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Prosthetics and Public Health: Investigating the Interface, Circa- 2024

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ABSTRACT

Prosthetics are one of the greatest medical wonders the world has ever confronted. From aiding in providing mobility to keeping intact human dignity, it has been working for the promotion of human welfare since a very long time. The process for production of prosthetics is multifarious, most of them being financially expensive. With greater precision comes greater perfection in the product so manufactured. Prosthetics undoubtedly belongs to a class of "precision engineering". The traditional mode of prosthetic production is generally subject to customization as a result of which mass production cannot be made possible. It becomes an expensive process and not every person can afford the tradition mode of prosthetics. Fortunately, there is an alternate process of prosthetics production. It is the 3D printing Technology where mass production can occur on a higher level. But it involves various technicalities. It involves the application of more than one genre of Intellectual Property and includes the application of patent, copyright and even trademark. The importance of the 3D printing technique of prosthetics production lies in the fact that it has indeed become a life-saver in helping specially-abled individuals in accessing the health system especially in a scenario wherein the costs of the production are immensely high. In this paper, the researcher has discussed the access to use of 3D printing technology of prosthetics production from the perspective of public health. The researcher has also focussed on this aspect to understand whether the balanced mechanism between promotion of the patent-holder's right in relation to the 3D printing of prosthetics and access to the patented product is well maintained under the Indian system of jurisprudence.

Keywords: prosthetics, access, 3D printing technology, public health, precision.

I. INTRODUCTION

Black's law dictionary has defined health as the freedom from pain and sickness and achieving a perfect state of life and the uniqueness and concordance in the parts of the living organisms. The World Health Organization Charter has discussed the concept of health as the complete physical mental and social well-being and not just the absence of any kind of inflammation or

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disease.² Therefore, it can be stated that the world has accepted the fact that health now connotes not only to physical health but also to the social health and mental health.³ The patent law has been designed with certain objectives one of which is to protect the invention, recognize the invention and in turn encourage other inventors to invent. The patent law entitles the right of a creator to exclude others from unauthorized manufacture, import or carrying out any similar rights with the patented product.⁴ However, every right has its own set of pros and cons.

Patent, too, has its own set of limitations. Often patented pharmaceuticals and branded medical companies which purchase the rights of patent from the inventor become responsible in fixation of the price of the same at a very high level. This leads to a lesser accessibility of a certain pharmaceutical product that may have a high demand in the market, leading to a great amount of distress among the general public. The main objective behind Article 27 of TRIPS⁵ is to promote a balance between the creator's right and the right of the public to access the creation. While it becomes extremely important to provide a sound mechanism of protection to the said product, it also becomes important to enable a greater availability of the product between the common masses in order to win battles against devastating diseases and make life easier to live.

II. CONCEPT AND MECHANISM OF PROSTHETICS PRODUCTION

The term amputation has been derived from the Latin term "*amputare*". It indicates and involves a procedure wherein elimination or cutting out any specific part of the body takes place. Amputation has also been clinically categorized into military amputation and civilian amputation.⁶ There are various situations: unfortunate, accidental or innate that leads to amputation of an organ of the human body. Amputation, irrespective of the rationale behind it, causes a setback to the locomotion, mobility and liberty of the human body. It hinders the right to personal liberty in a rather de-constructive manner. In order to combat against all the odds that arise from amputation, medical science has gifted human kind with the science of prosthetics.⁷

1) Traditional Mechanism of Prosthetic Production: Since prosthetics has become an

² WHO remains firmly committed to the principles set out in the preamble to the Constitution, Available at <https://www.who.int/about/governance/constitution> (last accessed on 10th July, 2024)

³ STEVE BRACHMANN, The Evolution of Prosthetic Devices: A Patent History, Available at <https://ipwatchdog.com/2014/12/01/the-evolution-of-prosthetic-devices-a-patent-history/id=52227/> (last accessed on 19th June, 2024)

⁴ Patent Landscape Data Overview of

Motorized, Motion-Actuated Prosthetic Hands, Available at https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_wk_ge_11/wipo_ip_wk_ge_11_ref_b_background.pdf (last accessed on 26th June, 2024)

⁵ Id.

⁶ Prosthetics after amputation, Available at <https://www.nhsinform.scot/tests-and-treatments/medicines-and-medical-aids/prosthetics-after-amputation/> (last accessed on 11th July, 2024)

⁷ Products and services from Ottobock, Available at <http://www.ottobock.co.uk> (last accessed on 10th July, 2024.)

integral part of medical science, specifically in the 20th century, the manner and mechanism of prosthetic production has also increased. While initially the sole process of production of prosthetics included the traditional mode of manufacture of artificial body parts, this was strictly within the scope of professionals and in most of the cases involved the professionals including a prosthetist and a surgeon who collectively contributed in the preparation of the prosthetic body part.⁸ The manufacturing process under the traditional mould included an injection moulding procedure and a vacuum forming procedure both of which are strictly conducted by professionals. A mould of the residual limb is revived and on the basis of the perfect size and shape, the mould is created using a cast.⁹ The same is fitted for a prosthetic liner. After the cast is attached to the residual limb the remnant space between the cast, the residual limb is fitted with the thermo-plastic sheet in order to avoid any kind of friction between the limb and artificial body part. Finally, the check socket is planted at the residual area and hence the fabrication of the prosthetic arm is successfully conducted.

- 2) **3D Technique of Prosthetic Production:** The second of the most important methods of prosthetic production include the 3D printing technique involved in prosthetic production. In this case there is an inbuilt digital file in the system that synthesizes the design and shape of the prosthetic part. The file is subject to copyright protection and such a file is built within the computer system. There are three kinds of files which are available and from which 3D printing can be processed. Computer aided design (CAD), blueprint including a design or a drawing and a Magnetic Resonance Image are the three categories of software available. These are eventually subject to copyright protection and involved in the printing technology. A 3D printer is attached to the computer system. After processing the necessary information and inserting the necessary components and cast to prepare a model the software is now set to motion. The printer prints the desired model and in course of this process, the necessary prosthetic body parts get manufactured.¹⁰
- 3) **Advanced Prosthetics: Bionic Mechanism of Prosthetic Production-** There are several other miscellaneous modes of production of prosthetics. One of the most expensive prosthetics include bionics. Unlike the commonly used prosthetic product these can be connected to nerves as a result of which their functioning becomes smoother. Once the

⁸ Ryan J. Mumper, *Limb Law: Licensing Solutions for the Prosthetic Industry's Patentability and Cost Crisis*, Available at <https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1416&context=jipl> (last accessed on 16th July, 2024)

⁹ Demand Shocks, Procurement Policies, and the Nature of Medical Innovation: Evidence from Wartime Prosthetic Device Patents, Available at <https://econweb.ucsd.edu/~j1clemens/pdfs/ProstheticsPaperLatest.pdf> (last accessed on 21st June, 2024)

¹⁰ Caio Rodrigues Da Silva, *Compulsory Licenses: Necessity or Threat?* CHEMISTRY WORLD (May 23, 2013)

artificial body part gets connected to the nerves the brain starts registering the function of the artificial body part and by a constant process of reception and transfer of stimulus, the brain can now assist in mobility of the artificial body part as well. However, bionics is extremely expensive and they cannot be manufactured with the help of 3D printing technique. They have to be manufactured by using the traditional mode of manufacturing as a result of which the process is both expensive as well as time consuming.

The procedures of prosthetics production are multifarious. They are not exhaustive and cannot be channelized into specific categories. Since the scope of this paper involves the 3D printing technique of prosthetic production, the regime involving the same and its relation with public health along with access issues has been discussed.

III. AN INSIGHT INTO THE 3D TECHNIQUE OF PROSTHETICS

A 3D printer uses more than just one technology to operate and manufacture a model that can later be used in the field of prosthetics. 3D printer is a multi-nozzle printer and the potential of such printers are consistently being made sharper by moderation of the technology that is involved in the printing mechanism. The very first 3D printer that came in the market belongs to Charles Hull who later obtained a patent in 1986. This was one of the most basic 3D printing mechanisms that was possible to be synthesized in the past. The mechanism leads to printing of layers of photo resins on one another to create a three-dimensional object. He further developed a software commonly referred to as the gold standard for data transfer between Computer Aided Design (CAD) and 3D printer. The standard tessellation language STL is a file format that enables the data from the CAD (computer aided design) software to reach the 3D printer. The main function of CAD in the process of 3D printing is that this file instructs the printer as to the quantity of material that has to be deposited in various parts of the model and the possible structure of the model. The process of printing involves overlapping of multiple triangles till the final prototype has been given shape. In fact, the benefit of using triangles in production of the prosthetic parts include:

- Comprises of complex surface designing
- Having non-collinear shapes
- Portrays sufficient Algorithmic efficiency

The mechanism involved in the production can be summed up as follows:

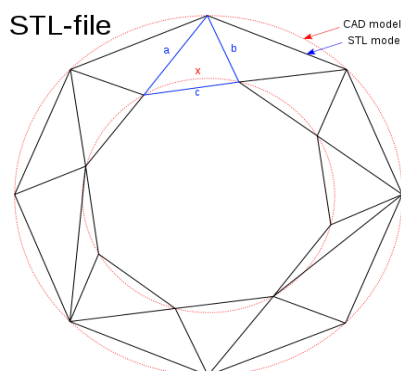
- 1) Pre-fabricated and post fabricated part.
- 2) MRI uploaded on system.

- 3) Information processed by CAD.
- 4) Analysis of cross-section.
- 5) Directions sent to the 3D printer about the mechanism.

The figure below represents the number of triangles utilized in each model of prosthetics to manufacture the concerned product.

<u>ANATOMIC MODEL</u>	<u>MAXIMUM NUMBER OF TRIANGLES</u>
SKULL	600,000
FACE	450,000
MANDIBLE	200,000

The models are prepared by multiplying and intersecting a number of geometric patterns. All of such geometric patterns are mostly triangular in shape. So, the mechanism used in construction of a specific model is mainly based on the intersection of a number of geometric triangles. The CAD file dictates the printer to construct these geometric triangles. This file format still forms one of the most basic components of every three-dimensional model used as a prosthetic.¹¹



IV. A MODEL STL DIRECTED STRUCTURE

Triangles have inherent properties that are used for calculation and rendering the fabrication of images. For example, triangles always reflect a convex surface when put through 3D printing process. The order of the vertices defines the direction of the normal and so on. So, triangles are best for implementing fast rendering processes on graphics hardware.¹² Technology that

¹¹ Medical 3D Printing for the Radiologist. Radiographics, Available at https://www.researchgate.net/figure/Recommended-Number-of-Triangles-Used-for-3D-Printing-of-Anatomic-Models_tbl1_273320151 (last accessed on 10th July, 2024.)

¹² Leah van der Walt, Quads vs Tris in 3D Modeling, Available at <http://wedesignvirtual.com> (last accessed on

was involved in 3D printing mechanism was turned into stereo lithography.¹³ However, this method has now become comparatively older and less advanced as a result of which few other technologies were required to be incorporated into the system. The fact still remains that the STL file format which is patented is still used in all these modes of 3D printing technique. Inkjet printing, Selective Laser Sintering and the fused deposition modelling are various forms of 3D printing technique which has been used lately.

V. POSITION OF PROSTHETICS: A BOON OR BANE FROM A “RIGHT TO HEALTH” PERSPECTIVE

When it comes to the conceptualization and categorization of prosthetics, there are certain concepts that arise from an umbrella concept of 'health'. While dealing with prosthetics the two main concepts with regard to health that come into play include health care and Public Health. Both of these concepts fall under the canopy of health. When the concept of right to health plays a fundamental role in shaping a certain discussion, these two sectors of health care and public health also to some extent take their respective positions. The **right to public health** while including numerous perspectives and prongs has a wide ambit and scope. Two of the most important branches of health include “**healthcare**” and “**public health**”.

1) The conceptualization of health-care and public health

The Centre for Disease Control and Prevention which is a government agency working and operating within the jurisdiction of United States of America dealing with national public health has expanded the meaning and concept of the term health. According to CDC, **healthcare** in general refers to an individualistic status of health while **public health** denotes health of a certain community within a certain area where the area is generally defined by the country in question.

The relevance of the difference arises owing to the fact that while dealing with prosthetics, it does not fall under public health. The term public health is often interchangeably used with population health. Oxford dictionary defines population health as the health of a certain population or community which is subject to government Regulation and can be improved by Government support. However, it has been debated a number of times that government regulations do not necessarily upgrade public health, rather it is the combined effort of the government, the private stakeholders and the population awareness that assists in the up-gradation of Public Health. Healthcare on the contrary deals with how health institutions and the service

28th June, 2024.)

¹³ Supra note 9

providers deal with and individual patients' health status.

2) Whether prosthetics come under public health?

The National Centre for Biotechnology Information (NCBI) which is a National Library of Medicine approved and funded by the government of United States of America has categorically discussed how prosthetics is inserted and can be dealt with under the concept of health-care. The NCBI has inserted health and mobility as a part of **health-care**. For the maintenance of the same, rehabilitation services are being provided. One of the most important conditions affecting mobility that has been mentioned under the NCBI norms is amputation. In this manner they have passively included the concept of prosthetics as a rehabilitation mechanism that can offer a solution against the lack of mobility. This has made prosthetics significantly a part of health-care and thus a part of “**health**” in general.

3) How the Doha Declaration, CESCR General Comment 14, TRIPS and UDHR uphold the balancing mechanism of patent and right to health?

The international instruments that occupy significance and form an integral part during any discussion on how right to health is a fundamental right are manifold. The most important in this consequence being the **Doha Declaration** which was adopted in 2001, **General Comment 14** which forms a part of United Nations Committee on Economic, Social and Cultural rights and finally the **Universal Declaration of Human Rights**.¹⁴

- The **Doha Declaration** is one of the most important Public Health Agreement that has so far been agreed to on a mutual consensus national emergency and urgent c and how waiver of patent may be called for during such and emergency situation. It's further Lays down a basic guideline on the granting of compulsory license. One of the most important discussions that have been approach to by the Doha declaration is the promotion of technology transfer from a developed Nation to a developing Nation in order to achieve balancing of health mechanisms throughout the world. Therefore the Doha declaration makes right to health a mandatory criterion which must be achieve and which override any other existing right.
- The **General Comment** operates on four primary provisions which include available accessibility, acceptability and quality. While acceptability may be treated as arbitrary it is most often the accessibility which is looked into while determining the quality of Medical Health that is being provided with in a certain Nation. If the service provided

¹⁴ Miki Fairley, Microprocessor-Controlled Knees 'Evolution of a Game Changer', O&P EDGE (June 2014)

by the prosthetic cast which is used by 3D printing mechanism is non-discriminatory with regards to the quality that is being used to manufacture the same and if the physical constituents of the said model which is being made available at a lower cost or almost similar to the original cast manufactured by traditional mechanism, it can be said that facility which prosthetic is providing is to a larger extent meeting the criteria of a fundamental right.¹⁵

- Article 7 of the Trade Related Aspects of Intellectual Property Right (TRIPS) and article 27 of the Universal Declaration of Human Rights also provide that every person will have the right to enjoy art and to share scientific advancement and for the purpose of sharing scientific advancement it is very much necessary to transfer technology from one Nation to another.
- Several do-it-yourself portals (www.instructables.com or www.thingiverse.com) to manufactured 3D printed prosthetics are being utilized across several Nations. In fact, the technological transfers are taking place from one Nation to another in order to ensure that it can be used regardless of where it has originated. Several hospitals even in India have incorporated the do-it-yourself portals on their software technology. Thus, regardless of the expenses which would have been initially imposed on a patient using a 3D prosthetics these hospitals are now granting the same at a much cheaper rate and even sometimes on a no cost facility. These portals generally use the fuel deposition modelling in order to manufacture the 3D component thereby gaining a fair share of accuracy.¹⁶

VI. CONCLUSION

The technology and software which is used to manufacture the 3D models is patentable. In India most of the companies which operate prosthetics centres have accepted technology from other nations for their respective branches. One addition has been made to the mechanism of fused disposition modelling by a group of IIT students. They have inserted a 4-bar geometry pattern in the mechanism so as to ensure greater mobility of the entire model and system thereby increasing therapeutic efficacy of the same.¹⁷ The scope and development of improvement of 3D printing prosthetic is enormous especially being relevant to right to health. By innovating indigenous technological aspects, it shall become holistically cost-effective as well as beneficial for the patients. An AI based task force was brought into force in 2018 which focussed on the

¹⁵ Fight chronic disease, Available at <http://www.fightchronicdisease.org> (last accessed on 19th June, 2024.)

¹⁶ Open Hand Project, Available at <http://www.openhandproject.org> (last accessed on 12th July, 2024)

¹⁷ National Commission on Orthotic and Prosthetic Education, Available at <http://www.ncope.org> (last accessed on 24th June, 2024.)

fact that there must be innovativeness in the creations made in India that would allow the public and the nation as a whole to benefit to a larger extent. By keeping the same into cognizance, the indigenous expression of prosthetics must be enhanced so as to also ensure the availability of the same among mankind.
