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3D Printing in Medicine and Healthcare: A Look at Changes and Improvements Impacting the Industry

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A decade ago, 3D printing, also known as additive manufacturing, was very different from the techniques used today. As well as what may be considered standard use in materials engineering to manufacture parts for mechanical systems back in 2013, there was a focus on starting to make the technique available to all, with Amazon and Staples selling home 3D printers.[1] Marketing teams saw the potential for novelty in the technique, with Coca-Cola offering customers 3D printed models of themselves[2], Victoria's Secret 3D printing angel wing accessories for their models[3], and Nike debuting the Nike Vapor Laser Talon, a 3D printed football cleat[4].

Since then, the technology has developed and specialized significantly. Looking at the fields of medicine and healthcare in particular, there have been great leaps in the techniques and applications of 3D printing to improve people's health and lives. The possibility to realize and personalize medical treatments using 3D printing allows for manufacturing efficiencies, improved compatibility with patients, better patient compliance, and fewer complications with the rejection of treatments.

What Exactly Is 3D Printing?

In recent years, 3D printing has emerged as a groundbreaking technology and a potential game-changer in healthcare. 3D printing provides a fundamentally different way of creating objects, and as discussed in this article, its impact on healthcare is nothing short of revolutionary.

3D printing is essentially a process that can be used to build 3D objects layer by layer, based on a digital model of the object to be printed. It may be thought of as a way of constructing an object by stacking and fusing tiny, individual slices of material atop one another until the final form is created. Originally used predominantly as a way of quickly creating a prototype object, the technique has been developed to allow for the manufacture of objects which can be challenging to form by other traditional methods or which have very specific or customized properties. Modern 3D printing allows for unparalleled precision and customization of manufacturing, setting it apart from traditional manufacturing methods and allowing for object engineering to be approached in a new way. The materials which can be used to form the end object and control its properties can range from plastics and metals to pharmaceutical compounds and biomaterials such as living cells, enabling the creation of diverse structures with various properties.

How Does 3D Printing Apply to Healthcare?

The applications of 3D printing in healthcare are diverse and represent the flexibility of the technique to be tailored for specific requirements. Some key examples are discussed below.

- *Custom Prosthetics and Implants*

One of the most celebrated applications in healthcare is 3D printing personalized prosthetics and implants.[5] 3D printing allows for the creation of tailor-made prosthetics, perfectly matching the anatomy of the patient. One of the most significant advantages of 3D-printed prosthetics and implants lies in their customisation. Traditional prosthetics and implants often followed a one-size-fits-all approach, which might not match the unique anatomical structures or functional requirements of each patient very well. However, 3D printing allows for the creation of tailor-made solutions based on patient-specific data, such as CT scans or 3D imaging, ensuring precise fit and function. Patients can now benefit from printed dental implants, prosthetic limbs, hip and knee replacements, braces, splints, and insoles,[6] customized to help ensure better comfort and functionality.

The versatility of 3D printing technology enables the production of prosthetics and implants with intricate designs and complex geometries that were previously unattainable through conventional manufacturing methods. This level of detail available allows for the development of lightweight, durable, and ergonomic prosthetic limbs or implants that closely resemble natural anatomical structures, enhancing both comfort and functionality for the wearer.[7] The prosthetics can be designed and constructed from a range of suitable materials, customized to be a perfect fit for the patient's particular healthcare need. Furthermore, the rapid prototyping capabilities of 3D printing facilitate iterative design improvements and quick adjustments, significantly reducing production time compared to traditional manufacturing processes. This agility in production allows for faster iterations and customization, meeting the evolving needs of patients while reducing manufacturing lead times.

Cost-effectiveness is another notable advantage of 3D-printed prosthetics and implants. The ability to create these items using precise amounts of materials minimises waste and contributes to more economical production. Additionally, the streamlined manufacturing process and reduced need for extensive manual labor translate to potentially lower overall costs for patients seeking customized solutions.

The impact of 3D-printed custom prosthetics and implants extends beyond individual patient care. It enables healthcare providers to offer more patient-centric solutions, fostering improved outcomes, increased patient satisfaction, and enhanced quality of life. Moreover, the advancements in this field hold promise for addressing global healthcare disparities by providing affordable, accessible, and high-quality prosthetic and implant solutions worldwide.

In examples of outwardly visible items such as prosthetics or orthopaedic supports, the ability to customise the design and aesthetics of the item can have arguably as great a positive impact as the functionality of the item itself – this can be particularly true for children where making the item appear fun or exciting can be a strong encouragement for the patient to persevere with the item to improve their quality of life.[8]

- *Anatomical Models*

3D printing can also be used to create anatomical models. Leveraging the precision and versatility of 3D printing, anatomical models can be created for use in medical training, surgical planning, and patient education. These models can be generated from patient scans, thus providing a realistic and personalized model of an actual patient. The versatility of 3D printing allows for the creation of highly accurate and detailed anatomical models that mimic the intricacies of human anatomy. From bones and organs to complex vascular structures, these models can be customized to replicate specific patient anatomies or pathological conditions, providing a level of detail that was previously unattainable through traditional methods.

The 3D printed models can provide surgeons with a tactile understanding of complex structures before performing a surgical procedure for preoperative simulation, allowing surgeons to visualise and plan complex procedures with a patient-specific model, and thereby improving precision and reducing surgical risks when a procedure is performed for real on a patient. 3D printing thus provides a valuable tool for surgical planning, allowing for the study and planning of a procedure using a realistic model before committing to surgery, allowing for reduced risks during surgery, enhanced precision, reduced operating times, and ultimately leading to improved patient outcomes.

Patients themselves can also benefit from understanding their medical conditions and treatment using 3D printed models and visual aids as an educational tool. Involving the patient in this way can help a patient's understanding of their condition and treatment, fostering better-informed decision-making and health condition management, and improve adherence to treatment plans through greater involvement and understanding of their care.

In medical education, 3D-printed anatomical models offer an immersive learning experience unavailable from traditional textbooks or two-dimensional images. These models provide a tangible representation of complex anatomical structures, allowing students to explore and understand human anatomy in a hands-on manner. By replicating specific anatomies, for example of bodily structures affected by a particular condition, educators can enhance the training of future healthcare professionals and provide a way of visualising the human body, as if it was affected by a condition which changes the bodily structures such as atherosclerosis, enlarged organs, or scar tissue, for example, in a realistic way, enabling them to grasp intricacies and variations that exist among individuals.

- *Bioprinting*

The properties of the build materials used to form objects have also advanced significantly over the last decade which has facilitated perhaps the most futuristic application in healthcare of 3D printing – bioprinting. In bioprinting, living cells are used as ink to create tissues and more complex structures, such as, potentially, functional organs. Bioprinting techniques involve the layer-by-layer deposition of biomaterials, living cells, and supporting structures to fabricate tissues that mimic the intricacies of native tissues in the human body.

Tissue and organ bioprinting are no longer in the realm of science fiction and research teams are making great progress in the ability to manufacture living tissues and biocompatible soft structures for implants. The ability to print functional tissues with unprecedented precision means that the ability to manufacture a functioning human organ remarkably appears achievable, even given the huge complexity of these biological structures.

Researchers have made significant strides in refining biocompatible materials and optimising printing techniques to create tissues with cellular-level accuracy, vascular networks, and functional properties. Scientists are exploring the feasibility of printing entire organs, such as hearts, kidneys, or livers, using a patient's own cells. The integration of bioprinting with stem cell research has been a game-changer in tissue engineering.

Issues such as vascularisation, scalability, and long-term functionality of bioprinted constructs remain areas of active research and innovation.[5] Furthermore, regulatory frameworks and ethical considerations surrounding the use of bioprinted tissues and organs in clinical settings require careful navigation.

However, these groundbreaking techniques could help to address problems with a lack of suitable donors for those requiring transplants, significantly reduce the waiting time for organ transplants, and mitigate the risks of rejection since the organs would be personalized to match the recipient's biological makeup. Thus, while still in the experimental stages, bioprinting offers hope for future organ transplantation, potentially contributing to mitigating the organ shortage crisis. There is a question of affordability with these solutions, though some commentators consider it may be comparable or even less than the cost of a traditional transplant from a donor.[9,10]

- *Drug Development and Delivery*

Individualized pharmaceuticals is a rapidly developing field, whereby personalized medicaments with individualized dosages tailored to the person's individual medical needs are prepared. Here there is great potential to improve drug delivery and patient compliance.[11] 3D printing is being developed to explore novel avenues in drug development. From creating customized drug formulations to fabricating precise dosage forms, this technology holds promise in optimizing medication delivery for individual patient needs.

Traditionally, pharmaceutical manufacturing followed a one-size-fits-all approach, resulting in mass-produced drugs that might not address the nuances of individual patients' requirements. With 3D printing, the precise formulation of medications for individuals is possible, considering factors such as dosage, composition, and release kinetics tailored to an individual's genetic profile or specific health conditions.

The process of producing personalized medicines via 3D printing enables the customisation of drug formulations, ensuring optimal therapeutic outcomes while minimizing adverse effects. One of the most remarkable advantages of 3D printing in pharmaceuticals is its ability to combine multiple active pharmaceutical ingredients (APIs) into a single dosage form. This polypharmacological approach allows for the creation of combination drugs tailored to address complex medical conditions or multiple symptoms in a single, patient-specific formulation.[12] Recent research considers how even the 3D-printed geometry of the pills affects drug release.[13] Moreover, 3D printing facilitates the creation of dosage forms that were previously unattainable through conventional manufacturing methods. For instance, intricate geometries, modified-release profiles, and novel drug delivery systems, such as implants or controlled-release capsules, can now be precisely crafted to meet the unique needs of individual patients.

The implications of personalized medicine provided by 3D printing extend beyond drug formulation. This technology streamlines the production process, reducing waste and enhancing cost-effectiveness in pharmaceutical manufacturing. Additionally, it opens doors to on-demand drug production, potentially mitigating drug shortages and improving access to essential medications. The impact of this innovation spans across various medical disciplines. In oncology, tailored cancer treatments with specific drug combinations optimized for individual genetic profiles hold promise for more effective and less invasive therapies. Similarly, in paediatrics and geriatrics, where dosage customisation is crucial, 3D printing offers a breakthrough in ensuring accurate and safe medication administration.

Where is the IP in Healthcare 3D Printing?

As 3D printing continues to evolve, its impact on healthcare is poised to grow rapidly. As discussed above, the ability to create patient-specific solutions, streamline production, improve efficiencies, and push the boundaries of medical innovation, heralds a new era in healthcare delivery.

For companies working in these fast-moving and innovative fields, protecting the related IP is crucial for maintaining a strong position in the market and protecting the company's brand to retain trust in the products and techniques. Protecting the available IP rights can become a challenging problem in view of the IP rights available and identifying the best way to protect a company's activities and offerings.

For businesses focussing on 3D printing, or if investing R&D in this technology space, it is worth exploring where there is IP and what may be valuable to protect. Patents, registered designs and trademarks can support businesses to stake a claim in the technological landscape to protect innovation, but also act as a valuable business asset for licensing, attracting investment, and demonstrating market leadership. Patent protection in particular can be available for various aspects of 3D printing in healthcare, provided the claimed invention meets the criteria for being new and inventive. The EPO recently reported that patent filings in 3D printing grew much faster than other technologies on average over the last ten years,[14] recently reporting that health is one of the biggest sectors of 3D manufacturing growth with a high demand for patent protection.[15]

There are various possible facets to 3D printing innovations which may be patent-protected. For example, patents can be directed to a method of printing an object, the printed object itself, a 3D printer for printing the object if that works in a specific way, software for controlling the printing process, and even software for controlling the printed object itself – these are all potentially patent protectable ideas.

For example, if a company provides 3D-printed functional prosthetics, such as lower arm or leg prosthetics, there are potentially many IP avenues available. Patent protection may be available to protect functionality of the prosthesis mechanisms (which may contain 3D printed parts), the method of forming the prosthesis material, incorporation into 3D printed material of sensors used to provide control feedback for operating the prosthesis, and the material itself (for example if it is a new biocompatible or easily-cleaned material). These consider the 3D printing aspects only, and further innovation may be protectable for the prosthesis, such as movement control software, non-3D printed support framework or material, and sensor control. Aside from patents, design rights may be available for the unique shape of the printed prosthesis or parts thereof. Trademarks can be used to protect the company name and possibly the particular branding used for the prosthesis.

As another example, a company producing personalized medicaments using 3D printing may wish to protect their innovation, but patent protection of a produced formulation may not provide valuable protection if the formulation is specific to a patient as there is unlikely to be clear infringement. It is better to consider whether a method used to produce a medicament having a unique composition, a method of ensuring quality compliance of a personalized printed drug, a device for producing a blend of medicaments, or even software for determining what an optimum combination of ingredients could be for a particular patient, offer more valuable IP protection, which is core to the business and applicable not only to a single personalized end product but to a more general step or aspect used in the manufacture of any personalized medicament. Again, there may be design and trademark rights to consider, for example in the shape of a pressed tablet or pill, or brand naming of a family of personalized medicaments.

In any process which is software-controlled, it is worth considering whether the software can be patent-protected, and whether trade secret protection offers useful protection as well. A good IP strategy in the software space can often use both types of protection for a robust way of protecting software without giving away all the company know-how. For example, an AI-powered method of determining a personalized medicament blend for which a tablet can be 3D printed may be a core technology for a business. The method is potentially patent protectable if it is suitably novel, inventive, and disclosed in sufficient detail to allow another person in the field to implement the invention – for example, the type of machine learning model and some indication of how it is implemented can be enough to demonstrate the inventive feature. It is usually not necessary to disclose the actual code, the details of the training data set, or the exact number of iterations, weighting factors, or other mathematical parameters of the model. This information can often be securely retained within the business as a trade secret, by taking the relevant steps to ensure data security and having agreements in place with employees or third-party programming to prevent those details from leaking out of the business. In this way, a company can both patent protect its software functionality without "giving the game away" and making all its detailed code or mathematical models public, which can be a real concern for software developers.

Navigating Ethics and Data Factors

In the ever-evolving landscape of medical 3D printing, thorough consideration of regulatory and legal compliance is crucial. As healthcare embraces 3D fabrication, particularly of personalized items and pharmaceuticals, patient privacy and data security are critical to adhere to strict medical privacy legislation and for the ethical treatment of sensitive data. Protecting sensitive medical data from unauthorized access or misuse is important, to obtain and retain trust in the technology and those providing the healthcare solutions, as well as for regulatory compliance. Ensuring equitable access to 3D-printed medical solutions without compromising ethical standards remains an ongoing challenge and should be considered at each stage of product and process development in this field.

Regarding 3D-printed personalized pharmaceuticals, there are challenges regarding ensuring regulatory and safety requirements of the resulting product with strict rules in place for these types of products. Another challenge relates to ensuring the security of the data used to formulate the drug – unauthorized access to the data used to produce the pharmaceutical may allow a hacker to change the data for malicious purposes, or to steal the formulation for the production of unregulated counterfeit drugs. Strong cyber security and procedures for managing pharmaceutical data are therefore paramount.

Future Trends and Predictions

The trajectory of 3D printing in healthcare is poised to revolutionise medical practices in unprecedented ways. Anticipated advancements in 3D printing technology are projected to magnify the scope and efficacy of personalized medicine, prosthetics, organ transplantation, pharmaceuticals, and more.

One promising area of development lies in the refinement of bioprinting techniques allowing for more personalized products and advancing printing of more complex and functional structures, possibly even complete organs.

Another area is the integration of AI and machine learning algorithms into 3D printing software, which has the potential to expedite the design and production of medical devices and implants, and determine personalisation parameters for 3D printed medicines, implants, and more, through the fusion of these design and production technologies to enable customisation based on patient-specific data and optimisation of the functionality and fit of printed items.

A further potential development is of so-called "4D printing", where printed objects such as tissues or functional structures can transform or self-adjust over time in response to environmental stimuli. In healthcare, this may mean the production of adaptive implants that adjust to the body's changing conditions, or drug delivery systems that respond dynamically to a patient's needs in response to feedback signals from the patient's body.

With future developments of 3D printing in healthcare, we may expect to see changes in the regulatory landscape. There will be a growing need for comprehensive regulations that balance innovation with patient safety and legal compliance. Anticipated changes might involve the establishment of clear guidelines specific to 3D-printed medical products, encompassing aspects like design validation, material standards, and quality control.

Moreover, the rise of decentralized manufacturing through 3D printing could challenge traditional supply chains and distribution models. This decentralisation might prompt regulatory bodies to re-evaluate how they oversee the production, distribution, and quality assurance of medical devices and pharmaceuticals.

The intersection of intellectual property rights and 3D printing in healthcare is also an evolving domain. With the ability to replicate patented medical devices locally, or produce customized pharmaceutical products, patent licensing may play a key role in ensuring a company's technological offering and claim in the market is not diluted, as well as ensuring that products are suitably quality controlled and meet the relevant safety standards.

Additionally, the emergence of open-source platforms and collaborative efforts in the 3D printing community could prompt discussions on novel licensing models that promote innovation while ensuring equitable access to technology and healthcare solutions.

Conclusion: 3D Printing is Reshaping Healthcare

In conclusion, the future of 3D printing in medicine and healthcare promises an evolution that extends beyond technological advancement and has the potential to offer a way to reshape healthcare delivery. Its capacity to tailor treatments, refine surgical precision, provide accessible medical solutions, and play a role in improving patient care, presents an unparalleled opportunity for the future of healthcare.

Progress in 3D printing in healthcare may face challenges in ensuring that legislative and regulatory compliance is achieved, particularly in view of personal patient healthcare data, for example in producing personalized medicaments or customized prosthetics.

Alongside navigating the legal requirements in this field, IP can play a key role in supporting a business's activities in this exciting and fast-moving field. Attracting funding, retaining a claim in the marketplace, and creating valuable licensing opportunities can be supported by a clear patenting and IP strategy, and stakeholder trust can be bolstered through robust trademark and design protection. Innovations involving software, for example, to carry out inventive methods of manufacture or patient customisation, can be protected through a strategic combination of patent protection and retaining trade secrets, particularly for methods using AI.

In summary, the revolutionary potential of 3D printing in healthcare provides an exciting opportunity for transformative improvements to patient health, and a strong IP strategy underpinning the technological advances can provide a valuable safeguard for businesses to excel and drive innovation in this dynamic field.

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