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Law and Technology of 3D Printing and Medical Devices

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Law and Technology of 3D Printing and Medical Devices

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Abstract:

From both the legal and technological standpoint the thing to preserve and protect in 3D printing is the design file, as this includes the blueprint for carrying out the manufacturing process. Without this file, using 3D printing (3DP) is simply impossible. Hence, the importance in assessing whether the patent system, as such, envisages protection of design files, or if the system is only poised to protect processes and/or end products. Either way, the proliferation of 3D printers poses a challenge to the enforcement of patent rights for either processes or products, given that printing these is just a button away.

Traditionally, patents are granted for products or processes, that is either for an end product or for a method in all fields of technology. 3D printing – also known as additive manufacturing (AM) - has revolutionized traditional manufacturing processes by allowing the manufacturing of individual parts with a small modification or change in the virtual 3D model –hence, personalizing items. To this extent, the whole notion of 3DP may defy the current approach toward interpreting the scope of patent protection.

Nevertheless, patents in the field of medical applications of AM are challenging, given that just manufacturing something with different technology might not be innovative in itself. However, determining the technology involved when changing a process from analogue or manual to digital and automatic may constitute the real innovation – the use of a design or CAD file. Most of the current patents involving 3DP are in the areas of the 3D printing process, materials, post-processing itself, or products. Furthermore, there is an increasing interest in obtaining patents focusing on the applications by utilizing 3D-printing processes.

The ease at which patent rights can be infringed with 3D printing, or related innovations, is not the only challenge when addressing the topic. For instance, interpreting the patent scope – understood as breadth and width- of 3DP inventions may be among the toughest challenges modern patent law can face. Subsequently, aligning patent law with public policy and technological advancements, without stalling innovation, is another major concern.

The aim of the present chapter is threefold. Firstly, it seeks to understand what should fall within the scope of patent protection in terms of 3DP medical devices and the subsequently dependent digital models – design or CAD file. Secondly, after defining the scope of patent protection, we shall address the issue of obviousness related to 3DP processes; and thirdly, we intend to demonstrate how the personalization of medical devices, through 3D printing, challenges the boundaries of traditional patent law – application, implementation, and enforcement. The overall goal of the present discussion is to determine whether digital models should receive patent protection, and if so, if this could undermine future innovation.

The discussion will be kept at a general level without analysing in depth what CAD or design files are, nevertheless, their importance will be addressed within the chapter. When assessing the scope of patent protection several aspects need to be taken into consideration from both the legal and technical perspectives, namely the doctrine of equivalence, the use of functional language in patent claims, and lastly, what should be the ideal width for 3DP medical device patents – processes or products. In this regard a comparison will be drawn between the US and EU scholarship.
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Introduction

For the development of this chapter we will use two examples to illustrate the complexities in protecting inventions using 3D printing. For instance, the scope of patent protection is challenged by the development and use of this technology to the extent that the breadth of the patent claim needs to be defined. The doctrine of equivalence may pave the way for patent protection to allow for a certain level of flexibility when examining patent applications. The level of flexibility should not be understood as a manner to decrease or manipulate patentability requirements, but more on the lines as to allow new concepts and definitions to be taken into consideration, enabling them to fall within the scope of the patent protection sought after, e.g. by the inventors.

3D printing is a process where material is joined, usually layer upon layer, to make an object from 3D-model data, as opposed to subtractive manufacturing. The geometry of the part can be complex and producing different kinds of parts requires only a modification to the 3D file. This opens new possibilities for medical applications since every patient is different. Current products that have already been made using 3D printing include: personalized implants, dental crowns and bridges, prosthetic parts, medical models of patient anatomy, drugs, medical instruments, and orthodontic devices. Future applications include tissues such as bone, cartilage, liver, and heart. When medical imaging using computed tomography is performed in the hospital, these images can be used to create a
medical model from an imaged subject such as bones, vascular and soft tissue. The same virtual 3D model can then be used as a reference for 3D modelling personalized implants, which can be produced using 3D printing from, for example, a titanium alloy. Teeth can be scanned directly from the mouth or from a plaster model taken by a dentist. This can be continued by 3D modelling dental crowns and bridges, or 3D modelling orthodontic devices. These can then be 3D printed, directly or indirectly, using 3D printing to create an example mould for the process. Drugs, for example, are 3D printed to achieve rapid dispersion and for the future development of innovating personalized drug pills. In prosthetics there is a personalization through a connection to the body and the dimensions of the prosthetics are related to the dimensions of the patient. As children grow, for example, the need to remanufacture slightly bigger parts creates large costs. By 3D printing parts, it can be quite easy and affordable to manufacture when needed and a 3D model can be modified according to the growth of a patient.

**Personalization with 3D Printing in Medical Devices: Understanding the Technology ...**

The definition for what constitutes a medical device is quite broad, as it may include, for example: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which is: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals [FDA modified]. In the context of 3D printing this is often the part that is made directly or indirectly using 3D printing and serves in this kind of purpose.

In the personalization of medical devices patient-specific anatomy is crucial and when 3D printing is utilized this anatomy needs to have a 3D format in the computer. Current methods capturing data of a patient include: computed tomography, magnetic resonance imaging, ultrasound, positron emission tomography, and others. Usually, these methods create 2D slice images of the patient and from these multiple slices a 3D model can be reconstructed. Other methods include different scanning technologies such as laser scanning, structured light, and photo-based scanners. These are used for skin or teeth which are not inside the body. Also, gypsum models taken from teeth or other body parts can be scanned with these technologies. When these are used in the processes of making medical devices, at least a small part of the product’s geometry comes from the patient’s own unique geometry. This raises the questions of what are a patient’s rights over his or her personal geometry and how does this relate to intellectual property?
Technical development in materials, processes, medical imaging, and 3D modelling have opened these new possibilities that challenge old ways of doing things. In the future, such development could be even faster, and the utilizing of 3D technologies will see more and more personalized applications in the medical field.

Patents in the field of medical applications of AM are challenging. Simply manufacturing something with different technology might not add anything innovative. However, changing process from analogue or manual to digital and automatic, may involve an innovative process on its own. Most of the innovative potential is in how this is technologically done, not in the process itself. Mostly, current patents related to 3D printing are in the area of the 3D-printing process, materials, or post-processing itself, but more and more patents are focusing on the applications utilizing 3D printing. Rapid digitalization also brings new terminology, which might be harder to understand than older technologies.

**Defining Data Sets and CAD Files through Actual Patents: A Technical Perspective**

New technological developments tend to challenge the law in different ways, for instance, the intellectual property system may find itself in need of refurbishing concepts about patentable subject matter or even revisit its core principles to allow a balance between the utilitarian approach to patent protection and the trade-offs with society.13

**Dental Aligners (Align Technology - Invisalign)**

Align Technology has protected Invisalign clear aligners with multiple patents related to the process itself, manufacturing, data handling, and processing. Also, big pharmaceutical companies have started to look at what 3D printing could offer and how to protect their inventions.

Align Technology has a patent for a method and system for incrementally moving teeth.14 The following has been stated in the patent claims 1 and 2:

1. A method for making a predetermined series of dental incremental position adjustment appliances, said method comprising:
   a) obtaining a **digital data set** representing an initial tooth arrangement;
   ...

2. A method as in claim 1, wherein the step of obtaining an initial digital data set representing an initial tooth arrangement comprises **scanning a three-dimensional model** of a patient’s teeth.'

This leaves the questions of what is a digital data set and what is the relation to the three-dimensional model? Products made using 3D printing and patents
related to these pose an essential question since the standard definition defines additive manufacturing, or 3D printing, as a process of joining materials to make objects from 3D-model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies. In patent protection this gives an interesting perspective, if one is able to protect the 3D model then no 3D printing is possible without infringement. Usually, in the medical field, when creating personal medical devices using 3D printing, the starting geometry comes from the patient like in this process of incrementally moving teeth.

‘Digital data set’ is quite a wide definition. By defining it as a representation of an initial tooth arrangement, it narrows it down to represent something somehow geometric. But there are many ways to represent the geometry. An example of this has been demonstrated in Figure X. A digital data set representing geometry can be measurements of the geometry, layer images, or a 3D model. In simple cases, like for cube measurements of the geometry, it includes height, width, and depth. In layer images there could be, for example, ten layers which all represent squares where the distance between the slices is one tenth of the height. 3D models have dozens of different kinds of formats. The STL (STereoLithography) file is the golden standard in 3D printers and describes triangulated surfaces by the unit normal and vertices. A cube would consist of twelve triangles, all of which require corner points and unit normal information. The STL file describes only the geometry, but no material or manufacturing information such as orientation or post-processing.

A CAD file can include the material and other manufacturing information and usually CAD programs have geometric primitives, for example, a cube can be defined by the relations to other geometry, or reference co-ordinates, and by knowing the height, width, and depth. In this regard, it might be connected so that the dimensions are also modified when other geometry is modified, so-called parametric modelling. A full CAD model also often includes full blueprints of the item.

In the patent application Align Technology might have looked for as wide of protection as possible by using as general terms as possible. Digital Imaging and Communications in Medicine (DICOM) is a standard format in medical imaging. It describes geometry in layers of pictures.
3D Medical Pills (Spritam, Epilepsy)

The Aprecia Pharmaceuticals Company has presented ZipDose Technology, which is based on 3D-printing principles. The technology is used to manufacture medical pills, which rapidly disintegrate in seconds, can contain high doses, and offer a wide range of taste-masking capabilities. Manufacturing does not require forces, punches, or dyes. The innovation behind that is the process of how to make the pills and mostly how the conveyor system is included, but more importantly the geometry and density of the pills. The end product is protected with the following major claim\textsuperscript{18} 1:

1. A taste-masked rapidly dispersible dosage form comprising a **solid porous non-compressed bound matrix** comprising:
   - taste-masked wax-coated particles comprising topiramate and at least one waxy material present at a weight ratio ranging from 20:80 to 50:50, respectively; binder; and surfactant; wherein, the dosage form disperses in less than 90 seconds when placed in aqueous fluid.

The claim does not take into account anything about the manufacturing of the pill. The manufacturing has been protected with another patent with the major claim \textsuperscript{19}:

A three-dimensional printing equipment assembly comprising:
- a three-dimensional printing build system comprising:
  - a **conveyor system adapted to conduct plural build modules**;
  plural build modules engaged with the conveyor system, wherein the build modules are adapted to receive and temporarily retain powder from a powder layering system; and at least one build station comprising: 1) at least one powder layering system adapted to form incremental powder layers within build modules;
and 2) at least one printing system adapted to apply a liquid according to a predetermined pattern to incremental powder layers within build modules; wherein the conveyor system repeatedly transports the build modules from the at least one powder layering system to the at least one printing system to form a three-dimensionally printed bed comprising one or more three-dimensionally printed articles in the build modules; and the equipment assembly excludes a printing system adapted to apply liquid to the powder according to a polar coordinate algorithm.

It might be that with previous technologies, like pressing similar structures, it is impossible or at least economically unfeasible. Without protecting the end product, competitors might use other, or quite similar, solutions to produce similar products.

TNO presented a conveyor system combined with 3D printing in April 2012, a couple of months before Aprecia Pharmaceuticals filed their patent application. TNO's process uses a different material jetting class of technology and Aprecia Pharmaceuticals has claimed a kind of powder bed process, most probably a binder jetting process. The difference might also be that TNO uses railcar types, like when one layer of material is added once a railcar goes under the material jetting heads. The processes are different and require different kinds of technical solutions to work, but on a conceptual level they are really close to each other and have lots of similarities.

![Figure 2 ZipDose piller (Aprecia Pharmaceuticals Company, screen capture from video)](image)

**Personalized Implants**

Patient-specific medical implants are made utilizing 3D printing. The comprehensive workflow consists of four steps: medical imaging, 3D modelling, 3D printing, and clinical application. Traditionally, implants have been manually bent and shaped, either preoperatively or intraoperatively, with the help of anatomic solid models or standard implants. In medical imaging, patient data is captured to layer images using, for example, computed tomography. From the
layer images, a 3D model of a patient’s anatomy can be calculated using density as a threshold. This process is not protected by a patent since it was gathered using multiple processes that already exist. Many patents are related to the 3D-printing process and material related to medical implants. But still most beneficial patents are for the end products. In 2007 the first CE-certified hip implant, Fixa Ti-Por, was released in the European market. The product was not customized, but was the first implant made with 3D-printing technology. Patents related to this can be divided into two categories. Firstly, patents related to 3D printing and materials, and secondly, patents related to the end products. In the claims no manufacturing methods are mentioned but it is obvious that before 3D printing it was not possible to manufacture these kinds of products. The major claim in the patent is:

‘A prosthetic element comprising a cap made of metal material, having inside an acetabular seating, said cap having an internal wall that lines the seating and the external part consisting of a lattice with cells making a plurality of cavities disposed three-dimensionally, open and intercommunicating, connected with each other, said lattice being solid with the part facing toward the outside of the internal wall,

at least part of the lattice is formed, without a break in continuity, by one or more models of a plurality of geometric meshes repeated in space over all or part of the body of the prosthetic element, having a cellular geometry with elementary cells open and contiguous, to define a plurality of polygons with a spatial development delimiting the cavities, so the lattice is able to promote osteo-integration.’

Again, the patent claim does not take into account how it is manufactured. The keyword which connects this to 3D printing is lattice structure and the figures within the patent claim. These kinds of structures are almost impossible to manufacture by other means and poor surface quality of metal 3D printing processes are an advantage since cells and bone integrate better on this kind of rough surface. 3D printing has made it possible to manufacture these kinds of products, which are patented by Lima-Lto Spa.
Patent Protection of Health Technologies: A Case to Include CAD Files within the Scope of Protection for 3D Printed Medical Devices

The WTO was created in 1994 through the Marrakesh Agreement during the well-known Uruguay Round. The Organization became operational in 1995, and this international organization not only deals with trade rules between nations, but is also responsible for setting the rules for international trade.22 Annexed to the Marrakesh Agreement Establishing the World Trade Organization, the agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (hereinafter TRIPS Agreement) was ratified by 158 members on the 2nd of February 201323 re-conceptualizing intellectual property rights as trade issues24 when minimum standards of protection where not only established, but also extended to all fields of technology, hence, the pharmaceutical field.25 The terms of protection were extended to a period of twenty years26 for both products and processes.27 A transitional period had been established to implement the Agreement, specifically patent protection for pharmaceutical products, until 2016.28 Article 65 (4) from the TRIPS Agreement,29 in paragraph seven seems to be ambiguous in terms of the so called ‘mailbox provision’ and if countries are to either grant ‘exclusive marketing rights’ or implement the mailbox provision before the end of the transitional period.30

In light of the TRIPS Agreement’s Article 70 (9), member countries that did not provide patent protection for pharmaceutical products, whose health agency still granted marketing approval for new products, had to grant it for a period of
five years.\textsuperscript{31} However, the General Council on the 8\textsuperscript{th} of July 2002 decided to waive exclusive marketing rights for the least developed country members.\textsuperscript{32}

Allegedly, the terminology ‘exclusive marketing rights’ was unusual in the legal jargon and was introduced with the TRIPS Agreement, therefore, presenting member countries with a new challenge. It has been suggested that exclusive marketing rights, following the dictionary’s definition and logic, strictly means that a product that obtained marketing approval in a country making use of the transitional period, can only be commercialized in that country by the applicant, however, this is not to prevent third parties from producing, exporting, and commercializing the product in foreign markets.\textsuperscript{33}

The TRIPS Agreement as an ‘agent of change in the health sector’\textsuperscript{34} allows protection for inventions related to pharmaceutical products and processes. The Agreement, besides extending patent protection to all fields of technology and stating patentability requirements, does not, however, define what an invention is. In this respect, the lack of consensus in a universal or unique definition has been highlighted, which is not indicative of an omission or loophole in the TRIPS Agreement.\textsuperscript{35} Allegedly, this is not the only definition not provided by the Agreement. The same Article 27(1) aims at defining inventions by giving their patentability requirements –new, inventive step, and capable of industrial application- but none of these are defined, except for the ‘inventive step’, which can be taken as ‘non-obvious’.\textsuperscript{36}

Article 27(2) and (3) also foresee patentability exceptions, namely those contrary to public order or morality including: health, plants and animals, and diagnostic and/or therapeutic and surgical methods.\textsuperscript{37} Patents, as understood traditionally, grant exclusive rights to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions. Precisely, these legal means to prevent others are heavily relied upon by the pharmaceutical industry, since they allow companies to recoup R&D costs. Thus, the patent system is said to contribute to the legal certainty for investors/ companies to engage in further R&D. Taking into consideration that the cost of developing a new drug in 2012 can be up to $1.5 billion, it is only reasonable to provide a framework allowing for the recuperation of investments, especially when the cost of failure is also high.\textsuperscript{38}

Patents are by no means a marketing approval. Pharmaceutical products are required not only to prove their efficacy and safety in long and expensive clinical trials, but are also required to obtain a certificate attesting to their quality before they reach the market. Traditionally, the process can take up to twelve years, however, in the case of 3D prosthetics or implants, the regulatory agencies (FDA)
have had to speed up the approval procedure as to make the product available to the patient as soon as possible.\textsuperscript{39}

Several questions have risen questioning the efficacy of both the IP system and the health policy framework in providing the right scope of protection for 3D technology, and the health requirements of today’s world. Of particular interest for this chapter is to shed light on what should fall within the scope of patent protection in terms of 3DP medical devices and subsequently dependent on digital models – design or CAD file.

Among the examples highlighted above, the inventive activity behind, i.e. identifying how the conveyor system is included in the process of making the pill for epilepsy, or how has the transparent plastic shell was created to straighten teeth, are by far more important aspects of the innovative process to protect than those related to geometry and density of the aforementioned pill. Thus far, 3DP involves the creation of a unique object from a computer file – computer-aided design programs (CADs).\textsuperscript{40} These files, as defined above, contain data or can be perceived as the blueprint necessary to replicate the invention using a 3D printer. However, objects manufactured with this technology do not necessarily require the file to be reproduced if reversed engineered or manufactured with traditional processes, which is an argument used in favour of not extending patent protection to CAD files through, or as part of, the patent claim.\textsuperscript{41}

3DP in general challenges the patent system because of the digitization factor incorporated into patent claims, paving the way, in a sense, for the re-evaluation of the role of the patent system and what intellectual property ought to do,\textsuperscript{42} whether allowing cumulative innovation to take place or limiting the trade-offs between innovation and access to information though the disclosure requirement in the patent system.

Part of the challenge for patent law is to determine whether or not a CAD file is, or should be considered, an essential element of the invention. Even when the purpose of this chapter is to revisit the definition of ‘scope of patent protection’, it may be necessary to briefly assess the doctrine of indirect infringement to illustrate how detrimental it could turn out to be that CAD files are not considered an element of the patent nor a means to infringe the patent.\textsuperscript{43} As Ballardini, Norrgård, and Minssen have pointed out in their paper about patent enforcement in the era of 3D printing, case law prevalent within the EU seems to differ in terms of what should be considered an essential element of the patented invention, which at the same time leads to complications in determining the type of infringement to be sought by right holders – whether direct or indirect. For the purpose of infringement, if the ‘means’ plays a role in replicating the invention – or producing the actual ‘effect’,\textsuperscript{44} in this case the CAD file, then this should be
considered an essential element of the invention. Therefore, defining the scope of patent protection within a claim seems to be a key factor in determining the role played by a CAD file within the patent claim in itself.

Across the pond, scholars seem to agree on the need to protect CAD files, but nevertheless, finding the right kind of protection can be equally challenging. For instance, claiming protection for a CAD file in the US appears to be unclear since 2014, when the Supreme Court weighed in on patent claims addressed to forms of software. If CAD files are defined or considered a form of software, then protection for this may not be possible. Nevertheless, expanding the scope of patent protection for an invention by including the CAD file within the claim may be the right avenue to provide some sort of protection to the file without having to grant or seek individual protection for the file itself. Even when re-assessing the way patent claims should be drafted to include the CAD file or digital data sets, its interpretation is a completely different thing. Patent law protects the invention within the claim, and these inventions generally regard either a manufacturing process or the production of a physical object, which is highly relevant for the purpose of interpreting the claim and subsequently determining the kind of infringement. As Osborn and Holbrook highlight, downloading a CAD file might not necessarily directly infringe a patent for a physical object, however, if the file is used to actually print the claimed physical object, then infringement takes place. Whether making or using within patent law, which, as we know, are both reserved to the patent owners, the copying or creating of a CAD file could not be necessarily the same as making or using under the current patent law as to account for an infringement, even when this makes sense from the technological point of view, it may not be so in the legal context.

Scope of Patent Protection

Protecting a CAD file may face a set of challenges within the current framework. Even when the file is mentioned within patent claims, protection may not fall directly onto this, given that the claim primarily covers a physical object. The CAD file contains a set of instructions, which needs to be complimented with further details before the invention itself can be reproduced with a 3D printer.

The definition of a CAD file falls outside the domains of this chapter, however, it is important to analyse some of its characteristics as to understand the ways in which the patent system is being challenged. For instance, some have argued in favour of perceiving a CAD file as a blueprint, while others as a set of instructions or a digital file containing data to print the invention. Others argue against considering computer-aided files as software, but rather as a mere 'structured string of data which needs to be interpreted by software in order to render it either onto a screen or into a 3D physical object'. Regardless of the semantics in
defining the characteristics of a CAD file, the challenging aspect is reduced to the fact that the file is an intangible object, which is not stored onto a physical medium, which at the same time has limited protection under the current patent system.51

Defining or identifying what falls within the scope of patent protection, as derived from a claim, calls for a thorough evaluation on the concept of ‘scope of patent’ protection and its implications for the future development of 3DP technologies. An invention, before receiving patent protection, must fulfill all patentability requirements – be new, involve an inventive step, and be capable of industrial applicability. All of these requirements are expressed when drafting the patent claim, which will translate in the scope of the patent as the inventor defines and describes the invention, together with the areas controlled by the patent.52

The aforementioned description entails the disclosure of the invention, which will enable the man skill in the art to replicate it on basis of the patent claims, or to make and use all the embodiments of the invention encompassed by the claims.53 Thus, the inclusion of a 3DP process could, in theory, support the inclusion of the CAD file within the context of the scope of the patent. However, scholarly work has shown a lack of agreement on the matter. As will be examined below, the use of the doctrine of equivalents may provide a useful tool to expand the scope of a patent beyond the literal language of the patent claims.54

Besides describing the use of the doctrine of equivalents to justify the inclusion of CAD files within the scope of patent protection as drafted in the patent claims, it is also necessary to review some of the arguments presented by economic theories depicting the advantages and disadvantages calling for a broad scope of patent protection. Although the length of patent protection is twenty years independent of the field of technology – whether for process or product; economists seem to challenge the breadth or width granted by patent protection to certain inventions, questioning how similar a competitor’s product may be from the originator’s to still obtain patent protection without infringing the former.55 From this perspective, patent breadth, according to economists, should also consider ‘the cost-effectiveness problem’ as a necessary piece of optimal patent policy.56 Even when this chapter seeks to strengthen the legal argument for a re-evaluation of the concept of patent scope, it is important to assess how law is complemented with the economic approach to understand the theory of technological cost embedded in the emergence of disruptive technologies, such as 3D technologies in the medical sector which are challenging the law. To achieve this we will analyse the scope entailed by patent protection from the legal and economic perspectives, to thereafter demonstrate the need to push toward legislative reforms that take into consideration the societal benefits of 3D technologies – hence, balancing stake-holder rights on the basis of the technology-cost theory presented by Harry Surden.
Legal Perspective: Doctrine of Equivalents

The scope of patent protection to both the length -twenty years- and breadth – subject matter- object to protection. Given the evolving nature of technology, the breadth of protection seems to be challenged, as shown in the ClearCorrect vs. Allign Technology recent dispute,\(^5\) where the import of a CAD file into the United States from Pakistan (by uploading it onto the company's server) brought to the spotlight the legal difficulties in both classifying the file –as an object of commerce or not; and ruling over the potential infringement. This case is particularly important not only because it is one of the few cases dealing with the enforcement of 3DP related matters, but also because it highlights the role of the judge in steering the development of the law through their interpretative capabilities.

The Align Technology process works as follows: firstly, the patient goes to the dentist and has x-rays, pictures, and impressions taken of the teeth. The information is then gathered and used to create a digital 3D image where the teeth are virtually straightened and the desired set of movements is calculated. Subsequently, a copy of these positions is 3D printed using the vat photopolymerization process to serve as a mould for vacuum forming. A plastic sheet is formed over the mould and aligners are cut out. After the set of aligners has been finished it is then sent to the patient. The patient uses the first aligner of the set for a certain time and then changes to the second one. After completing the set, the teeth should be in the planned places. This process is protected with multiple patents, process patents, but the most innovative aspect of this technology is the use of clear plastic to make the aligner as a shell over the teeth. This process could have possibly taken place even before reaching the 3D-printing stage or even without the 3D model, however, traditional manufacturing practices might have made the product economically unfeasible. This argument is rarely used when discussing if there was something innovative in the Align Technology process or not when compared to previous solutions and understandings. Some scholars have pointed out the importance of the innovative process, which follows a sequence whereby a discovery is made, an invention is created, and subsequently innovation expands the idea into something consumers want.\(^5\) Hence, true innovation must essentially create a unique product or service, be valuable, and worthy of exchange.\(^5\)

In the patents, CAD files or 3D models are mentioned, nevertheless, it is unclear whether the CAD files received protection or not. The US Court of Appeals for the Federal Circuit (USCAFC) overturned the ruling from the US International Trade Commission where 'CAD file' had been defined as an ‘article of commerce’ independently of its intangibility –hence ruling over the infringement.\(^6\) Instead, the USCAFC determined that CAD files could not be considered ‘articles’, while quoting the literal meaning of Section 337 from the US Tariff Act of 1930.\(^6\)
Court of Appeals did not find grounds to extend the ‘article’ notion to the CAD file when it was clear from the statutes that the term ‘article’ only referred to a material thing, thereafter, ‘digital goods’ such as electronically transmitted data are not ‘tangible things’, thus escaping the context of the US Tariff Act of 1930. Although the Court of Appeals did not rule over the infringement itself, it did ‘state that importing digital items might well amount to a patent infringement.’ 62 The authors of this chapter ponder on whether manufacturing the object would have changed the judges’ ruling over this matter? Could 3D printing be a way to, for example, circumnavigate customs, or a way to bring illegal or patent-protected products as a digital file inside a country where the manufacturing could be performed? Monitoring such activities seems to be a pressing issue for the industry.

(Align Technology, Inc.)

The doctrine of equivalents ‘is a judicial creation that allows right holders to exclude others from the use of subject matter beyond the textual scope of a patent’s claim’, 63 even when its applicability is said to allow the patent scope to grow overtime as the technology also evolves, since determining the infringement occurs at a post-grant phase and not at the time of filing the application. 64 An important concept, as highlighted above, is the subject matter or its extension thereof by the patent claims. In the ClearCorrect vs. Align Technology case, the use of the doctrine of equivalents may have allowed for a clearer interpretation on the scope of protection, hence the infringement. Accordingly, the doctrine of equivalents can be invoked so long as the device or process in question performs substantially the same function in the same manner and obtains the same result as the product/process from the originator.65

Even when the equivalents of the end product –dental aligners, were not in question, the inclusion of the CAD file within the scope of protection may have potentially shed light on the interpretation given to the claims. For instance, Article 69 (1) of the European Patent Convention allows the use of the description and the drawings to interpret the patent claims.66 Similarly, in theory, Section 113 (ii) allows for the applicant to supplement the original disclosure with the
drawings for the purpose of interpretation of the scope of any claim. Nevertheless, admitting to the essential character of these drawings –CAD files, may, on the other hand, be more challenging, since it is not clear which element is determining the level of ‘essentialness’ of the CAD files in replicating or interpreting the invention. 3D-printing technology has, to a certain extent, blurred the line between a physical object and a digital description of a physical object.

Although the doctrine of equivalents may provide a compelling argument to reassess whether CAD files should be considered an essential element or if they should fall within the scope of patent protection as embodied within the patent claims, it is required to examine the same theory from the technical and economical perspective.

**Technical and Economic Perspective: Finding the Ideal Width ....**

'When a broad patent is granted or expanded via the doctrine of equivalents, its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor's actual result.'

Redefining the scope of patent protection based on the doctrine of equivalents may balance society’s interests with the inventors seeking to recoup their investment. From an economical point of view, it is socially desirable that competitors are able to rely on the information disclosed within the patent claims to continue with the innovative process. While broader patents may hinder the entry of competitors into the market, extending the term of patent protection seems to indicate a likelihood in increasing the probability of imitation – competition and prices. Patent breadth, on the other hand, indicates the maximum price that the right holder can charge for the product, since patent policy in itself may determine the cost of imitation.

In broad strokes, the legal and economic approaches to patent scope seeks to balance social benefit and the interests of right holders, similarly to patent rights. For the models analysed by different scholars, independently on the angle, the importance is the substitutability of the product, which is determined not only by the ability of imitators to enter the market, but also by competitors seeking to innovate on the basis of known products. Price is another factor strictly related to the breadth and length of the patent, accordingly, price could be controlled indirectly by narrowing the scope of patent protection. In the case of personalized 3D printed medical devices, the cost of the end product plays an important role in terms of access to the product, but the role the scope will play in allowing substitutability may require further analysis.
Other models base their support for a wide scope of patent protection on consumer behaviour toward choosing higher-priced patented goods, rather than lower-priced unpatented goods with lower or devious characteristics.\textsuperscript{75} At the same time, the importance of using patent scope as a policy instrument has been pointed out, since this affects not only the valuation of the company, but also other important stakeholders.\textsuperscript{76}

The cost to society is not necessarily translated into a price issue, instead greater or wider scope of patent protection has a direct correlation with the monopoly power granted to the technology owner and an incentive decrease for other competitors to develop new potentially infringing technology.\textsuperscript{77} In this regard, patent scope has been defined ‘as the size of hypothetical developments of the technology that, together with the main configuration, are also subject to patent protection. Patent scope is the set of hypothetical “embodiments” of the technology that were originally envisioned by the inventions, and can be likened to the fence around a real property’.\textsuperscript{78}

Drafting broad patent claims seems to be an adequate strategy, accordingly with the theories described above, however, some less lenient to a broad patent scope point out the right in spilling over information due to the increase change of patent claims spanning over multiple domains.\textsuperscript{79} A conservative approach to drafting claims may be advisable when the scope spans multiple classes, since the ability of companies to build upon their own claims may be limited in comparison to better settled competitors.\textsuperscript{80}

The term –understood as length, of patent protection has been settled on twenty years. Nevertheless, there seems to be a pressing need to allow for a ‘variable’, or flexible approach, to determine the scope of patent protection, which seems to be highly influenced by the type of technology itself. The development of 3D-printing technologies seems to correlate to the evolution of patent law in terms of the reception of the digitization of patented objects,\textsuperscript{81} or at least to shed light on the right holders’ ability to pursue infringement, since the legislation, as is, might allow for the ‘unawareness’ of the existence of the patent to justify a third party escaping liability.\textsuperscript{82} For 3D-printing technology diffusion of the invention is important and, in this respect, patents may be an important tool to limit imitation via disclosure, since the original innovation is in this way protected against direct copying.\textsuperscript{83} However, the limitation of the said protection may be tangible on the inability of the current patent system to extend protection to the CAD files through the patent claims, in which case, secrecy has been pointed out as a powerful tool or instrument of protection.\textsuperscript{84}

Regardless of the breadth or width of protection sought by different theorists, the current patent system seems to be challenged by the nature of the technology and
the need to re-visit the scope of patent protection, at least in the field of 3DP medical devices. Despite claims attributing 3D printing with the ability both to 'save the world' or to exceedingly pressure for a definition of the scope of protection to address consumer engagement in infringing activities, some authors warn that not only are there a number of limitations in the 3D-printing ecosystem, particularly applicable to low-end and consumer home printers, but also concerning the need to distinguish between 3D printing for personal use and 3D printing, for instance, for personalized medical devices -industrialized.

**Patenting of Digital Models, the Pitfall of Medical Innovation? Concluding Remarks**

Admittedly, 3D printing is changing the technological costs by not only allowing fast production of physical objects from electronic designs, but also by significantly reducing the complexity in manufacturing or producing physical objects manufactured under traditional industrial practices. The dissemination of the technology, as indicated above, is a critical aspect challenging the current patent system. The Technological Costs model highlights how the presumptions of implicit technological constraints, which were present when the IP system was 'harmonized' in TRIPS, may not be present anymore. Thus, at the time, the legislation could not foresee the feasibility of 3D printing, for example, a dental aligner at home.

Revisiting the concept, or what shall be understood as the 'scope of patent protection' within the context of the 3DP of medical devices, might be a step in the right direction when seeking protection for the patent product and those elements of essential nature to replicate the invention. Thus far, scholars have focused on the implications of patent infringement of 3D-printed inventions and how an infringement could be proven. Whether it be direct or indirect infringement, one of the key factors related to the scope of the patent itself is the role played by the digital data sets within the claim. The digital model, or data sets, are 'necessary' to replicate the invention. However, determining whether this set of 'instructions' is also an object of patent protection is a completely different thing. Furthermore, determining protection for a CAD file may be beneficial in terms of consumer protection or product liability, since a pirated CAD file could be corrupted or contain errors translating into a security problem.

Patent law traditionally protects the invention claimed in the patent –product or process. The digital file, in itself, might not necessarily infringe the patent for product if the file is considered neither essential nor the same thing as the physical object claimed for protection in the patent. Recent case law seems to struggle in defining the role of, e.g. CAD files within the patent claim. Some have considered
them as a blueprint, which can be transmitted for others to replicate the physical object, and some consider it as an essential part of the process to replicate the product. Despite the lack of agreement on the role of the CAD file, the fact is that these files allow for a product to be replicated, potentially leading to patent infringement. Thereafter, defining what should be done to discourage illegal dissemination of these files and how to increase protection for 3DP medical devices remains open. Perhaps the answer falls outside the boundaries of the patent-law system, and the solution to track and limit CAD file sharing should be of a technical nature more than a legal one.

However, if we were to insist on challenging the patent system as to allow CAD files to fall within the scope of patent protection, then patentability requirements should be revisited and redefined in a manner consistent with the technological developments of the future. The law has been challenged throughout time by technology and reforms have taken place to cope with such advancements, the IP system is not indifferent to reforms nor to revisit the applicability of its own framework of protection in all fields of technology.

The IP system, as is currently in place at the international level, cannot be a one-size-fits-all system. Given recent technological advancements, for instance 3D printing, the need has been brought to the spotlight for the patent system to be complemented with other regulatory frameworks providing or strengthening innovative activities and their protection. Several scholars have pointed out the importance of interpreting the spirit of the law by judges, who should also evaluate each situation on a case-by-case basis. This interpretative activity could lead to the drafting of a set of guidelines applicable to patent claims in particular fields of technology or, when necessary, with the caveat that such practice may be deemed discriminatory. Nevertheless, implementing separate guidelines to allow, on the one hand, examiners to verify the fulfilment of patentability requirements when examining a patent comprising, i.e. 3DP invention, and on the other, to allow the right holder to obtain a ‘fairer’ assessment, translating to an adequate threshold of protection, seems somewhat more viable than reassessing the efficiency of the whole IP system just because the system, as is, is not sufficient to provide protection or incentive in all fields of technology.

3D-printing technology may seek for effective protection beyond the frontiers of patent law, for instance, trade-secret protection might be a good ally to foster protection for the technological developments before reaching the CAD file stage. Extending protection to the CAD file, through the patent claim, may be the right thing to do from the point of view of the right holder, however, one cannot stop wondering whether this would stifle innovation. Another recommendation to protect CAD files calls upon the industry to adopt, for example, secure streaming of 3D CAD files via ‘pay-per-print’ business models. The patent system should
foster innovation and create the necessary incentives to do so, but often times the solutions to secure certain aspects from the technology may need to come from outside the patent system, since this may not be able to provide effective protection without the risk of over regulating or achieving the opposite of what it was intended for.
References

23. See WTO, Members and Observers, fix quote
26. Article 33 from TRIPS Agreement
27. Article 27(1) from TRIPS Agreement. The non-discrimination principle is embedded within the Agreement since patents cannot be refused on basis of the field of technology.
28. Paragraph 7 from Doha Declaration.
29. Article 65(4) from TRIPS Agreement “To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”
31. Article 70(9) from TRIPS Agreement “Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”
34. Philippe Cullet, ‘Patents and medicines’ supra note .., at 145.
36. Footnote 5 from Article 27(1) of the TRIPS Agreement. See also, Correa Ut supra at 82. Arguably the fact that patentability requirements are not defined, 'opens some room for flexibility at the national level' as indicated by Correa.
37. Article 27(2) from TRIPS Agreement “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to ... health, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”
38. This is a common argument supporting the patent system as a means to finance R&D
41. See the articles relating to the doctrine of indirect infringement.
44. Ibid.
47. See (Lucas Osborn, 3D Printing and Intellectual Property) 261.
51. Id. See Daniel Harris Brean, Patenting Physibles: A Fresh Perspective for Claiming 3D-Printable Products, 55 Santa Clara L. Rev., 837, 846 (2015). To amplify the discussion on the nature of the CAD file and its storability on a physical medium see the Beauregard Patent article
53. Id.
54. Ibid 845
55. See Paul Klemperer, How Broad Should the Scope of Patent Protection be?, 21 Rand J. Econ., 113 (1990). The real question posed by the author is: If a company invents a new drug to alleviate a heart condition, how similar a drug should a competitor be allowed to sell?
59. Ibid.
61. See 19 U.S. Code §1337 (a)(1)(B), and Section 337 of the U.S. Tariff Act of 1930
66. See Convention on the Grant of European Patents of 5 October, 1973. Article 69 (1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.
67. See 35 U.S.C §113 (i)(ii)
Although private exception may allow for a product to be printed without infringing patent rights, it is important to remember that an attempt to commercialize a 3D-printed product based on the presumption of it not having been patented may not be a good defence. *Ignorantia juris non excusat.*