The 3-D printing revolution: Opening the doors to new opportunities — and risks associated with IP infringement

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As the use of 3-D printing has increased exponentially, so has its potential. Stella Wong, counsel focusing on patent litigation at our Hogan Lovells office in London, compares a 3-D printer to a sophisticated copying machine; one that is able to replicate a 3-D object. The first step in the process of 3-D printing involves creating a virtual design of a 3-D object — this can be done using a 3-D scanner, which scans a 3-D object then creates an electronic file/virtual design. Software is used to prepare the virtual design into a 3-D print file format; this process involves "slicing" the design into many layers. Finally the virtual design (also known as a CAD file) is put into a 3-D printer and the object is printed, often layer by layer.

3-D printing is used to make a vast array of objects, including: surgical implants, human tissue, dental aligners, automotive parts, buildings, and clothes and shoes. A 3-D printer enables an object with a complex shape to be made without the need for assembly of multiple parts. It also enables customized goods to be made. For example, 3-D printers have the potential to manufacture drugs tailored to an individual's unique characteristics (such as age and liver or renal function) or to combine several drugs that a particular patient is taking into a single pill.

3-D printing exposes new risks to intellectual property (IP) rights. In this hoganlovells.com interview, Wong discusses the IP issues introduced by 3-D printing and offers strategies to reduce many of the risks. And she describes partnering strategies companies should consider now so they can take advantage of new developments in the 3-D printing space as they evolve.

What are the potential risks to IP right owners from 3-D printing technology?

Wong: If you think of a 3-D printer as a sophisticated copying machine, then the IP risks become more readily apparent; in particular, if a 3-D printer replicates a product that is trademark, copyright, patent, or design right protected then it is likely that an infringing good is produced. A 3-D printer gives a person the ability to reproduce something that normally would be quite difficult to copy — and there is no need to own a 3-D printer either, since there are a number of 3-D printing services available. So, all a person needs to do is use a 3-D scanner to scan the 3-D object they wish to copy (and this can be done using an application on a mobile phone along with its camera) and send the electronic file produced to a 3-D printing service for

the item to be 3-D printed.

However, it has to be commercially worthwhile to copy an object using 3-D printing and this makes certain items more likely to be copied using this technology. For example, a complex-shaped plastic toy or character figure from a movie that is trademark protected is more likely to be copied by 3-D printing than certain other objects. This is because it is made from a cheap, readily available material and 3-D printing overcomes the additional burden of its assembly. Contrast this with a pill that is patent protected and is probably cheaper to manufacture using traditional compression or extrusion techniques rather than 3-D printing.

How can companies facing IP infringement tackle the challenges associated with enforcement?

Wong: Companies need to police what's going on — who is doing what and where? How are infringing products getting onto the market? Typically what happens in IP infringement is that there is a central manufacturer producing goods that infringe an IP right. Once manufactured the infringing goods are then distributed from the factory to various locations. For example, a medical device may be mass produced by company A in a factory in Ireland, then distributed by company B to the UK, and sold in the UK by company C. In this scenario you're looking at three potential infringers; the manufacturer, the distributor, and the seller of the medical device. The issue of who to sue is relatively easy since the number of potential infringers is small.

But with 3-D-printed products there is the potential for a large number of infringers due to "decentralized" manufacturing; where, instead of a central hub manufacturing products which are then distributed to a number of locations, the products are manufactured on demand at the numerous locations that they are needed.

For example, it is foreseeable that hospitals or pharmacies could 3-D print IP infringing medical devices or pills on location, as required for a particular patient. So, instead of having the infringing pills and medical devices delivered and stored on site until needed, only the "inks" or raw materials for such products would be delivered and stored — and such "inks" may not infringe any IP. This could lead to a situation where there are hundreds of hospitals and pharmacies that are alleged infringers in litigation. Not only would this increase the cost of asserting IP rights but identifying all the infringers in the first place may prove challenging and expensive. Even when the infringer is found, it may not be worth asserting an IP right against them, for example, if they are not producing many goods — an injunction and/or damages would have little overall impact on the market. Further, IP right holders may wish to avoid the possibility of negative PR associated with suing a hospital — the very institution treating sick people.

So these are some of the likely challenges in policing and enforcing IP rights when 3-D printing is involved.

How do CAD files for 3-D printed objects add a layer of complexity to enforcement?

Wong: Another issue is that you're also dealing with CAD files, and that complicates enforcement. Currently, customs can seize patent (or other IP) infringing physical goods; we recently arranged this for a client in the UK. But CAD files are not physical objects — they can readily be transported across borders undetected, and that is basically a person's recipe to infringe a product that has IP protection. Even if the CAD file is detected coming into a particular jurisdiction, in order to prove infringement — the IP right holder would need to show that, for example in the case of a CAD file, it could be used to 3-D print a product infringing a patent, the product had actually been 3-D printed, or that the CAD file was intended to be used to put the patented invention into effect.

What best practices can companies employ to mitigate risks related to 3-D printing?

Wong: The immediate 3-D printing and IP risks apply to many industries. Anti-counterfeiting protocols could be used, for example, on trademark protected trainers that you don't want to be 3-D print copied. This could involve the use of unique markings or materials on the original IP right protected goods such that it cannot be 3D printed. For example, the use of a reflective material on the surface of the original good may prevent it from being successfully scanned and converted into a CAD file. Alternatively a unique marking could be applied to the good that is difficult to replicate by 3-D printing.

There are a number of CAD file-sharing websites allowing users to have access to CAD files for all sorts of things for free. Any user can download a CAD file of interest and if they don't have a 3-D printer themselves, they can send that file to a 3-D printing service and have that item 3-D printed. One thing that companies with trademarks can do is go on these CAD file-sharing websites and search their brand names to see what kind of files are available to the public that infringe their IP rights. Once they find those, they can contact the website and ask it to take that particular CAD file down. It's not expensive — usually it's a take-down letter — and that can send a strong message to the public that an IP right holder is not going to tolerate the 3-D printing of infringing goods.

For those companies affected by these CAD file-sharing websites, there is also the possibility of building relations with such websites — an "*if you can't beat them, join them*" strategy. For example, an entertainment company might consider producing its own CAD files, such that consumers can download them in order to get a genuine 3-D printed version of the IP protected product. Such a strategy has been employed successfully in the music industry. If the CAD file for the original product is made available at a reasonable price, this may reduce the risk of an IP infringing good being manufactured — since the consumer might prefer to buy the original

because it's only marginally more expensive than the counterfeit one.

In respect of a company that holds IP rights in a 3-D printed product, such as an automotive component, the CAD file for that component is the company's crown jewel; effectively the recipe for its IP protected component. So that company needs to protect its crown jewel — that CAD file — and that means restricting access to those files, encrypting them, and ensuring confidentiality is maintained by having confidentiality agreements in place amongst those workers who have access to the CAD files.

You've identified IP risks related to 3-D printing, but there are also potential opportunities. What are some of those opportunities?

Wong: Companies should consider the advantages of 3-D printing and whether their business could benefit from it — and think about creating some IP around any use of the technology at the same time. The potential cost savings from 3-D printing include that it enables complex shaped products to be manufactured without assembly; allows products to be readily customised by amending the original CAD file; can reduce delivery and storage costs, for example, if the product is made at the site where it is needed rather than in a factory, and reduces material wasted because only the material that is needed is used — there is no need for a mold or template.

For example, a toy manufacturer with existing trademarks could decide to use 3-D printing to allow its toys to be customized by consumers — and create new trademarks in doing so. Another example is in the pharmaceutical industry — one company took an old, known drug that patients were poorly compliant with because it was too big and difficult to swallow. 3-D printing the drug allowed it to disintegrate rapidly in a patient's mouth and made it a lot easier to take. This was the first 3-D printed pill to be FDA approved and a number of patents have been filed for that particular pill. As discussed next, there is further research underway in this area already.

Should companies be looking at partnering with universities and other research institutions active in the 3-D printing space?

Wong: There are a number of universities researching 3-D printing techniques. For example, researchers at University College London are working on new types of 3-D printed pills with accelerated drug release properties. Wake Forest University researchers have developed a computer algorithm for dose adjustment according to a patient's biological and clinical parameters. The algorithm then generates CAD files in order to 3-D print a pill. Such a pill could have increased efficacy and reduced side effects. Perhaps in the future a 3-D printed pill may allow multiple pills to be put together and then released at different rates — so that a patient with multiple chronic diseases can just take one pill that is released at various times of the day, and hopefully be more compliant with that one pill for all his or her illnesses. The National University of Singapore's research into 3-D printed pills that control the dosage and release rate

of the drug according to the patient's treatments could provide this solution.

Pharmaceuticals should think about joining forces with institutions that are researching 3-D printed pills. They should review their existing portfolio of medicines and consider whether there are any opportunities within 3-D printing available — is there a way to 3-D print a pill to make it easier to take? If so, could that method be patented?

About Stella Wong

Stella Wong is dual qualified as a medical physician and a solicitor. She is a counsel in the intellectual property team of the firm's London office and works predominantly on multijurisdictional patent litigation. She specializes in life sciences patent litigation, in particular relating to medical device and pharmaceutical patents, but has also worked on patents relating to mobile phones LEDs and rare earth catalysts. Wong graduated from University College London with degrees in Medicine and in Physiology. She has qualified as a member of the Royal College of General Practitioners. Wong worked as a doctor at University College London Hospital and still practises as a general practitioner at the weekends.

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