utilized the Jefferson rules was during the infamous living organism case of Diamond v. Chakrabarty. A General Electric engineer named Ananda Mohan Chakrabarty developed a new strain of bacterium named "Pseudomonas putida". This new bacterium derived from a naturally existed strain called "Pseudomonas". This newly invented bacterium was capable of breaking down crude oil, effectively providing an environmental friendly solution to handling oil spill crisis. Once again, the Supreme Court referred back to the Jefferson philosophy to examine whether living organism can be included within the patentable subject matter. At that time, Chakrabarty's invention was denied due to the "product of nature/natural phenomenon" limitation (35 U.S.C. § 101). The Commissioner of Patents and Trademarks, Sidney A. Diamond commented that the eligibility of living organism was contrary to the Congressional understanding of patentable subject matter. Furthermore, Diamond argued that living organism cannot be "manufacture" as they are "grown" and they are not "composition of matter" as microorganisms are organic beings.

During the ruling, Chief Justice Warren E. Burger stated that the constitutional philosophy of Jefferson still allowed for the extension of patentable subject matter scope for new technology and it was the court's duty to provide appropriate clarification on the Jefferson language. With this, the court stated that "Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting the Progress of Science and the useful Arts with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms". [11] Conclusively, Chakrabarty's invention has shown real ingenuity that should receive a liberal encouragement.

From thoroughly analyzing the Jefferson philosophy, constitutional references and the two related cases of Graham v. John Deere and Diamond v. Chakrabarty, it is theoretically possible to establish whether the Bioprint Technology will be in keeping with the Jefferson rules. Firstly, it is necessary to define the "ingenuity" within the Bioprint Technology. The Merriam-Webster dictionary defined ingenuity as (1) skill or cleverness in devising or combining: inventiveness and (2) cleverness or aptness of design or contrivance. First, the ability to three-dimensionally print complex organic structures on demand can be considered as highly inventive and original. Secondly, the Bioprint Technology derived from a non-obvious combination of 3D printing and biotechnology, which comprises of: (1) Bioprinter (2) Bioink and (3) Bioprint products. The construction of these unique elements of the Bioprint Technology required considerably knowledge and skills, making the technology qualify as being inventive. By using Chakrabarty's invention as a comparison, similar can be seen with the ingenuity of the Bioprint Technology. Moreover, Bioprint Technology also serves as a foundation to multiple branching technologies in the future such as: biomimicry,

11 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

regenerative therapy or In Situ printing. The technology can also provide resources to assist medical and scientific research in the coming future.[12] As such, it's apparent that the Bioprint Technology truly upholds the philosophy of Jefferson. Conclusively, it would be logically sound to presume that the Bioprint Technology will fit within the patentable subject matter scope of the modern US patent system as envisioned by Jefferson.

III. Two Prong Test

Since the invention of the Bioprint Technology, companies are working hard to secure patent rights for various parts of the technology. Under this development, Bioprint related patents are rapidly increasing with the addition of commercialized Bioprinters already available on the open market.[13] Traditionally, elementary interpretation of § 101 would suggest that Bioprint related patents would violate "laws of nature" restriction. For the time being, it would seem that Bioprint related patents are not granted due to their true validity, instead granted on mere "technicality". To avoid the pothole of § 101, patent attorneys, patent prosecutors and patent engineers have been using cleverly crafted terms to avoid rejection. For example: U.S. Patent 8,143,055 granted on March 27, 2012 titled "Self-assembling multicellular bodies and methods of producing a three-dimensional biological structure using the same". The first claim reads:

"A three-dimensional structure comprising: a plurality of multicellular bodies, each multicellular body comprising a plurality of living cells cohered to one another; and a plurality of discrete filler bodies, each filler body comprising a biocompatible material that resists migration and ingrowth of cells from the multicellular bodies into the filler bodies and resists adherence of cells in the multicellular bodies to the filler bodies, wherein the multicellular bodies and filler bodies are arranged in a pattern in which each multicellular body contacts at least one other multicellular body or at least one filler body".[14]

This shows an example of how language can be crafted to avoid the pothole of § 101. The first claimed sum up how a living tissue is made by using construction of multiple living cells. One adept in scientific knowledge could content to the similarity of this claim to the principles of natural tissue creation process. Under the principle of biology, tissues are created by connections of cells and organs are created by connections of tissues.[15] In this instance, expertly crafted terms do little to change the

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12 Aastha Chokshi, 3D BIOPRINTING INNOVATION (2016), http://princetoninnovation.org/magazine/2016/03/21/3d-bioprinting/ (last visited May 23, 2017).

13 Printing a bit of me, THE ECONOMIST (2014), http://www.economist.com/news/technology-quarterly/21598322-bioprinting-building-living-tissue-3d-printer-becoming-new-business (last visited May 23, 2017).

14 US Patent No. 8,143,055 (issued March 27, 2012).

15 Tissues, organs, & organ systems, KHAN ACADEMY, https://www.khanacademy.org/science/biology/principles-of-physiology/body-structure-and-homeostasis/a/tissues-organs-organ-systems (last visited May 24, 2017).

original principles of nature. Second example is U.S. Patent 8,691,974 granted April 4, 2014 titled "Three-dimensional bioprinting of biosynthetic cellulose (BC) implants and scaffolds for tissue engineering". The first claim reads:

"A method of producing 3-D Nano-cellulose based structures comprising: providing bacteria capable of producing Nano-cellulose; providing media capable of sustaining the bacteria for the production of Nano-cellulose; controlling microbial production rate by administering media with a microfluidic device, for a sufficient amount of time, and under conditions sufficient for the bacteria to produce Nano-cellulose at a desired rate; continuing the administering of the media until a target three-dimensional structure with a target thickness and target strength is formed which has a morphology defined by a network of multiple layers of interconnected biosynthetic cellulose".[16]

This second example essentially described genesis of cells. In a natural setting, cellulous are the substance that holds the structure of cells together by acting as walls. Without cellulous, living cells would have no rigidity and eventually collapse.[17] This patent effectively described how to use cellulous to create wall-like structure for cells, again replicating laws of nature. These examples illustrated the "technical" validity of these patents. On the other hand, scientific advocates could also argue that these Bioprint related would also be in violation of 35 U.S.C. § 101. As a result, an appropriate tool should be employed to identify the true patent eligibility of these patents on a wide scope.

For its time, Chakrabarty's unique invention challenged the former understanding of the patent doctrine, while also representing the growing scientific landscape to the lagging legal framework. Seeing this problem, the Supreme Court deemed it necessary to maintain the balance between technology and law by implementing a specialized test.[18] According to the 35 U.S.C. § 101, product of nature (living organism) was considered as unpatentable subject matter. Hence, Chakrabarty's invention (*Pseudomonas putida)* was rejected. However, viewing that Chakrabarty's invention represents the change in social climate and technological advancement, the Supreme Court saw fit to provide new statuary interpretation and update the Patent Act to properly reflect the growing technological landscape.[19]

First, the Supreme Court concluded that Chakrabarty's invention was fully in compliance with the Jefferson rules as discussed in the first section. Second, the court enact "two-prong test", in which required the resulting product to satisfy to be patent eligible, the requirements are: (1) must result from non-obvious ingenuity and (2) must

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16 U.S. Patent No. 8,691,974 (issued April 4, 2014).

17 Martin Chaplin, CELLULOSE, https://web.archive.org/web/20051001072830/http://www.lsbu.ac.uk:80/water/hycel.html (last visited May 23, 2017).

18 Supra note 13

19 Id at 20

be non-naturally occurring.[20] For the first test, the court examine whether the bacterium (*Pseudomonas putida*) were created through unconventional means. Under close inspection, it was found that a naturally existing gram-negative bacteria originally known as "*Pseudomona*s" was genetically modified to create an entire new genus of bacteria.[21] *Pseudomonas* is a naturally occurring bacterium which can usually be found in bodies of water and plants.[22] Due to the ease of *in vitro* cultivation and availability of strains for genome sequencing (genetic materials), *Pseudomonas* became one of the top choice for scientific research.[23] Chakrabarty inventively modified specific portion of the bacteria's DNA molecules known as plasmids with the ability to break down hydrocarbon bonds within organic compounds. On Earth, hydrocarbons are generally found in crude oil mainly used as main source of energy in our civilization. Vehicles' fuel such as: petroleum and jet-fuel derived from manipulation of hydrocarbon bonds within the crude oil.[24] Through genetic engineering, Chakrabarty created a new genus of *Pseudomonas* that was capable of breaking down hydrocarbon bonds within crude oil. This effectively created a new environmental friendly method for dealing with oil spill crisis. With this assessment, the court established that *Pseudomonas putida* resulted from non-obvious ingenuity. For the second test, it was discovered that the chance of *Pseudomonas putida* to be naturally occurring is virtually impossible. Without Chakrabarty's intervention naturally occurring *Pseudomonas* would never possessed hydrocarbons disintegration ability. Even though the former understanding of 35 U.S.C. §101 would not allow "product of nature" to be patented but *Pseudomonas putida* was proven to surpass this restriction. As a result, the Supreme Court deemed *Pseudomonas putida* to be non-naturally occurring. Thus, concluded that *Pseudomonas putida* should be held as an exception to "product of nature" restriction. Under this assessment, the Supreme Court stated *"His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity having a distinctive name, character and use"*. Conclusively, Chakrabarty clearly produced new bacterium with markedly different characteristics from any found in nature that also possessed great practical applicability.[25]

Much similar to Charkrabarty's invention, the products of Bioprint Technology includes organic tissues and synthesized organs which can be broadly interpret as the replication of laws of nature and natural phenomenon. By broadly interpreting § 101, it

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20 Id at 21

21 Gene Quinn, JUNE 16, 2010: 30TH ANNIVERSARY OF DIAMOND V. CHAKRABARTY 30TH ANNIVERSARY OF DIAMOND V. CHAKRABARTY (2010), http://www.ipwatchdog.com/2010/06/16/june-16-2010-30th-anniversary-of-diamond-v-chakrabarty/id=11268/ (last visited May 23, 2017).

22 Norberto J. Palleroni, *The Pseudomonas Story*, 12 ENVIRONMENTAL MICROBIOLOGY 1377–1383, 1377-1383 (2010).

23 Ignacio Poblete-Castro et al., *Industrial biotechnology of Pseudomonas putida and related species*, 93 APPLIED MICROBIOLOGY AND BIOTECHNOLOGY 2279–2290, 2279-2290 (2012), https://www.ncbi.nlm.nih.gov/pubmed/22350258.

24 Francis A. Carey, HYDROCARBON: CHEMICAL COMPOUND ENCYCLOPÆDIA BRITANNICA, https://www.britannica.com/science/hydrocarbon/Physical-properties (last visited May 23, 2017).

25 Supra note 13

would be logical to presume that replication of human tissues or organs can potentially violate the same principle as Chakrabarty's bacterium once did. If genetic engineering of naturally existed bacteria was once regarded questionable, similar concerns can be raise with the Bioprint processes. After all, Chakrabarty genetic engineering method and Bioprint processes both operates by utilizing the available scientific technology to manipulate the laws of nature to effectively yield man-made invention.

Another notable case involved the two prong test was *AMP v. Myriad*. In this dispute, the patent eligibility of human DNA and genes are the subject of debates. DNA (Deoxyribonucleic acid) is known to be the building block of all life on Earth, storing genetic information passed down from generation to generation and play a large role in cell genesis. In layman's terms, DNA acts like a biological printer where genetic information are the data waiting to printed and the cells are the printed data. Under this principle, defective DNA can lead to the creation of faulty cancerous cells. Consequentially, cancer and tumour are the result of these faulty creations.[26] Due to lethality of breast cancer, scientists have been hard at work to find an early detection method to halt the progress of the tumor as soon as humanly possible.[27]

In 1990, a group of scientists working at UC Berkeley Laboratory discovered a human gene named "BRCA". It is theorized that if a person's BRCA gene contains abnormality, the likelihood for the patient to develop breast cancer will increase by a factor of 50 – 80%, making the patient susceptible to breast cancer. Since the discovery of the BRCA gene, many scientists and laboratories began a race to find the quickest and most precise method to analyze BRCA gene for abnormality. By 1994, a group of scientists working at University of Utah (later founded Myriad Genetics) discovered a method to precisely detect the abnormalities within the BRCA genes. This method was done by isolating the DNA to precisely pinpoint the breast cancer susceptible gene known as the "BRCA 1". Myriad Genetics later obtained multiple granted patents in regard to the method for discovering and analyzing BRCA1. The company also sold testing kits which enable doctors to test patients for genetic abnormalities within the BRCA 1 gene.[28]

Ultimately, Myriad's patents are based on the discovery methods of BRCA genes (Myriad later discovered and patented BRCA2 gene) located within the natural human DNA, Myriad was clearly claiming legal rights to natural phenomenon and laws of nature. Subsequently, Association of Molecular Pathology (AMP) argued that any patents related to either subjects should not be patentable under 35 U.S.C. §101. Additionally, scientists and medical professions claimed that Myriad's monopolization of the BRCA genes hindered future breasts cancer research and Myriad's exclusive BRCA testing kit was also limiting the ability to freely asset the risk of breasts cancer development for patients. Myriad counter claimed that these discoveries are made based on innovative research of isolated DNA and patent rights to the BRCA genes will fuel

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26 What Is Cancer?, NATIONAL CANCER INSTITUTE, https://www.cancer.gov/about-cancer/understanding/what-is-cancer (last visited May 23, 2017).

27 What Is Breast Cancer?, AMERICAN CANCER SOCIETY, https://www.cancer.org/cancer/breast-cancer/about/what-is-breast-cancer.html (last visited May 23, 2017).

28 D.t. Bishop, *BRCA1, BRCA2, BRCA3… A myriad of breast cancer genes*, 30 EUROPEAN JOURNAL OF CANCER 1738–1739, 1738-1739 (1994).

future cancer related research. Furthermore, the BRCA testing kits are also sold at reasonable price on the market. Under these controversial issues, the Supreme Court was request to provide clarifications.[29]

Respectively, the Supreme Court proceeds to examine Myriad's patents. First, U.S. Patent No. 5,747,282 claimed BRCA determining chains of amino acids. In nature amino acids dictates proteins genesis that will later form into DNA.[30] Mainly, these amino acids are listed as: Methionine (Met), Aspartic Acid (Asp) or Leucine (Leu) etc. They are later linked together in chains called "polypeptide" for the DNA replication process. Genes respectively determine the formation of these amino acids chains. With this principle, a defective gene can cause inaccurate creation of this polypeptide. Therefore, resulting in flawed DNA replications which can lead to the formation of cancerous cells.[31] In layman's terms, the human genes works as architects of the body (stage 1), the polypeptides are the tools of these architectural genes (stage 2), DNA is the blueprint of the body (stage 3) and cells are the final products (stage 4). Using this easy principle, any errors made by the architect can consequentially cause the finished building to be faulty and eventually collapse. Turning back to the Myriad issue, claim 1 of Patent 5,747,282 claimed the sequence of polypeptides determined by the BRCA 1 gene. Seeing this, AMP argued that 80% of human polypeptides shared common similarities and Myraid was clearly holding the rights to laws of nature. To provide support to AMP's argument, a scientific research group conducted a factual research and found that Myriad's claimed of BRCA 1 sequence had 340,000 matches with normal human BRCA 1 gene stored on GenBank database (Database collecting human's DNA information for research). With this finding, Myriad's claim 1 attempted to claim 80% of polypeptide existing in the average human BRCA 1 gene.[32] As a response, Myriad argued that that their patents utilized "DNA isolation method" which introduced inventiveness and considered to be different from the natural DNA. Furthermore, Myriad argued that all elements found within the isolated DNA should be patent eligible due to the use of DNA isolation method. With this being said, factual findings still suggested that the resulting genetic data received from both types of DNA remained largely similar and consisted of human genetic materials that already existed in nature. Despite the use of DNA isolation method, Myriad claimed of isolated DNA and BRCA genes bare little to no difference to those already existed in nature.[33] Imagine two cups of espresso coffee, one hand brewed by a ballista and one brewed by a coffee maker. Despite the different brewing methods, the resulting product is still a cup of Espresso. Although not exactly identical but both method yielded the same type of coffee. With this principle, Myriad's owned BRCA genes exhibited no different to those in nature.

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29 Chester S. Chuang & Denys T. Lau, *Patenting human genes: The myriad controversy*, 32 CLINICAL THERAPEUTICS 2054–2056, 2054-2056 (2010).

30 US Patent No. 5,747,282 (issued May 5, 1998)

31 Anthony JF Griffiths, GENE-PROTEIN RELATIONS AN INTRODUCTION TO GENETIC ANALYSIS. 7TH EDITION. (1970), https://www.ncbi.nlm.nih.gov/books/NBK21811/ (last visited May 23, 2017).

32 Thomas B. Kepler, Colin Crossman & Robert Cook-Deegan, *Metastasizing patent claims on BRCA1*, 95 GENOMICS 312–314, 312-314 (2010).

33 *Assoc. for Molecular Pathology v. Myriad Genetics, Inc*. 569 U.S. __ (2013).

From past applications and theoretical frameworks, the two prong test should be able to provide clues to the patent eligibility of Bioprint Technology. Under the application of the two-prong test, invention can be broken down using a simple logical equation as so: "A + B = C". After having applied this equation to Chakrabarty's invention, it is discovered that naturally occurring bacteria named "*Pseudomonas"* was genetically modified into a new type of bacteria called "*Pseudomonas putida"*. Pseudomonas (A) + genetic engineering (B) = Pseudomonas putida (C).Under this application, it is clear that the original bacterium (natural occurring) underwent a non-obvious transformation process which yielded new and useful result (non-natural occurring). On the other hand, BRCA genes (A) + detection method (B) = BRCA genes (A). From using similar application of the test, it is apparent that Myriad process did nothing to transform the original article. Myriad's patents were merely methods to "discover" a naturally occurring phenomenon. Therefore, Myriad's patents were held as invalid. Similarity was also witnessed in *Mayo v. Prometheus* where the court ruled that a discovery of an effective method to administered medicine was not patent eligible because it was only an observation of a natural phenomenon.[34] By using a similar test on the Bioprint Technology, the equation illustrate the following: cultured cells (A) + Bioprinting process (B) = synthesized tissues and organs (C). Much alike Chakrabarty's invention, Bioprint Technology fully satisfied the application of the two prong test. On the first account, the original article (cultured cells) is connected to a Bioprinter (inventive method). Then, the cultured cells are transformed into organic tissues/organs via the Bioprinting process (non-natural occurring). Nonetheless, the Supreme Court strictly stated that the two prong (machine-transformation test) should not be use as the sole test for patent eligibility and other elements of the invention must also be taken into consideration.[35] However, on a certain application the two prong test can still provide useful clues to patent eligibility. Conclusively, the applications of the two prong test had sufficiently disclosed the patent eligibility clues of the Bioprint Technology.

IV. Scope of Human Organism

The last part for the patent eligibility test of the Bioprint Technology will be in accordance to the "human organism" limitation as prescribed within the latest American Invention Act (AIA). Accordingly to the Leahy-Smith America Invents Act (AIA), Congress has excluded all inventions and claims directed to or encompassing a human organism. With this being said, The Leahy-Smith America Invents Act (AIA) reads:

"Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism".[36]

The term "human organism" used by Congress cast a rather broad range of limitation over inventions that are directed to or encompassing human organism. By broadest interpretation, it can be assumed that any inventions that mentioned or related

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34 *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012).

35 *Bilski v. Kappos*, 561 U.S. 593 (2010).

36 Leahy-Smith America Invents Act (AIA), Public Law 112-29, sec. 33(a), 125 Stat. 284.

to "human organism" would be unpatentable. To properly understand this reasoning, the terms "human" and "organism" must be analyzed in full details.

By the definition of the Merriam-Webster dictionary the term "human" is defined as the following:

1. relating to, or characteristic of humans e.g. *the human brain or human voices;*
2. consisting of humans;
3. having human form or attributes and susceptible to the sympathies and frailties of human nature.

Secondly, the Merriam-Webster dictionary defined "organism" as follows:

1. a complex structure of interdependent and subordinate elements whose relations and properties are largely determined by their function in the whole;
2. an individual constituted to carry on the activities of life by means of parts or organs more or less separate in function but mutually dependent.

As shown above, the Merriam-Webster dictionary defined the term "human" as anything "relating to or having characteristics of humans". By definition, individual parts or characteristics such as: human heart, human brain or human voices are under the human definition. Broadest interpretation would suggest that human DNA and genes should also be cover under this term. Moreover, scientific sources would concur that the human DNA is what differentiate human from other species.[37] For decades, DNA is known to be the blueprint that defined the human characteristics. Human body compositions are dictated by the human DNA. Within the DNA sequences, genes are passed down from generation to generation forming the very identity of the human species. Every human of this Earth share similar DNA sequences with very tiny genetic differences.[38] Although, DNA existed in all life on our planet ranging from complex animals to simple plant life. However, there are identifiable similarities between species across the Earth, for examples: human share 96% of genetic similarity with chimpanzee, 90% similarity to a cat, 80% to a cow, and 60% to a banana.[39] In conclusion, DNA and genes are important factors to every unique species on this planet. Therefore, broadest interpretation of the term "human" would suggest that any inventions in relation to human DNA and genes should also be unpatentable.

This conjecture of "human" seem to be true as it is backed up by the ruling from *AMP v. Myriad* where the Supreme Court held that Myriad "Isolated DNA" is

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37 What does it mean to be human?, GENETICS | THE SMITHSONIAN INSTITUTION'S HUMAN ORIGINS PROGRAM (2010), http://humanorigins.si.edu/evidence/genetics (last visited May 23, 2017).

38 Norsk Teknisk Museum, DNA AND IDENTITY: HISTORY WRITTEN IN THE GENES? NORSK TEKNISK MUSEUM, https://tekniskmuseum.no/besok-oss/helgeprogram/1399-dna-and-identity-history-written-in-the-genes-22-may (last visited May 23, 2017).

39 Lydia Ramsey and Samantha Lee, OUR DNA IS 99.9% THE SAME AS THE PERSON SITTING NEXT TO US - AND WE'RE SURPRISINGLY SIMILAR TO A BUNCH OF OTHER LIVING THINGS BUSINESS INSIDER (2016), http://www.businessinsider.com/comparing-genetic-similarity-between-humans-and-other-things-2016-5 (last visited May 23, 2017).

unpatentable.[40] Despite the fact that Myriad had claimed that isolated human DNA is different to the normal human DNA via man's intervention. Nonetheless, the Supreme Court still saw this as an attempt to patent laws of nature and natural phenomenon. In this regard, Myriad's claimed over the human BRCA genes were also unpatentable. It would be logical to assume that from the current patent framework will not accept any direct replication of laws of nature or natural phenomenon. This interpretation could potentially poses as a problem for the Bioprint Technology as the technology directly involved the replications of human tissues and organs. However, as seen in *Diamond v. Chakrabarty*, the court had been known grant exemption if ingenuity can be proven to surpass the laws of nature restriction.[41] Interestingly, the US Supreme Court has ruled that the cDNA mentioned in Myriad's claim is patent eligible.[42] cDNA stands for "Contemporary DNA", which is the result from a DNA transcriptase process. The cDNA enables scientists to copy, edit and replicate normal DNA to better fit the complex research and experiment. In biotechnology, cDNA is the manipulation of the normal DNA to express certain genetic codes or proteins.[43] The cDNA creation method is known as "reverse transcriptase".[44]

After appropriately reviewing the properties of cDNA, The Supreme Court ruled cDNA to be patent eligible. The court stated that cDNA displayed adequate human ingenuity and transformative elements to be eligible for patent protection.[45] However, many biotechnology scientists have disagreed with the court's decision by stating that the court lack of scientific understanding will harm the future of genetic research.[46] They argued that cDNA does actually existed in nature, specifically inside retro viruses. Thus, the court understanding of cDNA was partially accurate. Additionally, experts further commented that the court should no longer make reference to *Diamond v. Chakrabarty* because the case can no longer represent the modern biotechnology landscape. With this reasoning, past benchmarks should be updated.[47] In a general sense, DNA reverse transcriptase process is comparable to the copyright – vidding concept. Under the vidding principle, copyright videos and images are allowed to be "cut" and "transform" into a new article (i.e. documentary film). The US IP framework

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40 Supra note 35

41 Supra note 13

42 Supra note 35

43 cDNA (Complementary DNA), HUMAN GENES, http://humangenes.org/cdna-complementary-dna (last visited May 23, 2017).

44 New England Biolabs, REVERSE TRANSCRIPTION (CDNA SYNTHESIS) REVERSE TRANSCRIPTION (CDNA SYNTHESIS) | NEB, https://www.neb.com/applications/cloning-and-synthetic-biology/dna-preparation/reverse-transcription-cdna-synthesis (last visited May 23, 2017).

45 Supra note 35

46 Megan Krench, *New Supreme Court Decision Rules That cDNA Is Patentable What It Means for Research and Genetic Testing Scientific American (2013)*, https://blogs.scientificamerican.com/guest-blog/new-supreme-court-decision-rules-that-cdna-is-patentablewhat-it-means-for-research-and-genetic-testing/ (last visited May 23, 2017).

47 Supra note 48

appears to be having a similar systematical approach to the transformation of original article (DMCA – the video exemption).[48]

The second term "organism" is more definite. As discussed earlier, the Merriam-Webster dictionary defined "organism" as a complete structure with many integrated parts working in unison. Broadly, an organism is seen as a "complete lifeform" of something, whether be simple microorganisms, animals or even humans. Under scientific definition, an organism must possess multiple functioning parts to be living; any absence of crucial parts will rendered the organism defective. Therefore, by joining the two terms of "human" and "organism", it would be logical to assume that the Congressional term of "human organism" means a complete lifeform that possess all human characteristics, including DNA, genes and other bodily parts. Under this assumption, the products of The Bioprint Technology such as: human tissues, heart or lungs should be patent eligible as this only involve the creation of "human parts" rather than "whole human organism". Furthermore, this assumption is affirmed by the statement given in the House of Representative on November 21, 2003 by Hon. Dave Weldon of Florida, whom was directly involved with the amendments of the Leahy-Smith America Invents Act. His statement to the House of Representatives reads:

"This summer I introduced an amendment that provides congressional support for the current U.S. Patent and Trademark Office policy against patenting human organisms, including human embryos and fetuses.

On November 5th of this year, I submitted to the Congressional Record an analysis of my amendment that offers a more complete elaboration of what I stated on July 22nd, namely, that this amendment has no bearing on stem cell research or patenting genes, it only affects patenting human organisms, human embryos, human fetuses or human beings.

However, some have continued to misrepresent my amendment by claiming it would also prohibit patent claims directed to methods to produce human organisms. Moreover, some incorrectly claim that my amendment would prohibit patents on claims directed to subject matter other than human organisms. This is simply untrue. What I want to point out is that the U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter". [49]

In this regard, the words of Representative Weldon would suggest that products of Bioprint would be patent eligible. His assurance on the continued allowance of stem cells, genes and DNA would also back up this assumption. AIA section 33 was created to specifically restrict the patenting of cloning related technology, where a complete organism is the final product. Additionally, the provision also prescribed the terms "directed to" and "encompassing". These two terms further put emphasis on the ban of

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48 The Digital Millennium Copyright Act, Pub. L. No. 105-304, 112 Stat. 2860 (Oct. 28, 1998).

49 149 Cong. Rec. E2417 (2003) (statement of Hon. Dave Weldon of Florida).

complete human organism patenting.[50] [51] This assumption is further supported by the decision of Ex parte Michael M. Kamrava (Untied States Patent and Trademark Office, The Patent Trial and Appeal Board, Appeal 2010-010201 for Patent Application 10/080,177).[52]

In the appeal case of Ex parte Michael M. Kamrava, the applicant was attempting to patent a surgical device used for in-vitro fertilization (IVF).[53] The IVF process involves "embryos implantation", in which the female egg can be fertilized outside of normal condition (*in vitro*), then later implanted into the uterus to initiate pregnancy.[54] Ultimately, Kamrava attempted to claim a process for implanting the embryos into the uterus. In accordance with the AIA section 33, the patent examiner rejected all claims "directed to" or "encompassing" human embryos. The applicant later filed an appeal with the Patent Trial and Appeal Board. After careful examination, the Appeal Board affirmed the original rejection.[55] The Appeal Board's decision fully upheld the restriction as prescribed within the Leahy-Smith America Invents Act.[56] From analyzing Ex parte Michael M. Kamrava, it would be logical to assume that if the broadest interpretation of an invention should involves the patenting of a complete human organism, then it should be considered as unpatentable subject matter. On the other hand, the broadest interpretation of the Bioprinting process shows the patenting of human parts rather than human organism.

Conclusively, Bioprinted products (i.e. tissues and organs) only involves with the creation of human "parts" not whole organism. Furthermore, the language interpretation between "whole" and "parts" are incredible vast with clear differences. Despite the logical theory established by this report, it is still necessary for the judiciary branch to step in and provide proper clarification to this dilemma.

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[50] Ava Caffarini, *Directed To or Encompassing a Human Organism: How Section 33 of the America Invents Act May Threaten the Future of Biotechnology*, 12 J.MARSHALL REV.INTELL.PROP.L.768 (2013).

[51] Id at 52

[52] Ex parte MICHAEL M. KAMRAVA, Appeal 2010-010201, Application 10/080,177.

[53] Id at 54

[54] Embryo Implantation After IVF, IMPLANTATION OF BLASTOCYSTS & IVF EMBRYOS IN HUMANS, http://www.advancedfertility.com/implantation.htm (last visited May 23, 2017).

[55] Supra note 54

[56] The Biology of Prenatal Development, THE BIOLOGY OF PRENATAL DEVELOPMENT, https://www.ehd.org/resources_bpd_illustrated.php?page=6 (last visited May 23, 2017).

V. Conclusion

Conclusively, this analysis report fully establishes the bases for the patent eligibility of Bioprint Technology by using various assessments and analytical tools. First, the technology adequately satisfied the Jefferson Rules governing with patentable subject matter scope of the US patent system. Second, application of the two prong test further provided clues to the patent eligibility of the Bioprint Technology by evaluating (1) non-obvious ingenuity and (2) transformative elements. Lastly, logical analysis to the Congressional langue and meaning of "human organism" led to the assumption that the Bioprinting process does not encompassed or directed to the patenting a "complete human organism". Therefore, the AIA section 33 restriction should not apply to the Bioprinting Technology.

Despite the fact that the scope of the Bioprint Technology has passed all three in-depth assessments of this report. Nonetheless, the technology still remains controversial which certainly required the full attention of the judiciary branch to analyze the true patent eligibility. Finally, in order for this Technology to fully develop into viable application, it is important that both scientific and legal branch cooperate to establish appropriate frameworks for the Bioprint Technology.

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