H2020

Call FoF-05-2016

AM-motion

A STRATEGIC APPROACH TO INCREASING EUROPE'S VALUE PROPOSITION FOR ADDITIVE MANUFACTURING TECHNOLOGIES AND CAPABILITIES

Grant Agreement Nº 723560

Regulatory, EHS and IPR framework and actions draft report

Deliverable number: D3.3

Document Details

Due date of Deliverable	M14
Lead Contractor for Deliverable:	PRODINTEC
Dissemination Level:	PU

Contributors:

EPMA

CECIMO

AIRBUS

SIEMENS

MATERIALISE

Table of Contents

1 Introduction

The present document constitutes Deliverable D3.3 in the framework of the AM-Motion project "*A strategic approach to increasing Europe's value proposition for Additive Manufacturing technologies and capabilities*" (Project Acronym: AM-motion; Contract No.: 723560). This document is the result of the activities performed within task T3.1 "*Regulatory, EHS and IPR frameworks assessment*", within the framework of work package 3 (WP3), titled "*Analysis of Non Technological Aspects*".

This document is intended to provide a global view on four non-technological factors associated with additive manufacturing (AM) technologies, which are currently considered to be highly relevant in order to ensure maximum implementation and development of these technologies over the next years:

- Intellectual Property Rights. The fully digital nature of additive manufacturing technologies and attached to it, the possibility that a 3D file can be reproduced by any organization or user with access to additive manufacturing means, opens up a new dimension for the consideration of the property rights associated to the creation, distribution, exploitation and general management of designs and products.

- Regulation. The emergence of AM is an important turning point when it comes to verifying how existing legislative frameworks can (if this is required) include the capacities and consequences of the use of these technologies.

- Environmental impact. Additive manufacturing technologies introduce new manufacturing systems with their own characteristics, which can be analysed from the point of view of the reduction or increase of impact that they can entail, compared to previously existing manufacturing technologies.

- Health and Safety. Like any other technology, people play an important role in the manipulation of additive manufacturing technologies and their associated materials and operations, so it is also necessary to consider the risks and prevention measures associated with them.

Thus, this document provides an overview of these aspects as a basis for the detection of possible gaps and needs to be tackled in order to accelerate the market implementation of AM technologies.

2 Intellectual Property Rights

Technological developments bring both opportunities and challenges for the distribution and control of Intellectual Property (IP) assets[1]. ICT, and now additive manufacturing, have facilitated the dissemination of IP assets in dematerialised form and allowed the development of new distribution models. Easier distribution has however also significantly increased difficulties in controlling unauthorised distribution of IP assets, and in enforcing IP rights. AM technologies will allow almost anyone to recreate any existing product design, change, and manufacture the product, and use or distribute it (and its 3D CAD-STL file). Therefore, AM may stress the patent system in the same manner that the digital revolution, the Internet, and file sharing stressed the music industry and the copyright system[2].

From the point of view of the owner of the intellectual property right, there is only a limited number of ways to protect its intellectual property for any kind of product or idea. This is not different for AM-parts. It is however a problem that most tools to protect physical products are defined with large series production of identical products in mind. One of the major advantages of AM is that small series and even unique parts become economically viable to produce. This does however not mean that the standard protection tools cannot be used for AM-parts. They just need to be formulated in the correct way.

Additionally, the increasing diffusion and implementation of AM technologies (both at industrial and domestic level) poses very important challenges from the point of view of infringement and liability of intellectual property rights. In addition to the consideration of possible problems arising from the quality of the parts not-legally copied (consumer safety, functionality, etc.), the copying of CAD files should be of concern to all stakeholders (end consumers, equipment manufacturers, online distribution platforms, etc.).

Some of the questions that could be raised by the user of the technology could relate to the implications on industrial property of the manufacture of, for example, a spare part for a device. Can I scan the part and manufacture it by AM freely? Can I distribute it later? What if the scanned and manufactured product is copyrighted? Can I use it privately?

Industry additive manufacturing concerns with IPR are mainly based on the ease of digital file sharing and increased access to 3D scanning and printing[3]. CAD and STL files are the mechanism of this infringement and present a particularly complex issue. Enforcing IP infringement is especially hard in this case as tracking private use of these files is nearly impossible.

Therefore, although the current IP regime does offer mechanisms for protection, these will not be sufficient to resolve all the copying problems[4]. Just as with the entertainment industry, new business models will likely emerge to address some of the issues raised.

---

[1] The ICC Intellectual Property Roadmap. Current and emerging issues for businesses and policymakers. 2017

[2] 3D Printing and Intellectual Property: Initial Thoughts. Hornick, John F. 2013

[3] Additive manufacturing: an analysis of intellectual property rights on Navy acquisition. Carrie Paben, 2015

[4] Thomas Kurfess & William J. Cass (2014) Rethinking Additive Manufacturing and Intellectual Property Protection, Research-Technology Management, 57:5, 35-42

2.1 Patents and Utility Models

According to the World Intellectual Property organization (WIPO) definition, a **patent** is an **exclusive right** granted for an invention, which is a **product or a process** that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application and, as remuneration, the patent owner has the **exclusive right to prevent or stop others from commercially exploiting the patented invention**. In other words, patent protection means that the invention cannot be commercially made, used, distributed, imported or sold by others without the patent owner's consent. The protection rights are territorial (exclusive rights are only applicable in the country or region in which a patent has been filed and granted), limited in time (generally 20 years from the filling date of the application) and they are associated to the payment of the corresponding taxes on a periodic basis.

Concerns about the costs involved in the European patent system should not be underestimated. One relevant factor at the basis of this is, among the others, the need of multiplying patenting costs by the number of countries in which the patent is intended to be enforced. Also the time between filing and granting a European patent application represents another problematic aspect[5]. Estimates[6] calculate the cost of a sample European patent is about 30.000 EUR[7].

Therefore, a patent gives the applicant a temporarily exclusive right for the invention. The disadvantage is that it is public. The patent is free for everyone to read and other might do further research on it and patent new developments.

2.1.1 Patent application trends

A number of patent trend studies related to additive manufacturing technology have been identified and analysed (Table 1). These studies cover a period up to 2013 and have been based on complex search equations.

In AM-MOTION project, the results of the previous studies have been compared with a specific study carried out on the Derwent Innovation tool of Clarivate Analytics in the period not covered by those previous studies, that is, for the years 2014- 2016. The information has been collected using the database Enhanced Patent Data - DWPI and DPCI, that contains one record for each patent family. A patent family is defined as a patent set containing all documents directly or indirectly linked via a priority document, providing an indication of the number of inventions an applicant may hold, as opposed to how many individual patent applications are filed in different countries for the same invention.

[5] CECIMO (2017). European Additive Manufacturing Strategy. Retrieved from: ttp://www.cecimo.eu/site/fileadmin/Additive_manufacturing/AM_European_Strategy_2017_LQ.pdf

[6] Roland Berger Market Research (2005). Study on the Cost of Patenting. Retrieved from: https://effi.org/system/files?file=cost_anaylsis_2005_study_en.pdf

[7] Typical Euro-direct patent has 10 claims on 3 pages, 11 pages of description and is validated in 6 countries. Costs of in-house preparation are excluded.

Table 1. Patent application trends previous studies

Title - Author	Search Period	Database	Nº references
3D Printing. A patent overview - United Kingdom Intellectual Property Office	1980-2013	Thomson Reuters World Patent Index (WPI); EPODOC European Patent Office (EPO)	4.015 (patent families)
3D Printing. Technology insight report – Gridlogics Technologies	1990-2013	Patent iNSIGHT Pro & PatSeer	2.653 (patent families)
Potential Challenges of 3D Printing technology on patent enforcement and considerations for countermeasures in China – Liu Xin, Yu Xiang	1995-2013	Innography	-
Understanding patent portfolio and development strategy of 3D Printing technology – Yen-Tzu Chu, Hsin-Ning Su	1977-2012	USPTO	1.089

A new specific International Patent Classification (IPC) code for additive manufacturing activities (B33Y) has been created in 2015 which covers additive manufacturing, irrespective of the process or material used. AM-MOTION search has been made using this classification code as the period covered by the search (2014-2016) is near to the creation of the code and taking into account that Derwent Innovation frequently updates all records in the database.

The study made by Gridlogics Technologies identified 2.653 relevant records (patent families). The study made by the United Kingdom Intellectual Property Office identified 9.145 relevant patents, equating 4.015 patent families. AM-MOTION study has identified 7.647 patent families, demonstrating an important increase in the number of applications in the last years (227 records in 2014, 2.253 records in 2015, and 4.984 records in 2016). Both the number of patent applications and patent grants increased with time in this period.

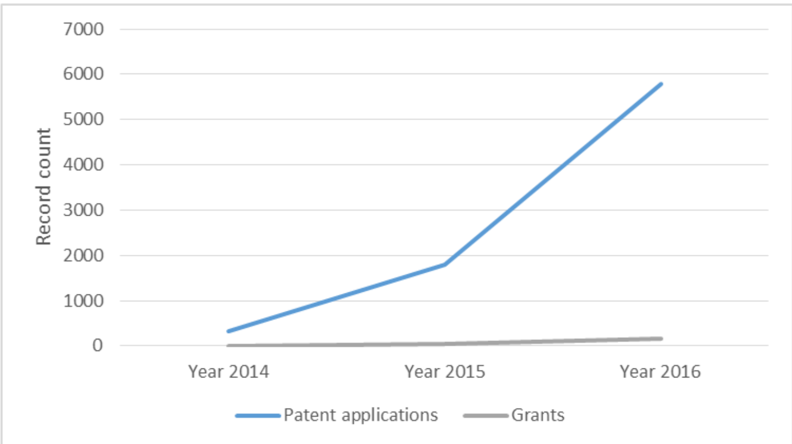

Figure 1. *Comparison of granted patents and published patents applications by publication year. AM-MOTION results, 2014-2016*

A priority country analysis is a reasonable indication of where the innovation is originating. Previous studies (up to 2013) showed that the United States ranked first in 3D Printing patent applications for more than 10 years. However, those studies have also shown that the number of patent applications in China were increasing noteworthy. AM-MOTION study for recent years (2014-2016) reveals that this increasing trend has finally derived in China being the top country in terms of patent applications. From 2015, the United States is set aside to the second position.

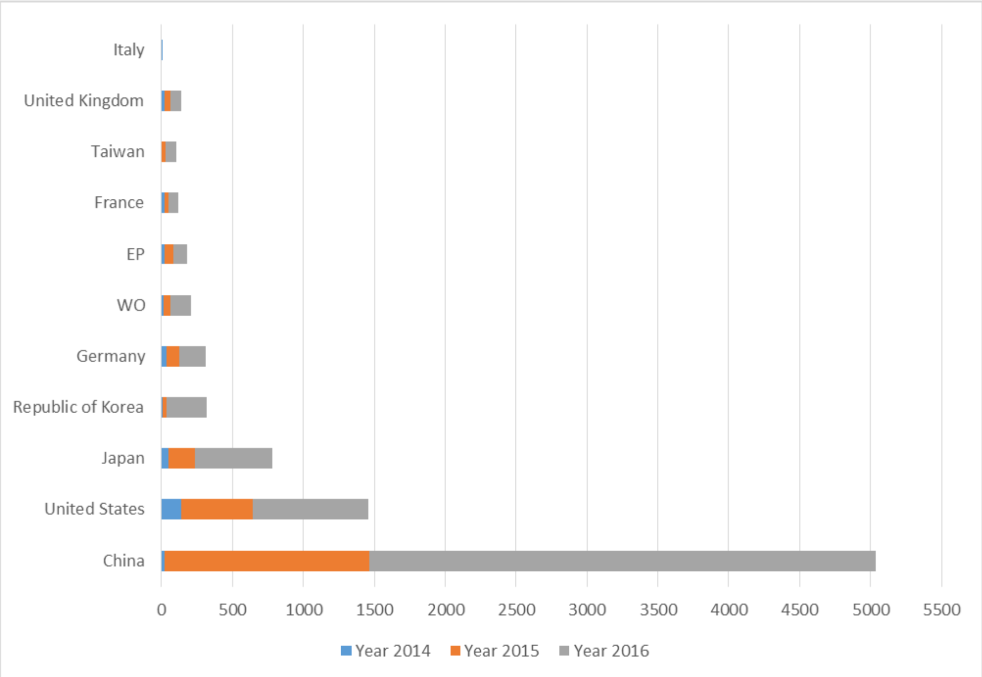

Figure 2. *Priority country distribution for the top countries. AM-MOTION results, 2014-2016*

Top patent applicants are different according to the database and search criteria employed for each study. Table 2 summarizes main applicants derived from previous studies.

Table 2. Top patent assignees according to previous studies

UK IPO	Gridlogics	Liu Xin et al.	Yen-Tzu Chu et al.
Fujitsu	3D Systems	3D Systems	3D Systems
Stratasys	Stratasys	Stratasys	Massachusetts Institute of Technology
3D Systems	Massachusetts Institute of Technology	The Boeing Company	Objet geometries
Samsung Electronics	Hewlett-Packard	MIT	Z Corporation
LG Philips	Hitachi	Siemens	Hewlett-Packard

Top patent applicants identified by the study conducted within AM-MOTION project are slightly different. New top entrants such as Seiko, United Technologies or Xerox appear. The previous top assignees (such as 3D Systems or Stratasys) keep their patent application activity, but its number of applications are widely overpassed by the new entrants.

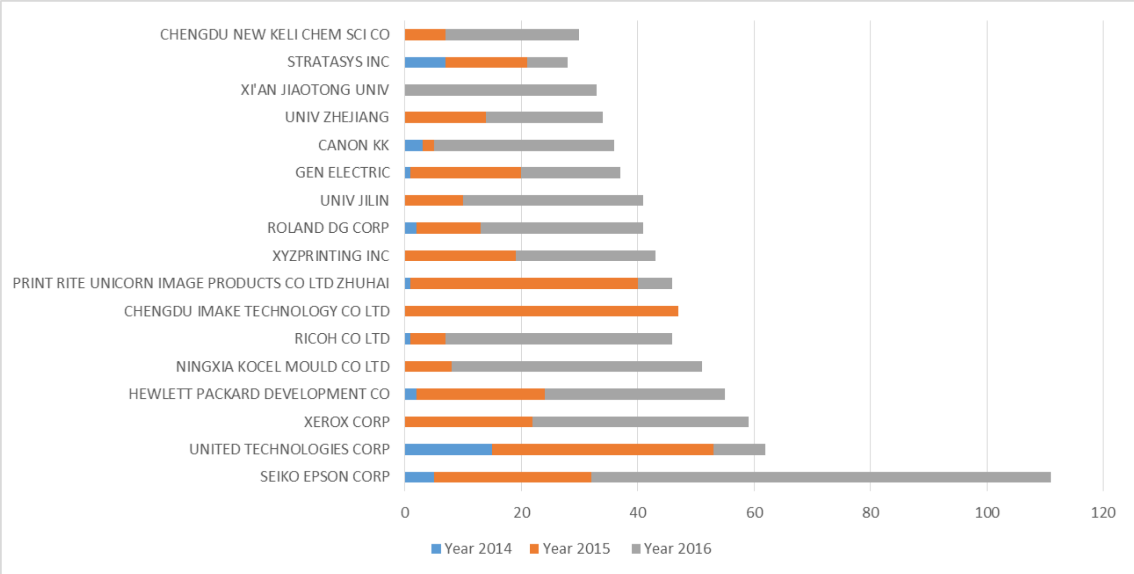

Figure 3. *Top patent assignees. AM-MOTION results, 2014-2016*

When filtering the results considering exclusively those documents published in Europe (EP patents and patents filled in European countries), the landscape of the top applicants is slightly different. The main applicants are Xerox, Voxeljet, General Electric, EOS Electro Optical Systems and SNECMA. It is also interesting to mention that two EOS patent applications are co-owned with MTU Areo Engines; and SENECMA patents are co-applied with entities such as Association pour la Recherche et le Développement des méthodes et processus Industriels-Armines (ARMINES) (2 co-applications); MBDA France (2 co-applications); European Aeronautic Defence and Space (EADS) (1 co-application).

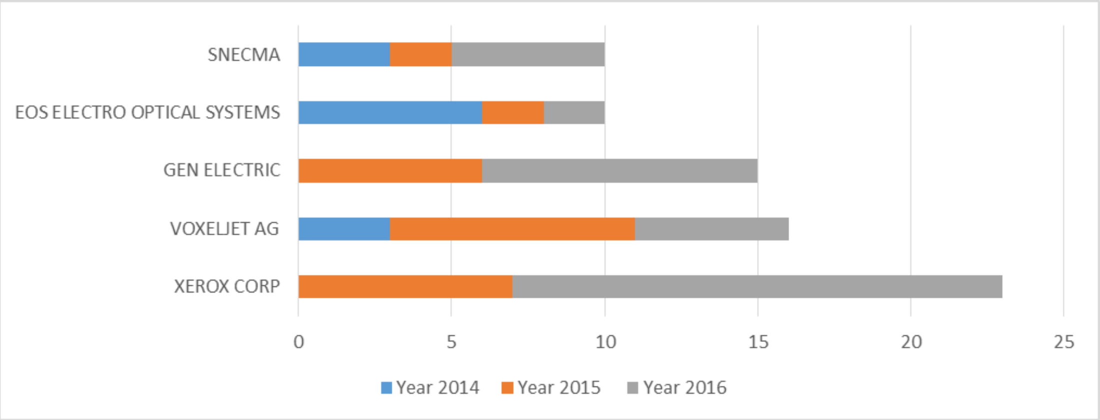

Figure 4. *Top patent applicants in Europe (EP applications and applications filled in European countries). AM-MOTION results, 2014-2016*

Top patent applicants in the United States are also different: the main applicants are Xerox, XZY Printing, Seiko, Stratasys and Roland DG.

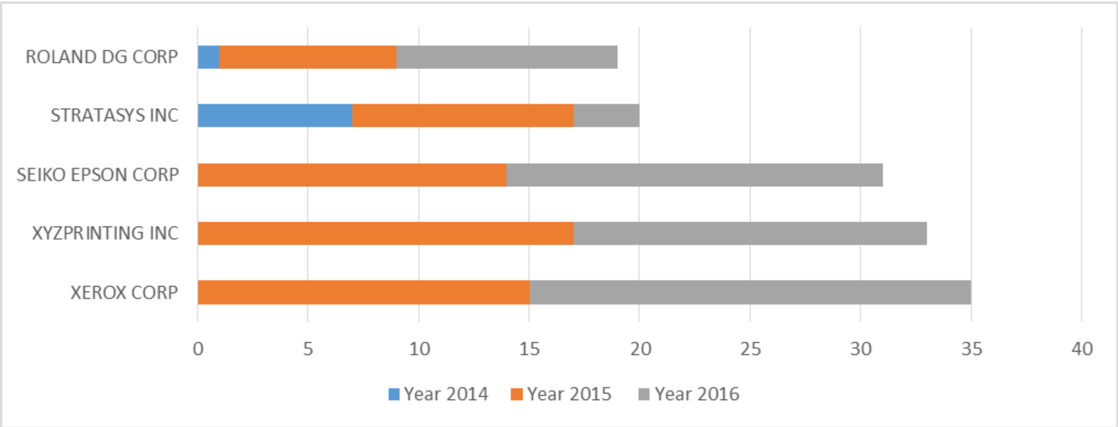

Figure 5. *Top patent applicants in the United States (US applications). AM-MOTION results, 2014-2016*

According to AM-MOTION study, AM patents under B33Y International Patent Classification (IPC) code are mostly being classified into IPC B29C 67/00 sub- groups (shaping of plastics or material in a plastic state and after-treatments), B33Y sub- groups and B22F 3/00 sub- groups (manufacture of work pieces or articles from metallic powder characterised by the manner of compacting or sintering; Apparatus specially adapted therefor). Therefore, it can be noted that although plastic additive manufacturing continues being the main interest, metal additive manufacturing is emerging in terms of patent applications.

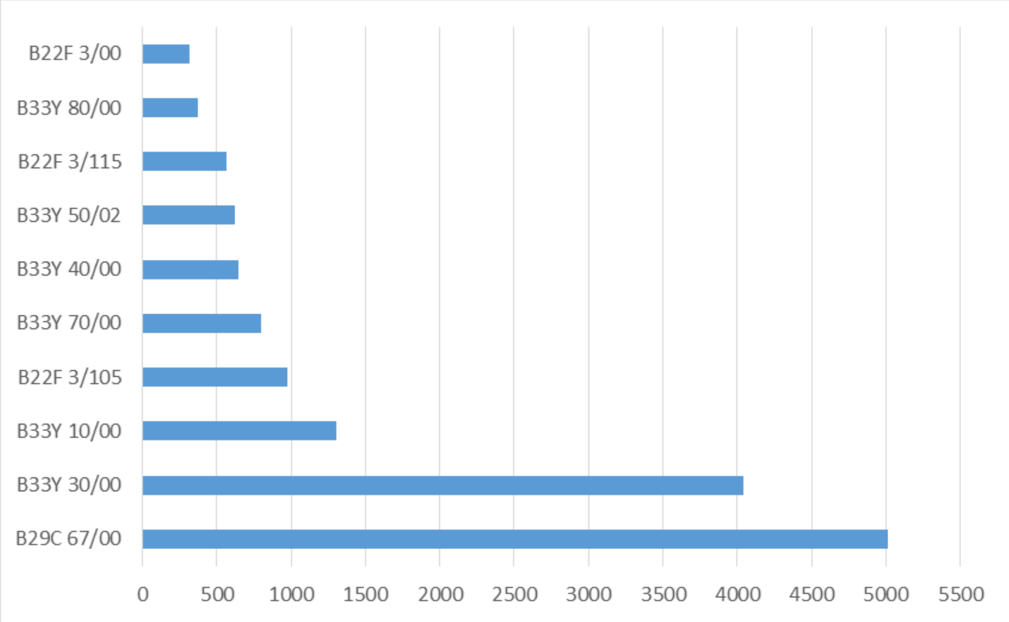

Figure 6. *Top International Patent Classification (IPC) sub-groups. AM-MOTION results, 2014-2016*

Table 3. IPC sub-groups definition

IPC sub-groups	Definition
B29C 67/00	Shaping or joining of plastics; shaping of material in a plastic state, not otherwise provided for; after-treatment of the shaped products. Shaping techniques not covered by other groups
B33Y 30/00	Apparatus for additive manufacturing
B33Y 10/00	Processes of additive manufacturing
B22F 3/105	Manufacture of workpieces or articles from metallic powder characterised by the manner of compacting or sintering; Apparatus specially adapted therefor. Sintering only by using electric current, laser radiation or plasma.
B33Y 70/00	Materials specially adapted for additive manufacturing
B33Y 40/00	Auxiliary operations or equipment, e.g. for material handling
B33Y 50/02	Data acquisition or data processing for additive manufacturing for controlling or regulating additive manufacturing processes
B22F 3/115	Manufacture of workpieces or articles from metallic powder characterised by the manner of compacting or sintering; Apparatus specially adapted therefor. Sintering only by spraying molten metal, i.e. spray sintering, spray casting.
B33Y 80/00	Products made by additive manufacturing
B22F 3/00	Manufacture of workpieces or articles from metallic powder characterised by the manner of compacting or sintering; Apparatus specially adapted therefor.

The number of forward citations of a patent document is usually considered as an indicator of the quality of the document. Table 4 shows the 20 more cited patent documents within the set of documents analysed (2014-2016 period).

Table 4. Patent documents with the most forward citations. AM-MOTION results, 2014-2016

Pub. Year	Assignee	Title	Publication Nº	Nº citations
2010	NIKE INC	Articles and methods of manufacture of articles	US20100095557A1	69
2004	HOWMEDICA OSTEONICS CORP	Laser-produced porous surface	EP1418013A1	49
2004	CADENT LTD	Method and system for fabricating a dental coping, and a coping fabricated thereby	WO2004087000A1	48
2002	GENERIS GMBH	Method for producing a part using a deposition technique	WO2002026419A1	45
2014	OTISMED CORP	Method of manufacturing an arthroplasty jig	US20140324205A1	42
2008	VALSPAR SOURCING INC	Powder compositions and methods of manufacturing articles therefrom	WO2008057844A1	41
2001	OBJET GEOMETRIES LTD	Compositions and methods for use in three dimensional model printing	WO2001068375A2	40
2006	3D SYSTEMS INC	Laser sintering powder recycle system	EP1700686A2	39
2017	ORANGE MAKER LLC	3D printing using spiral build-up	US20140265034A1	38
2000	OBJET GEOMETRIES LTD	Apparatus and method for three dimensional printing	WO2000052624A1	35
2003	STRATASYS INC	Material and method for three-dimensional modelling	US20030004600A1	35
2013	GLOBAL FILTRATION SYSTEMS	Apparatus and method for forming three-dimensional objects using linear solidification	US20130001834A1	33
2014	ARCAM AB	Method and apparatus for additive manufacturing	US20140348691A1	33
2008	3D SYSTEMS INC	Improved wall smoothness, feature accuracy and resolution in projected images via control of exposure levels in solid imaging	EP1894704A1	31
2013	ARCAM AB	Method and apparatus for generating electron beams	US20130300286A1	31
2015	ARCAM AB	Powder distribution in additive manufacturing of three-dimensional articles	US20150071809A1	31
2015	ELWHA LLC	Systems and methods for additive manufacturing of three dimensional structures	US20150064047A1	31
2014	UNIV TEXAS	Methods and systems for embedding filaments in 3D structures, structural components, and structural electronic, electromagnetic and electromechanical components/devices	US20140268604A1	30
2004	OBJET GEOMETRIES LTD	Rapid production apparatus	WO2004096527A2	30
2000	ALLISON ENGINE CO INC	Method and apparatus for production of a cast component	WO2000051761A1	29

2.2 Design Rights

According to the World Intellectual Property Organization (WIPO), an Industrial Design constitutes "the **ornamental or aesthetical aspect of an article**. An Industrial Design may consist of three dimensional features, such as the shape of an article, or two dimensional features, such as patterns, lines or colour". Industrial designs are applied to a wide variety of products of industry and handicraft items.

The protection of an industrial design is different according to national law. In most countries, an industrial design needs to be registered in order to be protected under industrial *design law* as a "*registered design*". In some countries, industrial designs are protected under *patent law* as "*design patents*". Industrial design laws in some countries grant –without registration– time and scope limited protection to "*unregistered design rights*". Depending on the particular national law and the kind of design, industrial designs may also be protected as *works of art* under *copyright law*.

At the European level, The European Union Intellectual Property Office (EUIPO) suggest two routes for the protection of designs:

- **Registered Community Design (RCD):** designs effectively registered with the EUIPO. RCD is initially valid for 5 years from the date of filling, and can be renewed up to a maximum of 25 years. RCDs are protected against similar designs even when the infringing design has been developed in good faith, i.e. without knowing of the existence of the earlier design.
- **Unregistered Community Designs (UCD):** they create an effective right since the date of disclosure. Disclosure is making the design available to the public in such a way that the interested circles operating within European Union can reasonably be aware of the design. UCDs only give protection for a period of 3 years from the date of disclosure. UCDs grant the right to prevent commercial use of a design only if that design is an intentional copy of the protected one, made in bad faith, i.e. knowing of the existence of the earlier design.

Both RCDs and UCDs offer similar protection against infractions. For example, manufacturing a product incorporating a protected design without the consent of its proprietor would be considered illegal. However, the UCD shall confer these rights if the contested use results from copying the protected design. According to the Council Regulation (EC) No 6/2002 of 12 December 2001, a **Community Design** is protected if it is new and has individual character (Art. (4)(1)) and **the rights conferred by it shall not be exercised in respect of acts done privately and for non-commercial purposes** (Article 20).

Therefore, according to EC 6/2002 (and also according to some national regulations), the copy of a (registered or unregistered) design would not be considered an infringement if it is carried out "privately and for non-commercial purposes". **It is essential that both criteria are met**[8]. That is to say, Design Rights apply when commercial purposes arise: a CDR could be 3D printed at home for private and non-commercial use without committing infringement. In these cases (private uses), copyright laws could be much more relevant.

On the other hand, 3D Models shared on online platforms (Internet Services Providers, ISPs) could potentially be in breach of the law - even if the designs are being shared for non-commercial purposes as it

8 The current status and impact of 3D Printing within the Industrial Sector: an analysis of six case studies. Reeves & Mendis. 2015

can be considered a not-private act. Disseminating a CAD file of a protected design for purposes of 3D printing via such online platforms will infringe Unregistered Design Rights (secondary infringement) according to some national regulations. For example, section 227 of the “Copyright, Designs and Patents Act 1988” (United Kingdom law) states that a design right can be infringed by a person who without the licence of the design right owner “sells, lets for hire, or offers or exposes for sale or hire, in the course of a business, an article which is, and which he knows or has reason to believe is, an infringing article”. It can be understood that the Council Regulation (EC) No 6/2002 confers a similar protection to the designs when talking about “making, offering, putting on the market, importing, exporting or using of a product in which the design is incorporated or to which it is applied, or stocking such a product for those purposes”.

Design rights could be highly impacted by the spread of additive manufacturing technologies in the coming years. The design-related issues raised by 3D printing include[9]:

- The potential scale of infringement resulting from reproductions and/or customisation of consumer products by a multitude of individual persons.
- The authorship of designs. The status of CAD/scan files and of derivative designs issued from mixing parts of several designs is key to understanding at which point the author of the initial design lost control of the authorship of subsequent versions of the design, and whether this can be remedied, e.g. through licensing. Identifying the IP rights-holder in a CAD file is also not always easy, as they can be collectively created.
- The broadening possibilities for design licensing to which design owners will have to adapt, as partnerships develop between service providers, manufacturers of consumer 3D printers and companies holding portfolios of designs.

There are several ways to get the 3D model geometry of an object to be manufactured by additive technologies (CAD – STL): a) original designs; b) purchased and/or downloaded designs; c) designs coming from reverse engineering. Obviously, if the design is stolen or hacked, problems inherent to the use of digital data files and of the Internet to store and share design files should arise[10].

2.3 Copyright

Copyright (or author’s right) is a legal term used to describe the rights that creators have over their **literary and artistic works**. The expression “literary and artistic works” shall include every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression. Works covered by copyright could be books, music, paintings, sculpture, films, advertisements, maps, and technical drawings (WIPO definition). Furthermore, the WIPO Copyright Treaty (WCT) mentions two subject matters to be specifically protected by copyright: (i) computer programs, whatever the mode or form of their expression; and (ii) compilations of data or other material ("databases"), in any form, which, by reason of the selection or arrangement of their contents, constitute intellectual creations. Copyright protects the original expression

[9] The International Chamber of Commerce Intellectual Property Roadmap (13th edition 2017)

[10] Additive Manufacturing and Intellectual Property Protection: An Overview. Lakhdar. 2016.

of ideas, and not the underlying ideas themselves.

There are two types of rights under copyright:

- Economic rights, which allow the rights owner to derive financial reward from the use of his works by others; and
- Moral rights, which protect the non-economic interests of the author.

Most copyright laws state that the rights owner has the economic right to authorize or prevent certain uses in relation to a work or, in some cases, to receive remuneration for the use of his work. The *economic rights* can prohibit or authorize, among other, its reproduction in various forms, such as printed publication or sound recording. Examples of widely recognized *moral rights* include the right to claim authorship of a work and the right to oppose changes to a work that could harm the creator's reputation.

In the majority of countries (Berne Convention), copyright protection is obtained automatically without the need for registration or other formalities. Most countries nonetheless have a system in place to allow for the voluntary registration of works. Such voluntary registration systems can help solve disputes over ownership or creation, as well as facilitate financial transactions, sales, and the assignment and/or transfer of rights.

The copyright implications of Additive Manufacturing are being widely discussed. Firstly, there is one consideration about how copyright could affect to the physical object and to the CAD-STL 3D model. In that sense:

Physical objects may be protected by copyright when they can be classed as an "artistic work"; *products that have a functional or utilitarian nature are not usually protected under copyright laws*. Therefore, most industrial products will not be considered under this kind of intellectual protection due to its inherent functional nature. However, there could be lots of examples of printed at-home products that could be included under the definition of "copyrightable": figurines, statuettes, decorative articles, etc. These products do not present a functional or utilitarian nature, as they have mainly decorative or aesthetic purposes. Duplicating those items is simple, making counterfeiting as easy as illegally downloading music[3].

As mentioned, copyright is generally applied to articles considered works of art, that is, articles that do not have a functional consideration. However, there may be objects which have both aesthetic and functional considerations. In these cases, the "severability test" applies and those decorative or aesthetic features of the article (nor related to its functionality) could be considered copyright protected[11]. This effect can be extended to additive manufacturing: if a user wants to manufacture an article with functional and aesthetic characteristics, from the point of view of copyright, the user could freely manufacture those elements that confer the functional character provided that the aesthetic elements were not manufactured.

[11] It will be awesome if they don't screw it up. 3D Printing, Intellectual Property, and the fight over the next great disruptive technology. Michael Weinberg. 2010

It must therefore be considered that there are exceptions contained in the EU Copyright Directive[12]. Relevant exceptions for 3D printing could be private coping (Art. 5 (2)(b)) and repair (Art. 5(3)(i))[13].

3D Models bring to scene a second and paramount level of discussion; some authors are discussing about the CAD-STL consideration as "technical drawings" whilst other authors are considering them "computer programs" (or even databases)[14]. What is more likely is that 3D printing CAD files fall under the category of "pictorial, graphic, and sculptural works" protected by Copyright, which is defined as including "technical drawings, diagrams, and models".

In any case, it may appear questionable whether the legal nature of the CAD should be addressed separately from the legal nature of the objet that the CAD represents[15]. At first, it could be thought that the CAD files and the objet that they represent could be copyright-protected if they accomplish the requirement of originality. The difficult lies in whether these two are distinct copyrightable subjects or just one[16]. In the second case (the file is a representation of the object and shall not be granted an independent copyright), the file could be copyrightable if the object is. In the first case (separate copyrights), then the file could qualify for copyright protection even though the objet does not meet the necessary requirements. Therefore, the discussion lies in the nature of the CAD files.

A recent study[17] has reviewed literature related to United States and United Kingdom regulations; while some authors argue against copyright subsisting in CAD files, other authors consider that a CAD file may be protected by literary copyright in the same manner as other types of computer software. However, the copyright status of CAD files remains unclear at present. The lack of clarity and consistency can lead to complexities borne out of the territorial nature of copyright law coupled with the exterritorial nature of online platforms and CAD files shared amongst users around the world.

Furthermore, the **conversion of a CAD model into an STL file** could have intellectual property implications as a consequence of changing data structure. In this regard, lessons can be learnt from the music industry where changing the format of a music file (for instance, converting a WAV to an MP3 file) does not affect the eligibility of the music stored to copyright protection. A similar argument could be used to expand the protection to the source code and data structure captured in a CAD or STL file. Converting CAD files to an STL format may modify the information that is stored in the file, but it does not substantially change the information content needed to produce the part. The part can still be made using various processes and materials, but its geometric information is well defined and easily transmitted in the STL file. Therefore, the conversion of a CAD model to an STL file should not eliminate the copyright protection of the design, in the

---

[12] Art. 5 of Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society

[13] Strowel, A. (2016). Additive Manufacturing (AM) and Intellectual Property (IP) [PowerPoint slides]

[14] Printing the Impossible Triangle: The Copyright Implications of Three-Dimensional Printing. Brian Rideout. 2011

[15] Ballardini, R.M., lindman J. & Flores ituarte I., "Co-creation, commercialization and intellectual property – challenges with 3D printing". European Journal of Law and Technology, vol 7, nº 3, 2016

[16] Online Platforms in the consumer 3D printing: Business Models and legal challenges with copyright. Rosa Ballardini, Marcus Norrgard, LL; Kan He.

[17] A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour. Mendis & Secchi. 2015

same way that compressing digital music into various file formats does not change its copyright status[18].

While digital blueprints (with the exclusion of shapes having a purely technical function) and 3D software can be generally protected by copyright, just as for 3D-printed objects there are exceptions with regards to private copying and repair. An additional exception refers to reverse engineering and the exhaustion of downloaded software[19]. To this extent, the 2012 ECJ's ruling on the so-called "Usedsoft" case mentioned that a software copyright owner may not prevent the resale of software copies that are downloaded with the copyright owner's consent over the internet, notwithstanding the initial acquirer's earlier agreement with the software copyright owner that the software copies are licensed only to the initial acquirer and shall not be resold[20].

Another issue to analyse is the **role of Online Platforms (Internet Services Providers, ISPs)**. The document "A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour[21]" has analysed IP implications arising from online platforms dedicated to the dissemination of 3D models for 3D printing. This study has selected the three platforms with the highest number of registered users: a) 123D; b) GrabCad; and c) Thingiverse. Online platforms permit 'registered users' to create, edit, upload, download, design, re-design or indeed purchase the physical model if they also act as a 'bureau service'.

The following paragraphs reproduce specific terms of use for some of these platforms.

123D: the company states that they are "not responsible or liable for, and we don't necessarily endorse, any Content. All Content, including Your Content, is the property of its copyright owner(s) or other rightsholder(s)". Additionally, when talking about the registering process, the user must agree not to do or attempt "use the Service, any feature thereof or any Content in a way that could or does violate any law or the rights (including without limitation, the copyright, trademark, patent, trade secret other intellectual property, proprietary or other rights) of any person, firm or entity or expose us, any users or any of Our Parties to legal liability".

GrabCad: The user represents and warrants that "User Submissions will not infringe, misappropriate or violate any third party's Intellectual Property Rights, moral rights, privacy or other personal right, or any Law".

Thingiverse: The user must agree "not to use the Sites or Services to collect, upload, transmit, display, or distribute any User Content that violates any third-party right, including any copyright, trademark, patent, trade secret, moral right, privacy right, right of publicity, or any other intellectual property or proprietary right". When content is uploaded to Thingiverse a user is asked to select a secondary copyright license, which is in addition to the license the user grants to Thingiverse and its affiliated companies and partners. This license governs how third parties, including other users, may use uploaded content[22].

---

[18] Thomas Kurfess & William J. Cass (2014) Rethinking Additive Manufacturing and Intellectual Property Protection, Research-Technology Management, 57:5, 35-42

[19] Strowel, A. (2016). Additive Manufacturing (AM) and Intellectual Property (IP) [PowerPoint slides]

[20] Lothar Determann and David Nimmer, Software Copyright's Oracle from the Cloud, 30 Berkeley Tech. L.J. 161 (2015) pp 182

[21] A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour. Mendis & Secchi. 2015

[22] Printing the Impossible Triangle: The Copyright Implications of Three-Dimensional Printing. Brian Rideout. 2011

Both GrabCad and Thingiverse have adopted and implemented a policy respecting intellectual property that "provides for the removal of any infringing or unauthorized materials and for the account termination, in appropriate circumstances, of users ... who are repeat infringers of intellectual property rights or who repeatedly submit unauthorized content". Their Copyright Policy is pursuant to the Digital Millennium Copyright Act. Additionally, these policies include specific procedures so that any entity that considers that its intellectual property is being unlawfully infringed or misappropriated may be able to provide adequate notice.

i.materialise: The Company contractually *"*prohibits its users from using the service to order and/or sell products that infringe third party intellectual property rights (including among others copyright, trademark, design and model, patent, trade dress and right of publicity, etc.)". The user is "solely responsible for the content" that he/she uploads on the Site. "By submitting an order to i.materialise, the user confirms that he/she is the owner and/or he/she has obtained from a third party the rights necessary for submitting the order to i.materialise for production and commercial use without any violation of any intellectual property rights. If the design submitted to Materialise risks infringing the intellectual property rights of third parties, Materialise reserves the right to either not produce the design or produce the design without the part that risks infringing the rights of third parties. Should the user generated content nevertheless be found to be infringing and/or in violation of any law, the user will defend i.materialise against third party claims, and be held liable for all (direct and indirect) damages and costs incurred by i.materialise with respect to such claims". Furthermore, when someone submit a design, he/she states that he/she is "the sole creator of the model" and that he/she does "not infringe any copyright or other intellectual property right (trademark, design and mode, patent, etc.) of a third party" and/or that he/she "obtained all the necessary permissions in order to duly allow" license to i.materialise to display the design submitted and/or a reproduction of this design for marketing purposes.

As can be seen, **the online platforms absolve themselves of liability**, thereby pointing the finger in the direction of the user with specific terms set out as to the jurisdiction where the user will be held liable[23]. The Platforms emphasize that the users maintain ownership of and responsibility for their uploaded content.

Therefore, taking all these aspects into account, it will be highly probable that **new business models arise in the future** to counter the violations of intellectual property caused by 3D printing in a similar way as it has happened in the music industry with the development of solutions such as Spotify or iTunes. For example, 3D printing companies could introduce a pay-to-print system[24], a solution proposed to address the issue related to the possible further re-distribution of a file once it has been downloaded. With this kind of system, the customer will purchase the design and the exact quantity of printing instructions would be sent directly to the machine; however, the STL file containing the information on the geometry of the object to be printed will not transmitted. Additionally, the development of encryption codes directly into STL and CAD files could become an effective way of protecting intellectual property sensible data. This will require cooperation between software companies, manufacturers and internet-based 3D printing marketplaces. In order to tackle

[23] A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour. Mendis & Secchi. 2015

[24] Additive Manufacturing and Intellectual Property Protection: An Overview. Yazid Lakhdar

the issue posed by reverse engineering, physical protections against the use of 3D scanning technologies may be implemented in the form of anti-counterfeiting tags embedded in 3D printed objects.

Other example of new business models that could arise with the growth of the AM market can be found in the alliance of the online platform *Shapeways and Hasbro*. Those companies have launched SuperFanArt, a website that enables fans inspired by Hasbro brands to showcase their artwork and sell their 3D printed designs there and on Shapeways. It's the first time a global brand has opened up their Intellectual Property to enable fans to co-create products. Consumers can visit SuperFanArt to browse 3D printed products designed by the artists and then click through to each artist's shop to place an order.

Additionally, the web service *Traceparts* offers manufacturers a vehicle to advertise and sell digital files to customers. Customers have free access to a database of hundreds of supplier e-catalogs and millions of 3D models[25]. When a customer selects a part, he or she can request a quote from the supplier. The customer then selects either a 3D downloadable file or to have the part 3D printed and mailed. Each manufacturer provides terms of use. For example, 3M advertises and offers quotes for its parts through Traceparts, but provides further user terms through its website. Specifically, 3M allows its customers to view, download, and reproduce its products for non-commercial use and requires inclusion of 3M's copyright notice

2.4 Trade Mark

A trademark, trade mark, or trade-mark is a recognizable sign, design, or expression which identifies products or services of a particular source from those of others. It is therefore not straightforward to use a trademark to protect an idea or a family of products.

Trade mark issues relating to 3D printing of replacement parts arise where a 3D printed product is sold that includes a trade mark embedded into it. According to the United Stated law (section 10 of the Trade Marks Act 1994 -as amended-). As such, commercial use of a trade mark without the consent of its proprietor will infringe the trade mark.

Additionally, 3D Models present additional concerns related with the ease of changing a digital file[26]. One primary concern is the ability of a user to remove the trademark section of a file when it is uploaded allowing for reproduction without attribution to the original author. Other concerns can arise if a publicly available or pirated design is modified with a defect—either intentional or unintentional— while still retaining the original brand markings. In this scenario, organizations run the risk of having their brand tarnished[27].

2.5 Liability and Infringements

Industries based on intellectual property have been proactively working to combat piracy and

[25] Additive manufacturing: an analysis of intellectual property rights on Navy acquisition. Carrie Paben, 2015

[26] Additive manufacturing: an analysis of intellectual property rights on Navy acquisition. Carrie Paben, 2015

[27] 3D opportunity for intellectual property risk. Additive manufacturing stakes its claim. Matt Widmer, Vikram Rajan. 2016

counterfeiting in all its forms. Many sectors have been working closely with law enforcement agencies to investigate and prosecute criminal infringements of intellectual property[28]. In general terms, using an IPR without permission from the owner will constitute an infringement of that IPR unless exceptions should apply. Generally speaking, infringement conduct gives raise to two types of liabilities:

- **Direct Infringement Liability (primary liability)**. According to the Council Agreement on a Unified Patent Court (2013/C 175/01), a patent shall confer on its proprietor the right to prevent any third party not having the proprietor's consent from:
  a) making, offering, placing on the market or using a product which is the subject matter of the patent, or importing or storing the product for those purposes;
  b) using a process which is the subject matter of the patent or, where the third party knows, or should have known, that the use of the process is prohibited without the consent of the patent proprietor, offering the process for use within the territory of the Contracting Member States in which that patent has effect;
  c) offering, placing on the market, using, or importing or storing for those purposes a product obtained directly by a process which is the subject matter of the patent.
- **Indirect Infringement Liability (secondary liability)**. A patent shall confer on its proprietor the right to prevent any third party not having the proprietor's consent from supplying or offering to supply, within the territory of the Contracting Member States in which that patent has effect, any person other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect.

To simplify, direct infringement includes for example the manufacturing and selling of a protected (patented) product, whereas indirect infringement could be characterized as aiding and abetting a direct infringement[29]. In this sense, if a patented product is composed by several essential elements, a user that manufactures all the essential elements might be liable for direct infringement, whilst a user that manufactures a subset of essential elements might be liable for indirect infringement.

Recent studies have shown that additive manufacturing might led to "unsuccessful, costly, inefficient, or too risky patent enforcement" both in direct and indirect infringement.

- *Direct infringement*: according to the general rights conferred by a patent, anyone who manufactures (by additive manufacturing or any other manufacturing process) a product protected by a patent without permission of the patent owner could be directly infringing because he/she has "made" the product without authorization. However, *the rights conferred by a patent shall not extend to acts done privately and for non-commercial purposes*. Therefore, as far as the private and non-commercial use of 3D printings (home equipment) is concerned, direct infringement of patents (and industrial designs) would be difficult to prosecute.

[28] The ICC Intellectual Property Roadmap. Current and emerging issues for businesses and policymakers. 2017

[29] Enforcing patents in Europe: challenges from 3D printing technology. Rosa Maria Ballardini, Marcus Norrgard

- *Indirect infringement*: indirect infringement doctrines are very scarce and carry a great level of uncertainty. Additive Manufacturing adds complications to this matter by interpreting the types of “means” to an “essential element” of the invention required in order to find infringement, as well as the requirements of “suitable” and “intended” for “putting the invention into effect”. And the discussion will focus again on the presence of a digital file to allow the execution of the process.

Additionally, different scenarios could be considered depending on the nature of the patent[30]:

- If the patent protects exclusively the product, then the patent could cover whatever process or method used for its manufacturing.
- If the patent describes both a product and a method for manufacturing, then two scenarios could be considered:
  - If the patented product was originally designed by the inventor by applying CAD software and it was stated in the claims that the product could be manufactured using additive technologies, then the CAD file can be both the means and the essential element of the patented product.
  - If the patented product is not considered to be manufactured by additive technologies, then the CAD file can be the means but not an essential element of the invention.

One of the markets that may be most affected by the consequences of counterfeiting is that of *spare parts*. When it becomes possible to manufacture spare parts using AM processes, it is a paramount concern that the parts perform correctly and are safe to use[31]. Manufacturers could be required to show that the data that is used to produce a part comes from an approved source and that it will give them a safe and useable part, as well as provide a method of determining liability in the event of failure. It is, therefore, recommended to establish a method of certifying the origin of printable files for the spare parts sector.

Another issue that is been analysed is if the manufacturers of additive manufacturing equipment are indirectly liable for possible copyright infractions by the users of the machine. In this case, exemption from liability for possible copyright infringement by machine manufacturers can be based on the results of the Betamax case[32]. In this case (Sony Corp. of Amer. V. Universal City Studios), Sony was pursued arguing that its Betamax video tape recorders (VTRs) were being used by end consumers to record copyrighted content. However, the court concluded that the main function of the VTRs was legal and, therefore, exempted Sony from any liability. A similar argument could be used with manufacturers of additive manufacturing machinery, who would then be exempted of liability with regard to the possible illegal use of their machines (copyright infringement) by end users. Owners who feel their IP is being infringed would need to show that the technology in question (3D scanning devices, for example), have no legitimate purpose other than to copy existing IP. For the most part, however, parties involved in legal disputes will likely be restricted to the designer and the businesses using the design.

Yet another concern related to copyright infringements relates with the liability of the Online Platforms. In this case, a similarity could be found with the Napster case, where it was analysed if Napster was at fault

[30] Patent enforcement in the era of 3D printing. Rosa María Ballardini. ECTA Roundtable on 3D Printing. 2015

[31] The current status and impact of 3D Printing within the Industrial Sector: an analysis of six case studies. Reeves & Mendis. 2015

[32] 3D opportunity for intellectual property risk. Additive manufacturing stakes its claim. Matt Widmer, Vikram Rajan. 2016

for providing users with the tools to infringe on copyrighted music. Napster platform provided its users the ability to transfer music (copyrighted or not) to other users; Napster servers temporarily stored a list of the file names that each user was willing to transfer. The courts found Napster to be at fault, saying it directly facilitated the peer-to-peer interactions of its end users, and the main purpose of these interactions was to infringe on copyright. Although the end users themselves were the real culprits with regard to infringement, finding and prosecuting the vast numbers of anonymous people sharing music became impractical. This similarity may potentially translate to AM, where finding all the people making use of infringing designs will be unapproachable. Therefore, as previously mentioned, the online platforms are including terms of use related to its exoneration of any liability regarding any inappropriate use by the end users.

Similar considerations could apply to the providers of manufacturing services. Service providers could be pursued by secondary infringement by the fact of facilitating the manufacture (putting the invention into effect) of a protected product. Therefore, just as online platforms have done, manufacturing service providers should establish in their terms of use that the user of the service is the only liable for ensuring the intellectual property of the products they are sending for manufacturing.

Additive manufacturing technologies will bring therefore some challenges for businesses in controlling the unauthorised production and distribution of their products and services and the use of their brands[33].

2.6 A look on IPR for AM technology users and related agents

2.6.1 A landscape that involves multiple stakeholders

Additive manufacturing is a technology that can be employed nowadays by many stakeholders at different levels: we can find users with 3D-printers at home, creatives, industrial level organizations, engineering services, etc. Furthermore, there are many options that currently allow any person or organization to make use of this technology. Therefore, from the point of view of IPR, there are several profiles of users/involved stakeholders that would have to be taken into account:

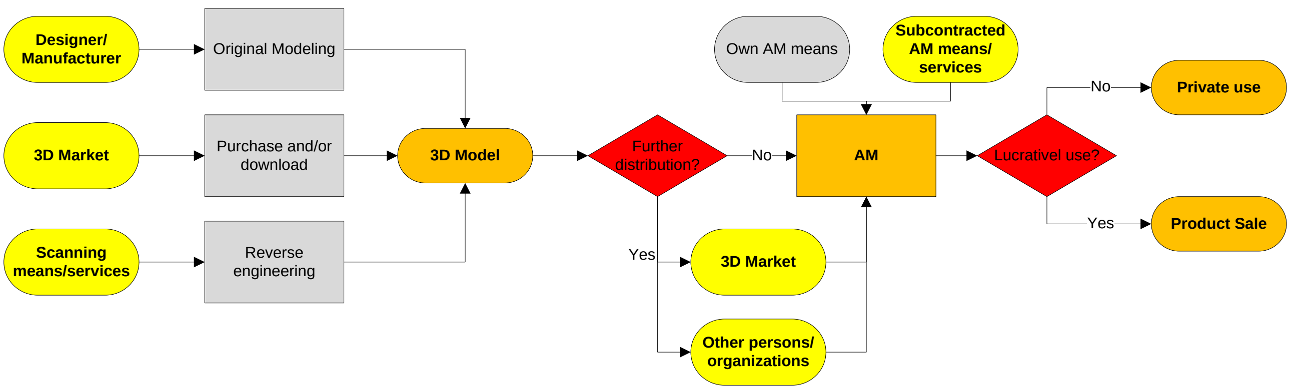

Figure 7: *AM process and involved stakeholders*

[33] The ICC Intellectual Property Roadmap. Current and emerging issues for businesses and policymakers. 2017

- **Designers**: original creators of 3D models that can be manufactured using additive manufacturing technologies. They generate the designs, which may be attributed to themselves or to the organization for which they work, and which in turn can be sold to a third party for commercial exploitation, released free of charge or protected under IPR. The designer/organization can manufacture its own design if it has the appropriate means, or can subcontract such means (service bureaus, etc.). In any case, the designer of an original object defines the protection and exploitation of its creation and, therefore, the possible IPR rights derived from the creation could be under infringement.
- **Manufacturers:** users of 3D printing technologies to make elements from 3D models. The designer / design organization itself may act as a manufacturer if it has the necessary means, but may also refer to an organization that obtains the manufacturing right through a license.
- **Online Platforms (3D market):** networks or portals on the Internet through which it is possible to access and download (remunerated or not) 3D models. Depending on their characteristics they will be able to give access to 3D models protected with some IPR tool, not protected, or whose IPR situation is not clear.
- **Reverse engineering service providers**: organizations with capacity to generate 3D models from real elements, owned or not by their clients.
- **AM manufacturing services providers:** companies providing 3D printing services for the additive manufacturing of products usually from 3D models provided by the customer (service bureaus, collaborative workshops, etc.). This companies manufacture elements from 3D models supplied by the customer for a fee, whether or not the latter may be the original creator or holder of rights over said 3D models.
- **AM manufacturers (equipment, raw materials)**: developers and manufacturers of additive manufacturing equipment and raw materials, also with capacity to manufacture elements from printable 3D models.

2.6.2 Study cases

Regardless of the technology used, any additive manufacturing process begins with a CAD based digital file. However, the way of obtaining such CAD based digital file can be very different and can have different implications regarding Intellectual Property issues:

[a] Original Model
[b] Purchased or downloaded Model
[c] Reversed Engineering Model

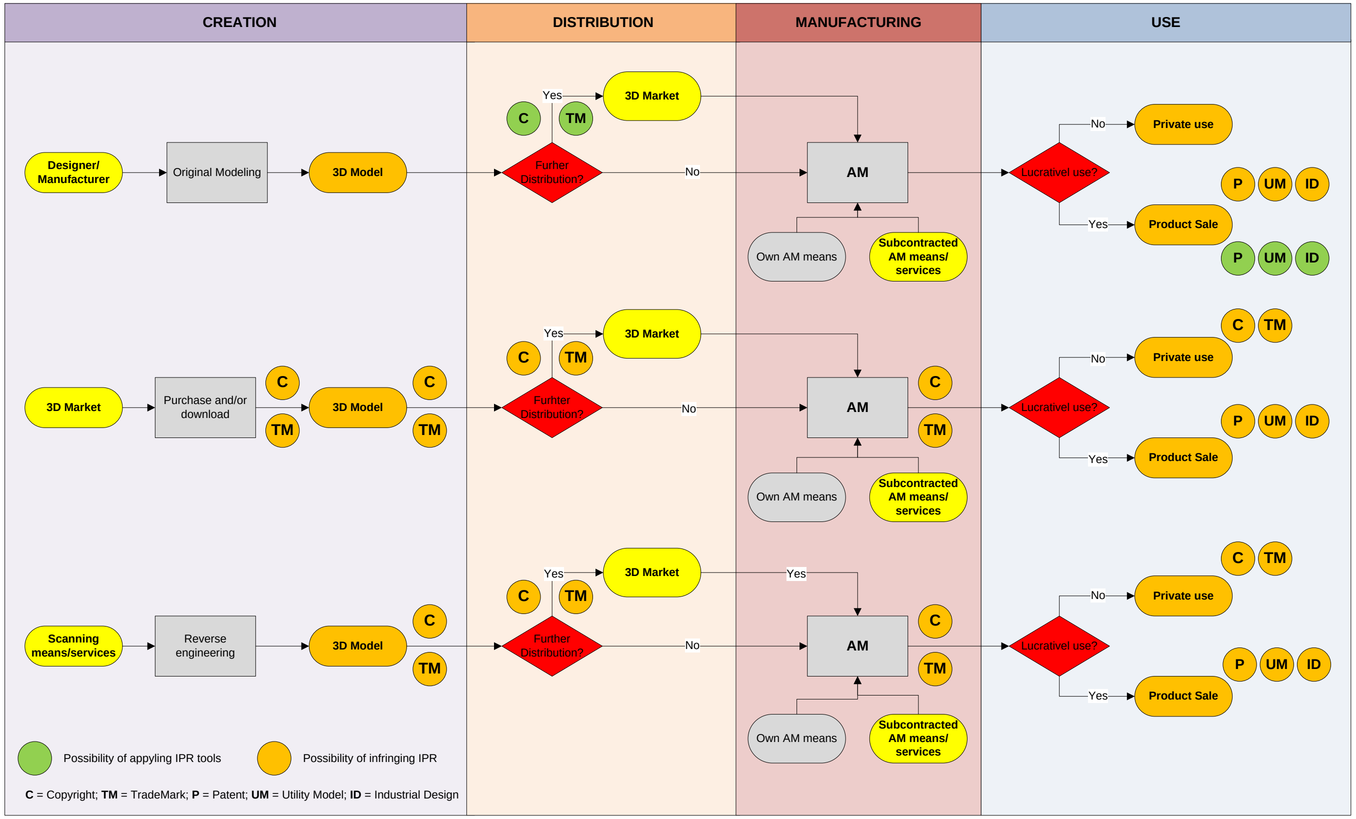

Figure 8: *IPR different study cases*

2.6.2.1 AM of Original Designs

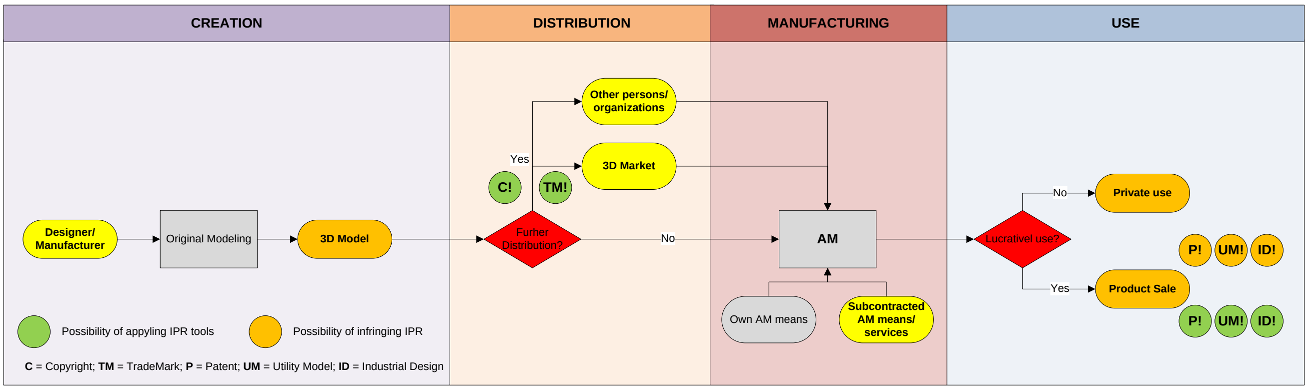

Figure 9: *Original design study case*

<u>Creation</u>

When a person or organization has its own design and engineering capabilities, it is possible to give rise to original 3D models, on which the creator (person or organization) is the potential owner of all reproduction and exploitation rights.

It will also be possible for the generation of a 3D model to take place within a contractual relationship whereby another person or organization is hired to develop an element or product, which may involve the generation of 3D models. This contractual relationship must establish IPR issues that are applicable to such 3D creations and models.

In the case of use of AM technology, the creation phase does not necessarily involve differences with other manufacturing technologies. If the user is working with an original file, then no infringement of IPR from third parties is expected. Additionally, from the point of view of the IPR rights of the "creator", he/she must select the IPR instrument that better fits with its "creation": industrial design, copyright, patent, etc.

<u>Distribution</u>

The original 3D model may or may not be distributed later, understanding distribution as any form of making available the original 3D model to any other people and/or organizations. As previously mentioned, taking into account that it is an original creation, the creative person/organization should consider whether or not to protect its creation before proceeding to its distribution, using those IPR instruments more suitable and applicable at the moment, as well as defining and establishing the contractual relations that can be applied in case that distribution is part of a commercial relation.

When the generation of a 3D model by an individual is not framed within a labour or contractual relationship, the creator can think of the distribution and selling of its creation in the online platforms. In that sense, the creator of the original design should take into account aspects related with the intellectual property policies of each platform.

<u>Manufacturing</u>

When a person is the original creator of a 3D model and he/she wants to manufacture elements based on that model, he/she can do it using its own means or by subcontracting 3D printing services. In the first case, there will be no implications affecting existing IPRs, but in the case of subcontracting such services, it should be taken into account that this 3D model must be transmitted to the provider of such services, this being a work of distribution and, for that reason, may be susceptible to implement measures for IPR protection.

As previously mentioned, the providers of AM services should include in their terms of use intellectual property clauses disclaiming liability over the files received, in order to avoid becoming accused of possible secondary infringements.

Use

When evaluating the possible use of elements manufactured from a 3D model by AM, two general uses are considered: exclusively private use or a use intended for commercial exploitation.

- Private use: in this case, being the model an original creation of the user, it is assumed to be free of further IP implications.
- Commercial use: the prospect of a commercial exploitation may make the application of IPR instruments (registered industrial design, patent) advisable, depending on the novelty and inventive step associated with the product. The fact that a possible commercial exploitation starts from an original 3D model does not necessarily imply that the elements and functions that can be developed from it do not infringe pre-existing IPRs (industrial designs, patents, utility models) from other individuals or parties, since it would be possible to reach similar solutions without incurring in a conscious action of copying.

2.6.2.2 AM of Purchased/Downloaded Designs

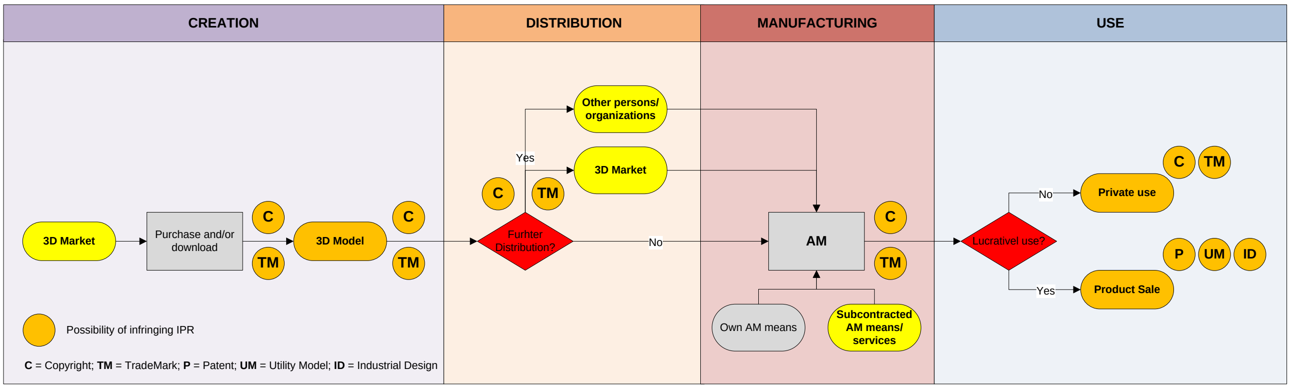

Figure 10: *Purchased/downloaded model study case*

Creation

When accessing to a 3D model (whether it is downloaded, purchased, or generally obtained through any personal or public means of distribution), it is necessary to consider that such creation may have associated a set of intellectual property rights, in such a way that it is necessary to know what they are, as well as the scope of the actions legally allowed in function of them. Especially when 3D models are obtained from the internet, as with any other online content, it must not be understood that they are free of intellectual property rights just because they are publicly available. Therefore, the user of such a 3D model must previously identify and analyse its IPR rights and implications, taking into account any possible limitation of use (for example, commercial exploitation).

Furthermore, issues arising from the possible modification of a CAD file protected by some kind of IPR must be taken into account.

Distribution

When acquiring a 3D model developed by another person or organization, it will be habitual that a further distribution was not foreseen, but it is necessary to take into account how the distribution or later diffusion of these 3D models is contemplated within the contractual conditions established with the provider. Again, it is necessary to identify the IPRs associated with these 3D models, in order not to incur illegalities in carrying out acts of distribution not allowed by these IPRs or by the conditions of purchase of such models.

As previously mentioned, the online platforms are including within their terms of use specific considerations in the matter of industrial property to exonerate themselves of any type of liability. Therefore, according to those terms of use, if a person purchases an original model from a platform and the same user wants to further upload the model in other (or the same) platform, the online platform would have not liability for IPR infringement: the liability falls solely on the user.

Manufacturing

Assuming that the purchase of the 3D model(s) has been made under conditions that clearly ensure the definition and protection of the associated IPRs, a 3D printing with no commercial relevance should not constitute an act of infringement of IPRs as long as this action is in line with said IPRs. It should be noted that if in any of the previous steps the existing rights have been infringed, the act of manufacturing an element based on the 3D models is an action that can deepen this infraction.

Again, if the manufacturing of the model is going to be subcontracted, then IPR issues would arise from the point of view of the services provider. In this sense, the organizations that develop these kind of services normally act based on the requests of their clients, without making a verification of the IPRs and the property of the 3D models to be printed. Therefore, the services provider must ensure itself contractually that the liability lies in the user (the customer).

Use

The use given to printed items may be private or have a commercial outlook. If the previous steps are conducted in compliance with the established IPRs, the aspect to be considered at this point if a commercial use is to be made depends on how these IPRs may or may not contemplate this aspect. For example, there could be limited exceptions of potential infringement of patents and industrial designs when a private a non-commercial use is considered.

2.6.2.3 Designs coming from reverse engineering

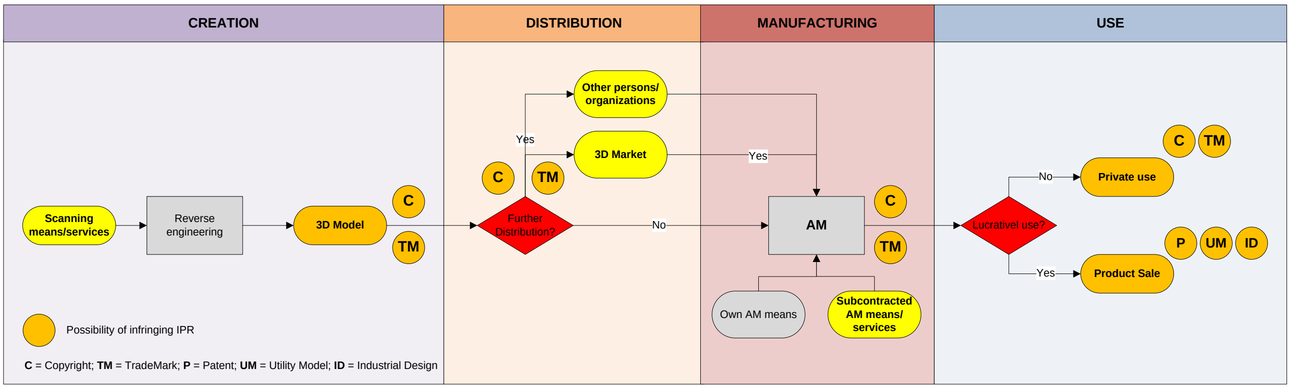

Figure 11: *Reverse engineering study case*

Creation

In this case, the origin of the 3D models that give rise to a 3D printing process is totally different. Although reverse engineering will involve design work to generate a 3D printable element, the essence of the process is the generation of a 3D file of a physical object through scanning technologies. In essence, this process should not be considered an original creation. Therefore, scanning a copyrighted (or protected otherwise) work constitutes copying, thus requiring permission to avoid infringement[34].

Reverse engineering is devoid of any vulnerability to IPRs when it is used to reproduce own property elements (for example if the blueprints or models necessary for its manufacture by any original manufacturing technique are missing or lost), but may have significant implications when reproducing elements over which the property is not owned.

Distribution

Similar to the other case studies, the 3D models can be distributed after their conception. In the case of an organization that generates the 3D model from engineering services, it is necessary to consider again what are the rights associated with the original element that is being reproduced, and also to take into account that (as in any other cases where there is a 3D model with IPRs owned by third parties) modifications made on said 3D models may not be sufficient for said revised 3D models to constitute a creation that can be considered original.

[34] A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour. Mendis & Secchi. 2015

In those cases, in which the 3D model responds to the scanning of an element whose IPRs are owned by the organization, it must be taken into account that the same indications as in case 1 may be applicable: the application of IPR instruments to ensure the definition of rights applicable to transfers beyond our person or organization could be highly recommended.

Manufacturing

The 3D printing of a model obtained from reverse engineering activities does not make a difference at this point, so that the act of printing a 3D model may or may not constitute violation of IPRs depending on whether they are owned or not, from not supposing any infringement (if for example the model is obtained from an element owned by the organization) to delving into previous infringements (when printing a 3D model obtained from an element whose IPRs are not held).

As in the previous case studies, it can be usual to use external 3D printing services, with the same IPR implications than previously explained.

Use

On this point, same indications as in the previous study cases are of application.

3 Regulation

3.1 General Framework for regulation of Additive Manufacturing

As for any other technology used to manufacture products from raw materials, there are three key areas that regulation can be addressed from:

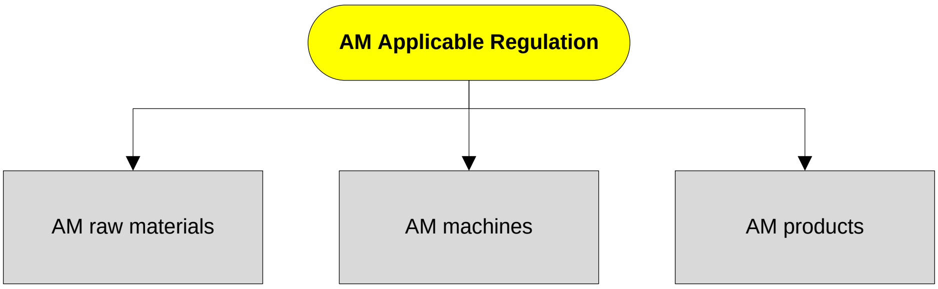

Figure 12: *general fields of application of Regulation to AM*

- **AM raw materials**. Regardless of the final use of the elements manufactured by these technologies, any material must today comply with a series of regulations, oriented in particular to ensure its safe use and respect for the environment. At European level, such important and omnipresent regulations within the single market as REACH and CLP are a fundamental basis through which raw materials for additive manufacturing are regulated.
- **AM machines**. At present, additive manufacturing is possible thanks to machines of scale or small or medium, marketable and obtainable by any person or organization. Within the European framework, CE marking (as for any other product) is a requirement for this type of machines, which is proof that these machines comply with the essential requirements applicable to them in the single market space.
- **AM products**. Although nowadays these technologies have a very important field of application in the manufacturing of prototypes, in the future their uses for the manufacture of final products will be in progressive increase, so that for each of them the requirements that are within their respective sectors will be applicable.

3.2 AM Raw Materials Regulation in Europe: REACH and CLP

At the European level, there are two clear references when it comes to the regulation of chemical products: REACH and CLP regulations.

REACH[35] (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals, that came into force on 2007) was developed and adopted to:

[35] European Parliament. «REACH.» *REACH (EC 1907/2006) Registration, Evaluation, Authorisation and Restriction of Chemicals.*

- Facilitate and improve the protection of human health and the environment, against the risks associated with the use and handling of chemicals.
- Encourage and promote the competitiveness of the European chemical industry.
- Promote the adaptation of alternative methods to animal testing, for the evaluation of chemical hazards.

On the other hand, **CLP**[36] (Classification, Labelling and Packaging) is a system of classification and labelling of chemical substances whose purpose is to ensure the correct presentation and communication of the risks posed by the use of chemical substances to European workers and consumers.

Both regulations are complementary, in the following way[37]:

- The main purpose of the REACH regulation is registration, and the CLP regulation main purpose is notification, classification and labelling.
- The CLP regulation applies to any chemical substance, regardless of the quantity marketed.
- While the CLP regulation lays down general rules for the labelling of chemical substances, the requirements relating to safety data sheets are established by the REACH regulation.
- The CLP regulation establishes classification criteria for substances, which are applied through the registration of substances established by REACH.

Hereafter, we will develop both regulation schemes in a more extensive way.

3.2.1 REACH Regulation

The EU REACH regulation was launched in 2006 with application for all chemical substances, not only at an industrial level, but also applicable to the chemical substances used by any user on a daily basis: cleaning products, paints, clothing, electrical appliances, and in short, any substance or product that is partially or totally composed of pure or mixed chemicals, that may give rise to risks to health and / or the environment.

The REACH regulation requires organizations to identify the risks associated with substances that they produce and market, so that they are able to demonstrate to the European Chemicals Agency (ECHA) that the use and handling of these substances can be safe, based as well on the identification and communication of the necessary preventive measures. In this way, the application of the REACH Regulation gives rise to a market for substances that have been previously analysed and reviewed for their possible risks, with the assurance that they have reached the market once the appropriate measures for their use and handling have been approved.

In general, the application of the REACH regulation consists of a process[38] composed of the next stages:

- Companies must gather the available information on the risks associated with new substances that they wish to manufacture and / or market within the European Union.

---

[36] Parliament, European. «CLP.» CLP (EC 1272/2008) Classification, Labelling and Packaging of Substances and Mixtures.

[37] Service, Chemical Inspection & Regulation. *http://www.cirs-reach.com/REACH/REACH_CLP.html.* s.f.

[38] (ECHA), European Chemicals Agency. *https://echa.europa.eu/regulations/reach/understanding-reach.* s.f.

- Companies must register their substances under the REACH regulation in an environment in which normally the same substance can be manufactured and marketed by other organizations, so that risk assessment and indication of preventive measures must emerge from the consensus between the same, in a collaborative framework.
- The registration of new substances is evaluated by the European Chemicals Agency as well as by the EU Member States, in such a way that in that process it is determined if the risks associated with these substances can be managed properly. This process could result in a ban or restriction on the circulation and use of a substance if it is determined that the risks cannot be properly managed.

From the point of view of companies that need to apply REACH to manufacture, import, market or use chemicals within the European Union, there are obviously different levels of responsibility in the application of the regulation, so that while for manufacturers REACH will be a mandatory step for obvious reasons, importers of substances should take it into account in order to ensure that the products they distribute in the European Union comply with the applicable legislation and, finally, users should take into account both the risks as the preventive measures associated with them, in order to avoid harm to workers, people or the environment.

3.2.2 CLP Regulation

The CLP regulation[39] is focused on the correct communication to workers and consumers of risks associated with chemicals through a classification and labelling system, within the scope of the European Union. Essentially, the risks associated with a chemical are classified on the basis of their hazards, and labelled on the basis of a standardized system (based on statements, indications and pictograms included in the labels, as well as the information included in safety data sheets) in such a way as to facilitate the understanding of risks by workers and consumers prior to their manipulation.

From a hazard and risk classification point of view, suppliers of chemicals should themselves define the classification, following a process that includes the collection of available information, assessment of the reliability of the same, its review against existing harmonized CLP classification criteria, and the final decision as to its classification.

The classification described is a key element for the communication of the risks associated with other agents in the distribution and use chain, since this process results in a concrete determination of the risks, and therefore the elements applicable to the labelling (pictograms, Indications, etc.) and packaging thereof.

From the point of view of companies, any producer or supplier of chemicals within the European Union should classify, label and package the substances according to the CLP regulation, notifying the European Chemicals Agency of the placing on the market of the chemical Dangerous, within one month.

[39] (ECHA), European Chemicals Agency. *https://echa.europa.eu/regulations/clp.* s.f.

3.2.3 Raw Materials regulation beyond Europe

Both REACH and CLP are classification, communication and application registration systems for chemicals marketed within the European Union. Therefore, it is valid for all organizations (European or non-European) that wish to distribute and market products within this scope, and are not applicable outside those boundaries. In this regard, there are comparable systems in other parts of the world.

Looking for REACH alternatives beyond Europe, and looking to the main major global powers, in the United States[40], each new chemical must be reported and registered in accordance with Section 12b of the Toxic Substances Control Act, so that notification must include detailed information on the substance and its toxicological hazards as well as the agreement with the Chemicals Abstract Service (CAS), in order to obtain a CAS number and denomination. Looking to Russia, in this case manufactures and importers have to have to comply with the requirements of the Russian Register of Potentially Hazardous Chemical and Biological Substances, notifying toxicological and Eco toxicological information that is evaluated by Federal Services.

In the case of CLP alternatives, CLP is really the translation at the European Level of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This system was developed by the United Nations in order to standardize the process of definition and classification of hazards of chemicals, and lead to a unique and universal system for the communication of information related to health and safety through standardized labels and Safety Data Sheets. GHS is not a law, but a guide that describes voluntary adoption practices, basically focused on providing a framework for different countries to develop their own systems, as has been the case for the CLP in the case of the European Union, or the case of OSHA's Hazard Communications Standard (HCS) in the United States.

3.3 AM Machines Regulation in Europe: CE-Marking

In order to be placed for the first time on the extended single market of the European Economic Area (EEA), AM machines must be CE-marked, which indicates that the machine complies with all requirements for CE marking, having passed the relevant conformity assessment procedures[41]. All this is aimed at ensuring the product meets all EU legal conformity standards. With regards to those for industrial purposes, obtaining CE marking is dependent upon compliance with the safety, health and environmental standards set out by the EU Machinery Directive. Machines complying with that Directive also benefits from free movement in Switzerland and Turkey, by virtue of the mutual recognition agreement[42] and the EU-Turkey Customs Union respectively. It means that CE marking is not compulsory in Switzerland but it is recognized as a presumption of conformity with Swiss national technical regulations. If the Swiss legislation requires conformity marking, the non-mandatory CE marking can be used instead. On the other hand, as Turkey adopted the Machinery Directive, products sold there should comply with the requirements laid down in that regulation, which equates to CE marking. Furthermore, Australia and New Zealand also have mutual recognition agreement

[40] GROUP, DHI. «https://www.dhigroup.com/.» *https://www.dhigroup.com/-/media/shared%20content/dhi/flyers%20and%20pdf/solution%20flyers/prodsafetyenviro_solutionflyer_reach%20registration.pdf.* s.f.

[41] Please refer to Article 12 and 13 of the Machinery Directive.

[42] Consolidated version of the Agreement between the European Union and Switzerland (14 April 2015) : http://trade.ec.europa.eu/doclib/docs/2013/december/tradoc_152006.pdf

under which, among other related measures to facilitate trade between the parties, these countries will accept conformity assessment results performed by the EU on machinery.

Following the procedures detailed in the directive, the manufacturer of the industrial machine has to assess whether this meets essential health and safety requirements which are set out in Annex 1 to the Directive. The first among these refers to conducting an appropriate risk assessment. After examination of market surveillance authorities across EU Member States and the provision of a declaration of conformity (DoC in short) –which must indicate the EU directives which apply to the product- by the manufacturer, the industrial AM machine can obtain CE-marking and thus be tradeable within the EEA. [43] No additional special procedure is required for AM machines, being such products excluded from those listed in Annex IV of the Directive.44 In this framework, it must be pointed out that EU authorities are granted market surveillance powers, which they can use when the industrial AM machine is first placed on the market and after its placement, to ensure that it has been subject to the requisite conformity assessment procedures and that it complies with the applicable essential health and safety requirements.[45]

Further requirements for affixing CE-marking are those related to compliance with the EU Electromagnetic Compatibility (EMC) Directive. In this case, requirements for CE-marking refer to the need of ensuring that electrical and electronic equipment in the industrial AM machine does not generate, nor is affected by, electromagnetic disturbance. In addition, components of the machine such as the sieving station for powder and the vacuum cleaner for powder coating must observe requirements of the EU ATEX Directive in order to obtain CE-marking. This directive applies to equipment and protective systems used in potentially explosive atmospheres and the related components, as well as devices for use outside potentially explosive atmospheres. It is particularly relevant for the metal segment of the market, as powders such as titanium or aluminium are highly flammable. The storage and handling of these materials for AM must therefore be conducted with systems that meet ATEX-defined safety standards. In 2016, the European Commission took further steps to deepen legal predictability on the applicable standards set out by this directive and the type of information to be communicated by the producer to the authorities[46].

With regards to desktop 3D printers, there remains an outstanding question today as to whether certain compact '3D printers' could not be considered as ordinary office machinery or IT equipment, a category of products exempted by the risk assessment provisions set out by the EU Machinery Directive and instead and subject to the requirements of the EU Low Voltage Directive.

Last but not least, the manufacturer should keep in mind that all relevant technical documentation in relation to a CE-marked product must be kept for specific period of time, in order to present it to the competent authorities on request.

---

[43] http://www.engineersjournal.ie/2014/09/01/machinery-directive/

[44] http://www.ul.com/wp-content/themes/countries/downloads/am/3D-PRINTING-EQUIP-SAFETY-GUIDELINE_EDITION2.pdf

[45] Guide to application of the Machinery Directive 2006/42/EC - 2nd Edition - June 2010

[46] http://www.orgalime.org/page/equipment-and-protective-systems-intended-use-potentially-explosiveatmospheres-directive-atex

3.3.1 CE Marking for Manufacturers

Within the European Economic Area, manufactures are responsible for ensuring that the products they bring to the market are safe and are therefore responsible for ensuring that they comply with all requirements applicable within the Union in the fields of health, safety and environmental protection. Specifically, this is done through the CE marking[47] of a product, a process that is generally illustrated in the following image:

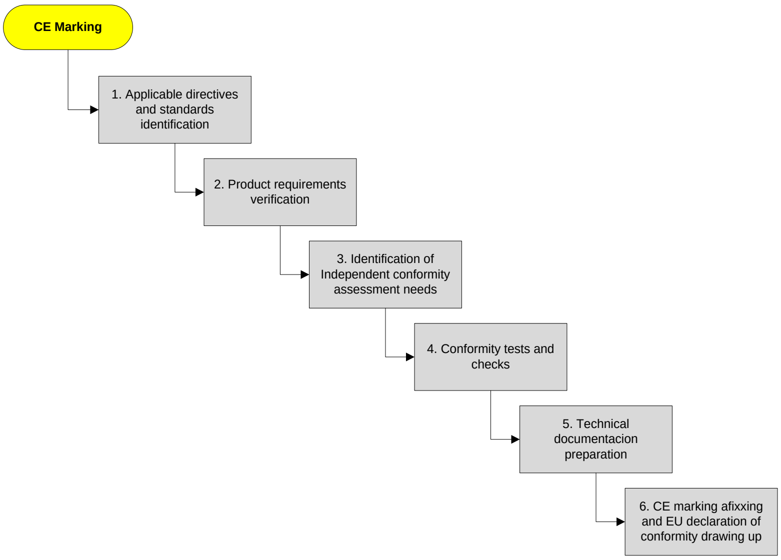

Figure 13: *CE Marking process*

These six steps (which may differ and adapt depending on the specific product) describe a process through which the manufacturer:

- Analyses the directives and standards that are applicable to a product, in order to establish the requirements that each product must meet to be labelled with a CE marking.
- Based on the above, establish for each product the specific application requirements.
- Identify whether an independent requirements assessment is necessary to obtain the CE marking.
- Check that the product meets the requirements of application.
- Prepare the technical documentation necessary to obtain the CE marking.
- Affix the CE mark to the product and draw up the EU Declaration of Conformity.

3.3.1.1 Application of CE Marking Process to AM Machines

When establishing the application criteria for an AM machine to obtain a CE marking, it is necessary to consider first how these products can be classified, as a way to establish the requirements that are applicable

[47] Comission, European. *https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en.* s.f.

to them. At present, the following product groups are identifiable[48]:

Table 5: CE Marking Product Groups

CE Marking Product Groups	
Active implantable medical devices	Measuring Instruments
Appliances burning gaseous fuels	Medical devices
Cableway installations designed to carry persons	Noise emission in the environment
Construction products	Non-automatic weighing instruments
Eco-design of energy related products	Personal protective equipment
Electromagnetic compatibility	Pressure equipment
Equipment and protective systems intended for use potentially explosive atmospheres	Pyrotechnics
Explosives for civil uses	Radio equipment
Hot-water boilers	Recreational craft
In vitro diagnostic medical devices	Restriction of Hazardous Substances in Electrical and Electronic Equipment
Lifts	Safety of toys
Low voltage	Simple pressure vessels
Machinery	

Of the 25 product groups that have been identified, the nature of AM equipment currently available makes it classifiable within (at least) the following groups:

- Electromagnetic compatibility. As equipment running on electric power, an AM machine is likely to be affected by electromagnetic emissions, as well as to generate emissions that may affect other equipment. These types of products are governed by the EMC Directive 2014/30/EU[49], which establishes the associated requirements to ensure that both the electromagnetic emissions of a product and its operation in the presence of electromagnetic disturbances of any type (including radio waves), are within the established thresholds.
- Low voltage. Current AM machines operate below the limits established by The Low Voltage Directive (LVD) 2014/35/EU[50] (voltage between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current), so that said Directive applies to them.
- Machinery. Due to the characteristics of some of the available AM machines and technologies (oriented to a professional-industrial use), they can be classified as machinery. In this sense one of the main laws governing the harmonization of essential health and safety requirements for

[48] Comission, European. *https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en.* s.f.

[49] Commission, European. http://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive_en. s.f.

[50] Commission, European. *http://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive_en.* s.f.

machinery at EU level is Machinery Directive 2006/42/EC51, with a particular focus on ensuring a high level of protection for workers and users of this machinery, as to promote the free movement of machinery in the Single Market.

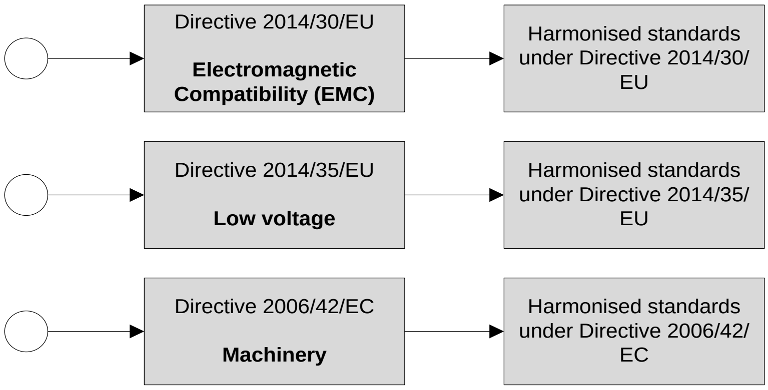

Figure 14: *Directives of applications for AM machines*

Nevertheless, the technologies and machines of additive manufacturing will still be considerably evolved over the next years, and their foreseeable incorporation into fields such as construction or its progressively greater integration in environments connected by different wireless communication technologies, can make the applicable directives for each case vary, and complement the main group consisting of the three groups of products indicated above. On the other hand, and as for any other product with factory and productive capacity, the products manufactured thanks to additive manufacture machines may be subject to the different directives that are applicable in order to obtain the CE marking, but this obviously gives rise to needs and requirements associated to the products manufactured with these machines of additive manufacture, but not to the machines themselves.

3.3.2 CE Marking for Importers and distributors

When distributing and marketing a product in the Single Market of the EEA, intermediaries must ensure that the products they are incorporating into that market are compliant[52] with the applicable legislation within EEA, and must have a general knowledge of the legislation applicable, ensuring that:

- Its work does not alter the product in a way that could alter its compliance with the legislation applicable at European level.
- The information and documentation necessary to ensure compliance with the legislation associated with the CE marking of each product is available.
- They not introduce to the market products that are not in compliance with current legislation.

This is especially important when these importers and distributors manage products manufactured

[51] Commission, European. *http://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en. s.f.*

[52] Commission, European. *https://ec.europa.eu/growth/single-market/ce-marking/importers-distributors_en. s.f.*

outside the Single Market, where they must verify and ensure, prior to their incorporation into the market, not only that these products include the corresponding logo with the CE marking, but also comply with the requirements associated with the 6 steps illustrated in the previously described process for obtaining the CE marking.

3.3.3 AM Machines Regulation abroad

Since the CE marking is a requirement associated within the EEA, outside this scope it is necessary to consider that there are other schemes that may be applicable for an AM machine to be introduced in other markets. In this sense, this section briefly correlates the requirements comparable to the CE marking in other countries and regions of interest[53] [54]:

- United States. In this country there is no global certification system equivalent to the CE Marking, so the establishment of these requirements arises from the consensus between customers and market sectors in establishing certain voluntary and recognized standards as mandatory, in order to ensure quality and safety of the associated products. This is for example the case of UL certification, the most recognized brand in the US market for most electronic products, which is also recognized in other markets (such as Mexico or Argentina).
- Russia. This country has a certification system of some complexity, which is mandatory for most products. One of the most common certification schemes is Gost-R Marking, based on Russian Standards (not harmonized with European ones or with other international standards), but in the last years it is being made compatible with the new EAC certifications, applicable to Russia , Belarus and Kazakhstan.
- China. Most of the imported products have to undergo a compulsory certification, called China Compulsory Certification (CCC), with different certification schemes for each product.
- Markets without their own certification systems. In those markets that do not have their own certification systems, there is usually a requirement for a customs certificate, which acts as a trade barrier for imports. Thus, exports to countries such as Saudi Arabia, Egypt or Cuba usually require the assistance of independent bodies with the capacity to issue a certificate of conformity accredited by the administration in question.

3.4 AM products regulation

From a regulatory point of view, there is no practical difference between a product manufactured by conventional technologies and a product manufactured by AM, in the sense that in both cases, within the European scope both will demand the CE marking. In this sense, and as already indicated in point 3.3.1.1 of this document, each product may be associated to the fulfilment of the requirements associated with the various directives of application to the various product groups. However, there are a number of obstacles that a product made using additive manufacturing technologies must address, basically related to the doubts

[53] Applus+LGAI. *http://www.infocalidad.net/archives/opinion/productos-con-pasaporte-para-entrar-en-nuevos-mercados.* s.f.

[54] http://www.gostrussia.com. http://www.gostrussia.com/es/. s.f.

regarding the behaviour and requirements compliance of these products throughout their useful life, with the consequences that this can have from the point of view of the safe use of these products for workers and users (one of the basic objectives of the current CE marked system).

Due to the above, and with a strong relationship with the field of standardization, one of the main current challenges for the application of the existing regulation and with the assurance of the quality and safety of the products manufactured by AM is the development of systems, methodologies and processes for the adapted test and certification of the same, able to show the capacity of these products to satisfy the applicable requirements[55].

3.4.1 Different sectors, different "regulations".

On section 3.3.1.1 of this document it was described how there was no single product certification system in markets such as the United States, but each sector and customer market could lead to particular requirements that, without being properly categorized as legal requirements (because they do not arise from the legislative scope), are considered as mandatory for certain types of products. Thus, from a sectoral point of view, it can be said that each sector of activity is a potential generator of its own "regulatory" environments (note that the use of "regulatory" here has the meaning of requirements of enforced compliance without the need for such "regulation" to be imposed from the regulatory environment itself), based fundamentally on processes, standards and ways of working applicable within the environment of the sector.

As can be deduced from the previous reflection, this is an aspect where the barriers between the terms "regulatory" and "standardization" are blurred, as it can bring to the same level of practical obligatoriness for the manufacturers of AM produced products, if appropriate agreements are reached within a sector. Given that, from a regulatory point of view, existing schemes within the European Union are aimed at the accreditation of products that can be placed within different groups (and not necessarily or specifically associated with objectively recognizable sectors), it is not expected that from this scope and given the variability of each sector, an evolution that gives rise to new regulatory schemes or adapted to AM technologies will happen, but it is on the contrary expected that the sectors themselves, in a self-regulatory activity, seek those requirements that must be taken into account and marked as mandatory for products manufactured with additive manufacturing technologies.

Although as has already been said, this is a field where regulatory can overlap with standardization, it may be appropriate to review from this sectorial perspective some of the most remarkable recent efforts in areas as relevant as health and aerospace.

3.4.2 A view on sectors in the vanguard of AM regulation: Medical Sector

At European level, for additively manufactured standard medical devices a CE-marking is required. This

[55] Finantial Times. *https://www.ft.com/content/bfab071c-6abc-11e4-a038-00144feabdc0?mhq5j=e1*. s.f.

is for example the case of hip implants.[56] The circumstance implies that the manufacturer must abide to the same procedures that govern the first placing on the market of conventionally manufactured medical devices. For customized additively manufactured medical devices, CE-marking is instead not foreseen, as it is stated on the recently approved (April 2017) European Medical Devices Regulation[57] [58].

However, usually in addition to above, there are certification needs that be implemented for end-users using industrial AM machines. Certification of parts and components can entail a long time and require significant resources. In the case of customized surgical implants for example, there are three parties involved for the approval of the use of a 3D-printed implant for surgery:

- The request for manufacturing an implant via additive manufacturing has to come from a specialist (surgeon).
- The ethical commission of the hospital has to approve the technique and material used for the surgery.
- The patient has to agree with the use of 3D-printed implants for surgery.[59]

It is interesting nevertheless to briefly review the strategy that an actor as important as the FDA (Food and Drug Administration of the United States) is implementing focusing on the introduction of medical devices manufactured by AM technologies, since its work is certainly giving rise to certain results and progress. In 2016, the FDA issued a Draft Guidance (not final or in effect at this moment) on the Technical Considerations for Additive Manufactured Devices[60] to advise manufacturers who are producing devices through 3D printing techniques. This draft focuses on providing recommendations for device design, manufacturing, and testing of 3D printed devices and addresses topics as design, manufacturing and testing of medical devices. Being a draft, this document is for the moment “just” a good piece of guidance for all organizations related with medical devices design, manufacturing and commercialization, but it is for sure a basis for future actions when defining mandatory requirements for medical devices manufacturing through AM technologies.

3.5 Global Trade of AM Goods

While the existence of the European Single Market and the freedom it provides in distributing AM products within that area, it is necessary to take into account that, outside these borders, there is still a limitation in the existence of controls and customs tariffs that entails the export of European products to other countries and regions. In this sense, both the additive manufacturing machines and the products

[56] Additive Manufacturing of Titanium Alloys: State of the Art, Challenges and Opportunities byBhaskar Dutta and Francis H Froes (2016)

[57] European Parliament. *https://www.emergogroup.com/sites/default/files/europe-medical-devices-regulation.pdf.* s.f.

[58] Kommerskollegium National Board of Trade. http://www.kommers.se/Documents/In_English/Report-Servicification%20on%20the%20Internal%20Market%20%E2%80%93%20a%20regulatory%20perspective.pdf s.f.

[59] Final report: Identifying current and future application areas, existing industrial value chains and missing competences in the EU, in the area of additive manufacturing (3D-printing)

[60] FDA. *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf.* s.f.

manufactured with them are subject to certain relevant limitations. At present, these limitations are basically two[61]:

- “Dual-use” export control regulation. There are national legislations that regulate the circulation of products that can have a civil and military use, being this the case of certain technologies of additive manufacture and some of its components or fungibles. Since these laws can be applied, they are products linked to export restrictions, and the need to obtain the respective accreditations and licenses in the process of selling them to certain countries. Although work has been initiated at European level to create a harmonized system for the export of products subject to a "double use" principle, this will, and will continue to be, an additional requirement for European producers and distributors of products and AM machinery abroad. Then, a further engagement and involvement with external actors must be met, so European producers of AM equipment don´t see this as a limitation for export.
- Product nomenclature. The World Customs Organization (WCO) has developed an harmonized Commodity Description and Coding System, comprising 5,000 commodity groups, that is used to calculate custom tariffs and international trade statistics and that is currently under review (hopefully approved in 2019 and implemented from 2022) and that is considering the creation of a specific heading and/or related sub-headings for classifying additive machines.

[61] CECIMO European Association of the Machine Tool Industries http://www.cecimo.eu/site/fileadmin/Additive_manufacturing/AM_European_Strategy_2017_LQ.pdf. S.f.

4 Environmental impact of Additive Manufacturing Technologies

4.1 Overview of the AM Process from an environmental point of view

From an environmental point of view, additive manufacturing is a new field of study in which, although from a conceptual point of view can give rise to aspects in which apparently the environmental impact may be smaller than that of conventional technologies (consumption of materials) and in other cases greater (energy use per unit produced, especially in small elements), there are still many unknowns associated with the lack of a higher level of information and case studies in this regard. This is why it is currently difficult to state categorically that for a given product, and given an AM manufacturing process, the environmental impact of both the manufacturing process and the product produced throughout its entire life cycle is greater or lower than that of a conventional process. However, this section will try to analyse existing information from both qualitative and quantitative points of view, in order to draw a series of conclusions.

4.1.1 Basics for understanding AM environmental impact

When estimating the environmental impacts of an additive manufacturing technology, it is necessary to understand that, like any other manufacturing technique, when assessing its possible environmental impacts, it all comes down to a quantification of the following elements:

Figure 15: *Additive manufacturing process global environmental inputs and outputs*

- Energy consumption. Energy needed to carry out the manufacturing work, consumed based on the different operations that each of the different AM technologies demand (powering a laser or EBM for powder-based technologies, pre-heating of materials, mechanical movement of lasers / fields or print heads, etc.)
- Raw materials consumptions. Although each AM technology will consume raw materials in quantity and form marked by the technology itself, they will all consume a certain amount of material, marked by the size and volume of the parts to be manufactured, as well as the necessary supporting structures and materials.
- Emissions generation. Due to the use of high temperatures for material deposition or particle sintering/melting fumes, gases and particles can be generated by the AM processes. Some technologies may require to provide specific inert atmospheres (e.g. explosive materials in powder state) for avoiding risks to health and safety.
- Waste generation. While these technologies are generally characterized by an efficient use of the material versus subtractive technologies, this does not mean that they do not produce waste, in the form of non-reusable raw material, or disposable support structures.

4.1.2 Understanding the environmental impacts of AM

As it has been previously described, there are various sources of environmental impact that have to be taken into account when assessing AM technologies:

- Energy consumption. At present AM technologies cannot yet be considered as ecologically friendly, fundamentally because most of them must subject the raw materials to processes of fusion or heating in order to make feasible the principle of manufacture layer by layer. If this process is already by its very nature energetically non-optimal, AM machines current technologies are actually the first generations of current AM technologies, and are therefore not energy efficient machines[62]. It is for this reason that applied to volumes of production of some consideration would lead to energy consumption considerably higher than traditional manufacturing technologies; however, the same characteristics make existing technologies more applicable to small batches or customized parts, so the previous scenario is not strictly the most feasible nowadays.
- Raw Materials consumption. One of the main potential advantages of most additive manufacturing technologies is a more rational use of the material than in traditional technologies, especially when compared to traditional machining technologies. In this sense, layer by layer concept of manufacturing involves that only the necessary amount of material to make up each layer of the piece to be manufactured is used, but it is necessary to take into account that in most cases there will be an associated material expenditure: support structures that must then be removed and cannot be recycled, plastic dust that has been altered during the process and cannot be recycled, etc. On the other hand, although the material consumption may be lower during the manufacturing process itself, the processes necessary for the manufacture of the raw material are generators of added environmental impact, so that the lower impact due to the savings in the consumption of materials could be countered by the upstream impacts added per unit of raw material produced.
- Emissions generation. Beyond the emissions associated with the generation of the electrical energy necessary for these technologies to work (major or minor as the case may be), and operating exclusively thanks to this energy source, current AM technologies tend not to introduce In the environment emissions that can be considered significant with respect to those already mentioned, not wishing to say that they do not occur. To give an example, AM machines based on the FDM concept may lead to the production of fumes from heating the plastic, and machines operating with particulate material that may be flammable or explosive need to operate in atmospheres with high presence of inert gases. However, these emissions are often of little relevance from an environmental point of view, and if they constitute an element to take into account, they do more from the perspective of the safety and health of workers and users, rather than from the point of view of the environment.
- Waste generation. While the technologies of additive manufacturing operate under the ideal principle of using the material strictly necessary to form a part, the reality is that the different AM technologies vary in their need to use additional support structures and in terms of recyclability of the material used. Thus, in technologies such as FDM, the material used corresponds to that necessary to form the part to be manufactured plus the necessary support structures (structures that must later be removed), in others such as the sintering of particulate plastic material supports are not necessary, but the process can alter the characteristics of the non-sintered used material and make its recyclability reduced. In other cases, as in the sintering of particulate metal, the recyclability

[62] Domniţa Frăţilă, Horaţiu Rotaru. «Additive manufacturing – a sustainable manufacturing route.» *MATEC Web Conf. Volume 94*, 2017.

of the non-sintered powder will be very high (since it will hardly be altered by the AM process), but on the contrary it will require support structures of some consideration, which will require mechanical means for its elimination.

4.1.3 Different AM technologies, different environmental impacts

Since there is at present a great variety of AM technologies, it is not possible to carry out a generalization about the environmental impact assessment of the same, and it must be taken into account that each one will have a series of own characteristics in this regard.

Although it is not the purpose of this section to make a detailed comparison and quantification of the different AM technologies in terms of their environmental impacts, it is possible to give a simple sample of the differences between perhaps two of the most representative AM technologies today: Powder Bed Fusion Processes and Fused Deposit Modelling (FDM) Processes:

- Powder Bed Fusion Processes: due to their use of energy demanding elements such as lasers or EBM systems (which also generally demand a high temperature of the powder in the manufacturing chamber), their energy consumption per kg of raw material can be high compared to traditional technologies or other AM technologies. When metal parts are manufactured, they often must also be heat treated in order to relieve residual mechanical stresses.
  As for its efficiency on consuming raw materials, although the manufacture based on plastic powder does not demand support structures, in the metallic additive manufacture they are required, resulting in a material that will have to be removed later. In contrast, the re-use ratio of the non-sintered / molten powder is often high in these technologies, so its efficiency in this regard can be considered to be high and that it produces a reduced level of waste.
  In the field of metal fabrication, some technologies can work with materials that are potentially explosive in particulate (e.g. aluminium) states, so in these cases the consumption of certain volumes of inert gases is demanded.
- Fused Deposition Modelling Processes: these technologies work by depositing through a head a material that is previously heated, so that its electrical consumption comes mainly from the energy required for such heating, as well as to allow movement of the head that deposits it. These technologies only heat the material to be deposited, so it can be said that while its energy consumption may be estimable per unit of raw material, it will undoubtedly be lower than the energy consumption of the previous technologies, for obvious reasons.
  As for its efficiency in the use of materials, it is likely that the FDM is one of the most efficient AM technologies, as it only deposits the material strictly necessary, nevertheless demanding support structures that, as in the previous case, must be eliminated, and are not in principle reusable. In any case, their level of waste production can be considered by the previous features greatly reduced.
  These technologies currently tend to not operate with materials that pose safety problems during manufacture, so they usually do not pose special needs in terms of inert atmospheres in the manufacturing chamber.

Of course, it has to be noted that although these technologies can be qualitatively compared under the previous scope, their capabilities regarding usable raw materials and the mechanical properties of the resulting parts are completely different, being powder bed fusion technologies generally speaking substantially more capable than fused deposition modelling technologies.

4.1.4 AM a step of a whole lifecycle

Although the Additive Manufacturing process itself (the act of printing one or several parts) is a source of environmental impact, it is necessary to take into account that the possible impacts are not only generated at this stage, but before and after carrying out this act of manufacture, when there will be a series of stages that will (before manufacturing) generate the raw materials and energy necessary for such manufacture, and (later) those steps necessary to post-process and finish the pieces, send them to the customers, without forgetting the very life of the printed item, and its final disposal. That is, when assessing the environmental impact of AM it is necessary to take into account that this stage is one more of the whole life cycle of a product, as well as to assess the impact of that AM manufacturing stage on the rest of the stages of this life cycle.

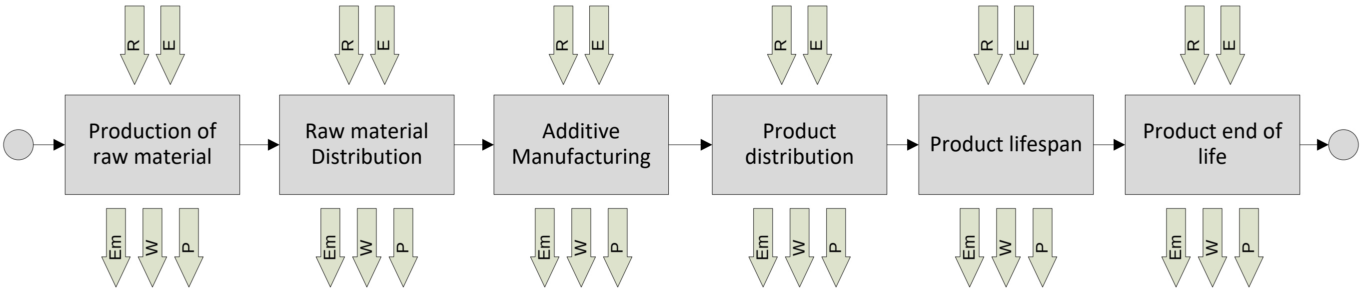

Figure 16: *Additive manufacturing process sub-stages environmental inputs and outputs*

Let´s analyse every one of the stages:

- **Production of raw material**:
  Because of their relative novelty, additive manufacturing technologies make use of highly specific raw materials at the moment, whose production processes often involve several steps added to those of the manufacturing process / preparation of a "standard" raw material[63]. Perhaps one of the best examples of this fact is the metal dust preparation process for Powder Bed Fusion AM technologies.
  The production of metal powders necessarily involves an "atomization" process, in which processes like the next ones will be required: fusion of the raw material or intermediate products, proper atomization and solidification of the resulting dust particles, screening, mixing, presence of inert atmospheres for the processing of material that may be flammable or explosive, need for vacuum, etc.[64]. In accounting for

[63] KarelKellens, Raya Mertens, Dimos Paraskevas, Wimm Dewulf, Joost R. Duflou. «Environmental Impact of Additive Manufacturing Processes: Does AM Contribute to a More Sustainable Way of Part Manufacturing?» *Procedia CIRP, volume 61*, 2017: 582-587.

[64] Farinia Group. *http://www.farinia.com/additive-manufacturing/3d-technique/environmental-impact-metal-additive-manufacturing.* s.f.

environmental impacts (through LCA methodologies) associated with these raw material manufacturing processes, they are still poorly documented, so in practice there is still uncertainty about the actual impact on these AM raw materials manufacturing processes.

- **Raw material Distribution:**
  Transport is an element that, although it does not add value to the final product, affects the same in terms of cost and environmental impacts, the greater the distance from the point of generation to the point of use. Trying to estimate how the emergence of additive manufacturing can modify the logistics chains associated with the transport of raw materials, it is possible to glimpse a scenario in which probably there is no really significant modification of the impacts associated with this stage, for the following reasons:
  - The market for raw materials for additive manufacturing technologies can now be considered to be relatively small in comparison with other areas, so that this market is still currently limited to a small number of producers and consumers, with increasing volumes of business, but still far from its maximum potential in the future. In this sense, the current situation gives rise to suppliers located predominantly in their countries of origin, so that logistical needs depend on this factor.
  - In a future in which the market has grown in size and is approaching maturity, both the processing needs of these materials, as well as the greater volume of raw materials to produce, will probably lead to the centralization of production activities at points where it is most advantageous from economic points of view, as it happens at present with any productive activity.
  - Given the characteristics of the materials used for AM, it is necessary to see the role that the emergence of organizations and services dedicated to the recycling of materials and AM products can have in the supply of raw materials. In this area, and depending on how this will be articulated, this could lead to the emergence of nearby recycling networks, capable of supplying valid material, but from production centres that are considerably closer to the customer; it is necessary to take into account that this recycling task would also have an environmental cost, which should be considered.
- **Product Distribution:**
  Perhaps one of the most important aspects of additive manufacturing is its ability to relocate manufacturing activity, traditionally geographically centralized and heavily dependent on logistical structures that allow the resulting products to reach potential customers, hundreds or thousands of km far for the manufacturing site. In this sense, and provided that networks such as 3D Hubs are arising and giving virtual access to hundreds and thousands of providers of additive manufacturing services, it is expected that in the near future we can attend a change in the paradigm of the manufacture of certain elements and products, especially when it comes to customized products or small series; especially in these cases it is feasible to foresee that centralized manufacturing processes that take place hundreds or

thousands of kilometres from the end user may be replaced by national, regional or even local producers (organizations with 3D printing capabilities)[65]. In the growth of this phenomenon, the integration of these technologies within the current concepts of "internet of things" and "Industry 4.0", will allow in conjunction with services such as those cited that in the near future the possibilities and manufacturing capacities for a product are quickly presented and analysed, according to the interconnection between the different service providers and their machines.

- **Product Lifespan:**
  The advantages of additive manufacturing in this sense are not that it will lead to more durable products (and therefore reduce the impact associated with the generation of a new substitute product), but to products that, due to their characteristics (and only possible with AM) generate a lower impact during the life of the product than that of products manufactured using traditional technologies. In this sense, the impact of technology is very visible at industrial level, in sectors such as automotive, naval and aerospace, where the ability to design and manufacture structural elements with a lower weight, can give rise to a considerable Reduction of the environmental impact associated to the use of said elements during its useful life. An example of this[66] is the comparison that in 2014 3D printer manufacturer EOS and Airbus made between a bracket manufactured by DMLS technology (direct metal laser sintering) compared to a bracket manufactured using rapid investment casting process. Thanks to 3D printing, it was possible to design and manufacture a bracket weighing less than 40% to the original, reducing the combined weight of all brackets of the model airplane in which it was used by 10 kilograms, leading to a 40% reduction in CO2 emissions over the lifetime of the device.
- **Product end of life:**
  The end of the useful life of a product and its subsequent withdrawal is a phase with a considerable potential environmental impact, the greater the less recyclable the product is, since its non-recycling implies a greater consumption of natural non-renewable resources. In this sense, and when estimating how the additive manufacture can in this sense be or not more advantageous, it must be taken into account that the recyclability of a product depends on the technical capacity to recycle the materials that compose it, but also of how waste separation systems (generally governmental dependant) are; in summary, it is not only about being able to recycle a specific waste material, but to have the required infrastructures and logistics to identify, separate and give that specific waste a proper treatment for its recycling[67].
  However, this problem is not only due to a lack of adaptation of the general systems of separation, treatment and recycling of waste, but also to the general lack of implementation of the concept of circular economy in the market (as a whole, not only in the Potential AM product market), in which producers rarely develop business models in which "the product returns to their hands", to reuse and

[65] www.engineering.com. *http://www.engineering.com/3DPrinting/3DPrintingArticles/ArticleID/13224/How-Green-Is-3D-Printing.aspx.* s.f.

[66] www.engineering.com. *http://www.engineering.com/3DPrinting/3DPrintingArticles/ArticleID/13224/How-Green-Is-3D-Printing.aspx.* s.f.

[67] www.engineering.com. *http://www.engineering.com/3DPrinting/3DPrintingArticles/ArticleID/13224/How-Green-Is-3D-Printing.aspx.* s.f.

recycle their components. It is in essence a global problem, and not only applicable to products that may be based on AM.

On the contrary, and as a positive aspect of AM at this point, being able to potentially produce products with a smaller number of components, this characteristic would result in a smaller volume of waste, and therefore a simpler end-of-life treatment.

4.2 Quantitative Assessment of AM technologies environmental impacts

As we have seen in previous sections, it is possible to make a quantitative assessment of the possible impact of additive manufacturing on the environmental impact of additive manufacturing processes, but it is only through quantitative evaluations that it is possible to make categorical assertions; in this sense, to date the LCA tool (Life Cycle Analysis) is used by organizations and government agencies for this purpose. LCA is an analytical tool used to comprehensively quantify and interpret the environmental flows to and from the environment (including air emissions, water effluents, solid waste, and the consumption/depletion of energy and other resources), over the life cycle of a product or process. The International Organization for Standardization (ISO) provides a set of standards and a framework (ISO 14040:2006 and ISO 14044:2006) for LCAs and their relevant stages.

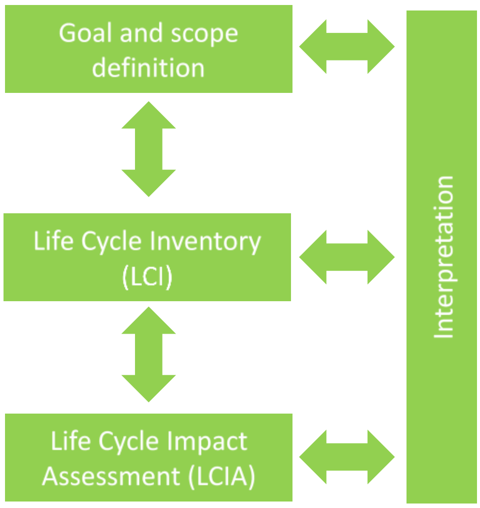

Figure 17: *LCA basic steps*

There are currently studies of some relevance, which have tried to establish certain comparisons between non-AM and AM manufacturing processes from the perspective of an LCA analysis; is the case, for example, of the article "Environmental Impact of Additive Manufacturing Processes: Does AM contribute to a more sustainable way of part manufacturing?" [68], published in 2017, which uses the LCA analysis system to compare the environmental performance of different AM technologies (selective laser melting, selective laser sintering, electron beam melting, fused deposition modelling and stereo lithography) with respect to

[68] KarelKellens, Raya Mertens, Dimos Paraskevas, Wimm Dewulf, Joost R. Duflou. «Environmental Impact of Additive Manufacturing Processes: Does AM Contribute to a More Sustainable Way of Part Manufacturing?» *Procedia CIRP, volume 61*, 2017: 582-587.

traditional technologies (machining and injection moulding), taking into account not only the AM manufacturing stage itself, but the previous and subsequent stages. Some of the most interesting conclusions of this article are:

- The energy consumption per unit of processed material tends to be in the additive manufacturing technologies 1 or 2 orders of magnitude higher (in comparison with traditional technologies), also taking into account the added energy consumptions that can be required in the stage of preparation of the raw materials and in the post processing of the manufactured elements stages.
- Due to the above and in order to make a global assessment of environmental impact, it is necessary to take into account the reduction of the impact that the structural optimizations achievable by the use of AM technologies. In those cases, where these optimizations are applied to elements with long lifetimes and significant weight reductions are provided (specially aerospace and rail industries), impact reductions can be quantitatively estimable, and in fact counteract the greater impact of the AM manufacturing phase, even getting a better net result. In other cases, such as the automotive industry or consumer products, the prospect of additive manufacturing leading to reduced environmental impact is not particularly realistic, given the relative importance that structural optimizations may have on the impact of the products manufactured by AM during its life cycle.
- As another interesting conclusion, the study warns that existing LCA studies generally involve very partial analysis or are focused in very specific (and therefore not fully representative) cases, and there is still a certain lack of information regarding the existing inventories of environmental impacts related to AM (around which the LCA analyses are developed) that allow LCA analysis to be performed based on fully reliable information.

5 Health and safety

5.1 Understanding health and safety impacts: Additive manufacturing process

While additive manufacturing is from an industrial point of view a relatively new technology, from the point of view of health and safety, its treatment must follow the same scheme as for any other technology at industrial level, and it is for this reason that it is important to take into account that its risks to the health and safety of are really the sum of the risks along all stages involved in its use:

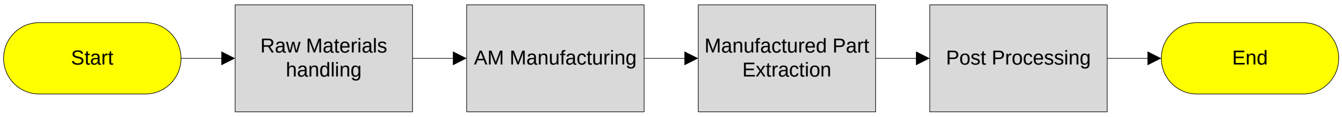

Figure 18: *AM General Process*

- Raw Materials handling. Depending on the AM technologies, the raw materials can be presented in various forms, from the convenience of cartridges (of the type of a traditional printer) containing the material without the possibility of direct contact, to the need to manipulate micro-particulated material and gases (for the generation of inert atmospheres), through rolls of thread of material. Each of these materials have their own characteristics of toxicity and / or handling and storage, which will establish how they must be manipulated prior to their previous use and feeding to the AM machine.
- AM Manufacturing. The manufacturing process itself has the inherent risks associated to the selected AM machine, which characteristics vary depending on the base technology. The simplest desktop machines are nowadays open machines, with direct access to the manufacturing chamber, where they deposit plastic material at a certain temperature; on the contrary the most common machines for the manufacture in metallic materials have manufacturing chambers that cannot be acceded during the process of 3D printing. All machines of course use electrical energy for their operation, and in the case of certain particulate metallic materials (such as aluminium) that may be explosive, they will be used in inert confined atmospheres, with the necessity of preventing as well the production of discharges of electrostatic electricity in tasks such as extraction and cleaning once the AM machine finishes its work.
- Manufactured Part Extraction. Some technologies will present a very simple extraction of parts (such as FDM for common use plastics) where with a simple spatula and due to the reduced weight of the parts, they can be extracted manually from the manufacturing chamber; in other cases mechanical means for extraction (for example in the case of technologies which work on particulate metals, which manufacture parts on thick and heavy steel plates), or means to prevent contact and penetration into the organism of micro particulated powder, are required.
- Post Processing. Again, there are important differences depending on the technology used. In the simplest cases (FDM), the support structures must be removed manually or with simple mechanical means, and in the most complex cases (power bed fusion technologies), it will be necessary to eliminate support structures with mechanical means, the separation of the manufactured parts from the metal plate by cutting the parts, heat-stabilization, sanding, shot-blasting, manual or mechanical machining, etc.

5.2 Different AM technologies, different health and safety risks.

As we have seen in the previous section, there is a great variability in the typology of the risks associated with the different AM technologies available nowadays. Because the number of additive manufacturing technologies is considerable, only the two most prevailing technologies area analysed in detail: powder bed fusion and FDM.

5.2.1 Powder Bed Fusion.

Taking the general AM process depicted in the previous chapter, every one of the steps shown will be addressed:

- Raw Materials handling. This group of technologies is undoubtedly one of the most sensitive in terms of raw materials handling, since in the form of particulate material of very small diameter (even between 5 microns and 45 microns in diameter for metal powders[69]), contact with the skin or airways penetration is highly possible if proper protection equipment is not provided, leading to various health complications[70] [71].
  Powders for additive manufacturing undergo logistical operations, preparative steps for processing and the build-up process itself. As of today, some of these steps bring the powder into contact with the operator and ambient air conditions. Depending on the specific additive manufacturing process employed there are steps like sieving, filling powder into the machine, filling powder from one container into the other. Also, the process itself may necessitate the contact between powder and operator. Powders for additive manufacturing undergo logistical operations, preparative steps for processing and the build-up process itself. As of today, some of these steps bring the powder into contact with the operator and ambient air conditions. Depending on the specific additive manufacturing process employed there are steps like sieving, filling powder into the machine, filling powder from one container into the other. Also, the process itself may necessitate the contact between powder and operator. Figure 19 shows an exemplary process chain for the LBM-process including the powder path.

[69] RENISHAW. «Safety in additive manufacturing.» 2017.

[70] UL. *http://library.ul.com/wp-content/uploads/sites/40/2016/10/10336-AdditivManu-FINAL_10-18.pdf.* s.f.

[71] Srivastava, Anshika. *http://blog.thors.com/safety-concerns-in-additive-manufacturing.* s.f.

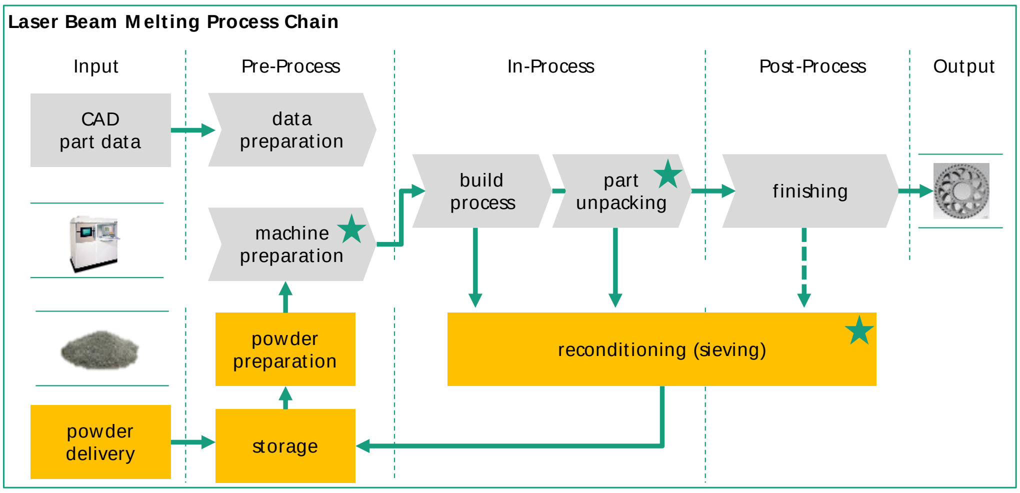

Figure 19: *Exemplary process chain for the LBM-process, according to Lutter-Günther et al.72 Process steps with increased risk for airborne powder are marked with a star (*).*

In general, the particle size distribution of the used powders also contains a fraction which is considered respirable dust or even so called alveolar dust. Respirable dust can reach the lung through the respiratory system while the even more noxious alveolar dust particles have an even smaller diameter and can reach the pulmonary alveoli. Several alloys including most steel powders contain alloying elements which are carcinogenic. Other alloys like aluminium or titanium are reactive and could therefor lead to a risk of explosion. In order to avoid these risks, the formation of airborne dust should be avoided wherever possible. However, in some process steps this goal cannot be fully achieved for the current state of the art machine systems.

In summary, the main risks associated with the handling of powders are as follows[73]:

- Absorption into the body through skin contact.
- Inhalation if the powder is suspended in air.
- An explosion risk if the powder is suspended in air.
- Dispersion through poor environmental controls.
- Ingestion through poor cleanliness.
- Contamination from clothing.

Thus personal protective equipment (PPE) should be worn during powder handling. It is advisable to foresee at least the following personal protection equipment showing a non-exhaustive selection:

[72] M. Lutter-Günther et.al «Quantifying Powder Losses and Analyzing Powder Conditions in order to Determine Material Efficiency in Laser Beam Melting.» *Applied Mechanics and Materials Vol.856*, 2017: 231-237.

[73] RENISHAW. «Safety in additive manufacturing.» 2017.

  - Dust mask to avoid the inhalation of airborne powder
  - Safety shoes with protection against electrostatic discharge (ESD) combined with an electrostatically dissipating ground to avoid possible ignition sparks
  - Protective clothing to avoid powder contamination on regular clothing
  - Protective gloves to avoid powder contamination on skin.

  In addition, a poor level of housekeeping can lead to accumulations of powder, which can be disturbed by a small incident resulting in a secondary, and potentially larger fire or explosion. Simple housekeeping measures, regularly applied, eliminate this risk[74].

- AM Manufacturing. Although the manufacturing stage itself does not normally involve the participation of a person (except stops and adjustments during the process), there are nonetheless a series of risks worth highlighting. While there are significant differences between all the processes categorizable within the powder bed fusion AM technologies group, they all share the principle that they apply a highly energetic source to particulate material for the shaping of parts. Although in the processes involving the use of plastic material the risks are considerably lower, in the case of metallic materials the risks may become significant if the process does not take place under controlled conditions, since some materials may be flammable or explosive in the presence of air and a source of energy (even static electricity). Because of this, most systems for metal fabrication incorporate measures that provide the process of inert atmospheres, in order to avoid the aforementioned risk, and at the same time to avoid the introduction of impurities during the manufacturing process[75] (oxygen and moisture). Argon or nitrogen gas are used depending upon the type of metal being processed, that in high concentrations can lead to oxygen displacement in the air up to unsafe levels; thus, malfunctions and gases leak could lead to suffocation risks, especially if the machines are not suited in opened and well ventilated places[76] [77].

  As these systems are provided with high energy sources like lasers or electron beams, the use of these systems has associated a number of additional risks, since poorly adjusted, addressed or maintained, can result in burns to the skin or damage to the eyes.

  Thus, in this sense the preventive measures indicated would be:
  - Establishment and rigorous monitoring of maintenance and calibration programs.
  - Installation of machines in open and well-ventilated spaces.
  - Use of personal protective equipment and anti-static elements during operations that require stops and adjustments during a manufacturing process.

- Manufactured Part Extraction.

  The stage of extraction of the manufactured parts is one of the stages that involve greater risks of direct contact between an operator and the particulate material, since today, this work is usually done by manual means, involving the extraction of the unused particulate material for Its later recycling or discard. In this way, the indications established in the section "raw materials handling" are fully applicable in this case, and are translated more concretely into measures such as:

[74] RENISHAW. «Safety in additive manufacturing.» 2017.

[75] RENISHAW. «Safety in additive manufacturing.» 2017.

[76] Srivastava, Anshika. *http://blog.thors.com/safety-concerns-in-additive-manufacturing.* s.f.

[77] RENISHAW. «Safety in additive manufacturing.» 2017.

- Establishment of protocols for the extraction of parts, covering aspects such as cooldown times, definition of specific extraction equipment and individual protection equipment, etc.
- Use of breathing apparatus and filters to avoid inhalation of dust.
- Use of specific clothing and gloves for the extraction work, and storage and separate treatment of such clothing.
- Carry out the extraction work using anti-static electricity footwear and surfaces.
- Transfer of unused material to specific containers.
- Use of suitable suction equipment, conform to the relevant ATEX, DSEAR, NFPA or the equivalent local standards for the zone of operation.

- Post-Processing. At this point there is great variability between the processes that use plastics as raw material and those that use metal, since while the former (SLS technology) give rise to a complete piece, made without support materials and without being attached to a manufacturing platform, in the case of metal-based technologies, further work is required to separate the parts from the manufacturing platform and for removal of support structures, in addition to the previous need to carry out heat-stabilization (oven) work for the elimination of residual stresses. In any case, any part may also require subsequent finishing, which may involve machining (manual or mechanical), painting, polishing, etc.

  All the described operations carry their own risks, and therefore, for each of them, they must be identified and evaluated individually, establishing the necessary precautions, means and measures of protection.

5.2.2 Fused Deposition Modelling.

As in the previous case, we will make a brief analysis of the safety connotations in each part of the general AM process:

- Raw Materials handling. The materials used in this type of technologies are usually as much by their composition (plastics as PLA or ABS), as by their presentation (coils of material thread) materials directly manipulable by the user. Of course, it is necessary to take into account that most of these materials may be flammable due to their organic nature given the proper conditions, but assuming storage conditions in which they are separated from highly energetic sources, they can be manipulated and managed on the basis of basic precautions, applicable to any other material of similar characteristics.
- AM Manufacturing. The principle of operation of these technologies is the heating of a wire of plastic material, so that it can flow and be deposited for the shaping of a piece; this process can produce fumes containing ultrafine particles, which some studies show may be detrimental to health when exposure is prolonged. In this sense, recent studies have shown that FDM processes using polylactic acid (PLA) feedstock can release up to 20 billion particles per minute, and others such as the acrylonitrile butadiene styrene (ABS) feedstock can release up to 200 billion; exposure to high concentrations of this type of nanoparticles is associated with cardiorespiratory problems, asthma symptoms, and in some cases heart attacks. On the other hand, the thermal decomposition of some of these materials can lead to the

generation of toxic substances[78] [79] .

Many of the existing machines are desktop devices, in which the operator can have a direct access to the space where the manufacture takes place. Taking into account that the temperatures necessary for the melting of the plastics can easily reach 200 ^{0}C, the non-careful handling of these equipment can give rise to burns of some consideration. In some equipment the platform on which the manufacture is made can be hot (at temperatures around 120 ° C), so it is necessary to take into account that in any case, and although there is usually no production volumes available which can cause harm beyond hands and arms, there are clear risks of burns[80] and even fires if a failure in the heat control system is provided. Especially for this desktop machines the possibility of a direct manipulation by the user can lead to substantial electric risk.

Thus, preventive measures to be taken for this type of equipment during this phase are related to the location of these devices in places with good ventilation, as well as the special care when performing adjustment and manipulation works.

- Manufactured Part Extraction. The extraction of the parts of the AM machine is usually simple, since although there may be some adhesion between the manufactured parts and the base of the manufacturing platform (in the machine itself), it can be easily manually overcome, or with a spatula. Since these machines usually only heat the material being deposited, there is usually no risk of burns on direct contact with the parts manufactured, although some machines may incorporate other heating systems which, although they may not reach extreme temperatures, involve an added precaution when opening or accessing the manufacturing chamber and extracting the parts. Especially when the manufacturing has just finished, it is necessary to take special care that the user does not come into contact with parts of the machine that can store some residual heat, such as the material injection head.
- Post Processing. FDM technologies demand the provision of support structures for the success of the manufacturing process, so that they must then be removed, usually by manual means or simple mechanical means. Although these technologies are usually not associated with the manufacture of functional parts of high requirement or precision, in any case the parts could demand additional work of adjustment or finishing. These tasks, carried out with the necessary means, will demand in each case the establishment and application of the protection measures applicable by the risks that they may entail.

5.2.3 Other AM Technologies

In the analysis of the two previous technologies from the perspective of health and safety we have seen how there are important differences between what are two of the most common AM technologies nowadays, but there are other groups of technologies on which we can provide a series of general indications, in order to contribute with a broad vision:

[78] University of South Australia. «3D PRINTER TECHNOLOGY - PRE-PURCHASE CONSIDERATIONS AND SAFE USE .» 2015.

[79] University of Vermont. *http://www.uvm.edu/safety/shop/3d-printer-safety.* s.f.

[80] 3D Print Headquarters. *http://3dprinthq.com/desktop-3d-printer-safety/.* s.f.

- Direct Energy Deposition. These technologies (based on the direct contribution of material based on processes similar to welding) have a very clear industrial orientation, and are fundamentally focused on the repair and maintenance of existing parts. In this sense, this type of technology has certain similarities with more traditional industrial machines, since in their base they consist of heads mounted on diverse CNC systems. They are also technologies with a high degree of complementarity with existing technologies in such industrial machining environment, so from a safety and health point of view, all applicable safety risks and measures will be those already existing in that field.
- Binder Jetting. These technologies operate similarly to technologies within the powder bed fusion group, but in this case, the energy source is replaced by a binder that is applied by selectively depositing heads. In this sense, the risks associated with this type of technology will be fundamentally associated with the handling of particulate materials, as already described in section 5.2.1.
- Vat photo polymerization. In this case, 3D printing is produced by selective curing of photopolymer material, placed in a vat of liquid material. The risks associated with the handling of these resins are reduced (the parts manufactured are themselves of this material, cured), and the application of ultraviolet light is usually properly addressed and confined within the machines that use it.
- Material Jetting. These technologies operate on a principle very similar to that of inkjet printing, in such a way that the material (photopolymer resin) is directly deposited on a platform or on the previous layer, and then a UV light cures the material and gives it solidity. It has high similarities with the previous process, with the added convenience that the materials are usually contained in cartridges, so that there is no possibility of manipulating them directly.
- Laminated Object Manufacturing. The basis of this technology is the application of sheets of material made in rolls (metal sheets, paper, etc.), their forming by means of laser cutting systems or other machining systems, and the addition and subsequent forming of new sheets. It is a technology with a rather industrial scale, and therefore the risks and precautions will be those of the environment and the technologies described.

6 Summary and conclusions

Intellectual Property Rights

In this report, we have reviewed literature about the implications of Intellectual Property issues and additive manufacturing technologies. Although the number of studies carried out so far is quite relevant, there are no unified conclusions or recommendations to plan actions to be taken in the future. In any case, copyright and design law seem to be more relevant in the process than other IP instruments such as patents.

The application of IP rights in additive manufacturing processes involves relevant challenges related to the digital nature inherent to the global manufacturing process, which disrupts enforcement mechanisms in all areas of IP Law, as well as the implications regarding possible risks of infringement, both direct and indirect.

As the growth of the implementation of additive manufacturing technologies continues at both the industrial and private levels, it is essential to address the IP issues related to these technologies from all points of view: product developers, manufacturing service providers, private users, industrial users, etc. The needs of each of these stakeholder groups are different, and the implications in the process may also be quite diverse. In this sense, as happened in the past with the digital revolution and the piracy of artistic works (music, films, etc.), it is essential to raise awareness among all stakeholders about the importance of IP aspects and the implications that the unauthorized use of third-party creations may have.

In addition, it is necessary to establish clear guidelines about the IP elements that affect both the products manufactured by additive technologies and the 3D models that allow their manufacture (CAD and STL files), as well as the possible considerations that changing file formats could have on the protection. The legal nature of the CAD and STL files should be also addressed, as well as the relation between the IPs in the products manufactures in respect to the IPs in the digital files.

It is also worthy to mention that the tendency currently being followed by the online platforms (and other manufacturing services providers) is to exonerate themselves from any liability, making that responsibility fall on the user of the service. Therefore, as previously mentioned, it is essential to increase the level of information of end-users and raise awareness between all the stakeholders about IP considerations in the process.

Regulation

At European level, the applicable CE marking and chemical substances regulation (REACH, CLP) establishes a strong framework for all products related to additive manufacturing technologies, which are the way to ensure that products (machines, raw materials, manufactured products, etc.) are safe and do not endanger their potential users. Since additive manufacturing technologies make use of previously existing technologies, but applied to a new manufacturing concept, from this point of view, existing legislative frameworks can be valid for the assurance of their safety. However, in the area of quality assurance, it is expected that this will be imposed by the development of standards, which assumed as mandatory by the different sectors and agents, give rise to requirements added to the regulatory.

Environmental impact

Although there are some preconceptions about the ability of additive manufacturing technologies to lead to manufacturing processes with less environmental impact, the current characteristics of these technologies, and especially those with a higher industrial focus (such as the ones based on the sintering or fusion of particulate material) make them pretty energy intensive, and in a direct comparison with traditional technologies (some of them as efficient as the injection moulding) tend to have greater potential impacts. While it is expected that the energy efficiency of these technologies will increase with the emergence of new machine generations, the greater ability of these technologies to reduce the environmental impact of manufacturing activity is the manufacture of structurally improved and lightened products for applications where this parameter can lead to large savings in energy and fuel consumption (aerospace and rail applications), leading to a lower net entire product life of cycle impact.

The capacity of additive manufacturing to delocalize the manufacturing process and bring manufacturing closer to the final consumers cannot be neglected, as it could lead to a significant reduction in the energy consumption associated with the transport of goods.

In any case, no analysis of these characteristics can be objective until there is sufficient life cycle analysis (LCA) in the field of additive manufacturing technologies, since at present these studies are not enough in number and scope, and the databases on which they are based have significant shortcomings in accounting for the impacts of many of the operations involved in AM technologies.

Health and Safety

Current AM technologies are varied and therefore have different connotations from the point of view of safety and health, being perhaps the risks associated to those technologies with greater industrial applicability those with a greater relevance, especially to take into account in those ones that make use of particulate material.

Technologies such as FDM have a high potential to be used in their desktop versions by home users; although these technologies do not make use of materials or mechanisms that pose a great direct risk to health, the fact that these machines generate heat for the fusion of plastic materials leads to risks that require the application of a series of security measures, which although basic must be rigorous.

In both areas, it could be demanded that technology manufacturers make an effort to provide organizations and users with full information about the risks associated with their use in order to generate a secure environment for the growth of such technologies.

Acknowledgments

We would like to thank Ms. Rosa Ballardini (Senior lecturer in IP law, University of Lapland - Finland) for her revision and comments about the Chapter 2 of the document (Intellectual Property Rights).