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3D Printing Legal Workshop – A Deeper Dive

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The Allens 3D Printing Practice recently held a workshop in Melbourne and Sydney which explored key legal issues arising from 3D printing, particularly for the healthcare industry. Our Allens panel members – Sarah Matheson, Ric Morgan, Phil O'Sullivan, Dr Tony Shaw, Tracy Lu and Rob Munro – were joined by industry leaders:

- Alex Kingsbury – founder of specialist additive manufacturing consulting firm Additive Economics and prominent thought leader in Australia on all things additive manufacturing.
- Dr Will Parr – co-founder of 3DMorphic, a Sydney-based company that offers 3D printed orthopaedic devices and related software technologies, and Post-Doctoral Research Fellow at the Surgical and Orthopaedic Research Laboratories at the Prince of Wales Hospital.
- Jason Aldworth – co-founder and chairman of 3DMEDiTech, a Melbourne-based company that offers 3D printed medical devices and manufacturing services, and an expert in regulatory and corporate affairs.

This article summarises the four key themes that were examined at the event.

IP protection and enforcement

The technologies involved in the production of a custom medical device using 3D printing are much broader than the 3D printing itself. As Will explained, it generally includes:

- Capturing the patient's specific anatomical parameters using medical imaging technology, for example CT, MRI or planar x-rays.
- The generation of a 3D model of the patient's existing pathological anatomy.
- Using virtual correction techniques to create the planned, post-operative anatomy.
- Designing a device to achieve and maintain the post-operative anatomy.
- Recording the design in a suitable file format.
- 3D-printing the device using suitable materials.

A range of IP protections may be available for these processes, which could include **patents** for imaging technologies, new materials, processes for making new materials, and any algorithms used in correcting planned anatomy and device design; **registered designs** for device design; **copyright** for design files or software used to manipulate 3D models; and **confidential information** for know-how which is generated by doctors and engineers in the design process.

From her experience with companies' commercialisation efforts, Alex cautioned that: '***companies may be missing out on the opportunity to exploit IP that they have developed but not properly protected, or they may be wasting their development efforts if they have not properly secured their IP or adequately assessed the IP landscape***'.

It is crucial to get the right assistance in surveying the existing IP landscape and navigating complex issues such as the patentability of computer-implemented inventions, 3D CAD files and bioprinting. In some of these areas, the law is already in a state of flux, but developments in the technology may render the position even more uncertain. For example, we can foresee bioprinting technology developing to the point that it can reproduce tissues and organs that are structurally and functionally indistinguishable from real tissues and organs. In that case, while the process of creating those printed tissues and organs themselves may still be patentable, the tissue and organs themselves may cease to be eligible for patent protection.

Other challenges in IP protection and enforcement include: **(a) the lack of copyright protection for data per se and the extent of any copyright protection for databases** (which only extends to the architecture of the database); **(b) the increased exposure to counterfeiting** (given the ease with which counterfeiting can occur using 3D scanning technologies or design files); and **(c) needing to balance the interests of different collaboration partners** (since cross-disciplinary collaboration and collaboration between businesses and research institutions is critical to the industry).

As both an academic and entrepreneur, Will observed that: '***I struggled for a long time to manage publishing my research and protecting the company's IP***'. However, filing a patent application should not necessarily hinder publication of the research, so long as there is sufficient planning and communication between the commercialisation, research and IP teams to ensure that the right steps are taken at the right time.

Tips:

- Consider all relevant IP across the whole of the process and not just the 3D printing of the final product.
- As each type of IP protection has different eligibility requirements, scope, duration, costs and benefits, take a tailored approach as to what, where and how protection is sought.
- Be innovative and adaptable in IP enforcement, e.g. shift from physical enforcement to digital enforcement or exercise tighter control over distribution channels for example considering the application of blockchain technologies.

Protection of data and privacy

3DMEDiTech's workflow is completely digital. It collects data from patients before, during and after their use of the relevant medical devices. In Europe, comprehensive patient data is required to be collected and submitted to the regulator pursuant to the European Medical Device Regulation (***MDR***). Jason explained that 3DMEDiTech benefits from the richness of the data that it collects, continually improving its design and manufacturing processes by matching particular data with the clinical results collected from third-party sources or its other patients.

3D printing involves a lot of new, innovative practices. In Australia, entities still need to manage the data collected and generated by the 3D printing process within existing data protection and privacy regulatory frameworks that by design are '**technology neutral**'. These privacy laws often grant a higher degree of protection to **sensitive health information** – including health records, patient scans and potentially the underlying designs for custom 3D printed devices – and largely centre around the notion of consent. Such consent must be current and specific and should address use of information in product design and manufacturing, use in software to model the product and use in simulation technologies to qualify or test the product.

Businesses need to consider these obligations not only in the context of customised devices developed using an individual's personal information, but also in circumstances where they seek to later commercialise or replicate such devices for other patients (even where small customisations are made) – as that latter device may still contain the original individual's personal information, and therefore require their consent for commercialisation.

We anticipate that in the next 5-10 years, there will be continued emphasis on businesses operating within a '**social licence**' in relation to the access, use and sharing of data. However, this doesn't mean businesses have to be conservative in their approach to data, provided that they: (a) develop a clear set of data management principles; (b) are transparent in relation to all their data use cases; and (c) build their internal data governance practices and policies to align with the businesses' overarching data strategy and use cases *and not the other way around*.

Tips:

- Adopt 'privacy by design' and avoid 'set and forget' – formulate data protection and privacy strategies from the outset to achieve regulatory compliance and reassess regularly.
- Closely manage the chain of data control (particularly as it is common in the industry to transmit data to third parties).
- Prepare a detailed data management plan as to the retention, security and flow of data, including how and when to discard data.
- Develop internal data handling training – the latest OAIC quarterly report on data breaches identified malicious/criminal attacks and human error accounted for 94% of all notified breaches, which confirms that the human element is a key area of risk, even in 'high technology' businesses.

Product liability and allocation of risk

3D printing and associated technologies may present new risks and disturb the existing understanding about who should carry those risks. However, the new technologies and the changing regulatory environment also provide opportunities to reduce risk and assign risk to those best able to control them.

Will identified the positive impact that the use of virtual or 3D printed models can provide. These models allow surgeons to plan precise surgical access routes to avoid damaging nearby arteries and cutting away too much tissue. He said: '***Many surgeons are kinaesthetic learners and giving them a 3D printed replica of the patient's anatomy can convey more information than a diagram, picture or verbal description. Also, a better fitting medical device which is produced via 3D printing can save a lot of time in the operating room***'. This is significant as the longer the patient stays under general anaesthetic, the greater the risk to the patient. The importance of these 3D models appears to be recognised by the TGA in its proposals to regulate these sort of models as medical devices.

Jason referred to the definitions for Personalized Medical Devices recently published by the International Medical Devices Regulators Forum (***IMDRF***), which make it clear that liability should sit with manufacturers. He agreed and said: '***Liability should sit with the person who has control over the production of the device and gets the benefit of the inclusion of the device on the register of approved devices. This shouldn't change just because a device is no longer mass-produced***'.

However, the position on liability could be uncertain where the role of the 'manufacturer' or the 'supplier', who traditionally would have been liable, is fragmented. For example, different entities may be performing the roles of product designer, software provider, materials maker and printer. The entity that 'makes' the product could be the person, including a health service provider or a user, who simply presses the 'print' button.

The use of AI in the 3D printing industry is only just starting, but also raises interesting questions. Alex thinks that AI has great potential in generative design and quality assurance. It can be used to make 'on the fly' judgments to adjust **during** the design and production process, rather than after the product has been made.

In 2017, the European Parliament considered the idea of granting legal personality to smart robots so that they could be sued and held liable. Robots can be insured so that compensation is paid by insurers to humans who suffer injury or damage at the hand of robots. Even so, it is unclear to what standard robots should be held accountable. Negligence law is all about the reasonable person and whether the reasonable person knew or ought to have known the risk of harm. It is obviously difficult to apply concepts such as knowledge to robots. **Should the applicable standard be that of a reasonable robot and what would that mean? Should humans be liable for the actions of a robot and under what circumstances?** These are questions with which lawmakers will need to grapple.

Tips:

- Put in place robust contractual and insurance arrangements to deal with how commercial parties themselves think liability should be allocated.
- Prepare to comply with the requirement to ensure goods are safe, which the ACCC is proposing to introduce into the Australian Consumer Law.

Regulation by the Therapeutic Goods Administration

In November 2017, the TGA released a consultation paper proposing changes to the regulatory framework in Australia relating to personalised and 3D printed medical devices. In May 2018, it published a summary of the public submissions on the consultation paper. However, these proposals are now likely to be superseded by the IMDRF proposals.

Both Jason and Alex emphasised the importance of a proper regulatory framework for businesses. Jason observed that: '***Regulatory frameworks for personalised devices are currently much more advanced in the US and China and this gives companies who comply with those regulatory frameworks a commercial advantage, as doctors and insurers would have more comfort in a device which has received regulatory pre-approval***'. Alex's view is that: '***The TGA should move faster in putting in place a regulatory framework in Australia, so as to create certainty and inspire more business confidence in the industry***'.

The greatest mindset shift for regulators is **to focus on regulation of the production system rather than the actual end product**. This is more appropriate as the same product will not be produced every time. In fact, the intention is to produce different products every time.

Tips:

Understand the three categories of Personalized Medical Devices under the IMDRF definitions and the impact they will have on your commercialisation plans or use case for 3D printing:

- **Custom-made**: the artisan or bespoke type of devices, with the person requesting the device (i.e. the healthcare professional) being responsible for making of the device.
- **Patient matched devices**: typically 3D printed devices made within a specific design envelope. While the design of the device may involve input from the patient's healthcare practitioner, the manufacturer is responsible for the design and production.
- **Adaptable medical devices**: mass produced devices where the healthcare practitioner using the device adapts the device to the patient's needs in accordance with the manufacturer's instructions.

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