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Medical 3D Printing, Intellectual Property and Regulation

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Abstract

This chapter gives an overview of applicable legal frameworks to the main uses of 3D printing in medicine. In particular, medical device regulation and intellectual property are explored. 3D printing is not an unregulated field, but there can be ambiguities about how particular legal frameworks, developed in a pre-3D printing era, can apply. Questions also arise about whether these frameworks need to be changed to better facilitate desirable uses of 3D printing and protect against undesirable uses. This chapter presents some of these debates, and gives a summary of legal issues those using 3D printing in the medical field need to consider, focussing on intellectual property and medical device regulation.

Keywords

3D printing; regulation; intellectual property; medical device regulation

1. Introduction

3D printing and 3D bioprinting are steadily advancing as techniques to manufacture medical products. Particularly in medical devices, 3D printing is starting to be more commonly used to manufacture those products. During the COVID-19 pandemic where conventional supply chains have been disrupted, along with an enormous need for products including personal protective equipment (PPE) and ventilator spare parts, 3D printing and makerspaces throughout the world were mobilized to meet this demand (Troxler, 2022). Usually such 3D printers, especially owned and used by makers, use fairly simple materials such as plastics. Medical and health settings such as hospitals may possess 3D printers using e.g. metals to make prosthetics. Even more complex and experimental materials for 3D printing are comprised by techniques such as bioprinting, which is at a promising but still early stage of research due to its inherent complexity.

Both 3D printing and 3D bioprinting, however, do not occur in a 'lawless' space, despite claims to the contrary (e.g. Michael, 2013). The processes and products are overseen by different regulatory and legal measures in different jurisdictional contexts. Such regulatory tools include technical standards, medical product regulations, and intellectual property, especially copyright, patents and trade secrets (Daly 2016; Horst et al., 2019). Beyond those more

specialized areas of law, general legal principles such as tort or criminal liability, may also be applied in certain contexts.

While bioprinting is still at an early stage of development and implementation, this has not prevented a debate emerging about how existing legal frameworks might govern bioprinting and whether they would do so in satisfactory ways (Tran, 2015). These regulatory tools have been criticised for their inadequacy in governing the manufacture and use of 3D printed and bioprinted medical products. Ethical and societal considerations and questions of safety and risk have also been discussed in this context.

This chapter gives an overview of the regulatory environment that 3D printing and 3D bioprinting are considered, focussing on intellectual property and medical device regulation as these are the two frameworks which are most applicable to uses of 3D printing in the medical sphere. After a broader consideration of the relationship between law and 3D printing in medicine, the application of copyright and patents to medical 3D printing will be set out, before proceedings to medical products regulation. Despite an increasing cognisance of 3D printing's use in medicine, which is most visible in the medical device frameworks and regulators' guidance, there are still ambiguities and uncertainties about their application to some 3D printing uses and contexts. While in IP law there is more international legal harmonisation, there is still a lot of uncertainty about the applicability of copyright to 3D printing design files in different jurisdictions, and questions about patentability of bioprinting.

2. Law and 3D printing in medicine

3D printing or additive manufacturing does not exist in a governance vacuum. Indeed, it is surrounded by what Brownsword (2020) calls a 'regulatory environment', made up of rules-based norms (such as legal frameworks) and non-rules based governance modalities, such as through technologies and technical standards.

3D printing's regulatory environment consists of a number of legal frameworks, ethical considerations and technical standards. The focus of this chapter is on legal frameworks, but it is important to remember that the law is not the only modality of regulation, especially for technological artefacts (Lessig 2006). Technical standards, which seek to promote quality assurance, consistency and meeting regulatory standards, have been a prominent tool of governance for 3D printing. According to Madla et al (2018):

> The first standards around terminology were developed by the American Society for Testing and Materials (ASTM) International, an international standards organisation that develops and publishes voluntary consensus technical standards for a wide range of materials, products and systems.

ASTM has also partnered with the International Standards Organization (ISO) to develop common standards for 3D printing, out of which a framework for 3D printing standards called the Additive Manufacturing Standards Structure, has been developed, which signals aspects

of 3D printing which need to be standardised (AMFG, 2020). A number of standards have since been produced by both organisations.[1] Accordingly, technical standards are a key element of the regulatory environment, but not this chapter's focus, which is on legal frameworks.

There are also ethical implications of using 3D printing in medical and health environments. Beyond where law and ethics coincide, these ethical considerations are beyond the scope of this chapter. However, some ethical issues have been identified (Cornwall 2016; Jones 2018) in the context of 3D printing anatomical models, especially if based on scans of donated bodies. Further ethical issues have been identified specifically vis-a-vis bioprinting, relating to the source and donation of cells used for bioprinting (which may have patentability implications too, as discussed below) and clinical translation (Vijayavenkataraman, Lu, & Fuh, 2016; see also Gilbert et al., 2018; Sekar et al 2.,021).

Here the main legal frameworks pertaining to 3D printing, in medicine, are intellectual property law and sector-specific medical regulatory frameworks, which are elaborated on in the following sections. However, these are not the only legal frameworks which make up 3D printing's regulatory environment. General principles of law, from both criminal and civil law, will also apply to uses of 3D printing, as they would apply to other activities and areas of life. This might include criminal liability for certain malicious uses of 3D printing e.g. to manufacture medicines without a licence (see e.g. Braithwaite, 1984) or other prohibited materials such as guns (Daly, 2016). General principles of private law may include liability for negligence if a 3D printer was used negligently, or harmed an operator in contravention of health and safety regulations. It is important to bear these general principles and frameworks in mind when using 3D printing, including in medical settings, however the focus now turns to intellectual property and medical-specific regulation, which are the two most prominent legal frameworks for medical 3D printing.

3D printing has posed challenges to both the design and enforcement of legal frameworks, both of which are:

> driven by the decentralisation of production brought about by 3D printing, and the possibilities for individuals to produce items in their homes and workplaces and bypass traditional gatekeepers and nodes of control (Daly, 2019).

Legal frameworks including intellectual property and medical regulation have presumed a centralisation of industrialised production in e.g. factories, while 3D printing opens the possibility of individuals without very specialised machinery and a without a high level of skills being able to produce complex items. A highly notorious example of this challenge to conventional legal frameworks is the Liberator 3D printed gun, although as Daly et al (2021) found, this challenge may be more theoretical than practical for the time being.

Nevertheless, as will be seen below, there are theoretical challenges that 3D printing posts to conventional categories of IP and medical regulation, raising some uncertainties and ambiguities in operation. Yet it is clear that these frameworks do apply to 3D printing, inasmuch as they apply to other new technologies (Horst & McDonald, 2020).

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[1] https://www.astm.org/get-involved/technical-committees/committee-f42/subcommittee-f42
https://www.iso.org/committee/629086/x/catalogue/p/0/u/1/w/0/d/0

2. Intellectual Property

Intellectual property (IP) is the area of law which protects and promotes creativity and innovation by granting exclusive rights over certain forms of creativity, innovation and information or knowledge goods. IP is the umbrella term for different kinds of rights, the most prominent of which are copyright, patents and trade marks. Trade secrets, protecting confidential information, are sometimes considered to be another category of IP (Risch, 2007). Here, the focus is on copyright and patents as these are the two areas of IP most likely to be encountered in medical 3D printing.

The purposes and justifications for IP are contested. Broadly speaking, IP exists to incentivise creativity and innovation, reward creators and innovators and recognise the extension of an individual's personality through their creations and innovations (Moore, 2008). However, whether IP as a framework actually does achieve these goals and objectives in reality is subject to controversy: for instance, Boldrin and Levine (2008) consider that IP has not actually led to more or better creativity and innovation in practice.

There is some level of international harmonisation of IP law through international treaties including from the United Nations World Intellectual Property Organization (WIPO) and, more controversially, the World Trade Organization (WTO), as well as other regional trade agreements and the influence of major national and regional jurisdictions such as the European Union (EU) and United States of America (USA), both in terms of their legislation and case law (see Abbott, Cottier, & Gurry, 2019). The WTO's Trade Related Aspects of Intellectual Property (TRIPs) agreement, by tying IP protections and enforcement to participating in the global trade order, was a major, if controversial, driver of harmonisation of substantive IP laws, such as the criteria for patentability (Weatherall< 2006). Controversies relate to the globalisation of IP law standards mainly emanating from western and developed economies, which may not be as appropriate for developing and non-western countries (Shiva, 2001; Halbert, 2005).

Nevertheless, even among western jurisdictions, and even with the harmonisation brought about by TRIPs as well as regional agreements and legal systems such as EU law, there is still a significant degree of divergence in e.g. what exactly is protected by copyright, what exceptions there are to IP rights, and, in some cases, enforcement mechanisms (Daly, 2016). This is also in spite of globalised technologies, such as the Internet and other ICTs, and now 3D printing.

While IP rights are envisaged as exclusive rights which the holder - not always the original creator or innovator, as they can sell or otherwise pass on their rights to others - has a bundle of exclusive rights to allow or prohibit others to use their IP without the rightsholders' permission, subject to certain exceptions. However, in recent decades 'open' IP approaches have become more prominent. These involve a 'hack' of IP rightsholders' exclusive rights over the IP by, for instance, using blanket licensing allowing others to use the IP-protected material

without having to ask specific permission, and often for no monetary cost either. For copyright, Creative Commons licensing facilitates this openness (Goss, 2007). Free software licences may cover both copyright and patent aspects of computer program protection (Evans & Layne-Farrar, 2004; Leveque & Ménière, 2007). In other sectors, such as health and biotech, other models such as patent pools and clearinghouses have been used to achieve more openness in IP (Van Overwalle, 2009).

There are various interactions and approaches to IP in 3D printing. The relationship between 3D printing and IP is a complex one and is likely to continue to be so in the future (Birtchnell et al., 2018). Indeed, as Bechtold (2016) puts it:

> Intellectual property protection played a beneficial role in 3D printing technologies in some instances (sometimes intended and sometimes unintended), and it may have played a neutral or detrimental role in other instances.

All IP rights can apply to different aspects of the 3D printing process, from materials, printing processes, digital design files to 3D printed object (Daly, 2016). For those in the medical sphere, patents may be the most familiar IP right, and they may have less familiarity with copyright, outside of areas like medical education resources and research papers. However, 3D printing 'CAD' design files are likely to be protected by copyright and may contain copyright-protected designs (Weinberg, 2013; Mendis, 2014), including when they relate to medical or health items. However, precisely what is protected by copyright vis-a-vis CAD files may differ from jurisdiction to jurisdiction, which clearly complicates matters for global discussions and dissemination in the health sphere, as in many other sectors. Part of this complication relates to the fact that in most (if not all) jurisdictions, there is no requirement to register copyright with e.g. an intellectual property office. Instead, copyright arises on creation and committal to some material form – copyright does not protect mere ideas, but does protect the expression of those ideas. Notwithstanding, there can be controversy over whether copyright actually subsists and whether it may be infringed by something which must have actually copied it: simultaneous creation is not an infringement of copyright without actual copying taking place. All of this can lead to uncertainty and evidential issues about precisely what is copyrighted and when infringement takes place.

3D printing has seen prominent use of open approached to copyright licensing of CAD files, especially through leading file-sharing platform Thingiverse (Moilanen et al., 2015). Thingiverse contains design files for a wide range of objects, including for medical/health-related purposes – at the time of writing there are design files for COVID-19 face masks, anatomical models and even leg prosthetics.[2] The presence of such items, at least some of which may be considered medical devices, and applicable regulatory frameworks will be discussed more in the next section. But here, suffice it to say, that there are medical-related design files hosted on a site such as Thingiverse and licensed using Creative Commons and other open licensing approaches.

While initial fears over file sharing sites like Thingiverse related to the possibilities of the IP, especially copyright, of large companies being infringed by files uploaded to the site by individual users, similarly to file-sharing site Napster and its ilk for music files, which fell foul

[2] See: https://www.thingiverse.com/search?q=medical&page=1&type=things&sort=relevant

of copyright law in the 2000s (Ku, 2002). However, the 'direction' of infringement was somewhat reversed for 3D printing. Indeed, individual users have experienced either infringement or misappropriation of their designs by larger corporations, or overly broad US Digital Millennium Copyright Act (DMCA) takedown requests from corporations where there may not have been a genuine copyright infringement by the individual user's files (Daly. 2016).

Thus, those creating or using 3D printing design files in health and medical sphere, and sharing them with others, need to be aware of copyright and have some basic understanding of how it works in their particular jurisdiction, to ensure that they are not infringing the copyright of others, and that their own copyright is not being infringed or used in ways inconsistent with e.g. the Creative Commons licence that they choose. This may be a novel consideration for some researchers, who may be more familiar with patents, if they have any familiarity with IP at all.

The criteria for patentability are more stringent than for copyright, so fewer items will be able to be patented, but the registration requirement for patents dispels the aforementioned uncertainty about whether a patent exists or not, as can be found sometimes with copyright. If a patent is granted, there is a shorter term of protection (usually 20 years, compared to life of the creator plus 70 years for copyright) compared to copyright, but during that period there is a stronger level of protection. For example, there is no need for copying to occur, simultaneous and independent creation of a patented item, without permission from the patent holder, or the operation of an exception or defence, will be an infringement.

Patents have tended to be less easy to infringe prior to the advent of 3D printing given the difficulty in making patented items, especially for ordinary, non-skilled people. The combination of 3D printers and file sharing sites has raised the spectre of more widespread infringement, including 'innocent infringement' by those who are not aware that they are infringing a patent (Weinberg, 2010; Desai & Magliocca, 2013). The issue of liability for intermediaries such as file-sharing sites for patent infringement by users is another conceptual problem given in some jurisdictions such as the US, intermediary liability regimes have been developed for copyright but not for patents. However, mass infringement, especially by hobbyist 3D printing enthusiasts, has not eventuated yet (Reeves & Mendis, 2015; Birtchnell et al., 2018).

Supply chain challenges brought about by the COVID-19 pandemic, coupled with a high and immediate demand for medical supplies led to the first major potential 3D printing patent infringement case. In northern Italy where a deadly first wave of the pandemic hit, a start-up Isinnova reverse engineered a ventilator valve part and printed it for a hospital which could not source replacement parts from the manufacturer (Mahr & Dickel, 2020). It was reported in the media that the original manufacturer threatened to sue the start-up for patent infringement (Kent, 2020). While it seems that Isinnova was not sued in the end, the mere claim of infringement may produce a chilling effect on those trying to respond to emergency situations such as this one, yet social acceptance of such uses of even IP-protected material increased as 'many front-line medical experts started (despite possible risks) us[ed] locally and privately 3D printed supplies' (Mahr and Dickel 2020).

In certain circumstances including emergencies such as a pandemic, there are mechanisms recognised under the WTO TRIPS agreement (especially via the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health) which permit governments to restrict patent rights and all third party access in certain circumstances – these have become known as 'flexibilities'. Article 8 of TRIPS sets out that member states may ' to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'. According to Abbott (2020), '[t]he main flexibilities relevant to addressing the COVID-19 pandemic are the compulsory patent licensing (Articles 31 and 31bis, TRIPS Agreement) provisions, and the patent-related limited exception (Article 30) provision'. However, it appears that most governments have not made use of these flexibilities in practice. A TRIPS Waiver has been proposed for manufacturing COVID-19 vaccines only, and not other forms of healthcare products and equipment, but so far it has not been agreed on and implemented given particular opposition from developed high-income nations (Thambisetty, 2021).

Moving on from the COVID-19 situation, other issues for 3D printing in health and patents relate to what can be patented, especially when it comes to bioprinting, issues have already been raised about whether bioprinting could be subject to patent protection. In particular, authors such as Li (2014) have noted that patents for bioprinting may not be in accordance with the morality exclusion from patentability contained in Art 27(2) of TRIPS (and implemented in many regional and domestic patent laws including the European Patent Conention), if, for instance, there are stem cells from human embryos involved and destroyed. Li (2014) also notes the exclusion from patentability of 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals. (TRIPS Article 27, implemented in the EPC in Art 53(c)). In illustrating the distinction between what might be patentable and what might fall within this exclusion, Li (2014) states:

> the method of 'using a 3d bioprinter in the treatment of the human or animal body by implantation' would need to be distinguished from 'using a 3d bioprinter for reproducing cells/organs'. the former is likely to fall within the meaning of the medical exemption; the latter provides technical effects of reproducing materials for further implantation and is unlikely to fall within the purview of 'methods for medical treatment' […] methods of reproducing cells/organs using a 3d printer will arguably merit patent protection. However, if the 3d bioprinter is used to print the reproduced tissues directly on the human body in accordance with real-time images acquired by 3d scanning technology, then the method is likely to be considered a surgical method, and will thus be excluded from patentability.

Notwithstanding this, many bioprinting related patents have been applied for and issued around the world - although concentrated in the US, China, South Korea and Europe - with companies like Organovo and Cellink prominent players (Bicudo, Faulkner & Li, 2021).

Those working in the bioprinting sphere need to be aware of these controversies around what may or may not be patentable; and also that patents which have been granted can also be revoked some years later if the criteria for patentability were not duly fulfilled. If bioprinting becomes more prevalent, it is likely that these issues will surface more

frequently and prominently, along with their ethical and social dimensions beyond the purely legal.

3. Medical Product Regulation

Medical products (medicines and medical devices) are protected by their own regulatory frameworks in many jurisdictions, which give manufacturers a framework in which to create and disseminate medical products in ways which ensure safety and minimise risk for patients.

These frameworks may be applicable to 3D printing in the health and medical spheres, if what is being printed, or possibly the printer itself, is considered a medical product. A wide variety of items, both pharmaceuticals and equipment, can be 3D printed for medical and health purposes, posing varying levels of risk to users. There is some use of 3D printing to create medicines already, but currently it is still at a fairly early and experimental stage, although 3D printing of medicines does have 'enormous potential to revolutionise the way medicines are produced by providing a simple and rapid means of fabricating customised small or 'one-off' batches', and be part of the transition towards 'personalised medicine' (Trenfield et al., 2018). Another aforementioned, also largely experimental, use of 3D printing is bioprinting, which could be regulated as a drug, biologic, medical device or combination product (Hourd et al., 2015). However, what would be considered as 'medical devices' for the purposes of medical device regulation are already widespread in 3D printing environments. This can be seen even on hobbyist-oriented sites like Thingiverse, where, as mentioned above, design files are available for a variety of different kinds of medical device. There is also extensive use of 3D printing to create medical devices in hospitals and other clinical environments to print implants and prosthetics at the point of care (Christensen & Wake, 2022).

From a legal perspective, there is no binding international law on medical device regulation. Instead, technical standards play an important role in governing this topic, including in the health/medicine 3D printing sector, especially for device testing (Schuh & Funk., 2018). This contrasts with the situation for IP, where the TRIPS Agreement sets down international legal standards (albeit controversial ones according to some). For medical regulation, one has to look then to regulatory frameworks in specific national and regional jurisdictions, such as the US, with the internationally prominent Food and Drug Administration (FDA), and the European Union's regulatory frameworks, which are harmonised throughout the bloc, but administered by national regulatory authorities in each Member State (Rafi et al., 2022).

Medical device regulation usually operates on a risk-basis, so devices posing higher risks to patients are subject to more regulatory obligations than lower risk devices. Traditionally, '[m]edical devices regulation in the USA and EU envisages the existence of a centralised, conventional manufacturer or supplier of the device and that the device will be 'marketed'', assumptions which decentralised and personalised 3D printing challenge, especially when files are shared for free for medical products on sites like Thingiverse (Daly, 2016; see also Horst and McDonald 2020).

For devices which are made for a particular patient, many medical device frameworks make a difference between 'patient matched' and 'custom made' devices: the former is usually produced for a specific patient but as part of a larger manufacturing run and usually produced by a manufacturer; while custom made devices are truly a one-off device made for an individual patient whose 'specific needs cannot be met or cannot be met at the appropriate level of performance by an alternative device available on the market' (Rafi et al., 2022). There are usually some additional obligations pertaining to custom made devices, such as limiting the annual number produced.

Various medical device regulators have issued guidance on how their frameworks apply to 3D printing, and in particular patient matched and custom made devices. The US FDA has been the most internationally prominent regulator issuing such guidance, while regulatory authorities in Australia, Canada and Singapore have also issued their own guidance (Rafi et al., 2022). The EU updated its medical device regulatory framework recently, with the new Medical Device Regulation (MDR 2017/745) coming into force in 2020. One notable change is that the new MDR has updated definitions for 'custom-made devices' and patient-matched 'mass produced devices', which seems to imply that many uses of 3D printing in the medical sphere will produce mass produced devices if they are

> adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices' (MDR Article 2(3)).

The EU's Medical Device Coordination Group (MDCG), consisting of representatives from each EU Member State and the European Commission, issued Guidance in 2021 on custom made medical devices, reinforcing that a '3D printed device does not qualify as a CMD by default'. Instead, the following criteria must be fulfilled:

- a written prescription, containing patient specific design characteristics, of an authorised person[…]
- the manufactured device is intended for the sole use of a particular patient, exclusively to meet their individual conditions and needs
- the device is not mass-produced.

An 'authorised person' does not necessarily have to be a healthcare worker; instead, it is up to EU Member States to define who qualifies as an authorised person in their domestic legislation (MDCG, 2021). Time will tell as to how these definitions and requirements will be implemented and enforced in the 3D printing scenario e.g. just how 'mass' 3D printing-enabled 'mass production' needs to be for something to qualify as a patient-adapted device rather than a custom-made device.

In any event, one key issue for all of these regulators is raising awareness of the very existence of their frameworks, especially when non-traditional actors i.e. organisations and individuals who are not conventional medical device manufacturers are de facto making medical devices with 3D printers (Daly, 2019). This is not an issue confined to 3D printing – there are a plethora of health and medical-related smartphone apps available, only a few of which are developed

by traditional medical software providers, so there may be analogous issues in ensuring that there is awareness of the need for some of them at least to comply with medical device regulation (as software can be considered as a medical device – see Ludvigsen et al., 2022).

Even when 3D printing is used in a hospital or clinical setting at the point of care, there may be regulatory ambiguity arising given some jurisdictions such as the US have presumed a distinction between 'healthcare provider, medical center and device manufacturer', distinctions which are blurred when 3D printing is used in this context (Beitler et al., 2022). The US FDA is currently working to develop a regulatory framework to address these settings, and released a Discussion Paper for consultation in late 2021.[3]

Prior to the COVID-19 pandemic, however, 3D printing had not been used in a widespread way to produce medical and health products, especially for use by clinicians and other healthcare workers. This entailed that the 3D printing which did exist for medical and health purposes largely took place either within more traditional manufacturing settings, or in healthcare settings such as hospitals. Hospitals and other clinical settings will be staffed by medical professionals and administrators who might be expected to have some awareness of regulatory frameworks such as those governing medical products, even if they may not be clear on how these apply to in-hospital manufacture of 3D printed products.

Yet the pandemic has seen the use of makerspaces, fablabs and even individuals with their own 3D printers creating a variety of equipment, especially personal protective equipment (PPE), for healthcare staff (Troxler, 2022). Such individuals and organisations may have a lot less familiarity and awareness of regulatory frameworks especially in medicine. Mobilising these resources to facilitate 'peer-production of personal protective equipment prima facies [was ..] a helpful response to disaster' (Troxler, 2022). Troxler (2022) investigated the maker community's response to COVID-19 in four European countries (UK, France, Germany and Spain) and found that as regards regulatory requirements and standards, makers' 'preferred strategy' was to interact with medical professionals and hospitals to ensure they were fulfilling these requirements, including in some cases obtaining CE marks. There were less successful interactions with regulatory authorities, which either occurred in private or not at all (Troxler, 2022). Overall, Troxler (2022) found:

> Makers were crucially aware of the strong regulations in the field of medical equipment and the reasons for these regulations. Working, and particularly co-designing with healthcare professionals was a necessary precaution to be able to provide safe and still quick solutions. However, meaningful interaction with regulator bodies or even an attempt at reconfiguring the regulatory regime remained beyond reach for makers.

While this study was confined to four European countries, it does suggest that makers in these countries at least are aware of the existence and purpose of regulation in the medical/health sectors, want to engage with other relevant actors such as medical professionals and regulators and want to fulfil regulatory requirements in order to ensure the safety and quality of their 3D printed products. It is disappointing that the makers did not have a more positive

[3] https://www.fda.gov/medical-devices/3d-printing-medical-devices/3d-printing-medical-devices-point-care-discussion-paper

and public interaction with regulatory bodies compared to medical professionals and hospitals; for the future, medical product regulators should engage with the maker community on a more pro-active basis to ensure regulatory requirements are met, and also to receive feedback on those requirements from a non-traditional sector of manufacturers.

4. Conclusion

Here an overview has been given of the applicability of two major legal frameworks to 3D printing in the medicine/health sector: IP and medical products regulation. Some aspects of these frameworks may already be familiar to medical personnel, especially the sector-specific regulatory framework and possibly patents. However, such people are less likely to be familiar with copyright, which plays an important role vis-a-vis 3D printing CAD digital design files. Furthermore, there are many more people involved with 3D printing, including in health and medicine, than as regards predecessor technologies, and those individuals and organisations may not be familiar with e.g. medical device regulation which may be applicable to their activities. Raising awareness of these different applicable frameworks is thus important.

The COVID-19 pandemic and associated disruptions to conventional supply chains along with unprecedented demand for certain healthcare products has been a key mobilising factor for widespread use of 3D printing, including in hobbyist/makerspace contexts. On the one hand, this has given rise to IP infringement claims, which is a disappointment given the imperative to protect health and save lives and IP's role in blocking that, an obstacle which still has not been removed by WTO members. On the other hand, there is good news from makers in Europe who have worked with health professionals to make equipment which complies with medical device regulation and standards, in order to ensure the safety and quality of products. A more pro-active approach from medical device regulators would be welcome, making themselves more accessible to this non-traditional community of medical device manufacturers, and engaging in meaningful dialogue activities.

There are a range of ambiguities and uncertainties in how IP and medical products regulation apply to instances of 3D printing, including in the health and medical sphere. Working to reduce these uncertainties in ways which facilitate low cost and widespread decentralised production and accessibility of medical and health products while preserving innovation, quality and safety should be a key goal for stakeholders in this space.

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