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EDITORIAL TEAM

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EDITORIAL NOTE ON THE VOLUME 6 NUMBER 1 ISSUE OF 2017

Editorial Note

Dr. Kuang-Cheng Chen,

Associate Professor,

Graduate Institute of Intellectual Property, National Taipei University of Technology (Taiwan).

Since the beginning of 2015, this journal has been included in the SCOPUS and WESTLAW citation databases. This reflects our steady efforts in maintaining the standard and quality of our academic publications and increases the visibility of the articles published in it. We would like to express our appreciation to all the authors, reviewers, editors, and advisors of this journal. The editorial board welcomes submissions from legal, managerial, or interdisciplinary areas related to IP issues from all over the world. In order to cover IP issues, we do not restrict the scope of this journal to any single jurisdiction.

In this issue, the selected articles are derived from legal analyses concerned that arbitration is the best option based on procedural and substantive justice in patent disputes of Taiwan High-Tech Industries. On examining the U.S. Supreme Court's Moore case from a Gewirthian perspective, it is seen that the decision seriously infringed on Moore's human rights, and that Moore should be awarded royalties in accordance with the market value created. A new form of human rights, incorporated into IP rights, can resolve issues relating to informed consent issues, including community rights as well as individual rights. With regard to the patent eligibility of Bioprint Technology, it has been found from various tests of past U.S. court cases that the technology still requires examination and clarification from a judiciary branch. Last, the scope of the technology is within the patentable subject matter of the Leahy-Smith America Invents Act. In addition to expressing our gratitude to all contributors who made this issue possible, we hope you continue to support us in the future to maintain the goal and quality of this journal.

Dr. Kuang-Cheng Chen

Associate Professor

Graduate Institute of Intellectual Property

National Taipei University of Technology (Taiwan).

CALL FOR PAPERS

NTUT Intellectual Property Law and Management is a multidisciplinary journal which concerned with legal, economic and social aspects of IP issues. This journal is included in the SCOPUS, WESTLAW, WESTLAW HK, LAWDATA, AIRITI LIBRARY citation databases, and it welcomes contributions to address IP topics at national, regional and international level.

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2. A regular manuscript is expected to be 6000-8000 words in length, including the main text and footnotes. Potential authors are encouraged to contact Dr. Kuang-Cheng Chen for a manuscript template.

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The Current Situation of the Predicaments of Taiwan High-Tech Industries for Patent Dispute Resolution

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ABSTRACT

Since patent dispute cases often involve industrial background and legal background in Taiwan High-Tech Industry, such as professional technology, short product life, time to market, uncertain patent claims, court judgments among different trial-level. But the rule of law and litigation emphasize the protection of procedural justice, which may be time-consuming and often leads to delayed justice. Actually, substantive justice is concern with the benefits of length time and cost, procedural justice is concern with the benefits of the trial court, and therefore, under the considerations of dual justice, applying for arbitration is superior to the sending of a warning letter, requesting a preliminary injunction, as well as filing a lawsuit. In practices of patent dispute solutions, OBM always not only rely on its own strengths with the large amount of capital and patent technique, but also take patent misuse to force competitors (OEM, ODM) out of the market by patent litigation. As a result, patent law is out of balance in legal system. Based on the above, this article discusses industrial background and legal background in Taiwan high tech industry, and patent misuse by patent holder, in order to explore which method is the best option under procedural and substantive justice. As a result, the findings of the study indicate that arbitration is the best option based on procedural and substantive justice.

Keywords: Patent Misuse, Arbitration, Time to Market, Short Product Life

I. Introduction

With the development of the knowledge economy and globalization, the environment of hi-tech industries has been changing constantly. Hi-tech industry business managers have been using various strategies to acquire patents and apply them more efficiently. Rationally considered, business managers are also concerned with increasing profits and decreasing time to market, and thus the commodification of patent technique. Only by doing so can enterprises acquire a predominant role in the global competitive market and thus upgrade their competence in all enterprises. However, in reality, patent dispute solutions of high-tech enterprises, due to laws stressing the maintenance of "procedure justice," must go through a number of processes at various levels of trial courts. Patent dispute cases often involve professional technology, but the rule of law and litigation emphasize the protection of procedural justice, which may be time-consuming and often leads to late justice. Even if each party wins the case, the victory may come too late for the viability of the product or procedure that has been fought for. After all, during the whole time spent fighting in court, the parties are losing business opportunities due to the shortness of product shelf life; even if they eventually win the case, the only prize may be a debt certificate with an apology for "delayed justice." Accordingly, due to constant environmental changes, regulating the procedure of justice and achieving legal distributive justice is not only important from the standpoint of abstract notions of fairness and justice and maintaining the citizens' confidence in our legal systems, but also profoundly influences trends and growth in the global market competition of high-tech enterprises. It is concerns about these matters that has inspired the present research.

In general, many patent lawsuits are filed by high-tech industries.[1] Common issues are protecting the patent holder's rights, compensation for patent losses, patent infringement, and to obtain licensing fees or royalties for the patent holder. However, there are also cases in which enterprises purse unfair competition and use litigation as a business strategy. Enterprises such as Nokia, Motorola, Samsung and Sony all have Own Brand Manufacturer (OBM) and frequently threaten the Original Equipment Manufacturer (OEM), Original Design Manufacturer (ODM) in Taiwan by demanding unfair and unreasonable licensing fees (royalties) or imposing license restriction clauses on these manufacturers. And sometimes they also may ask for court injunctions as business strategies in the global competitive market. If they win, they may ultimately take a leading role in the manufacturing of the relevant product. The methods mentioned above may not only violate the core idea of patent system but may be against the competition of the free market.

[1] Patent Assertion AND U.S. Innovation, Executive Office of the President, June 2013, https://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf. (last visited Feb. 20, 2016). Fiona Scott Morton, Carl Shapiro (2014), 79 Antitrust Law Journal, No. 2, 463-499, http://faculty.haas.berkeley.edu/shapiro/pae.pdf. (last visited Feb. 20, 2016)

Indeed, legal justice is dependent on the practice of procedural and substantive justice. However, in the process, there are some contradictions which seem to go against the common sense and universal values of the public, like the cases mentioned above where the enterprises are pursuing an unfair competitive advantage. If we put too much emphasis on the procedural justice, we may not be able to avoid the cases mentioned.

On the contrary, putting way too much emphasis on substantive justice can lead to bad results in some cases, leading to the conviction of some who are not guilty of any crime. Hence, the solution to the patent disputes should be based on the balance of procedural and substantive justice. Common law applies the equity law to legal regulations and judicial judgments. And the courts never make any judgments that violate the common sense and universal values of the public.

Based on the statements made above, this chapter discusses the present day patent system in three different aspects. 1. The background of the high-tech industry (including the specialization of high-tech products, the high confidentiality of high tech products, the short life cycle of the products, the promptness of the commodification of the Products, and the decision-making process of the business manager - the interchangeability of legal rationality and economic rationality). 2. The background of patent law (including how some patent claims can be highly uncertain, how judgment of patent effectiveness can be highly unstable, the difference between administrative and court judgments, the differences among the judgment of different trial-level courts, and the conflicts between national and transnational laws). 3. The misuse of the dispute solution mechanism by the patent holder (including the legitimacy of judgment for solving patent disputes - equity law, how the improper use of warning letters can violate anti-trust laws, how the improper use of injunction orders violate equity laws, and how the improper use of long proceedings violate substantive justice)

II. The Industrial Background of the Taiwanese High-Tech Industry

A. The Industrial Background of the Taiwan High-Tech Industry-The Specialization of High-Tech Products

Legal values can be quite multi-faceted, often being the result of balancing profits so as to pursue justice. The judicial concerns of the high-tech industries resemble other cases in other fields of industry. Nevertheless, when patents are related to high-tech techniques, the judgments of the patent cases should be made by those with high-tech knowledge in different spheres, such as physics, chemistry, electronics, semiconductor technology, Integrated Circuit (IC) design, TFT-LCD (Thin-Film Transistor Liquid-Crystal Display) Panel technology etc.

In general, in order to maintain the fairness of judicial judgments, laws have been designed to include both substantive and procedural laws, which not only put emphasis on legal proficiency but on knowledge in other fields, such as electronic engineering, biotechnology, etc. Thus, in Taiwan, the judicial system which deals with patent disputes has become central to the parties concerned, as it a key way to solve the disputes.

In other words, the regulations related to the patent disputes' solutions are not only relevant to the conditions of acquiring the patent but also to the abilities of the judges when making correct judgments. Even if the judicial system is destitute of professional knowledge and proficiency, the process may still be quite time-consuming and also may be questioned because of a deficiency of the abilities required, which may negatively influence the competence of the high-tech industries in the global market.

Because of this, the U.S. federal court has its own Expert jury (Blue Ribbon Jury), and the German federal court has its own separate system in which the composition of the Intellectual Property court is dependent on a few judges and many technical examination officers. Taiwan does not have a system like this. Under article 4 of the Taiwan (ROC) Intellectual Property Case Adjudication Act,[2] the performance and duties of the technical examination officer are limited to only an explanation to the parties concerned or the questioning of the parties, witnesses and appraisers. However, if the technical examination officers are not witnesses or appraisers, how can the technical examination officers be questioned by the parties?

[2] The article 4 of Taiwan (ROC) Intellectual Property Case Adjudication Act: The court may, whenever necessary, request a Technical Examination Officer to perform the following duties:1.Ask or explain to the parties factual and legal questions based on the professional knowledge, in order to clarify the disputes in action; 2.ask questions directly to witnesses or verification experts;3.State opinions on the case to the judge; and 4.assist in evidence-taking in the event of preservation of evidence.

Moreover, if the opinions of the judges are different from those of the technical examination officers and the judges insist on their own opinions, this will be against the purpose of the Intellectual Property Case Adjudication Act for establishing the intellectual property court.

Due to these shortcomings, I think the legal and judicial system here in Taiwan should be improved so as to boost economic development. This can be done by providing regulations which can keep up with times and making international manufacturers (including OBM, ODM and OEM) more likely to agree to accept legal and judicial judgments made and followed here in Taiwan and . If so, Taiwan's legal and judicial system will be as supportive of high-tech industry as many international competitors. The purpose of IP law is to discover the truth, and thus to win the people's trust. To accomplish this, we just need to imitate the jury system used in the US tech cases, or the system applied in German law, which lead to the people's trust in the courts. This will increase profits by ending costly and wasteful legal disputes.

B. The Industrial Background of Taiwan's High-Tech Industry-The High Confidentiality of High Tech Products

With the growth of knowledge based economies, knowledge management and innovation becomes a core value of industrial competition. In patent dispute cases, high tech industries not only use patent law as a kind of weapon to file lawsuits against competitors who don't get the permission in advance, but use the law as a kind of passive defending weapon to attain success in business negotiations. This makes the importance of patent rights ineffable.

As for IP protection, it is not only valuable with the legal protection but also is dependent on the effective managerial system used in the companies. In other words, an effective managerial system in high tech industries includes product technology, business strategy, etc. The acquisition of related information is not only relevant to the profits gained, but the key to success. As a result, if the patent technique is illegally used by opponents, the damage this may bring is beyond imagination. Thus, litigation concerning patent law should be kept confidential to avoid other competitors achieving the illegal advantages in improper ways, which has become the core issue of the relevant law.

The Playskool, Inc. et al v. Famus corp case was heard in U.S. Federal Court in 1981. The court viewed the pleas and statements about the evidence as business secrets and the protection of the legal rights of proceedings. First of all, as for the limitation of business secrets, the American federal courts take several factors into consideration when it comes to issuing the command of protection of business

secrets. These include:3 (1) the extent to which the information is known outside the business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken to guard the secrecy of the information; (4) the amount of effort or money expended in developing the information; (5) the ease or difficulty with which the information could be properly acquired by others.

Furthermore, as for the context of the operational secrets, the US federal court also cited article.26(c) of the Rules of Civil Procedure (FRCP) and determined that it applies to the cases concerned, including the following points: 1. Not to expose the evidence and discovery. 2. Only to discover the evidence and the truth under certain conditions. 3. Only to use certain methods to discover the truth. 4. Not to inquire about certain details and to limit the truth discovery to a certain range. 5. People other than the ones appointed by the courts should not take part. 6. Sealed testimonial statements can only be opened under the instructions of the court. 7. Not to expose business secrets or other confidential information. 8. The sealed confidential information provided can only be opened under the instructions of the courts. In addition, the context of the operational secrets is no longer limited to the statements made by the parties concerned.[4]

In contrast, article11-1 of the Taiwan (ROC) Intellectual Property Case Adjudication Act doesn't include the regulations and clauses mentioned above in the US Federal Rules of Civil Procedure. Moreover, article13-1 of Taiwan (ROC) Intellectual Property Case Adjudication Act is not as flexible and definite as the US Federal Rules of Civil Procedure, which balances the profits of both parties concerned. Obviously, article.26(c) of the Rules of Civil Procedure (FRCP) is a suitable response to environmental changes to balance the profits of both parties if compared with the Taiwan (ROC) Intellectual Property Case Adjudication Act.

The Industrial Background in Taiwan High-Tech Industry-The Short Life Cycle of Products and the Promptness of their Commodification

The competitive niche of the high tech industries is based on new technology commercialization. High tech enterprises appeal to the demands of the consumers; they just have to make the products promptly get them to retailers, i.e. time to market, to acquire a competitive advantage. Accordingly, in the process of the new

[3] Playskool, Inc. et al v. Famus corp., 212 U.S.P.Q.8(S.D.N.Y. 1981).:"(1) the extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the amount of effort or money expended by him in developing the information; (5) the ease or difficulty with which the information could be properly acquired by others."

[4] Yu-Shu Zhang, A Comment on the draft of Intellectual Property Case Adjudication Act and related to Protective Order – Discussion on US Legal Practice Models, 139 The Taiwan Law Review, Taipei: Angle publishing Co Ltd, 55 (2006).

technology commercialization, the life cycle of products is constantly shortening, making time a key factor in success. In view of the importance of the new technology commercialization, the OBM often uses time consuming litigations as a business strategy, intentionally posing market barriers to slow the development of their rival companies. This is a breach of fair competition in the market and violates the principles of fairness and justice. Therefore, how to improve the legal system to increase lawsuit efficiency for timely protection of the parties' legal rights has become an important issue.

Regarding patent disputes here in Taiwan, since the litigation system is divided into a dual legal system consisting of public law and private law, the jurisdiction of the court is divided into the general court and the administrative court, respectively responsible for civil criminal cases and administrative cases. Thus, the parties may use the dual legal system to claim their rights at the same time, but this may also lead to a contradiction in the two judgments which may arise from the different courts. If this happens, the claim proceeding may go back and forth to the intellectual property office, general court and the administrative court, wasting valuable time among the different authorities in charge of the cases. As for the levels of administrative relief, these include application, expositions, objection, withdrawal, and so on. First of all, it is necessary to apply the case to the Intellectual Property Office, and if not satisfied with the judgment, the parties can appeal to the Ministry of Economy. If again unsatisfied, the parties then can file a lawsuit to the administrative court.[5]

Due to the importance of time-to-market for the high tech industries, if the legal proceedings take a long time, the final verdict of the court, even if favorable, may have come too late for the products viability. This can lead to a case where justice delayed equals justice denied. Recognizing this problem, the dual legal system between public law and private law was amended by the Intellectual Property Court Organization Act (IPCOA);[6] this change is mainly to avoid different judgments arising from different courts and save time for both parties and judicial resources for the state.

With regard to patent disputes, the intellectual property courts adopted exclusive jurisdiction under the Anglo-American law system.[7] However, the two

[5] Article 32 of the Taiwan (ROC) Intellectual Property Case Adjudication Act: Unless otherwise prescribed by law, an appeal may be filed with the final administrative court against a judgment of the Intellectual Property Court.

[6] Articles 2 and 3 of the Taiwan (ROC) Intellectual Property Court Organization Act.

[7] 28 USC § 1338 (a) of the Federal Rules of Civil Procedure: The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights. For purposes of this subsection, the term "State" includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands,

laws newly announced don't have this exclusive jurisdiction at all, which may lead to its being dependent on the plaintiff to file a lawsuit. This may increase the controversies regarding courts and the judgments. Thus, the two laws mentioned above should be modified to make exclusive jurisdiction to avoid court options and controversies.[8]

The Industrial Background in Taiwan High-Tech Industry-The Way of Decision: Making of the Business Manager – The Interchangeability of the Legal Rationality and Economic Rationality

With the growth of globalization, the flows of thousands of goods are no longer limited to national boundaries. The establishment of law systems is related to culture, economics, politics and social values. The legal system is also dependent on input, output and feedback to reach a dynamic equilibrium. Nowadays, general economic knowledge has become more widespread, issues regarding patents have become core issues worth discussing.

Because of the business strategies of hi-tech industries used here in Taiwan, the concerns of business managers tend to be about costs, benefits and effectiveness. The reasons why business managers make certain decisions is based on economic rationality.[9] What business managers are really concerned about is how to pursue maximum profits in order to avoid time consuming problems and to solve disputes efficiently, not only based on the concept of substantive justice and predictability. Thus, how business managers reach a balance between economic and legal rationality has become an issue worth discussing.

Any solutions to disputes are all based on the principle of self-ruling and contract freedom. In general cases, both parties agree to the same court to settle litigation that may arise in the future. This is also called the Alternative Dispute Resolution (ADR). With this in mind, most patent disputes are solved with economic rather than the legal rationality.

As we know, quite a few high-tech industries have adopted arbitration as a way to settle patent disputes, such as the Motorola case in 2004, the Ben Q Mobile

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American Samoa, Guam, and the Northern Mariana Islands.

[8] Chung Hsin Chang, *The Progress Toward the Establishment and Operation of Taiwan Intellectual Property Court*, Taiwan Bar Journal, Vol.11 (4), Taipei: Taiwan Bar Association, 61-76 (2007).

[9] Godelier Maurice 1972, Rationality and Irrationality in Economics, The Translated from the French by Brain Pearce, New York and London, Monthly Review Press, 12-15 (1966)., cited by Wei-Ming Liao, *Preliminary Study of the International Law in the New Century – Legal Theory and Legal Education Consideration* , I MCU Law Review, 75-79 (2003).

case in 2006, and the Qualcomm case in 2007.[10] The professionals here in Taiwan also hold the view that[11] 1. Due to transaction cost, it is wise to decrease wasted time and money through arbitration. 2. In multi-national transactions, arbitration can avoid possible political factors 3. It is a great step for the community to adopt arbitration as a way to settle disputes.

III. The Legal Background in Taiwan High-Tech Industry

A. The Legal Background in Taiwan High-Tech Industry-Patent Claims are Highly Uncertain

As for the patent scope, usually it is based on the claims of the patent in the original application; the title, abstract, legend, and illustrations are all related to its effectiveness.[12] Under the circumstance where the specifications have been revealed but did not ask for protection, it will be considered a contribution to the general public. If the specifications are not revealed but still asks for protection, then the patent claim is deemed invalid. The patent applicant defines the technical field which requests the government's protection in the patent claim's wording; patent claims are the primary means through which various inventions gain patent protection. Usually the patent claim uses clear and simple language to describe its necessary elements and limited conditions. U.S. patent infringement litigation cases must first define the patent claim which applies. The interpretation of such claims is a "Question of Law," and is performed by the judge assigned to the case. Next it will define whether the accused approach or device is within the patents' claims. If it is disputed, it may need to be confirmed by a jury and is a "Matter of Law".[13] With regard to the academic theory of patent claims, there are Central and Peripheral definitions. For example, nations which use a Civil Law system, including Germany, Japan, and the Netherlands, apply the Central definition, while Common Law system countries, like England, apply a Peripheral definition. In

[10] Qualcomm Files Arbitration Demand Against Nokia to Resolve Dispute Over License Agreement), http://www.qualcomm.com/press/releases/2007/070405_files_ arbitra tion _ demand.html. (last visited June 06, 2008)

[11] Lin Yeu Chu (2002), *The Arbitration of High Tech Industry, Industry analysis* – ProMOS Co Ltd, (2002), http://www.promos.com.tw/website/chinese/industrylist.jsp?id=1025600004727. (last visited June 20, 2008.)

[12] The article 56(3) of Taiwan (ROC) Patent Act: The scope of an invention patent right shall be determined based on the claim(s) set forth in the specification of the invention. The descriptions and drawings of the invention may be used as reference when interpreting the scope of the claims in the patent application. The article 106(2) Taiwan (ROC) Patent Act: The scope of a utility model patent shall be determined based on the claim(s) set forth in the specification of the patented utility model. When interpreting the scope of claims, the description and drawings of the utility model patent may be used as reference.

[13] Philip Luo, *Designing Around of Patent Infringements*, Topics on Industrial Property, Self-Published Authors (2003).

America, patent rights were switched from a Central definition to a Peripheral definition when the Patent Act of the United States was amended in 1870.[14]

1. Central Definition

When the Patent Act of the U.S. was amended in 1836, it introduced the idea of patent claims. Article 6 of the Patent Act states:[15] the inventor shall "particularly specify and point out the part, improvement, or combination of his invention or discovery" which the regulation to "particularly specify and point out" the patent claims is of the Central Definition. The explanation of Central Definition is that creation itself is a case of technical thinking, and the description of the claims is only the concrete form of the creative thinking; thus the patent protection scope is not limited to the description of the patent claims. It is centered in the patent claim but recognizes there is a certain technical extension that may reach beyond the claim. So according to the Central Definition, the although judgment on patent infringement is centered on the patent claim, after consulting the

[14] 35 U.S.C § 112(2): The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicants regards as his invention.

[15] The 1836 Patent Act, Ch. 357, 5 Stat. 117, Section 6 (1836) : And be it further enacted, That any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others before his or their discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer; and shall desire to obtain an exclusive property therein, may make application in writing to the Commissioner of Patents, expressing such desire, and the Commissioner, on due proceedings had, may grant a patent therefor. But before any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of any machine, he shall fully explain the principle and the several modes in which he has contemplated the application of that principle or character by which it may be distinguished from other inventions; and shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery. He shall, furthermore, accompany the whole with a drawing, or drawings, and written references, where the nature of the case admits of drawings, or with specimens of ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment, where the invention or discovery is of a composition of matter; which descriptions and drawings, signed by the inventor and attested by two witnesses, shall be filed in the Patent Office; and he shall moreover furnish a model of his invention, in all cases which admit of a representation by model, of a convenient size to exhibit advantageously its several parts. The applicant shall also make oath or affirmation that he does verily believe that he is the original and first inventor or discoverer of the art, machine, composition, or improvement, for which he solicits a patent, and that he does not know or believe that the same was ever before known or used; and also of what country he is a citizen; which oath or affirmation may be made before any person authorized by law to administer oaths.

specifications and illustrations of the patent application, it may be necessary to moderately expand the record of the patent claim itself in accordance with the Doctrine of Equivalents.[16] The advantage of the Central Definition is that the main ideas of creation and invention are easy to understand, and the disadvantage is the record of the patent claim may be over expanded.

2. Peripheral Definition

Because of the disadvantage of the Central Definition, that is, that it might result in a patent claim that is not precise enough and so lead to uncertainty when enforcing the law, the United States amended its Patent Act in 1870. Article 26 amended the recording approach of patent claims,[17] making it so that the "applicant must particularly specify and point out the part, improvement, or combination of his invention or discovery, and clearly request" that the specific idea at its heart be recognized. Patent claims' focus moved from the Central Definition to the Peripheral Definition, a change which has been recognized ever since. Under the Peripheral Definition, the patent applicant shall define the maximum limit of the claims. The technical content not mentioned in the specification of the patent claim will be deemed outside of the patent scope. The advantage of the Peripheral Definition is that it makes it easier to understand the patent claim, while the disadvantage is that the applicant might make the description of the items specified for patent application too complicated and over-inclusive for fearing any omission, thus maximizing the protective scope of the claim.

3. The Compromise Definition

The two definitions have both advantages and disadvantages, leading to a need for a theory that combines the good points of both, while putting emphasis on the context of the patent application scope. This idea has become a mainstream theory in most countries and regions dealing with patent issues. For example, No. 69 is the European Union's invention patent protocol. Doubtlessly, the advantage of a Central Definition is that the main idea of the creation and invention is easy to

[16] The U.S. Supreme Court in 1853 Winnas v. Denmead case, which some commentators use the expression of "the principle of equivalent for the first time.

[17] Patent Act of 1870, Ch. 230, 16 Stat. 198-217 (July 8, 1870): And be it further enacted, That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall make application therefor, in writing, to the commissioner, and shall file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions; and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery; and said specification and claim shall be signed by the inventor and attested by two witnesses.

understand, and the disadvantage is the record of the patent claims might be over expanded. And the advantage of the Peripheral Definition is that it makes it easy to understand the patent claims. However, technology is changing and making progress every day, so if anything is left out in writing the specifications of a patent claim, it might lead to a later dispute. Due to the disadvantages of the above two definitions, the Compromise Definition advocates that the protective scope of the patent shall be based on the contents of the patent Claims, while the specifications and illustrations are used to explain such patent claims only. At present, this type of definition has become the main stream for patent applications in different countries, Article 69 of the Europe Patent Convention and its Protocol are good examples.[18]

Of course, a patent's scope can be unstable and not easy to determine, though there is a theory which combines the goods sides of the central and peripheral definitions, which can make the scope more specific. In actual cases, however, even the professionals still find it hard to determine the exact range of patent rights, which explains the uncertainty of the whole system. It is true that a patent is an intangible intellectual property and that patent claims usually contain some uncertainty. Due to the construction of some claims, some practical matters which include distinctions in the Central definition which may be hard to define or have some items left out, especially in patent infringement disputes. Even if a compromise definition is used, theoretically the patent claim should still be precise. For example: section 3, article 56 of the ROC Patent Act stipulates that:[19] The scope of an invention patent right shall be determined based on the claim(s) set forth in the specification of the invention. The descriptions and drawings of the invention may be used as reference when interpreting the scope of the claims in the patent application. However, in practice, even professionals may not be able to clearly point out the limits of the specification claims. Thus, different reviewers may have different evaluation results for the same patent. For the same reason, the judgment on a patent infringement case may be inconsistent. In view of this, there can be tremendous uncertainty when the patentee is trying to establish patent rights.

[18] Protocol on the Interpretation of Article 69 EPC：should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

[19] The ROC Article 56 (3) of Taiwan Patent Act: The scope of an invention of a patent right shall be determined based on the claim(s) set forth in the specification of the invention. The descriptions and drawings of the invention may be used as reference when interpreting the scope of the claims in the patent application.

A. The Legal Background in Taiwan's High-Tech Industry--The Judgment of the Patent Effectiveness is Highly Unstable

Patent rights are issued by a country to exclude other uses of the products with the traits of novelty, inventive step (non-obviousness), and industrial applicability (usefulness). Nonetheless, in order to avoid the misuse of patent rights, there is another reporting system to help secure the accuracy of the patent issuing matter. Patent rights are rights which the national authority gives the patentee whose invention and creation meet requirements of novelty, industrial applicability and usefulness, and pass certain criteria for originality and Non-obviousness, three elements. If the application passes, the national organization authorizes provides the patentee with an exclusive patent and monopoly right during a certain period of time. However, in order to avoid giving a patent right improperly and exercise patent technology unsuitably, in addition to the substantive review performed by the authorities during the first stage of an inspection, there are also patent laws that must be considered, as well as allowing possible objections, expositions, and even the possible revoking of a patent to assure the correctness in conferring the patent rights.[20]

Preserving transactions safety is the top priority to commercialize the patent techniques in time. However, according to the patent laws here in Taiwan, starting from the date of obtaining the patent right, it is possible to have it withdrawn at any moment, which can cause a lot of uncertainty. According to article 73-2 in the patent law here in Taiwan, when a patent right is withdrawn, it is expunged from the record, as though it never exists. This may lead to issues of transactions safety. As for the the trading safety mechanism, for the patentee the most important thing is to commercialize the patent technology and market products within the limited product shelf life. Therefore, patent holders will generally either engage in manufacturing and sales themselves, transfer their patent, or authorize others to use it. However, according to the regulations in articles 67[21]and 68[22]of the ROC Patent

[20] The article 71 of Taiwan (ROC) Patent Act: Any person may request for an invalidation action against an invention patent with the Specific Patent Agency under any of the following circumstances…The article 72 of Taiwan (ROC) Patent Act: Where the interested party possesses recoverable legal interests due to the revocation of a patent, such interested party may file an invalidation action after the said patent has become extinguished ipso facto.

[21] Article 67(1) Taiwan (ROC) Patent Act: Under any of the following circumstances, an invention patent right shall be revoked and the patent certificate issued thereto shall be recalled within a given time limit by the Patent Authority either by an invalidation action or ex officio, and if recalling fails, a public notice for revocation of said patent certificate shall be published:1. If the invention is found in violation of the provisions of Paragraph One, Article 12, Articles 21 through 24, Article 26, Article 31 or Paragraph Four, Article 49 of this Act; 2. If the home country of the patentee does not accept the patent applications to be filed by nationals of the ROC; or. 3. If the invention patentee is found being a person other than the person entitled to file the invention patent application.

[22] The article 68 of Taiwan (ROC) Patent Act: An interested party may institute an invalidation

Act, from the date the patent right is granted, it may be revoked anytime, even patents which have been reviewed and officially granted. This creates a degree of uncertainty for all producers. When the patentee exercises the patent right, he/she is faced with possible infringement from a third party, and there is a potential risk of the patent being revoked. In addition, the regulations in section 2, article 73 of the ROC Patent Act indicate that when the patent right is revoked by the authorities, its history is deleted. As a result, patent rights are still not solid guarantees of right, which not only shakes people's trust in the law, but also jeopardizes trading safety.[23]

Actually, the patent right review involves highly technical judgment, along with the constant development of professional skills. Thus, to decide whether an invention and creation meet the requirements of novelty, industrial applicability and usefulness, and inventive step or Non-obviousness, various judgments could be reached depending upon time and circumstances. Whether it is the intellectual property bureau in charge of the issuance of patent (administrative department), or the intellectual property court in charge of patent disputes (judicial department), the judgment on patent right acquisition or patent infringement often applies the present technical standard to evaluate the technique and standards at the time it the patent application is submitted. It is much more serious when the legal elements are regulated with uncertain legal ideas. This situation can occur when the intellectual property bureau in charge of the issuance of a patent (administrative department), or the intellectual property court in charge of patent disputes (judicial department) are entitled to judge the facts regarding the structural elements of a product and decide the legal aspects and decide whether the administrative handling and court judgment are consistent or not. This makes it impossible for the patentee to predict with complete confidence whether the patent rights effect exists or not. To know this with absolute confidence requires knowing both the intellectual property bureau in charge of the issuance of patent (administrative department), or the intellectual property court in charge of patent disputes (judicial department) to have a consistent standard on the judgment of patent right acquisition or patent infringement. Only this can guarantee the confidence of the people in predicting a patent dispute outcome.

action after the patent has expired or extinguished ipso facto if he/she has reinstatable legitimate interests as a result of the revocation of the patent.

[23] The article 73(2) Taiwan (ROC) Patent Act: The effect of an irrevocably-revoked invention patent right shall be deemed non-existent ab initio.

B. The Legal Background of Patent Law in Taiwan-The Difference between Administrative Action and the Court Judgment

Along with the growth of a knowledge-based economy and globalization, R&D techniques, intellectual property rules, and business operation types are in constant flux. Diversified development and intellectual property protection has become steadily more complicated, and steadily more different from traditional property protection. Patent rights are related to intellectual property rights. The national authority confers the exclusive patent right to the patentee based on the trade-off relationship of economics. In the national patent system, when the nation authorizes the patentee with the rights of the initial stage, the relation between the nation and the patentee becomes public and formally legal; when the patentee exercises his exclusive patent rights afterwards, it is within a private law relation. It can be said that the design of the patent rights has both the private and public law two kinds of relations.

In the first stage, when the nation authorizes the patent rights for the patent holder (public law relation), the related patent acquisition, report, approval, and revocation and other such administrative processes involve high level scientific technique. Whether the resulting judgment is correct or not depends on the technology related personnel of the intellectual property bureau. They are the ones involved in the substantive review. As for the related disputes deriving from it, these also involve litigation proceedings, and the disputes derived from it apply to the administrative proceedings. Nevertheless, since the litigation system of Taiwan applies civil and criminal binary systems, when the common civil courts handle patent infringement litigation, the party concerned often provides the patent rights necessary for an effective defense. The civil courts are usually based on article 182 of the Code of Civil Procedures;[24] article 90 of the Patent Law[25] is applied to make the decision to stop the proceedings and wait patiently for the judgment of the administrative litigation.[26] In this way the legal patent system deviates from

[24] ROC (Taiwan) Civil Procedure Code, Article 182 (1): When the decision on an action, in whole or in part, is premised upon the existence or non-existence of certain legal relations to be determined in another action, the court may by a ruling stay the proceeding until that action is concluded. ROC (Taiwan) Civil Procedure Code, Article 182 (2): Except as otherwise provided, the provision of the preceding paragraph shall apply mutatis mutandis to cases where the existence or non-existence of a legal relation is to be determined by an administrative proceeding.

[25] The article 90 (1) of Taiwan (ROC) Patent Act: For any civil proceedings pending in a court in connection with an invention patent, the court may suspend the trial process until a decision on the patent application, invalidation, or revocation action related thereto has become irrevocable.

[26] The article 182 (1) of Taiwan (ROC) Civil Procedure Code: When the decision on an action, in whole or in part, is premised upon the existence or non-existence of certain legal relations to be determined in another action, the court may by a ruling stay the proceeding until that action is concluded the article 182 (2) of Taiwan (ROC) Civil Procedure Code: Except as otherwise provided, the provision of the preceding paragraph shall apply mutatis mutandis to cases where

economic expediency. Because the proceedings are time consuming, even the party that wins the case in the final trial may end up losing, from the economic perspective, because of delayed justice.

In view of this, to solve disputes quickly and with economic effectiveness, article16 (1) of ROC (Taiwan) Intellectual Property Case Adjudication Act clearly stipulates that:27 When a party claims or defends that an intellectual property right shall be cancelled or revoked, the court shall decide based on the merit of the case, and the Code of Civil Procedure, Code of Administrative Litigation Procedure, Trademark Act, Patent Act, Species of Plants and Seedling Act, or other applicable laws concerning the stay of an action shall not apply. However, the judgment effect of patent rights made from the intellectual property court, since it does not apply to "the theory of issue preclusion" stressed in Civil Action, the approach may be different. According to article16 (2) of ROC (Taiwan) Intellectual Property Case Adjudication Act,[28] the judgment made by intellectual property court only has the relative effect of an individual case, not the relative effect of a common case. As a result, the judgment made by the intellectual property court (judicial authority) has no binding force on the intellectual property bureau (administrative authority). The party concerned must also file a report or revocation to the intellectual property bureau with the same evidence if there is a discrepancy between the administrative handling of the intellectual property court and the judgment made by the intellectual property bureau.

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the existence or non-existence of a legal relation is to be determined by an administrative proceeding. The article 90 (1) of Taiwan (ROC) Patent Act: For any civil proceedings pending in a court in connection with an invention patent, the court may suspend the trial process until a decision on the patent application, invalidation, or revocation action related thereto has become irrevocable.

[27] Article16 (1) of Taiwan (ROC) Intellectual Property Case Adjudication Act: When a party claims or defends that an intellectual property right shall be cancelled or revoked, the court shall decide based on the merit of the case, and the Code of Civil Procedure, Code of Administrative Litigation Procedure, Trademark Act, Patent Act, Species of Plants and Seedling Act, or other applicable laws concerning the stay of an action shall not apply.

[28] ROC (Taiwan) Intellectual Property Case Adjudication Act, Article16 (2)：Under the circumstances in the preceding paragraph, the holder of the intellectual property right shall not claim any rights during the civil action against the opposing party where the court has recognized the grounds for cancellation or revocation of the intellectual property right.

C. The Legal Background of Patent Law in Taiwan-The Differences among the Judgments of Different Trial-Level Courts

As stated above, the patent rights system has both a private and public law, and therefore two kinds of legal character. When patent holders exercise their exclusive patent rights late in the proceedings, it is of private law character. As to the patent rights claims regarding judgments of effectiveness and infringement, these depend on the professional knowledge of professionals involved in the substantive review. Therefore, theoretically, according to article 17 (1) of ROC (Taiwan) Intellectual Property Case Adjudication Act, "the court may, whenever necessary, order the competent intellectual property authority to intervene in the action" to express the professional comments on patent right effectiveness.[29] As a result, the judicial department may come up with a consistent judgment regarding the disputes on patent right claims, their effectiveness, and, when applicable, infringement. However, since the litigation system of Taiwan applies both civil and criminal law, when the common civil courts handle patent infringement litigations, the judgment of the intellectual property right infringement does not apply due to "the theory of issue preclusion," which stresses the jurisprudence of Code of Civil Procedure. Thus according to article 16 (2) of ROC (Taiwan) Intellectual Property Case Adjudication Act, the patent judgment of the intellectual property court will only have relative effects case by case, not absolute effects in general cases.[30]

Article 16 (2) of the ROC (Taiwan) Intellectual Property Case Adjudication Act allows the patent judgment of the intellectual property court to only have relative effects case by case, not absolute effects in general all cases. This can block situations such as that in which the party pursuant deliberately files tiresome proceedings on the civil and administrative sides simultaneously simply to hamper and wear down the opponent, waste their time, and keep them and their product out of the market. In this way the party concerned might not be able to settle the two disputes at the same time. As a result, the relation between the procedural justice and substantive justice become unbalanced. In addition, since the patent infringement civil action and patent report administrative action are governed by the intellectual property court, the courts must examine the effects of the same patent one after another, even when the evidence and arguments are identical. This wastes time, money, and resources, as the intellectual property issue the court has already made a judgment on. Sending the same case through the civil action court

[29] ROC (Taiwan) Intellectual Property Case Adjudication Act, Article17 (1)：To rule on the claims or defense raised by a party pursuant to the first paragraph of the preceding article, the court may, whenever necessary, order the competent intellectual property authority to intervene in the action.

[30] Lu-Lin Hung, Intellectual property case adjudication act (June, 2009), (unpublished LL.M. thesis, National Chengchi University) (on file with author).

and administrative action court might lead to differences between the judgments. Especially when the evidence and reasons are slightly different, the judgment on patent right effects may be inconsistent, leading to a tangled and complex legal predicament that could become even more difficult and time consuming to resolve.

To sum up, the design of the patent rights, according to the article17 (1) of the ROC (Taiwan) Intellectual Property Case Adjudication Act states that: "the court may, whenever necessary, order the competent intellectual property authority to intervene in the action." Theoretically, this may help avoid different judgments in different courts, however, because Intellectual Property Case Adjudication Act may not apply "the theory of issue preclusion" stressing jurisprudence of the Code of Civil Procedure, according to article 16 (2) ROC (Taiwan) of Intellectual Property Case Adjudication Act, it may allow patent judgments of the intellectual property court to only have relative effects case by case, not widely applicable general rulings. This will cause the judgment of the intellectual property court regarding the disputes on patent right claims to lack binding power in civil actions. In addition, administrative actions at a later stage in the proceedings will very probably lead to different judgments in court.

D. The Legal Background of Patent Law in Taiwan - Under the Globalization Trends, The Conflicts between National and Transnational Laws

Along with the rapid development of technology, the political, economic, social and cultural environments are changing too, and have led to effects which can cross national boundaries and accelerate the exchange and integration of related information, capital, commodities and labor among countries. As a result, the barriers of traditional national boundaries have gradually disappeared and been replaced with the borderless global village of the globalization era. Due to globalization, international legal affairs are becoming more diversified, which especially reflects on human rights, labor affairs, international trade, international finance, E-commerce, intellectual property rights, medicine and health, environmental protection, judgment and arbitration of foreign courts, etc., that together comprise the scope of Transnational Law.[31] Thus when law regulates the legal subject norms, activities, and behavior over national boundaries, it is not only

[31] Oxford Dictionary defines globalization as, "extending beyond national boundaries", quote in Thompson, The Concise Oxford Dictionary of current English, 9th ed, Oxford University press 1995, p1483. In addition, Harold J, Berman asserting that "world law" underpinning global civil society along the lines of common law, it is also includes Judge Philip's concept of "transnational law", cited by Harold J, Berman, "The Role of International Law in the Twenty-first Century: World Law", 18 Fordham Inte'l L.J., 1995, p1617, p1621. In this article, either "world law" or "global law" is collectively known as the "transnational law" to avoid confusion.

limited to International Public Law or International Private Law, but also includes other laws.[32]

Nowadays, under the rapid changes of the globalization, a complicated and diversified set of social value norms have appeared on the surface that often conflict with the legal systems between national and transnational laws. In fact, to look into the conflict between national and transnational laws, the logic hidden behind them is like the Laws of Physics; the point is not the individual elements made up by atoms or molecules, but the interaction formed by permutations and combinations between atoms and molecules. For instance, the reason why the carbon atoms that make up diamonds do not give light themselves is because the special permutations and combinations in the structure of the carbon atoms to give out the sparkle.[33] In other words, national laws truly contain the elements that make up the international social structure; however, many National Law member countries signed transnational legal agreements with one another to set up the rules of the game based on mutual interests to maintain order in an international society. The contents of these laws may have nothing to do with the specialty of the national law. In view of this, how to adjust the gap between national laws and transnational laws to connect them has become an important issue worth further discussion.

Actually, the acquisition of patent rights and judgments of patent infringement belong different institutions, the Intellectual Property Bureau (administrative department) is in charge of the patent issuance, and the Intellectual Property Court (judicial department) is in charge of the patent infringement. As a result, the judgement conflicts between the Intellectual Property Bureau (administrative department) and the Intellectual Property Court (judicial department). In addition, the judgement conflicts are not only seen in national cases, but also happened at transnational area. For example, article 138(1) of the 1973 Convention on the Grant of European Patents (EPC) stipulates the reasons why certain European patents are invalid. But the recognition of the effects of governing disputes, examining the courts, etc., depends on the regulation of domestic substantive law and procedural law among the membership countries. Currently EPC has 38 members, so when there is a dispute regarding patent effects, the laws of more than 30 countries may be applicable. Thus the conflicts among transnational laws for the trading partners of the patent legal cases are very likely to cause uncertainty.

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[32] Judge Jessupin Storrs Lectures, Transnational Law, 1956, "to include all law which regulates actions or events that transcend national frontiers. Both public and private international laws are included, as are other rules which do not wholly fit into such standard categories [as pure domestic laws]."

[33] MARK BUCHANAN, THE SOCIAL ATOM: WHY THE RICH GET RICHER, CHEATERS GET CAUGHT, AND YOUR NEIGHBOR USUALLY LOOKS LIKE YOU (2007).

IV. Nowadays, the Patent Dispute Solution in Taiwan High Tech Industry -The Misuse of the Dispute Solution Mechanism by the Patent Holder

A. The Legitimacy of Judgment for Solving Patent Disputes-Equity Law

Equity law is used as a medium to remedy the change between the law and the social environment.[34] To speak from the standpoint of statute law, equality law not only explains and supplements the law, but also helps support ideas of fairness and justice.[35] Thus it is possible to solve some problems based solely on the principles of equality law.[36] Furthermore, in physical civil law, the judge may cite equality laws as judge-made[37] like the case of the court of chancery in England, in which the judge reached judgment based on customary law at the end of 15th century, which later on developed into the Doctrine of Unclean Hands and Doctrine of Laches, and Estoppel such cases related to equality law.[38] In addition, in the Code of Civil Procedure, the judge may order the defendant to make compensation and rehabilitation, or issue an Injunction Order or forbid the disposal of property or a similar multi legal remedy. In view of the constant stream of changes in high-tech technology day after day, the existing law will never be able to fully synchronize with the high-tech development and advance with the times. As a result, the federal courts usually take the "Equity Law" as standard when facing patent dispute cases, using "judge-made law" to meet the problem, the implementation of a patent, the competition and combination between patents, anti-trust legal principles, or to connect equity law principles with modern technology enterprises. Accordingly, sending a Cease and Desist Letter, application Injunction, petition for arbitration, and filing for lawsuits are ways to seek solutions to patent disputes. Regarding the dynamic equilibrium of the patent legal system, whether they will comply with the requirement of the equity law is an issue worth further exploration.

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[34] HSIAN YUEN HO, *THE PRINCIPLE OF GOOD FAITH AND EQUITY LAW*, Taipei: San Min Bookstore Co, Ltd, 2-6 (1992).

[35] Ibid

[36] WOLFGANG. FRIEDMANN, *LEGAL THEORY*, 5Th Ed, New York: Columbia University Press, 1967, 533 (1967).

[37] Mao Zong Huang, *Legal Method and Modern Civil Law*, NTU Legal Science Collection, Taipei: National Taiwan University, 375-383 (1987). Ian, Mcleod, *Legal Theory*, 5th Edition, Basingstoke: Palgrave Macmillan Limited, 160 (2010).

[38] Hsian Yuen Ho, supra note 34, 157-164 (1992).

B. The Improper Use of Warning Letters is against the Anti-Trust Law

When a patentee discovers a patent has been infringed, before bringing the case to the court, a warning letter will usually be sent to the other party. In addition to pointing out which patent items have been infringed, the other party will be asked to stop making, using, and selling such items. If the situation carries on, a lawsuit will be filed and compensation or damages will be sought. The legal effect of the warning letter is deemed a notification, which is important in the proceedings since, upon receipt of such a letter, the patentee assumes the other party has learned about the patent infringement, so on judgment of any damages or compensation, it is difficult for the accused party to prove they are unaware of the matter or at fault. If the defendant does not receive said cease and warning letter before the filing of the lawsuit, then the starting point of the damages or compensation will become effective from the date of receipt of the complaint. If the defendant has received the letter, then the compensation will begin from the date the letter was received. Therefore, the defendant must be careful on receipt of the warning letter. It should not be thrown away or disregarded. If the court decides this case is "willful violation" then the defendant is likely to pay a fine for compensation up to triple penalties. It is also possible that the court considers the defendant to have tacitly agreed, based on the inner conviction system, so a short and precise response from the defendant is necessary.

However, to make the warning letter a notification with legal meaning, it must comply with certain conditions. According to the regulations of U.S. Patent law:[39] A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such a process was used. A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such a process was used. After sending the letter, the patentee shall contact the opposite party actively without the conditions stated on equity law as: laches or inequitable estoppel, otherwise, even though the court considered there was patent infringement evidence, they will not make a judgment to ask the defendant for damage compensation. In a manner likewise, the patentee sent a cease and desist letter to the competing customer to cause the improper interference in business has obviously gone over the necessary procedure of patent rights protection, and this not only commits the business behavior condemnation, but also affects the market

[39] 35 U.S.C. 287(b)(5)(B): A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder's belief, except that the patent holder is not required to disclose any trade secret information.

trading order, which apparently is in violation of Article 24 of the Fair Trade Law R.O.C. (Taiwan).[40]

C. The Improper Use of an Injunction Order is in Violation of the Equity Law

In patent dispute cases, since they are time consuming, it is unlikely to offer the patentee an instant and efficient relief mechanism. As a result, when other competitors come into the market, to efficiently prevent such competitors from coming into the market, the patentee will usually take the "Exclusion of Infringement" to file at the court for provisional seizure and sequestration, and ask the court to issue an Injunction Order to prevent the competitor from making, using and selling such items temporarily. This is a judicial relief mechanism and market competition strategy approach. However, the shelf-life of high-tech products is usually very short, and any profit in such products lies in the rapid time to market. Thus, once the court has issued an Injunction Order to stop a competitor from making, using and selling a disputed item, the competitor may suffer from losing business opportunities due to the short shelf-life of their product or forced to withdraw from the market due to natural selection. According to whether the design and operation of the Injunction Order is good or bad, this will affect the patentee's legal interest as well as the fairness of the third party to compete in the market. Thus, when the court issues the Injunction Order, it is especially important to consider carefully the principle of equity between the patentee's legal interest and the public interest of fair trade.

To the common law system of the Anglo-American Law, the judgment of the common law system or equity law system on the substance the lawsuit usually lays on the relief requested by the plaintiff. If the plaintiff appeals to the court for damage compensation or reinstatement from the defendant, then it is a common law relief, however, if the plaintiff asks the court to issue an Injunction Relief, then it is an equity law relief, so the issuance of the Injunction Relief originates from equity law policy. According to the regulations of the Federal Rules of Civil Procedure (FRCP), the Federal Court may issue one of three injunction orders: 1.A Temporary Restraining Orders (TRO), 2.A Preliminary Injunction Order, 3.A Permanent Injunction Order. Of the three, a Preliminary Injunction has the most significant impact on the rights of the patent dispute party, because it will both increase the litigation costs of the competitor and irreparable damage will occur. Therefore, Article 65(a) of the Federal Rules of Civil Procedure stipulates that whether or not to issue a Preliminary Injunction depends on five factors: 1. Notice,

[40] Article 24 of the Fair Trade Law, *R.O.C.* (*Taiwan):* No enterprise shall, for the purpose of competition, make or disseminate any false statement that is capable of damaging the business reputation of another.

2. Hearing, 3. Security, 4. Reason, 5. Scope on Injunction. First, the court must notify the opposite party when issuing a Preliminary Injunction, because if it fails to serve the appropriate notice, any subsequent legal affairs may be deemed invalid. Next, the court shall call a hearing for substantive examination when issuing a Preliminary Injunction. Then, the court shall ask the petitioner to provide a certain amount of security to compensate for any losses of the party concerned for improper restriction when issuing a Preliminary Injunction. In addition, the court shall have a good reason when issuing a Preliminary Injunction to explain the approval conditions and the restricted scope reasonably. The regulation of procedures of the Federal Rules of Civil Procedure of the U.S. has authorized the court to reach a judgment according to the case. In 1983, the United States Court of Appeal for the Federal Circuit (CAFC) for the case of Smith International, Inc. vs. Hughes Tool Co., clearly pointed out four standards when issuing a Preliminary Injunction, which are: 1. The plaintiff must prove it is possible to win the case; 2. The plaintiff must prove that if the Injunction is not approved, the plaintiff will suffer an irreparable loss; 3. The court has considered and compared the advantage and disadvantage, the gain and loss of the plaintiff and the defendant, and that the equity law relief is proper and reasonable; 4. The court approved Preliminary Injunction will not jeopardize the public interest.

D. The Improper Use of Long Proceedings is in Violation of the Substantive Justice

Along with the coming of the knowledge-based economy and the globalization of industrial competition, the technology enterprise operation environment is changing every minute. A major concern of the operational strategies of high-tech enterprises is how to obtain intellectual property rights and to protect, expand, and apply the same. In considering economic rationality, the major concern of business managers is how to maximize the technical effects and make the technique commercialized, and put such techniques into patent product within the short shelf-life of a product. Only by doing so can an enterprise gain an advantage in the market and take a leading place therein, and also upgrade its global competitive ability.

However, in reality, due to the law stressing the maintenance of “procedure justice”, patent dispute solutions for the high-tech enterprises must carry out the multi-level of the court procedure. However, patent dispute cases often involve highly technical issues in a complex legal field, and such a long procedure for seeking legal relief is time consuming, so any delays in the timing could mean that the patentee loses business opportunities due to the short shelf-life of their product, such that even if the case is successful, all patentee got was a debt certificate with a regret of “delayed justice”. Under the constant change of all kinds of factors and social conditions, the question of how to regulate procedural justice and substantive

justice and realize legal distributive justice is concerned both with people's trust in fairness and justice and also profoundly influences any upgrades to the global market competition of high-tech enterprises.

It is true that the fairness and justice of the pursuit of law depends on the realization of procedural justice and substantive justice. The two complement each other, like two wings of a bird and four wheels of a vehicle to. However, in search of fairness and justice, it is inevitable that the results of legal inferred logic often deviate from subjective common sense and any prevailing values, even as mentioned above, several high-tech personnel, upon legal economic analysis, and because of their wealth and financial status, and core technology, and use them as weapon with which to attack competitors by means of long and tiresome lawsuits. All kinds of abuse of rights and the misuse of legal prosecutions go against the goals of design and the core values of the patent rights system, and they also violate the principle of fair competition in the market.

V. Conclusion: Arbitration as the Best Option based on Procedural Justice and Substantive Justice

In practice, patent dispute resolution is nothing more than a warning letter by mail, requesting a preliminary injunction, and applying for arbitration and litigation. From a legal-economic viewpoint, a warning letter by mail is a minimum cost option with maximum effectiveness, but it will violate the anti-trust law[41] if the warning letter is used improperly. Therefore, it is clear that a warning letter by mail is not the best option under considerations of substantive justice and procedural justice. Requesting a preliminary injunction is in a similar category to the warning letter by mail, since any court injunctions must comply with equity law.[42] As a result, it is again clear that the requesting of a preliminary injunction is also not the best option under considerations of substantive justice and procedural justice. Since products with short life-cycles require rapid time to market, and litigation takes a long time to complete, it leads to the situation of 'justice delayed is justice denied', even if the parties will file the lawsuits after all. Consequently, litigation is also not the best option under considerations of substantive justice and procedural justice. Nevertheless, arbitration is superior to the sending of a warning letter and the preliminary injunction strategy in terms of the rule of res judicata, although it is not superior when considering the time and cost of such action. Arbitration is superior

[41] 35 U.S.C. 287(b)(5)(B): A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder's belief, except that the patent holder is not required to disclose any trade secret information.

[42] Smith International, Inc. v. Hughes Tool Co.,718 F.2d 1573, 1581 (CAFC 1983).

to litigation in terms of time and cost, and on par when considering res judicata. Evidently, arbitration is the best option under considerations of substantive justice and procedural justice when compared to warning letters, preliminary injunctions or litigation. It is true, the parties in the patent dispute solution were considering the "Economic Rationality", and the parties tried every legal relief means in the name of "Legal Rationality", which included filing civil and administrative litigation in Taiwan or demanding that the United States International Trade Commission (ITC) should promulgate an injunction. The attack and defense on all kinds of legal relief in the process of legal actions by the above mentioned both parties may have fully explained how their industrial strategy had the double considerations of "Legal Rationality" and "Economic Rationality". Doubtlessly, the final settlement was the best choice in the zero-sum game. In the viewpoint of this article,[43] if the parties apply for arbitration at the beginning of any disputes, it may save more time and costs in substantive justice, and may also comply with the due process of law.

[43] Article 35 U.S.C. 287(b)(5)(B)

REFERENCES

Book/ Journal

[1] Yu-Shu Zhang (2006), A Comment on the draft of Intellectual Property Case Adjudication Act and related to Protective Order – Discussion on US Legal Practice Models, The Taiwan Law Review, Vol.139 Taipei: Angle publishing Co Ltd.

[2] Chung Hsin Chang (2007), The Progress Toward the Establishment and Operation of Taiwan Intellectual Property Court, Taiwan Bar Journal, Vol.11 (4), Taipei: Taiwan Bar Association.

[3] Godelier Maurice 1972 (1966), Rationality and Irrationality in Economics, The Translated from the French by Brain Pearce, New York and London, Monthly Review Press.

[4] Wei-Ming Liao (2003), Preliminary Study of the International Law in the New Century – Legal Theory and Legal Education Consideration , MCU Law Review, Vol. I, Taipei: Ming Chuan University.

[5] Philip Luo (2003), Designing Around of Patent Infringements, Topics on Industrial Property, Self-Published Authors.

[6] Hung Lu Lin (2008), Intellectual property case adjudication act, Master of Laws theses , Faculty of Law, National Chengchi University [unpublished].

[7] Mark Buchanan (2007), The Social Atom: why the Rich Get Richer, Cheaters Get Caught, and Your Neighbor usually Looks like You.

[8] Hsian Yuen Ho (1992), The Principle of Good Faith and Equity Law, Taipei: San Min Bookstore Co.

[9] Wolfgang. Friedmann (1967), Legal Theory, 5Th Ed, New York: Columbia University Press.

[10] Mao Zong Huang (1987), Legal Method and Modern Civil Law, NTU Legal Science Collection, Taipei: National Taiwan University.

[11] Ian, Mcleod (2010), Legal Theory, 5th Edition, Basingstoke: Palgrave Macmillan Limited.

Website

[1] Patent Assertion AND U.S. Innovation, Executive Office of the President, June 2013. Data available at: https://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf. (Visit Date: 2016.02.20).

[2] Fiona Scott Morton, Carl Shapiro (2014), 79 Antitrust Law Journal, No. 2, pp.463-499. Data available at: http://faculty.haas.berkeley.edu/shapiro/pae.pdf. (Visit Date: 2016.02.20)

[3] Qualcomm Files Arbitration Demand Against Nokia to Resolve Dispute Over License Agreement), data available at: http://www.qualcomm.com/press/releases/2007/070405_files_ arbitra tion _ demand.html, (visit date: 2008.06.20)

[4] Lin Yeu Chu (2002)，The Arbitration of High Tech Industry, Industry analysis – ProMOS Co Ltd , data available at: http://www.promos.com.tw/website/chinese/industrylist.jsp?id=1025600004727 (visit date: 2008.06.20)

Justifying The Case Of John Moore V Regents Of The University Of California From A Gewirthian Perspective

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ABSTRACT

The case John Moore v Regents of the University of California sets a precedent as to the relationship between human body parts and property rights. In this case John Moore was not successful in claim a right to his own body parts once they had been removed for research purposes and the question has to be raised whether this decision indicates that every part of the human body manipulated through modern biotechnology cannot be regarded as the property of those from whom the information originated. This article will discuss the issues of ownership and consent to uses made of genetic material from a Gewirthian perspective. Gewirth's thesis is that every agent, by the fact of engaging in action, is logically committed to the acceptance of certain evaluative and deontic judgements and ultimately of a supreme moral principle, the Principle of Generic Consistency (PGC), which is addressed to every agent: Act in accord with the generic rights of your recipients as well as of yourself. From the examination of the Moore case under the PGC, the decision made by the Supreme Court has seriously infringed Moore's human rights. It is submitted that Moore should be accorded his human right and be rewarded the royalties in accordance with the market value created. A new form of human rights, incorporated into intellectual property rights, can resolve issues relating to informed consent issues, not just in respect of community rights but also for individuals.

Keywords: *John Moore v Regents of the University of California*, ownership, Gewirthian, Principle of Generic Consistency, PGC

I. Introduction

For the past few years, many fundamental questions have been brought up in public in respect of the commercial exploitation of parts of the human body. The questions are: can parts of the human body be claimed as the subject matter of a property right such as a patent? Is it right to patent parts of the human body? Is it morally justifiable to regard parts of the human body as commercial commodities? The *Moore* case sets a precedent as to the relationship between human body parts and property rights. In this case John Moore was not successful in claim a right to his own body parts once they had been removed for research purposes and the question has to be raised whether this decision indicates that every part of the human body manipulated through modern biotechnology cannot be regarded as the property of those from whom the information originated? If so, who can decide whether to grant rights to researchers and how can this be done?

In addition to the question of ownership, another question is , what kinds of rights can be awarded over human genetic material? Moreover, there are increasing public worries about the whole issue of the production of gene products involving human genetic material, and in particular the extension of the research to human beings themselves. It is therefore necessary, in addition to the consideration of the right of ownership, to ask should the impact and consequences of the science and intellectual property rights be considered as important factors relating to society as a whole. Whether or not these answers can fully be found in the decisions made by the court is one thing, the important question for discussion is whether all related issues have been comprehensively expressed in relation to human integrity.

II. The Facts of the Moore Case

The case of *Moore vs. Regents of the University of California* is one of the most important cases[1] in relation to commercial exploitation of parts of the human body through modern biotechnology.[2]

In this case, John Moore was a cancer patient who had been suffering from hairy-cell leukaemia. He had received medical treatment at the UCLA Medical Center in October 1976. Because of his bad condition, Dr. David Golde recommended splenectomy surgery and obtained written informed consent from John Moore authorising the surgery.[3] A team of doctors removed Moore's spleen and subsequently used the spleen for some experimental purposes.[4] Before and after the surgery, Dr. Golde and his hospital researcher, Shirley Quan, took samples of Moore's blood, bone marrow and other bodily substances They told Moore the samples were to be used for diagnosis and monitoring the surgery but not that they would be used for research.

The medical team soon realised from their research on Moore's tissue that "certain blood products and blood components were of great value in a number of commercial and scientific efforts"[5] and that access to a patient whose blood contained these substances would provide a "competitive, commercial, and scientific advantage".[6] However, they had no intention of informing Mr. Moore that his spleen and other cells were commercially useful and could be exploited via the research being undertaken.[7]

Later, following the surgery, the spleen tissue was bred into cell cultures and then developed into a new cell line. In order to confirm the success of the cell line, the researchers removed additional samples of Mr. Moore's body products. Dr Golde took samples of blood, blood serum, skin, bone marrow aspirate, and sperm during the next few years following the surgery when Mr. Moore returned to the UCLA Medical Center for post-operative treatment. The research team filed for a patent on the cell line and on March 20th, 1984 the University of California, Dr

[1] The Moore case is the only case to directly address the property rights of genetic material; there are other cases which are indirectly related to this issue such as Davis v. Davis, Hecht and the Devise of Sperm and Kass v. Kass. See Seeney, Erik B. 1998. "Moore 10 years Later-Still Trying to Fill the Cap: Creating a Personal Property Right in Genetic Material". New England Law Review. 32:1131-1191.

[2] See Boulier, W. "Sperm, Spleens, and other Valuables: The Need to Recognize Property Rights in Human Body Parts". Hofstra Law Review. 23: 693-731(1995).

[3] See Moore v. Regents of the University of California (1988) 249 Cal. Rptr, at 495.

[4] Moore v Regents of the University of California 793 P. 2d at 481(1990).

[5] See ibid at 479

[6] See ibid at 479

[7] See Gold, Richard. 1995. "Owning Our Bodies: An Examination of Property Law and Biotechnology". San Diego Law Review. 32: 1203(1990).

Golde and Ms Quan were granted U.S. patent No. 4438032.[8] The cell line was named the "Mo cell line."[9] Subsequently, the patent was used as the basis of a licensing agreement with the Genetics Institute and Sandoz Pharmaceuticals. The agreement included large licensing fees payable to the patent holders in return for the right to commercial development of the cell line and its by-products. Undoubtedly, the University of California, Dr Golde and Ms Quan profited from the Mo cell patent.[10]

When Mr Moore realised that a patent had been obtained over a product which originated from his own tissue, he took legal action against the University of California. His action had 13 causes, including conversion, lack of informed consent, breach of fiduciary duty, fraud &deceit, unjust enrichment, quasi-contract, bad faith breach of the implied covenant of good faith &fair dealing, intentional infliction of emotional distress, negligent misrepresentation, intentional interference with prospective advantageous economic relationships, slander of title, accounting, and declaratory relief.[11]

The California Superior Court rejected Moore's claim and upheld the defendants' demurrers[12] stating that, "there was no recognized cause of action for the claim ownership] and the court did not intend to create a new cause of action."[13]

Moore appealed to the California Court of Appeal.[14] In this second trial, the Court recognised a "right of commerciality"[15] in human tissues and a patient's property interests in parts of his own body, such as the cornea and bodily wastes. As Moore has not specifically abandoned his spleen by undergoing a splenectomy, he retained a right to the control of his own body and a property interest in his cells. In addition, the appeal court held that the oppositions of the defendants to the claim of conversion were "*improperly sustained because the plaintiff had adequately*

[8] See David W. Golde & Shirley G. Quan, U.S. Patent No. 4,438,032. (March 20, 1984) (Patenting a unique T-Lymphocyte line and derivtive products)

[9] Moore v. Regents of the University of California (1988) 249 Cal. Rptr, at 494, 501.

[10] According to agreement, Genetics Institute have to pay a number of sunstantial benefits including the rights to 75,000 shares of Genetics Institute common stock, a three years grant for at least $444,000. In addition, in 1982, The Regents and Golde received $110,000 by adding Sandoz to the agreement. See Appelbaum, B. 1992. "Moore V. Regents of the University of California: Now that the California Supreme Court has Spoken, What Has It Really Said?" Journal of Human Rights. 9: 504-505.

[11] Moore v Regents of the University of California (1990) 793 P. 2d at 482.

[12] Moore v. Regents of the University of California (1988) 249 Cal. Rptr, at 494, 502 (summarizing the holding of the trial court) (1988)

[13] See ibid (1988)

[14] See ibid (1988)

[15] See ibid, at 507 (1988)

stated a cause of action for conversion"[16] and the decision of the Superior Court should be overruled.[17] The patent holder, in turn, appealed this decision.

The decision of the Appeal Court was reversed by the Supreme Court of California.[18] In this final decision, the Supreme Court ruled that a person has no legally protected rights nor any ownership interest in tissue removed from his body and the Court denied Moore's claim for property rights over his own body. In respect of the assertion that Dr. Golde's actions had resulted in conversion (wrongful interference with another person's property), which raised questions of who actually has the right of ownership of the tissue removed from the human body; the Supreme Court of California ruled that:

"Moore had no property rights in cells taken from his body, but remitted for trial the issue of whether the doctors had been in breach of the duty to obtain Moore's informed consent and of the duty of loyalty to Moore as their patients."[19]

According to the case report, four main arguments were used by the majority in rejecting Moore's allegation that his property rights had been infringed. The main points of the four arguments were in brief, as follows:[20] Firstly, there was no precedent for the Supreme Court to follow in order to develop the law in this case. Secondly, the issue of who own body parts and any interests in those parts was a matter more appropriate for legislation. Thirdly, the patent granted to the University of California meant that they had an exclusive right to preclude Moore from a share of the profits. The fourth reason is that not all parts of the body should be open to claims of property rights; otherwise scientific progress would come to a halt. The court thought that if medical research could only be conducted after having obtained agreement from the patient, then it would be possible for a patient to bargain for the price of his body tissue until the price satisfied him. If these rights were held to exist then they could act as a barrier to research and the public would cease to benefit from medical research. Because of on this Moore could not succeed in his action. .

A review of these arguments suggests that they are somewhat unconvincing, yet the majority relied upon these four "reasons to doubt" Moore's claim. However, the court decision was not unanimous as Justice Mosk dissented. He argued that though there was a lack of precedent, the Supreme Court possesses the responsibility to make new law where necessary. Secondly, the highest court has a role to play in the development of the law. Thirdly, the patent granted to the

[16] See ibid, at 502 (1988)
[17] See ibid, at 500-01 (1988)
[18] Moore v Regents of the University of California (1990) 793 P. 2d at 482.
[19] See ibid, at 481 (1990).
[20] See ibid.

University of California which had the effect of completely excluding Moore from enjoying any benefit whatsoever from the use of his cell line, was incorrectly awarded in that it instinctively conflicted with any notion of fairness.

There are two significant features which should be noticed in the decision of the Supreme Court. The first is the Lockean labour-added theory of property. The second is the breach of fiduciary duty and lack of informed consent.

III. Lockean Labour-added Theory of Property

By rejecting Moore's claim to a property right in his body parts the Supreme Court favoured a Lockean theory of property which they used to exclude Moore from a share in the profits from the Mo cell line patent. The Lockean concept of property, simply stated, is that property is viewed as an extension of the individual who created it. The right to that property arising out of the fact that it required some physical or mental labour to create it. In the *Moore* case as it was the medical staff's effort which contributed 'labour' in using their research skills to transfer raw genetic materials of Moore's cells into a useful and medically valuable cell line they had the right to the property resulting from the use of those skills.

The Supreme Court therefore maintained that "Federal law permits the patenting of organisms that represent the product of 'human ingenuity', but not naturally occurring".[21] The Supreme Court focused on the development of the of Mo cell line rather than on the removal of the cells from Moore. It was this focus which leads them to think that Moore could not have a property right in the cell line as he had not intellectually contributed anything to its development. A patent is usually granted to the inventor. The Court considered whether Moore could be regarded as an inventor and decided that as he had not done anything to discover his cells' function or to improve their utility, nor had he helped in the research which transformed his tissues into a patentable cell line.[22] Then he could not be regarded as an inventor. It was for this reason that Moore was excluded from ownership of the patented cell line because a) the cell line was considered new and different from his own natural cells and b) he had contributed nothing to the creation of the new cell line. On one level the reasoning of the Court may appear reasonable where the sole ethical issue is the use of removed or discarded parts of the human body for medical research purposes but this is not the only consideration. There is also an argument that he should have inalienable property rights to the ownership of his own cells.

[21] See ibid, at 159.

[22] The court held that "the goal and result of defendants' effort has been to manufacture lymphokines. Lymphokines… have the same molecular structure in every human being…; it is no more unique to Moore than the number of vertebrae in the spine or the chemical formula of hemoglobin." See ibid, at 490 (1990).

The decision can also be challenged from the view of the application of the technical criteria and in particular inventive step. These techniques used to developing the Mo cell line were just common techniques of cell culture which most technicians would be expected to possess.[23] Neither specific techniques nor specifically designed machines were involved in the research on Moore's cell line, indeed all the techniques can be found in general cell culture textbooks. For this reason it can be argued that what the researchers did was not sufficiently inventive to justify the granting of a patent. It has been contended that it is wrong to consider a patient who has had cancerous tissue removed like Moore should not be entitled to have any right of his removed body parts even if it is used for research purposes.[24] Even though the material has been removed from body, it could be argued that "the moral significance of body parts remains even when they are separated from their original source."[25] Notwithstanding, the Supreme Court's ruling, the issue of individual interest of body rights in this case still lacks clear justification. Clarify this point; it could be argued that there should be a clear principle of fundamental equity. It is a matter of personal interest to the patient to protect his fundamental rights. One feasible way to resolve the problem is to design a legally secure form of consent model. A legal agreement of permissible form of consent model could be made in legal framework.

The Court did not consider the profits which Moore could obtain from his own cells, although it did consider that Moore was, to a certain extent, entitled to sue the medical staff who had failed to sufficiently inform him of the proposed use of his removed spleen cell including filing for a patent. Moreover, it should not be forgotten that in this case, a key issue discussed in court was whether Moore was entitled to participate in the process of pursuing intellectual property rights that derived from his removed cells. The Court, therefore, had to concentrate on the detailed examination of whether or not Moore has given up his control over the removed cells and whether he had done anything to contribute to the invention of the cloned cell line. It has been argued that the U.S. Patent Office has no remit to decide on the consequence of granting a patenting over parts of the human body. Their function is to determine whether the technical granting criteria have been met. It is also

Relevant to note that the U.S. Patent system does not include a specific exclusion of inventions which would be contrary to morality. Hence, in view of the above reasons, it is not difficult to understand why the Court has to concentrate on these criteria to the exclusion of other considerations such as issues of morality. Due to the lack of comprehensive considerations including an assessment of the

[23] This is a view based on my personal experience as a cell culture technician and also based on the overall review of the disclosure information of the Moore case.
[24] Laurie, Graeme. 2002. Genetic Privacy: A Challenge to Medico-Legal Norms. 317. (Cambridge: Cambridge University press).
[25] See ibid, at 318.

morality of granting the patent of *Moore* case cannot be used as convincing precedent. The US patent authority lost a great opportunity to set down appropriate criteria by which to determine ethical considerations when patenting biotechnological inventions.

Furthermore, apart from the use of known scientific techniques, there are two arguments which Moore could have used in support of his claim to a right in the patent. The first one is the immortal capability of cancer cells themselves and the second one is the idea that Dr. Golde used the immortal capability[26] to develop a rare cell line. Without the contribution of Moore's cancer cells, it would have been impossible for Dr. Golde to create a new cell line no matter how good the idea to create one is. If this argument is valid, then it follows that the California Supreme Court should not deny that Moore has made a greater contribution than Dr. Golde and should have right to share in the patent.

If a property right can be determined using the principle of contribution in which "distribution" of the right is determined by contribution and that contribution is such as to be taken to be part of the inventive act,[27] then, it is submitted, that Moore by his contribution of the tissue is also qualified to count as one of inventors. This analysis of the decision of the Supreme Court in *Moore* demonstrates why it is possible to argue that the current regime of applying the patent law to biotechnological inventions is not appropriate. The court neither attempted to move beyond a strict property analysis in order to protect Moore's overarching rights and interests. For this reason it is submitted that the Lockean theory of property is not necessarily the appropriate one to use.

[26] See David W. Golde & Shirley G. Quan, U.S. Patent No. 4,438,032. The main feature describes "Mo cell line" in the text of the patent as: "[a] cell line (Mo) has been established with spleen cells from a patient with a T-cell variant of hairy-cell leukaemia. The cells have been shown to be capable of continuous culture for an indefinite period of time, while maintaining the proteins…The cells provide a continuous source of the above proteins, as naturally modified which can be isolated by conventional ways. In addition, due to the constitutive production of the proteins, the cells provide either directly or indirectly, a source of the genes for the proteins of interest, which by conventional genetic engineering techniques, can be introduced into microorganisms for continuous large scale production of the proteins."

[27] See Gewirth, Alan, The Community of Rights. Chicago: the University of Chicago Press 204 (1996).

IV. Breach of Fiduciary Duty and Lack of Informed Consent

The Supreme Court stated that the spleen tissues had been taken from Moore's body under circumstances in which Dr. Golde was aware that there was tremendous potential research and commercial value in that tissue. "Moore clearly alleges that Golde had developed a research interest in his cells by October 20, 1976, when the splenecotomy was performed. Thus, Moore can state a cause of action based upon Golde's alleged failure to disclose that interest before the splenectomy."[28] The decision made by the Supreme Court considered "the patient's informed consent" as follows:

"First, a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment. Second, the patient's consent to treatment, to be effective, must be an informed consent. Third, in soliciting the patient's consent, a physician has fiduciary duty to disclose all information material to the patient's decision… These principles lead to the following conclusions: (1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgement; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty."[29]

The allegations of Moore's claim were not totally forsaken by the court. The court held that Dr. Golde had violated the fiduciary duty of a physician to a patient and he had not fully informed Moore of the financial potential of his tissues. "[A] physician who is seeking a patient's consent for a medical procedure must in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgement."[30]

The decision of the Supreme Court in *Moore* highlights numerous moral concerns about the patenting of human tissue. Many criticisms touched on commercial exploitation of the parts of human body and property rights. The scientific communities and biotechnological industries have studied this case closely. The outcome of the decision by the Supreme Court could have an enormous impact worldwide. "The court's ruling in *Moore* caused the biotech industry to heave a collective sigh of relief. Their worst nightmare- thousands of

[28] See Moore v Regents of the University of California (1990) 793 P. 2d at 486 (1990).
[29] See ibid, at 483.
[30] See ibid, at 485

tissue donors becoming part-owners in patented cell lines and other biotechnology patents and products- had been avoided."[31]

In the case of *Moore*, the conclusion of the Supreme Court could be justified if this requirement for fully informed consent had been met.[32] However, the requirement for informed consent may not apply or not be regarded as an important facet of the research process. One could ask whether the removal of human body parts through 'consent to medical treatment' equates to 'abandonment'. In light of the Nuffield Report, the UK position is now that 'tissue removed from donors is given free of all claims', and this has been given legislative approval through the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Anatomy Act 1984. If the abandonment thesis is officially used (notwithstanding that it is legally recognised) by doctors or scientists in most hospitals, then it would be difficult for patients like John Moore to claim a right over tissue once that tissue has been removed. As a result the abandonment theory has been officially sanctioned by health authorities (including hospital), despite the question marks which remain over the use of the abandonment theory in the context of the protection of inventions involving human genetic material.

A common feature to cases, such as the *Moore* case, is the moral concerns relating to property rights. As has been shown the Lokean theory is not appropriate and in the absence of a properly rigorous patent system there is a need for a more appropriate assessment of morality. It is argued that the Gewirthian theory is more apposite.

V. Applying Gewirth's Moral Theory-*PGC*

The chief novelty of Gewirth's argument is the logical derivation of a substantial normative moral principle from the nature of human action.[33] The connection between human action and normative moral principles has long been recognised. For example, virtue ethics theories emphasize that a virtuous person's ideas of the virtues connect ethics to action.[34] The role of one's character and the virtues that one's character embodies determine an evaluating ethical behavior. In Kant's categorical imperative maxims, the universal law states that '*Act only in accordance with that maxim through which you can at the same time wills that it* [*should*] *become a universal law*'.[35] Gewirth's thesis is that every agent, by the

[31] See Kimbrell, Andrew. The Human Body Shop: The Cloning, engineering, and Marketing of Life. Washington: Regnery Publishing, Inc (1997).

[32] The conclusion would be still in favour by the Court of Appeal and the dissenting minority in the Supreme Court.

[33] A. Gewirth, Reason and Morality (Chicago: University of Chicago Press, 1978) x.

[34] In western jurisprudence, most virtue ethics theories are derived from Aristotle who declared that a virtuous person is someone who has ideal character traits.

[35] Immanuel Kant, The Moral Law. Kant's Groundwork of the Metaphysic of Morals. Edited and

fact of engaging in action, is logically committed to the acceptance of certain evaluative and deontic judgements and ultimately of a supreme moral principle, the Principle of Generic Consistency (*PGC*), which is addressed to every agent: *Act in accord with the generic rights of your recipients as well as of yourself*.[36]

The major argument which structured Gewirth's theory is called 'the dialectically necessary method'[37] deducing evaluative statements from the internal viewpoint of a prospective purposive agent (*PPA*). Every rational *PPA* must logically accept that he and all other *PPAs* have rights to freedom and well-being, the generic rights referred to by the *PGC*.

A*PPA* is an agent who acts voluntarily for a purpose he has freely chosen and who has the capacity to exercise it and every *PPA* wants to be successful in his actions. Hence, freedom (the agent's ability to control his behaviour in accordance with his unforced choice) and well-being (the agent's ability to act successfully to realize his purposes) will constitute necessary goods for all rational agents. As for well-being, it has three levels: 'basic,' 'nonsubtractive,' and 'additive.' While basic well-being refers to preconditions of agency, such as life, health, and mental equilibrium, nonsubtractive well-being refers to the good of being able to maintain an undiminished capacity for agency (not being stolen from or lied to, for instance) and additive well-being refers to the good of being able to expand one's capacity for agency (for instance, by having education and earning an income).[38] And since no rational agent can accept being deprived of freedom and well-being, every rational agent must also claim rights to these necessary goods of agency.

Because the fundamental principle of the law proposed initially incorporates the *PGC* as a necessary criterion of legal validity in identifying of human rights, it is necessary to also discuss the justification for property rights through the use of the *PGC*. Under the *PGC*, property rights can be justified by reference to their role in protecting rights which are necessary for the advancement of "the work and the needs, the freedom and well-being, of the individuals, especially those who are most deprived and hence most in need of protection."[39] The protection of property rights, in accordance with the *PGC*, cannot be maintained just for the benefit of the rights of the community or the rights of the individual and this should be the main consideration in both the *Bioproperty Right* and patent law. The rights are granted using the principles set down in the *PGC* with human rights as the main consideration rather than the rights of the majority or the minority.

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translated by W. Wood (Yale University Press) 37 (2002).

[36] Reason and Morality, 135.

[37] Gewirth describes the dialectically necessary method as reflecting 'judgments all agents necessarily make on the basis of what is necessarily involved in action'. See ibid, at 44.

[38] Ibid, at.53-56.

[39] See ibid.

This view is entirely different from that of the utilitarian who dominate much of the current practical thinking on the concept of property rights. For a traditional utilitarian, property rights legislation should have been enacted in the most efficient way in order to enhance the operation of a market economy. However, merely considering the effect and impact of the economy obviously cannot be accepted by the international biotechnology community. This article argues that Gewirthian theory should replace the utilitarian approach to economic theory and property rights. In considering the issues of property rights in the *Moore* case, the question is: were the rights of John Moore compromised when looked from the perspective of the principles set down in the *PGC*?

Did the grant of the property rights to Dr. Golde, without obliging him to share that right with Moore, encroach Moore's human rights, given that the patented tissue and genetic information were taken from his body? It is argued that in applying for, and granting, the patent should the Dr Golde, together with his co-researchers, and the Patent Office should have justified the grant of a property rights using the universal morality proposed by the *PGC*. The *PGC* concerns the rights of the community and the rights of the individual. On conceptual grounds, the distinction between positive rights and negative rights is that negative rights let something happen or refrain from interference whereas positive rights seek to bring something about, or provide, active assistance. The *Moore* case can be analysed from four significant points using the *PGC*. 1) the right to private property 2) sufficient informed consent to a PPA's self-determination, 3) positive rights and 4) negative rights.

A. The Right to Private Property by the *PGC*

If Moore has the right to claim his removed tissues and genetic materials as his private property, then he has the right to claim a share in the patented cell line; if this is proved invalid, then will the ownership of his removed tissues belong to those who research into the genetic material, or, just shift the issue away, as the decision made by the Supreme Court appears to be saying?

Gewirth suggests the productive agency is entitled to have a right (both positive and negative) to private property, i.e. "exclusive powers to possess, use, transmit, exchange, or alienate objects."[40] Two arguments for property rights are proposed: the consequentialist and antecedentalist arguments. Gewirth suggests that "*the purposive-labor thesis*" of property rights through the generic rights of agency has its basis in the nature of purposive action itself. Thus, while productive agency develops certain abilities to approach their purposes, private property generated by the use of those abilities would be created. The consequentialist justification is universal and appeals to a "general right" of property, whereas the

[40] See ibid, at 166.

"antecedentalist" justification is particularist and applies to a "special right" of property.[41] The application of antecedentalist considerations is always under the control of consequentialist considerations as they have to be connected with positive rights.[42] Under the *PGC,* the mutuality and universality of the positive rights should be established under the principle: "everyone has the right to be treated in the appropriate way when she has the need, and when others have the relevant ability."[43]

The key to the concept of property has given agreement to the rule of preclusionary property. [44] The concept of the "rule-preclusionary" is to claim that "A owns P is the claim that A has a right to use *P* in any legitimate way and to exclude others (B) from using P, *for the reason that* A stands in a relation R to P that precludes A having to account on a case- by-case basis for A's right to use P and to exclude B from using P."[45]The adaptation of Gewirth's justification to rule preclusionary ownership of body parts by Beyleveld and Brownsword proposes that it is dialectically necessary to suppose that we own our bodies under the rule of preclusionary property. The considerations of "consequentialist" and "antecedentalist" of Gewirth purport to show that not to grant property control may have violated the *PGC,* thus property rights are granted by the *PGC*.

Moore's body and body parts (the Mo cell line) are metaphysically related to him, he acts through his body. It may affect his capacity to pursue his purpose successfully by depriving him of his body parts. It also violates his generic rights to remove his body parts for other purposes, without his consent. In taking Gewirth's purposive-labor thesis of property, we could argue that Moore's body parts are products of his labour in some sense. He must be granted rule preclusionary control over his body and body parts. Others (researchers or cancer patients) might need one or more of Moore's body parts, but they do not have as equal right to these body parts as Moore. Even though the researchers in removing Moore's body parts, did not cause Moore specific or significant harm, it is presumed that such an action is illegitimate without Moore's consent because the body parts are attached to Moore and the fact of the attachment is sufficient condition to give him a right to control access to and the use of his body parts. It is dialectically necessary to grant Moore preclusionary control to protect his private body property right.

As property rights are generic rights granted by the *PGC,* the failure to obtain sufficient consent from Moore, together with the Supreme Court's rejection of Moore's claim, violates the *PGC*. However the claim that John Moore has a

[41] See ibid, at 199.
[42] See ibid, at 201
[43] See ibid, at 201
[44] Beyleveld, Deryck and Brownsword, Roger. Human Dignity in Bioethics and Biolaw. Oxford: Oxford University Press 179-188 (2001).
[45] See ibid, at 172.

preclusionary right of exclusive use does not entail that he may transfer these rights, let alone that Regents of the University of California can commodify his body parts.

B. Sufficient Informed Consent

Moore as a PPA should have been treated without contradicting his right to have sufficient informed consent to his self-determination of his body because this right has been recognised by the *PGC*. "[Freedom] consists in a person's abilities to control his actions and his participation in transactions by his own unforced choice or consent and with knowledge of relevant circumstances, so that his behaviour is neither compelled nor prevented by the actions of other persons."[46] Some outrages, however, may occur under an informed consent form if it is not properly informed. Thus, under any circumstances, any medical treatment offered to a PPA without a fully informed consent, that informs him of all the possibility of the operation, all the facts after the operation, including any purpose that would involve in the medical research and the commercial use of any removed body parts, would amount to depriving his rights to his self-determination. Therefore, it amounts to an invasion of his privacy on his own body.

To avoid an invasion of his privacy, an appropriate alternative which has been a traditional behaviour in most medical treatment and research is to invite Moore to participate in a treatment or research project under Moore's self-determination. Also he should have been informed of any important progress in the project, e.g. the patenting of Mo cell line in this case. Additionally, the recognition of Moore's important contribution should have been given to Moore *per se*, who is a layman, lacking sufficient knowledge of this medical research. It would be an absurd reasoning that Moore would not have felt exploited and abused by Golde and his research team presuming that Moore should have the capacity to consent to everything in the operation. To avoid the risk of the exploitation or commercialisation of their bodies and tissues, a co-combination with an honorarium policy to donors of genetic material should be proposed to respect the patient's autonomy.

Based on such an alternative, the purposes between treatment and research have to be differentiated in a very strict way. In other words, the criteria for establishing informed consent between pre- and post- operation should be laid out. Therefore a second consent should be obtained from Moore providing that he has been given enough information for him to give informed consent if post-operation research is a procedure which needs to be consented to. The applicants have violated human rights in their research and development of Moore's cell line where there is evident the adequacy of the consent not given by John Moore.

[46] See Gewirth, Alan. Human Rights. Chicago: the University of Chicago Press 56 (1982).

C. Positive Rights to PPAO[47]

1. Moore is a cancer patient and he has the right to demand for cancer treatment because it is a basic right for a PPA to survive. However, when he claims his right for the treatment, other people should refrain from interfering with his therapy and furthermore he needs the active intervention of the doctors, nurses and the advanced equipment of the hospital.

2. Other cancer patients have the same right to demand for their cancer treatments because they are also PPA in the same way as Moore and health treatment is a basic right for all PPAs. When they each claim their right for treatment, Moore should refrain from interfering with their therapy and furthermore they need the active intervention of the doctors, nurses and the advanced equipment of the hospital in just the same way as Moore.

3. However, they are still dying even though they have been treated in hospital with the active intervention of the doctors and nurses. They need a special cancer cell line for special treatment and this cell line could only be derived from Moore's spleen cancer cell.

4. Moore's donation of spleen cancer cell would not harm him and it can benefit other patients. He would provide his active assistance to help other PPAs. The positive right to well-being such as helping them to have water, food, housing, education, and health care entails that when they cannot obtain this basic or additive well-being by their own effort, other people have the correlative duty to help them. This correlative duty should be borne not only by individuals but also by the economic and political structures of the whole society.[48] As Moore is the member of the society, he bears the correlative duty to help other patients in just the same way as other people help him.

[47] PPAO means all PPA except me. Because it is my due or my entitlement to have GF, PPAO are forbidden to interfere with my rights to have the GF. As GF are freedom and well-being, hence, all other persons must at least refrain from removing or interfering with my freedom and well-being. Furthermore, if it is possible, PPAO ought to help me in securing my GF if I have difficulty in securing it by myself.

[48] See Gewirth, Alan. The Community of Rights. Chicago: the University of Chicago Press 36 (1996).

5. Therefore, from the view of positive rights, if property right can be proven through the principle of contribution in which "Distribution should be determined by contribution",[49] then it is submitted that Moore is also qualified as one of inventors of the patent. Without

6. The key cancer cells that grew in Moore's body who has to suffer the pain caused by cancer, it cannot be denied that Moore did contribute in this invention himself. This suffering, looking at it from the contribution point of view, can be justified as another form of capacity, and therefore, Moore is logically needed to be considered and listed as a co- inventor.

D. Negative Rights to Moore

1. Moore's spleen cancer cells have the special function to stimulate different lymphokines in the long term. Usually cells taken from the body after a few hours will die quickly and the cell line has been developed by scientists to continue the cells' life for a longer period. However, it is not always easy to maintain these cell lines. Moore's spleen cancer cells can survive much longer than other people's cells. They are functional as long-term growth cells and they can be developed into long-term cell lines without it being a laborious and fatiguing task. Hence, these cells are very rare and they are like a needle in a haystack.

2. The University of California found the special function of Moore's spleen cancer cells and had developed them to become cell-lines for the indefinite reproduction of lymphokines. Furthermore, they applied for a patent for these cell lines as an invention. The potential value of these cell lines is unpredictable. However, these cancer cells are Moore's private property because they are strongly attached to John Moore. It is dialectically necessary to suppose that Moore owns his body under the rule of preclusionary property. He should have the right to claim some profit from the patenting of these special cell lines. For example, some people are good at music or mathematics or sports and so on. These talents are capacities from God and those properties raised from the capacities should be recognized. These talented people have the "special rights" to claim financial benefit from their capacities. That is to say:

3. Other people have the right to claim financial benefit if they have special property in just the same way as Moore does.

[49] See ibid, at 204. "the contribution principle: distribution should be determined by contribution; or, in comparative terms, how much goods or rewards persons get relative to one another should be determined by, and be proportional to, how much, by their prior work, they have contributed to the total products".

4. Other people are barred from interfering in Moore's having the right to his financial benefit. The basic right of well-being as regards to property is the right not to be stolen. John Moore "has a negative right to prevent someone from doing scientific research on his cells"[50]. The financial benefit of these special cell lines is derived from Moore's spleen cancer cells. The University of California has no right to patent Moore's own property without his formal informed consent. This is his freedom to provide his cells to them to develop the cell lines and it is his well-being to claim his financial benefits from these cell lines because the original cells are Moore's own property. He ought to defend his having the right to the financial benefits of these cell lines. However, when he is defending his negative rights by his own efforts, it is clear he still needs the corrective assistance from the legal structure of society.

From the view of negative rights, Moore has the freedom to provide his cells to the UCLA to develop the cell lines and it is part of his well-being to claim his financial benefits from these cell lines because the original cells are Moore's own property. Moore's basic rights cannot be interfered with by other PPAs. While Moore proposes a legal action to defend his basic rights in confronting the difficulty, the other PPAs should provide their assistance to Moore. It is clear that in this case, the judiciary in America should provide the corrective assistance to Moore. The failure of the appellant in this suit implies that the state of John Moore has been denied and this will contradict the *PGC*.

Hence, from the examination of the *Moore* case under the *PGC*, the decision made by the Supreme Court has seriously infringed Moore's human rights from the above points. Therefore, it is submitted that Moore should be accorded his human right and be rewarded the royalties in accordance with the market value created.

VI. Conclusion

From the discussion thus far, it is clear that the main focus of the *Moore* case is on human rights. It seems that the question of who owns the genetic materials from the human body can only be asked after an analysis of the basic foundations of moral rights has been done. It therefore has to be shown how property rights can be granted via a consideration of the moral rights of ownership rather than by just considering the legal rights. Thus before pursuing the claim for an intellectual property right, the first task must be to clarify the issue of property rights. If Moore has the right to claim the ownership to his removed tissue and genetic material, he has the right to a share of the patented cell line. The ownership of his removed tissues should not only belong in its entirety to those who have explored its utility. Hence, the case needs to be examined in the light of the ethical considerations

[50] See Grandolfo, Gina M. "The Human Property Gap". 32 Santa Clara Law Review. 987 (1992).

which the court failed to address fully, this would allow us to give appropriate weight to human rights rather than just to legal criteria. If the argument is true, then this demonstrates that the mere consideration of patent criteria and technical factors in the examination of patent applications will no longer be a sufficient legal examination of the problem in this modern biotechnological age.

Here summarises both the pleadings of John Moore and the concept of invention as viewed from both sides to the case using the *PGC*. From the appellate side, Mr Moore took the legal action against the University of California in 1984 for 13 causes of action. For the defendants the *Moore* patent met the requirements of novelty, non-obviousness and utility. The arguments of the two sides were carefully scrutinised and weighed by the court in the

U.S. and the appeals heard by first the Appeal Court and then the Supreme Court demonstrate the very different approaches taken by the judiciary in the period 1984-1990. The final decision of the Supreme Court of California rejected Moore's claim after weighing the importance of the contribution from the UCLA under California Law. In examining the *Moore* case from the perspective of *PGC* it is imperative to set out that there are four basic rights which John Moore could claim and these rights cannot be overthrown.

The first right is the right to private property that is recognised by the *PGC* after adapting Gewirth's theory to rule preclusionary rights in body parts. The second right is the right of self-determination which has been violated by the insufficient informed consent. The third is that John Moore has a duty to provide positive assistance to help other agents. The third right carries a reciprocal principle, which is the duty is to assist other agents who lack the capacity to defend their basic rights. It is essential that these rights are established and protected to ensure that the holder is not deprived of them. The fourth right is a negative one. The University of California has no right to patent John Moore's own property without his formal consent. In other words Moore had a right to prevent others from acquiring rights over his genetic material. The patenting interfered with his right to freedom and well-being. Moore chose to provide his cells for the purpose of developing the cell lines and it is right that he should be able to claim a benefit from these cell lines because the original material was his property. The lack of sufficient informed consent violated Moore's freedom and the financial benefits from patenting Moore's cell deprived Moore of the right to well-being. The decisions of the Supreme Court contradicted Moore's human rights and these human rights should have been and Moore rewarded with royalties.

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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

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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

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 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).

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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

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 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]

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

[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).

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]

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.

[10] Supra note 8

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, 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.

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

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

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 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:

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[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).

"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 be non-naturally occurring.[20] For the first test, the court examine

[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
[20] Id at 21

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 "*Pseudomonas*" 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]

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[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 ENCYCLOPÆ DIA BRITANNICA, https://www.britannica.com/science/hydrocarbon/Physical-properties (last visited May 23, 2017).

[25] Supra note 13

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 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]

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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

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 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,

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JOURNAL OF CANCER 1738–1739, 1738-1739 (1994).

[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*

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.

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

BRCA1, 95 GENOMICS 312–314, 312-314 (2010).

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

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

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 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.

[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.

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 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

[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).

[40] Supra note 35

[41] Supra note 13

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 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

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[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

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

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 complete human organism patenting.[50] [51] This assumption is further supported by the decision of Ex parte Michael M. Kamrava (Untied States Patent and

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

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.

[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.

Bibliography

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

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

Charron Kira, *Bioprinting Skin and Hair: a Good Look for Cosmetic and Healthcare Technology 3D Printing Media Network (2016)*, https://www.3dprintingbusiness.directory/news/bioprinting-cosmetic-healthcare-technology/ (last visited Jul 13, 2017).

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

Christophere Barnatt, *Bioprinting Bioprinting - Explaining the Future*, http://explainingthefuture.com/bioprinting.html (last visited Jul 13, 2017).

Dhakshinamoorthy Sundaramurthi, Sakandar Rauf & Charlotte Hauser, *3D bioprinting technology for regenerative medicine applications*, 2 INTERNATIONAL JOURNAL OF BIOPRINTING (2016).

Dino J. Ravnic, Ashley N. Leberfinger and Ibrahim T. Ozbolat, *Transplantation of Bioprinted Tissues and Organs - Technical and Clinical Challenges and Future Perspectives (2017)*, Wolters Kluwer Health, Inc.

Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 INTELLECTUAL PROPERTY & TECHNOLOGY LAW JOURNAL 12–15, 12-15 (2005)

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

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).

Embryo Implantation After IVF, Implantation of Blastocysts & IVF Embryos in Humans, http://www.advancedfertility.com/implantation.htm (last visited May 23, 2017).

Embryo Implantation After IVF, Implantation of Blastocysts & IVF Embryos in Humans, http://www.advancedfertility.com/implantation.htm (last visited May 23, 2017).

Francis A. Carey, *Hydrocarbon: Chemical Compound*, ENCYCLOPÆ DIA BRITANNICA, https://www.britannica.com/science/hydrocarbon/Physical-properties (last visited May 23, 2017).

Griffiths Anthony JF, *Gene-protein relations An Introduction to Genetic Analysis. 7th edition. (1970)*, https://www.ncbi.nlm.nih.gov/books/NBK21811/ (last visited May 23, 2017).

Hammond John & Gunderman Robert, *"Anything Under the Sun Th at Is Made by Man" …Well, Not Quite*, THE LIMITED MONOPOLY 10–10, 10-10 (2009), http://www.patent-innovations.com/documents/200901LimitedMonopoly-AnythingUndertheSun.pdf (last visited Jul 14, 2017).

Ibrahim Ozbolat & Hemanth Gudapati, *A review on design for bioprinting*, 3-4 BIOPRINTING 1–14, 1-14 (2016).

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.

Krench Megan, *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).

Lijie Grace. Zhang, John P. Fisher & Kam W. Leong, *3D bioprinting and nanotechnology in tissue engineering and regenerative medicine (2015).*

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

Meniscus Regenerated with 3-D Printed Implant, Columbia University Medical Center (2014), http://newsroom.cumc.columbia.edu/blog/2014/12/10/3d-printed-meniscus/ (last visited Jul 13, 2017).

Murphy, Sean V & Atala, Anthony, *3D bioprinting of tissues and organs*, Nature Biotechnology 32, 773–785 (2014)

Mossoff Adam, *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).

Nazia Mehrban, Gui Zhen Teoh & Martin Anthony Birchall, *3D bioprinting for tissue engineering: Stem cells in hydrogels*, 2 INTERNATIONAL JOURNAL OF BIOPRINTING (2016).

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).

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

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).

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

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).

Quinn Gene, *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).

Ramsey Lydia and Lee Samantha, *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).

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

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).

Thomas W. Cole, *Why Most Patents Are Invalid*, 14 IEEE ENGINEERING MANAGEMENT REVIEW 46–48, 46-48 (1986).

Transplantation, UNOS, https://www.unos.org/transplantation/ (last visited Jul 13, 2017).

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

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).

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

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).

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

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