**3D printing in medicine: some intellectual property issues (*Ben Hopper – 2017*)**

This note sets out in brief intellectual property (**IP**) issues under Australian law raised by 3D printing in medicine and surgery, with a focus on IP issues implicated by 3D printing of human body parts for educational and medical uses.

Intellectual property

IP refers to intangible assets that (i) have some intellectual, creative, aesthetic and/or reputational element and (ii) meet the criteria for protection under one or more IP laws. IP laws offer protection to the creators of IP in the form of exclusive rights in respect of that IP (e.g., to use or to reproduce that IP). IP should be distinguished from the physical objects it inhabits. As Bently and Sherman write:[[1]](#footnote-1)

While there is a close relationship between intangible property and the tangible objects in which they are embodied, intellectual property rights are distinct and separate from property rights in tangible goods. For example, when a person posts a letter to someone, the personal property in the ink and parchment is transferred to the recipient…[T]he sender (as author) retains intellectual property rights in the letter.

Different categories of laws protect different types of IP. The three main categories of relevance to use of 3D printing technologies in medical practice are: copyright, patent and design.

Copyright

Copyright law protects works of a literary, dramatic, musical or artistic nature. Copyright arises automatically upon creation. There is no formal registration process required to secure a copyright. In general, copyright lasts for the life of the author plus 70 years.

Basic principles of copyright law include:

1. *Originality* – a work must be original to an author to receive protection under copyright laws. Thus, if I copy another’s work, I will not have copyright in the copy (because it is not original to me).
2. *“Idea/expression” distinction* – copyright law protects only the form in which ideas and facts are expressed, not the ideas or facts *per se*.

Key copyright issues implicated by 3D printing body parts for educational or medical use are:

1. Copyright in the CAD file: Is there copyright in a digital scan of a body part stored in a CAD file? The answer will depend on the degree of independent intellectual effort involved in the making of the CAD file. If the maker of the CAD file has used a 3D scanner to scan in the image, relied upon software to make the CAD file, and made no alterations to the digital scan, then there is unlikely to be copyright. However, if the maker has exercised creative choices to produce a CAD file from the digital scan , then there is likely to be copyright.
2. Copyright in the 3D printed body part: Is there copyright in the 3D print of a body part? If the 3D print of the body part is to be used for medical purposes (and not, for example, as an artistic sculpture in an art gallery), the answer is probably no. A 3D print of a body part may qualify as a sculpture or a work of artistic craftsmanship. To qualify as the former, generally it must have some aesthetic appeal, which is unlikely to be the case if used for a functional, medical purpose. To qualify as the latter, generally its form must not be constrained by functional considerations, which again is unlikely to be the case if used for a functional, medical purpose. This is to be contrasted with a 3D print of a sculpture that a person creates from scratch using a computer program. In this latter case, there would likely be copyright.
3. Copyright in a database of CAD files of human body parts: There *may* be copyright in such a database *as a whole* if the particular arrangement, format and/or ordering of that database involves original expression (e.g., some original way of ordering that goes beyond a “garden variety” alphabetical order).
4. Copyright in CAD software: CAD computer programs are protected by copyright. Therefore, persons seeking to use them for education or medical purposes should take care to ensure they have appropriate licences in place before using them. Making a copy of a CAD computer program solely for the purpose of educational instruction of medical students *may* be a fair dealing which does not give rise to copyright infringement, e.g., where the copying is outside a commercial context and it is not possible to obtain the program within a reasonable time at an ordinary commercial price.

Patents

Patent law protections inventions. It only protects inventions claimed in patents that have been registered with the patent office. There are two types of patents:

1. standard patents: these last 20 years from the date of filing the patent application and involve an inventive step; and
2. innovative patents: these last 8 years from the date of filing the patent application and involve an innovative step (i.e., a lower threshold of inventiveness than standard patents).

Basic principles of patent law are:

1. To be valid, a claimed invention must meet certain criteria, including:
	1. novelty, i.e., never before published or carried out;
	2. non-obviousness, i.e., as at the patent’s filing date, a person of ordinary skill in the relevant art (e.g., a medicinal chemist for pharmaceutical products) would not have been directly led as a matter of course to try the claimed invention in the expectation of success. The “person of ordinary skill” is very often a team of persons each contributing a different skillset; and
	3. the invention must be accurately disclosed and claimed.
2. Patent infringement: a patent is infringed where the claimed invention is exploited without the patent owner’s permission (e.g., selling a product embodying the invention).

Patents can protect medical products (e.g., a drug), processes (e.g., a process of synthesis) and methods of treatment (e.g., a drug dosage regimen).

Key patent issues implicated by 3D printing body parts for educational or medical use are:

1. Patentability of methods of surgery using 3D printing: An important question in determining patentability is whether persons of ordinary skill in surgery would be led directly as a matter of course to try a given method of surgery using 3D printing in the expectation of success. It is not possible to answer this question in the abstract. There *may* be a patentable invention if, for example, the given method is non-obvious (e.g., it uses a material and/or builds 3D prints in a way that no person of ordinary skill in the art would ever think of). However, the mere application of 3D printing of a patient’s body parts in a given type of surgical operation without more is unlikely to be a patentable invention.
2. Infringement: Use of 3D printing in surgery *may* infringe another’s patent, e.g., if a patent-protected material is used without licence.

Designs

Design law protects the appearance of products. It only protects designs that have been registered with the designs office. The term of a design registration is 10 years from the date of filing the design application.

Basic principles of design law are:

1. A design registration protects the overall appearance of a product. It does not protect the functional aspects. However, visual features are capable of protection as designs regardless of whether or not they also serve functional purpose.
2. Registrable designs must be:
	1. new, i.e., not have been used or published before the filing date; and
	2. distinctive, i.e., not substantially similar in overall impression to a previous design.
3. A design registration is infringed where the claimed design is exploited without the design owner’s permission (e.g., through selling a product embodying the design).

Design law is unlikely to have application to 3D prints of human body parts. However, it may have application to instruments used in surgery. In the context of IP creation, a surgeon may develop a new design for a surgical instrument using 3D printing technology (e.g., using a computer program to “build” a digital design in a CAD file and then 3D printing that design). Provided the design is new and distinctive, it will be registrable. If there is a design registration in respect of that instrument, then reproducing it using 3D printing, or providing others with the tools reproduce it, may infringe the registered design.

1. Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, 2000) 1–2. [↑](#footnote-ref-1)