

Are you 3DP ready?

3D printing is already causing disruption in some industries. **Stella Wong** considers how to develop a 3DP IP strategy, with a particular focus on the medical industry

1 MINUTE READ

3D printing has already been around for decades and has disrupted certain industries, such as hearing aids. One likely impact is an increase in IP infringement, with Gartner predicting that this could reach \$100 billion a year by 2018. Now that a number of key patents have expired, 3D printers are becoming cheaper and offer many advantages over traditional manufacturing techniques, for example in making pills. An effective IP strategy to guard against a counterfeit object being 3D printed should start with considering multiple IP rights to protect a product. However, when it comes to enforcement and policing there are additional challenges, including what actually constitutes infringing use. Now is the time to review your strategy and learn lessons from others' experiences.

3D printing isn't the next big thing; it's been around for decades and has already caused substantial disruption in certain industries (see figure 1 as an example). Everything from drugs, medical devices and medical implants to vehicle parts, skin and buildings can be manufactured using a 3D printer.

A report by Gartner in 2013 predicted that by 2018, intellectual property theft due to 3D printing alone will create global losses of \$100 billion a year – but just how might this happen and how realistic is this estimate? 3D printing involves creating a virtual design of a 3D object in a digital (CAD) file which can be used to print the object using a 3D printer. The digitisation of an object raises significant IP risks since digital files can easily be replicated and hacked and can cross-borders much more readily than the 3D objects themselves. This, in addition to the technology becoming more mainstream, creates new challenges to existing IP regimes that were created in an era when only traditional manufacturing techniques were available. How will existing laws stand-up to the 3D printing world?

This article considers the impact of 3D printing on IP rights, how to mitigate those risks and the opportunities arising from 3D printing. A number of the key patents relating to 3D printing technology have already expired, making 3D printers cheaper. However, rather than become ubiquitous household objects, the widespread access to 3D printing manufacturing capabilities has been achieved through numerous commercial 3D printing services that connect consumers to the technology.

What is 3D printing and why bother with it?

3D printing is making a 3D object from a digital file. There are three key steps to making a 3D printed object which are shown in figure 2.

What is 3D printing? How does it work?

3D printing is making a 3D object from a digital file

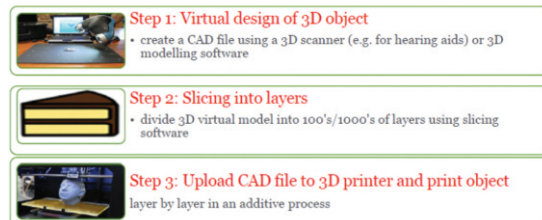


Figure 2: Key steps in making a 3D printed object

In the final step the CAD file is uploaded to a 3D printer and the object is printed layer by layer in an additive process; hence one of the alternative names to 3D printing is additive manufacturing.

3D printing offers a number of advantages over conventional manufacturing techniques including: (i) the ability to customise an object, for example a medical implant may be customised to a patient's size and shape; (ii) it creates less waste since the object is created using an additive (layer by layer) technique rather than the subtractive techniques used in conventional manufacturing which gives rise to scraps in order to obtain the desired shape; (iii) it allows more complex objects to be made in a single process, thus avoiding the need for assembly; and (iv) it disrupts the conventional distribution chain by making so-called decentralised manufacturing possible; instead of a central manufacturing hub from which mass produced items are distributed and subsequently stored in warehouses, the 3D printed item can be made rapidly, on location when it is needed—potentially avoiding lead-times for delivery and costs for storage. The advantages of 3D printing a drug compared to the conventional moulding or compression techniques for manufacturing drugs are discussed in figure 3.

Types of IP rights involved in 3D printing

Printers, component parts, software and scanners

There are a number of patents in all of these products and the processes that they use. The expiry of key patents in 3D printing technology (in particular stereolithography and fused deposition modelling patents) has led to 3D printers becoming cheaper and more widely available.

The number of patents in the 3D printing field has grown exponentially since about 2012. The US has the most patent filings followed by Japan and China. Differences in, for example, software patent eligibility between countries may contribute to the number of patent filings.

Figure1: 3D printing causing disruption in the hearing aid industry – case study

3D printing is a disruptive technology which is having (and has had) exponential growth in certain industries. This means that rather than having an incremental growth which merely improves an existing model (for example by making something slightly faster) it is a game changer that is not constrained by an old model.

The US hearing aid industry is a frequently cited example of how 3D printing is being disruptive: it is said to have converted to 100% 3D printing in less than 500 days. Those hearing aid companies that did not convert to 3D printing simply didn't survive. Today more than 10 million 3D printed hearing aids are in circulation.

There have been a small number of US patent infringement actions between 3D printer manufacturers. For example, in 2012 3D Systems sued Formlabs for infringement of US patent number 5,597,520 directed to stereolithography, and the parties settled in 2014. More recently EnvisionTEC also sued Formlabs in respect of two of its patents directed to stereolithography.

Of course other IP rights may also subsist, for example, the software used in 3D printing may be copyright protected and may be marketed under a particular trade mark.

CAD files

There has been some debate about whether a CAD file is copyright protected; for example the UKIPO considered whether it could be a computer program and therefore a literary work but it concluded that the UK position is unclear. A CAD file is a structured sequence of data (and embedded data) that is read by software.

It is also possible that design rights will extend to a CAD file if it is considered a "product" in which a design is incorporated.

3D printed object

The 3D printed object may itself have certain IP protection, for example the owners of the Zipdose technology described in figure 3 claim to have more than 50 patents related to pharmaceutical applications of 3D printing.

Intellectual property risks

Counterfeit goods

An object (or its component part) that has patent, copyright, design right and/or trade mark protection may easily be copied using 3D printing technology; simply use 3D software or a scanner to scan the object (this is possible even through an app on a

Detecting IP infringement may prove challenging in a 3D printing world. Unlike physical objects, CAD files easily cross borders, without being the subject of a Customs seizure

smartphone) and send the file to one of the numerous 3D printing services available online. The layer by layer printing that 3D printing technology provides may mean that it is difficult to distinguish the counterfeit/infringing product from the genuine one.

To prevent such copying of objects businesses should consider various IP rights. Copyright protection only protects a narrow range of objects; unless the object or its surface design has been created principally for its artistic merit it is unlikely to benefit. Design rights protect a broader range of products since lines, contours, colours, shape, texture or materials of the product (or part of it) can be protected. Therefore, although previously often overlooked, design rights are likely to become a more important source of IP protection to prevent the manufacture of a counterfeit product by 3D printing – subject of course to the “must fit”, “must match” and other design rights exemptions. In respect of trade marks, businesses should consider putting the trade mark not only on the packaging but on various parts of the object itself.

It is likely that Gartner's estimate of \$100 billion a year global IP losses by 2018 was based on: (i) the ease with which 3D printing enables counterfeit products to be manufactured; and (ii) 3D printers becoming more mainstream due to the expiry of patents in the field and emergence of 3D printing services online.

However, for the following reasons it may be that Gartner has overestimated the losses from IP theft due to 3D printing:

- a) Lack of commercial viability in counterfeiting certain objects: counterfeit goods will only be 3D printed in significant numbers if it makes commercial sense for the counterfeiter to do this. Certain industries are more likely to suffer losses from 3D printed counterfeit goods than others; for example, compression moulded counterfeit pills are probably cheaper to counterfeit than ones manufactured by 3D printing, whereas it may be commercially viable to 3D print counterfeit toys with complex shapes that would normally involve assembly.
- b) Hyped? It has previously been predicted that every household would have a 3D printer in every room. This hasn't happened yet and may not happen. Certain 3D print manufacturers have recently scaled back or even exited their printers aimed at the consumer market. The most likely reason for this is that 3D printing at home lacks application for most people. It can also be arduous and slow and involve multiple plastic, metal or other materials and therefore at least today is regarded as a novelty item for hobbyists. The widespread availability of 3D printer services may mean there will never be a need to have one at home.

- c) Cease-and-desist letters scaring off counterfeiters – for example the owner of the rights to the Game of Thrones series successfully blocked the 3-D printing of an Iron Throne iPhone dock.

Policing difficulties

Detecting IP infringement may prove challenging in a 3D printing world. Unlike physical objects, CAD files easily cross borders, without being the subject of a Customs seizure. Add to that the change in the supply chain model from centralised to decentralised manufacture and detection of infringement could become impossible.

Enforcement challenges

A consumer 3D printing at home for private, non-commercial use would be exempted from design right or patent infringement. The same would apply in respect of trade marks since to infringe a trade mark the 3D printing would need to be in the course of trade. If the predictions for a 3D printer in every room in every home ultimately prove to be correct (which currently seems unlikely) then this could have a significant impact on the sales of genuine objects.

Hospitals across the world including in Ottawa, Dubai, India and Madrid are using 3D printing to print prosthetic limbs, skin, surgical guides, prototype devices and more. The experimental use exemption to patent infringement may apply if the hospital is 3D printing an object that is patent protected. However, even if the use of the 3D printed objects is only in the experimental phase for the experimental use exemption to apply: (i) the dominant purpose of the experiment must be to test something unknown; and (ii) the experiment must relate to the subject matter of the patented invention. If experiments are done in the UK for the sole purpose of obtaining marketing approval of a medical device or implant then the experimental use defence to patent infringement will not apply.

If a hospital starts to 3D print patent infringing drugs the patentee may wish to avoid the bad PR associated with suing a hospital by going upstream to sue the supplier of the CAD file or 3D printer manufacturer instead. The supply of a 3D printer or CAD file is unlikely to be direct patent infringement of a patented product since the patented product itself has not been made, sold or supplied etc. The supply of a CAD file for a patented object could amount to indirect infringement but proving this could be challenging in view of the double territoriality requirement that the actual infringement and supply of the “means essential” (CAD file) must take place in the UK. There would also be the burden of showing the object had actually been printed.

Illegal CAD file sharing on websites could pose problems similar to that encountered by online file sharing in the music and film industries (for example in Pirate Bay). The law has evolved such that access to film and musical copyrighted material can now be blocked relatively easily. The problem with a CAD file lies in the uncertainty of whether it is copyright protected at all – is it an artistic or literary

work? If not then the copyright infringement blocking mechanisms that apply to the music and film industry will not help. Since CAD files are frequently shared online for free there would also be the hurdle of the non-commercial use exemptions that apply to any trade marks, patents and design rights in the CAD file.

Websites for 3D printing services allow word searches so that brand names can be searched and trade mark infringement can be more readily detected than other forms of IP infringement. However since the current practice appears to be individuals buying and selling low volume 3D-printed counterfeit versions of trade mark protected products it makes no economic sense to sue for infringement, particularly when there is no easy enforcement procedure (although perhaps a cease and desist letter would be enough).

The IP Crime Report 2015/16 published by the UKIPO highlights cross-border concerns in respect of 3D printing objects with unregistered design rights, stating:

If a copy of an article is made outside the UK and the file containing the information is emailed to the UK, copies can be made in the UK without legal redress. Moreover, the portability of 3D printing machines renders them difficult to track. It is likely that ... 3D printing will present multiple challenges to IP enforcement authorities.

Mitigating the IP risks of 3D printing

A company can try to mitigate the risks associated with 3D printing by:

- in the first instance seeking brand loyalty such that the consumer would not want to use the infringing item;
- implementing an anti-counterfeiting protocol by including a unique product marking on its product;
- policing CAD file sharing websites and aggressively enforcing IP rights if infringement is detected;
- in respect of CAD files, these should be recognised as powerful tools and a company should: (i) have internal policies to restrict access to and the downloading and distribution of CAD files; (ii) ensure that confidentiality agreements are in place with all those working for the business; and (iii) implement strategies to protect CAD files from cyber-attack;
- considering multiple IP rights to protect its products in order to give assertion options down the line.

Other ways in which the IP risks from 3D printing may be reduced include:

- equalising the maximal custodial sentences for online and physical copyright infringement to 10 years: in April 2016, the UK government announced that it intended to do this while ensuring that innocent or unwitting infringers are protected;
- 3D printers could be designed to only recognise genuine CAD files;
- criminal provisions could be introduced for infringement of unregistered design rights. However a study commissioned by the UKIPO in 2015 concluded that there was no

Figure 3: Advantages of 3D printed pills

In August 2015 the first 3D printed drug, Aprezia's Spritam drug for epilepsy was approved by the FDA. It uses ZipDose technology for an improved formulation. The generic ingredient used in this drug has been known for more than a decade but patients were poorly compliant since it was difficult to swallow. 3D printing the drug enables layers of the active ingredient to be packaged more tightly and precisely making it rapidly disintegrate in a patient's mouth –literally making it an easier pill to swallow.

In the future 3D printing could be used to manufacture pills which combine multiple drugs into a single pill (avoiding the need to remember to take medications multiple times a day) and importantly, 3D printing also offers the potential to customise a medication according to a patient's characteristics such as age, or renal or liver function, in the hope of providing a safer drug for a particular patient.

We could also find pharmacies and hospitals 3D printing drugs -so rather than dispensing medications perhaps they will order in the raw ingredients and 3D print them on location as required. This could give rise to both product liability (who is the manufacturer?) and IP issues.

immediate need to legislate specifically for 3D printing because it has not yet reached the wider commercial market.

IP opportunities in 3D printing – are you 3DP ready?

Businesses should assess whether there could be a benefit in adopting 3D printing technology. For example, pharma companies should consider whether any of their drugs that are known to have poor patient compliance could be improved by 3D printing them. Or perhaps the benefits of reduced waste or customisation may be sufficient for it to make commercial sense to switch to 3D printing, possibly manufactured centrally to start with. Part of that assessment involves the consideration of how to obtain IP in the 3D printing field – think about getting on the 3D printing patents and other IP bandwagons as well as a possible alliance with a 3D print manufacturer or university doing research in the field.

Companies already in the 3D printing field should consider a CAD file licensing strategy to try and avoid the challenges that come with online file sharing. Perhaps an authorised CAD file could be sold for a genuine one-off print at a reasonable price.

Assess the IP risks, mitigate them and assess the opportunities of 3D printing now. It is a disruptive technology and lessons should be learned from the hearing aid industry in the US.



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