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Published in:

JOURNAL OF MANUFACTURING TECHNOLOGY MANAGEMENT

DOI:

[10.1108/JMTM-12-2017-0270](https://doi.org/10.1108/JMTM-12-2017-0270)

Published: 15.10.2018

Document Version

Peer reviewed version

Citation for published version (APA):

Ballardini, R. M., Flores Ituarte, I., & Pei, E. (2018). Printing Spare Parts through Additive Manufacturing: Legal and Digital Business Challenges. *JOURNAL OF MANUFACTURING TECHNOLOGY MANAGEMENT*, 29(6), 958-982. <https://doi.org/10.1108/JMTM-12-2017-0270>

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Printed Spares: Challenges between Law and Digital Businesses

Journal:	<i>Journal of Manufacturing Technology Management</i>
Manuscript ID	JMTM-12-2017-0270.R1
Manuscript Type:	Article
Keywords:	Additive Manufacturing, Service operations, 3D printing, Digitization, Strategic management

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Printing Spares: Challenges between Law and Digital Businesses

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Abstract

Purpose:

This paper investigates business and intellectual property issues of producing spare parts using Additive Manufacturing (AM) from a digital source. The aim is to raise awareness of the growing digital spare parts market in Europe, to identify the major business and legal challenges that are currently impeding the growth of such markets, and to propose solutions to navigate these emerging issues.

Methodology:

This paper covers the use of literature review, theoretical analysis and case studies of key challenges that manufacturing industries in Europe are facing in the transition towards developing new digital businesses related to AM produced spare parts.

Findings:

The paper sheds light over core factors that may impede the development of new commercial activities related to AM produced digital spares, including business strategies, patent protection and patent infringement. The study reveals that a stable functional European market for digital spares in the context of AM is growing and it can only be built around the efforts stemming from multiple fronts, including technical, business and legal perspectives.

Originality/value:

The study provides valuable knowledge to promote the growth of a stable European digital spare parts market in the context of AM by pinpointing key issues that need to be addressed within the European AM business environment and the European patent system, and proposing recommendations for business and legal frameworks to foster and accelerate the development of the digital spare parts market.

Keywords: Additive Manufacturing, Spare Parts, Patent Law, Digital Businesses

Paper type: Research paper

1. Introduction

This paper investigates theoretically and empirically topical business and intellectual property (IP) related issues within the context of spare parts produced using Additive Manufacturing (AM) technology. The goal is to raise awareness of the growing digital spare parts market in Europe, to identify the major business and legal challenges that may hinder the growth of such markets, and to propose solutions to navigate these emerging issues. The study provides novel insights and new knowledge to promote the growth of a stable European digital spare parts market in the context of AM.

The integration of digital information systems and AM brings great opportunities, but also raises multiple challenges in terms of business and legal implications for digital marketplaces for the provision of spares.

Developments in AM technology have the potential for fundamental shifts in society (Steenhuis and Pretorius, 2017). The hypothesis underpinning the concept of “digital spare parts” is that AM-digitized supply chain systems will enable new decentralized operations-centric business models, which will become a key resource for competitive advantage in the 21st century manufacturing industry. The projection is that a more generic model that includes highly automated digital fabrication systems that could take into consideration a human centric approach can complement the current supply chain models (i.e. make-to-stock, make-to-order and engineer-to-order) (Holmström et al., 2014). There is a great potential for AM to assist manufacturers to compete in the rapidly changing and turbulent environment of businesses today (Rylands et al., 2016), especially in the after-sales service logistics (Knofius et al., 2016) (Eyers and Potter, 2015). **Before this shift can take place, key business, technical and legal issues need to be taken into account. In this regard, this research sheds light on research questions, such as what is the current situation of AM as a manufacturing alternative? Is AM ready to be integrated as a manufacturing alternative in the service business of original equipment manufacturers (OEMs)? What are its technological and operational shortcomings? The answers to these questions will help us to better understand the challenges for AM implementation, thus enabling companies to define a clear roadmap for decentralized manufacturing.**

Against this complex scenario, intellectual property rights (IPR, IPRs), i.e. the legal tool that naturally links innovation to the market place, play a crucial role to support new business opportunities in the context of AM-enabled services. At the same time, however, if not well calibrated, IPRs and IP-related policies might hinder, rather than promote such developments. Although these technological activities have the potential to affect all fields of IP law, this paper focuses on patent law. In the field of AM and spare parts, controversies may arise especially when patent ownership on the products subject to “repair” (via producing spare parts) is seen to be in conflict with claims of IPR ownership on the related components produced via AM. **In other words, the key issue revolves around the conditions under which it is lawful to impede third party “repairs” of patent protected products under current interpretations of patent infringement doctrines in Europe. Under current patent law provisions and interpretations, these key questions remain open. One one hand, the case law related to the concept of legitimate “repair”**

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3 in European patent law is very scarce and at times contradictory and, on the other, the scholarly
4 literature in the field only addresses some general issues and only on a scattered manner. At
5 the same time, however, these patent-related challenges must be addressed as they might
6 eventually block possibilities for a digital spare parts business to grow or even being created at
7 all.
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10 The paper begins with a literature review and a theoretical analysis of the key challenges
11 that manufacturing industries in Europe are facing in the transition towards developing new
12 digital businesses related to digital spare parts. A key focus of this paper is to identify and
13 discuss core factors that might impede the development of these new businesses, including
14 business strategies, technological advances and patent-related issues. Taking a step further,
15 we gathered empirical data using qualitative case studies to provide an in-depth analysis of the
16 business and IPRs issues at stake. This allows us to shed light and gain new insights on the
17 major deficiencies and shortcomings of the current business and legal frameworks that need to
18 be addressed within the European AM business environment and the European patent system,
19 so as to develop novel and potentially more workable solutions for both the business and legal
20 framework to foster and accelerate the development of a European digital spare parts market in
21 the context of AM technology.
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26 **2. Digital Spare Parts and Online Libraries**

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28 Spare parts play an important role in most manufacturing and consumer businesses,
29 accounting up to 45% of the total gross profit and approximately 24% of the revenue (Bacchetti
30 et al., 2012). Currently, three issues influence the spare parts business (Dekker et al., 1998):
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32

33 (1) Availability; spares are often not readily available when needed and this can result in
34 a detrimental knock-down effect that affects the reliability of products and services;

35 (2) Cost; the spare parts and tools are stored as a physical inventory that can add up to
36 increased logistical cost for companies;

37 (3) Time; producing a single spare part could take up time if the tooling is required and
38 this has a negative implication towards the operational reliability in terms of machine downtime.
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42 As traditional methods of manufacturing have high upfront costs and are dominated by
43 economies of scale, the use of AM can support Just-In-Time (JIT) manufacturing, reducing
44 operational costs and making the delivery and access to spare components much faster
45 (Kretzschmar et al., 2018). The use of AM can be an enabler for many manufacturing
46 businesses, whereby AM can be deployed to produce spare parts, product upgrades or retrofits
47 in a geographically distributed manner (Manenti, 2014).
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50 In the industrial context, research has shown that digital spare parts facilitate sharing
51 product information on the internet (Khajavi et al., 2014), monitoring distribution and optimizing
52 the production process (Li et al., 2016). At a consumer market level, digital businesses, such as
53 Turbosquid, GrabCAD, Thingiverse, 3D Warehouse and many others operate as an open
54 source library of 3D models (Ballardini et al., 2016). To a great extent, the reproduction of
55 physical parts in these online libraries are often low value components such as plastic gadgets,
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adaptors, sockets and buttons. However, this is changing. For instance, nowadays there are also publicly available files for multiple machine components, as well as (non-critical) spare parts of the McDonnell Douglas (now Boeing) F-18 Super Hornet jet fighter, such as air-cooling ducts that can be produced using AM. As an example of the relevance of digital spare parts, the Boeing Company holds a patent for a system that will enable on-demand AM of aircraft parts to order replacement components much quicker and at a lower cost using AM methods of fabrication. The system includes a virtual library of parts, along with a database of technical information and a part management system (Koreis, 2017). This allows aircraft service bureaus and maintenance teams to have less reliance on a stockpile of inventory that would require manpower and storage.

Currently, research and innovation projects are looking at novel ways of monetizing the service businesses based on digital spare parts and AM (VTT, 2016). In this regard, the geometrical data of the product to be replaced (i.e. the computer-aided design or “CAD”) and critical information is saved within a digital file (i.e. digital inventory) and then transferred to the manufacturing service on demand to be manufactured by AM, usually close to the end user’s premises. Digital inventories can then be connected to digital marketplaces, which can be used to link the need (i.e. the end customer’s need) with the supply (i.e. the digital supply chain), thus enabling novel business concepts, such as digital marketplaces, digital spare part supply, co-creation in product retrofits or upgrades, mass-customization and novel e-commerce business activities.

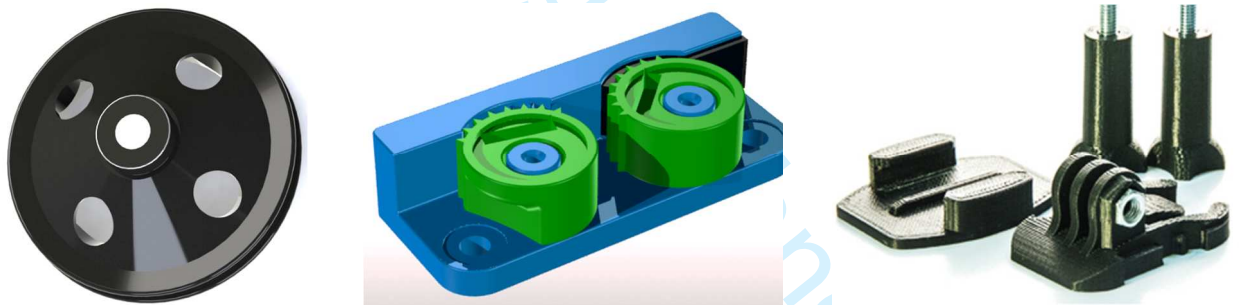


Figure 1. Digital spare part examples for automobile, machine elements and commercial devices. From left to right a (a) Renault 9 Water pump pulley (Karasu, 2013), (b) guiding element for Zcorp z650 printer (Robert, n.d.) and (c) GoPro camera mount spares (Omeraldi, 2015)

Figure 1 shows three exemplary parts that can be downloaded and replicated, with inexpensive AM equipment. The part then can be used to repair automotive motor parts, machine elements and consumer products. Indeed, the technological constraints and early stages of this business models determine that, currently, AM technology still faces several limitations, such as productivity issues, material limitations, part repeatability and manufacturing consistency (Conner et al., 2014). Thus, the upcoming technological developments are crucial to enable the integration of the technology with existing supply chains, which becomes a necessary step in the transition to digital spare parts (Flores Ituarte et al., 2016).

3. Patent Infringement and Repairing under Patent Law

3.1 *The Context of Patent Law and Patent Infringement in Europe*

Patent rights enable the right owner with the ability to prevent others from *inter alia* making, using, selling, placing on the market, offering, importing or storing the protected invention¹. Because third parties' "repairing" via producing spare parts might include prohibited activities with the protected product, there is a possibility to infringe upon the IPR of the product's owner. This paper focuses on primary markets of spares, i.e. markets for producing and selling new (although identical or highly similar to the original) products' components, as opposed to further transfers or distributions of the unadulterated (although used) original article or component.

The European patent law operates in a complex multi-level system consisting of national and regional patent laws. The European Patent Convention (EPC) has largely harmonized European patent law at a procedural and pre-grant stage, while leaving post-grant litigation activities related to infringement, as well as exceptions and limitations to infringements to national jurisdictions. As such, European Member States are free to decide on core substantive doctrinal elements of patent infringement, such as equivalents for direct infringement or the subjective requirements of indirect infringement actions, as well as the scope of exceptions and limitations to a patent right.

National laws in relation to post-grant matters were provided by the Convention for the European patent for the Common Market, also referred as the Community Patent Convention (CPC). Although it never entered into force, the framework provided a template for many European Member States to effect this into their national patent legislations. The most recent and on-going post-grant patent law harmonization effort in the European context is the "EU Unitary Patent Package" that is an initiative for a new Unitary Patent (UP), that will make it possible to get patent protection in all EU Member States by submitting a single request to the European Patent Office, and a Unified Patent Court (UPC) within the EU to offer users of the UP system a cost-effective option for patent enforcement and dispute settlement across Europe (McDonagh, 2016) (Callens and Granata, 2013).

Both the CPC and the UPC agreements approach two types of patent infringement and two different kinds of liability in terms of direct and indirect infringement. Direct infringement arises when someone without authorization makes, sells, places on the market, uses, offers, imports or stores the patented invention.² In the context of spare parts of product patents, the key infringing act is "making" or "producing" the patented invention. Conversely, indirect

¹ Agreement of a Unified Patent Court (UPC), [2013] C 175/1, Art 25.

² Although the wording of the laws in national European provisions in general are not identical, they very much resemble the dictate of the 89/695/EEC: Agreement relating to Community patents - Done at Luxembourg on 15 December 1989, *Official Journal L 401*, 30/12/1989 P. 0001 – 0027, Article 25 (originally number 29), and the UPC Agreement, Article 25.

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3 infringement occurs where “means” that relates to an essential element of the invention, is
4 supplied on the national territory (where the patent has effect) to any person other than a party
5 entitled to exploit the patented invention with the knowledge that such means will be used in an
6 infringing product, or method. Thus, in the case of spare parts when a third party knowingly
7 supplies an unpatented part related to an essential element of a protected combination product,
8 a patentee might be able to assert indirect infringement.
9

11 **3.2 Making, Repairing and the Context of Digital Spare Parts**

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14 The concept of the patent-related statutory right of “making” the invention has generally
15 been interpreted in similar ways in most European countries. “Making” refers to the fact that the
16 claimed invention described in the patent is carried out in practice. For product patents (i.e. the
17 focus of our study) “making” could equate to *producing* a product from raw materials, or
18 *transforming* a product to its form or function, *assembling* a product from simple or complex
19 pieces, or even *building* a product from an assembly kit.³ The making of a new product may take
20 place even if the parts used are not new, for instance if they are second hand or refurbished.
21 The product does not need to be completely finished in order to infringe. An unfinished product
22 is generally considered as “made” when it is so far in the manufacturing process that it
23 incorporates either literally or equivalently the elements of the patent claim. The method of
24 manufacturing and the quantity in which the product is produced is irrelevant so far as
25 infringement of a patent product is concerned.
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29 Patent rights are state granted monopolies to promote technological progress calibrated
30 to promote the benefit of society as a whole (Edwin C Hettinger, 1989). This is why the
31 exclusive rights granted by patents are subject to exceptions and limitations in the law,
32 balancing the interests of right holders and users (Lee, 2007). In the context of product patents
33 and spares, the most relevant limitation is the principle of exhaustion.
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36 All EU countries contemplate the principle of exhaustion although in different ways, such
37 as through statutory provisions or case law interpretations⁴. The doctrine of exhaustion limits the
38 extent to which patent holders can enforce their rights on a sold patented product after it has
39 been placed into the market with the consent of the right holder.
40

41 In Europe, the patent exhaustion doctrine originated from the European Court of Justice
42 (CJEU) ruling in *Centrafarm v. Sterling Drug*⁵ that spelt out two key elements required for the
43 exhaustion of patent rights in a sold product to take place:
44

- 45 (1) Placing the product covered by a patent on the market in the European Economic
46 Area (EEA);
 - 47 (2) By or with the consent of the patent holder.⁶
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51 ³ It should be noted that the “making” of construction drawings, plans, or the like, does not usually amount
52 to “manufacturing”. See M Norrgård, *Patentin loukkaus* (Sanoma Pro Oy, Helsinki 2009).

53 ⁴ When the UPC Agreement and the UP Regulation will enter into force, the European patent exhaustion
54 doctrine will, for the first time, be governed by statutory EU law. See Article 29 of the Agreement on
55 Unified Patent Court and Article 6 of the Unitary Patent Regulation.

56 ⁵ *Centrafarm v. Sterling Drug, Inc.* (C-15/74) 1974 2 C.M.L.R. 480.
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4 Putting the product on the market means that the patent holder transfers the rights to a
5 third party to dispose of the goods embodying the patented invention, so as to allow the patent
6 holder to realize the economic value of the right. In other words, the first authorized sale of a
7 product by the patent holder (or a licensee) results in exhaustion of the patent rights of the sold
8 product. Consequently, purchasers of the sold product may use, resell and import the product in
9 the territory where the exhaustion principle applies (which, in the case of “community
10 exhaustion” refers to the EEA area) without additional consent by the patentee (Haapanen,
11 2017). The exhaustion also covers the loan and *ordinary repair* of the product. However,
12 because the permitted acts following exhaustion cover only acts concerning the particular
13 product sold, making (as well as selling or offering for sale) a new product is not allowed. As
14 mention, ordinary “repair” of the product sold should be allowed under the exhaustion principle.
15 As such, the legitimate repair of the patented product that has been sold might be viewed as an
16 important limitation to the patentee’s exclusive right to “make” the invention. Clearly, in the
17 context of product spare parts and patent law, the interpretation of the term “repair” is of key
18 importance.
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23 Generally speaking, there is no harmonized understanding about the interpretation of
24 “repair” in the EU. The notion of “repair” is not mentioned in any patent statute in Europe.
25 Moreover, national case law across the EU on this issue is scarce. The concept of permissible
26 “repair” is interpreted with slight differences in different EU member states. In fact, although the
27 act of replicating the patented invention is clearly forbidden under patent law of all EU countries,
28 different European courts have interpreted the matter of whether and to what extent *producing*,
29 *transforming*, *assembling* or even *building* a product is legitimate. Indeed, if such conduct
30 amounts to creating a new product, this might equate to direct making and therefore be
31 prohibited. In contrast, if the conduct only amounts to repair, it might not necessarily amount to
32 making and thus would not be forbidden. Judging about making as opposed to repairing
33 becomes complex when the alleged infringer “starts” from the patented product, but replaces
34 only some parts of the product. Indeed, issues of repair versus making frequently arise in suits
35 against the manufacturer or seller of replacement parts for secondary liability, for instance by
36 asserting that the sale (or offer for sale) of a replacement part constitutes indirect infringement
37 (Holder and Schmidt, 2006) (Mohri, 2010).
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42 In Europe, it is considered that the patentee does not have any general “reparation-
43 monopoly” right.⁷ At the same time, however, some courts have also specifically stated that
44 there is no such right as the right to repair as such. Vice versa, courts have affirmed that the
45 most crucial question should reside on the fact that the “making” of a patented product is a
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48 ⁶ In Europe the concept of regional exhaustion is justified also based on the EU principle of free
49 movement of goods, enshrined in Art. 28 (ex. 30) EC Treaty.

50 ⁷ See, for instance, *United Wire Ltd v Screen Repair Services (Scotland) Ltd* [2001] F.S.R. 24 HL, *Schütz*
51 *(UK) Ltd v Werit (UK) Ltd (Rev 1)* [2013] UKSC 16 (13 March 2013), BGH 14.07.1970, GRUR 1971, 78,
52 80 *Diarähmchen V*, BGH 17.07.2012, docket no. X ZR 97/11 *Palettenbehälter II*, available in German at:
53 [http://juris.bundesgerichtshof.de/cgi-](http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=3c6d49f845dcefd695bb195c4e4722bb&nr=61447&pos=0&anz=1)
54 [bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=3c6d49f845dcefd695bb195c4e4722bb&nr=6](http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=3c6d49f845dcefd695bb195c4e4722bb&nr=61447&pos=0&anz=1)
55 [1447&pos=0&anz=1](http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=3c6d49f845dcefd695bb195c4e4722bb&nr=61447&pos=0&anz=1). See the the English translation in IIC, *Pallet Container II (Palettenbehälter II)*
56 (2013) 44 at 351–360, 351, DOI 10.1007/s40319-013-0044-3.
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3 matter of “fact and decree” (as stated in the UK decision in *Schütz v Werit*). This interpretations
4 highlight the need to find a balance among different considerations, including “the need to
5 protect the patentee’s monopoly while not stifling reasonable competition”⁸. Factors that are
6 often taken into consideration by European courts when deciding on issues of “making” as
7 opposed to “repairing” patented products include:
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10 (1) Whether and to what extent the technical effects of the invention are reflected in the
11 components replaced;

12 (2) The need for repair of the product (estimated in respect to the working life of the
13 device);

14 (3) The extent of the repair in comparison with manufacturing (i.e. whether the measures
15 taken maintain the identity of the specific patented product already put into the market, or
16 whether they are rather the equivalent of the creation of a new product);

17 (4) The extent of which the repaired part compete with the original parts.
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21 All of these considerations have to balance the interests of all the parties involved,
22 including the patent proprietors, users and third parties. It is commonly agreed that courts
23 should also make every effort to consider the interest of the inventor and the implications related
24 to the economy and trade.⁹
25
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27 There are many questions still unanswered with AM and patent law in terms of
28 infringement actions. For example, it may be clear that anyone who uses a 3D printer to
29 fabricate a component without authorization would be “making” the device. However, the legal
30 implications are ambiguous when only some parts or sections are produced using AM to classify
31 this as an act of repairing rather than making. Certainly, only once the claims are properly
32 construed and if the patent claims read on objects that are produced via AM, it is possible to
33 view whether such conduct amounts to infringement. However, some general basic points
34 should be clarified. For instance, the relationship in term of IPR protection with the digital CAD
35 file and the patented object that is being represented is unclear under existing legislation.
36 Moreover, it is unclear to what extent IPR can be applied to protect the valuable information
37 within the CAD data. It becomes even more questionable whether sharing a digital
38 representation of a patent protected object over the Internet, would be considered as patent
39 infringement either direct or indirect. It is also unclear whether a CAD file of a protected object is
40 capable of qualifying as “means” or even “essential element” for the purpose of indirect patent
41 infringement (Ballardini et al., 2015) (Ballardini and Norrgård, 2016) (Ballardini et al., 2017). The
42 situation becomes even more complicated whereby the use of CAD allows the data to be easily
43 modified, further blurring the line between making and repairing. It becomes difficult to
44 determine the extent of how much modification is allowed before it is considered as patent
45 infringement (Wilbanks, 2012).
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52 ⁸ See *Schütz (UK) Ltd v Werit (UK) Ltd (Rev 1) [2013] UKSC 16 (13 March 2013)*.

53 ⁹ See for instance German Federal Supreme Court, 21 Nov. 1958, Case No. I ZR 129/57, 1959 GRUR
54 232 - *Förderrinne* that highlighted the extent to which a purchaser of a product can use it (repair it)
55 without permission by the patentee as follows: “the scope of use should depend on 1) the significance of
56 the protected inventive idea to the repaired parts and 2) the type of correction or addition to the product”.
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4. Challenges with Digital Spares' Businesses and Patent Law: Empirical Analysis

4.1 Empirical Study

An empirical study in the form of a case study research was conducted (Yin, 2011). Case study analysis was chosen because an in-depth investigation was needed to provide a holistic understanding of the phenomenon (Yin, 2013). The case study relied upon qualitative analysis to uncover to what extent it is economically and legally feasible to develop a sustainable market for digital spare parts in Europe.

The subject of the study (i.e. our cases) was exemplified by representative companies operating in the field. A multiple case study was conducted because more than one case was available. The nature of the project and the type of research questions investigated justified an 'intrinsic' and 'collective' case study, namely a study where a group of cases or objects are studied (Stake, 1995).

4.1.1. Selection of Respondents

We derived our empirical data from seven expert interviews. To select the subjects of investigation, an information-oriented technique was used. The companies were chosen for their representativeness with respect to the overall purpose of the research objective of the study (i.e., they were 'key' cases) and to maximize what could be learned in the time available for the study. Respondents were chosen among private companies working in the different areas of relevance. In particular, we interviewed right holders working on different relevant industry fields, users, as well as experts in IP law (i.e. internal and external company lawyers and patent agencies). Especially, the companies were chosen both because of their operations in areas relevant for the study and due to the fact that the people working at these corporations were well-informed experts in the research topic. On the other hand, the size of the companies and their geographical areas of operation were not regarded as important factors in the selection of cases. The companies interviewed did not directly include intermediaries and service providers; however, perspectives from the point of view of intermediaries were thrown into the study indirectly via information provided by the other companies interviewed.

Table 1 – Details of Cases and of the Respondents

Cases	Interview Date	Company Description	Position in the company	Cluster
Case 1	23.05.2017	OEM which manufactures and services power equipment for the marine and energy industry	Director of IAM (Intellectual Asset Management)	Right holder
Case 2	04.05.2017	OEM which provides process technologies and services for metals and mining, industrial water treatment, alternative energy and chemical industries	IPR Manager	Right holder

Case 3	22.05.2017	OEM which provides cargo and load handling solutions	Vice President of Digitalization	Right holder
Case 4	04.05.2017	OEM which develops and markets systems, equipment and services for the railway sector	Digital, Sales and Customer service innovation. Program manager	Right holder
Case 5	13.06.2017	Service organization specializing in Intellectual Property Rights (IPR)	European Patent Attorney & Senior IP Advisor; European patent attorney & Partner; European patent attorney & Senior IP Advisor; IPR Specialist	Experts in IP law
Case 6	15.06.2017	Service organization specializing in Intellectual Property Rights (IPR)	IP Lawyer; European patent attorney	Experts in IP law
Case 7	13.06.2017	Service organization specializing in Intellectual Property Rights (IPR)	Senior Associate	Experts in IP law

4.1.2. Development of Semi-structured Interview Protocol and Data Analysis

Interviews were an important source of information for the study. The interviews were conducted using a semi-structured interview protocol, composed of several questions that were aggregated into three main categories related to operational and business related questions and two main categories (and three additional sub-categories) related to legal questions (refer to section 4.2.). The questions posed to the companies included:

- General and specific questions related to the existing situation of AM as a manufacturing alternative, including what extend the technology is used by the right holders and what are its technological and operational shortcomings in spare part applications. In addition, business related specific questions where discussed to understand possibilities as well as challenges for making AM technologies mainstream as a manufacturing alternative in the service business;
- Specific questions on patents and AM, especially on the challenges that the so called 'repair versus make' doctrine in European patent law might pose to further developments on the markets of AM produced spare parts in terms of enforcement, infringements, as well as exceptions and limitations standards, and the possible solutions that could be implemented to solve the identified problems.

The respondents were asked to answer the research questions from the perspective of their company, and also based on their extensive knowledge of the field. The semi-structured nature of the protocol meant that the questions were taken as starting points to the discussion. The respondents were free to propose solutions or provide insights into the subject matter, as well as to corroborate evidence obtained from other sources that were not included in the interview protocol. This interactive approach of data collection expanded the depth of data gathered and . Overall, the case studies aim at generating new understandings, rather than answering one (or a few) specific question(s). The interviews resulted in a rich corpus of discussion data which then served as material for the in-depth data analyses.

4.1.3. Data Analysis

The study used two different sources of evidence relevant for our study: documents and interviews. The documents used were business reports, publicly available company information on the use of AM in business, European legislation in the area of IPRs, Court cases from the European Patent Office (EPO), the Court of Justice of the European Union (EUCJ) and national European jurisdictions, as well as company policies in the field of intellectual property and AM and scholarly literature on AM technology, business and IP law. We transcribed the interviews and used pattern-matching techniques based on the identified categories of questions (business and legal questions) and on the selected clusters. A draft report was written based on the documents consulted and on the answers received during the interviews. The report was drafted in such a way that we discussed the answers that were gathered from the interviews together with the information collected from the documents and also adding our own perspectives and analysis.

The anonymity of the subjects interviewed and their respective companies was necessary because some participants considered the topic both controversial and confidential. As a compromise, a cross-case analysis was composed instead of a single-case report. The case study report does not portray any single company but rather a synthesis of lessons learned from key experts. Accordingly, none of the cases are presented as a single case study. Instead, examples from the cases are discussed under each research topic section (Yin, 2011; 2013).

4.2. Results and Discussion

4.2.1. Service and spare parts business using AM

A. Existing Bottlenecks for AM Technology Adoption in Spare Parts Applications

All respondents agreed that the integration of AM for spare parts is hugely relevant in particular for legacy systems to support replacement, re-design or repair of components for obsolete machines whereby the tooling facilities no longer exists. At the same time, the respondents were concerned that if AM was incorrectly utilized, it could lead to parts with inferior performance and quality issues, as well as being more expensive to fabricate. The respondents affirmed that the original materials of these parts are standardized (e.g., ASTM steels, aluminums, casted irons, molded polymers etc.) and their manufacturing processes (e.g. subtractive and formative methods) are highly matured. Thus, in many cases the justification of utilizing AM manufactured parts becomes difficult (Case 1).

The respondents highlighted that, on the one hand, there is a legacy of non-digitalized product and component information. While on the other hand, CAD models often do not exist. Moreover, at times the original 2D technical drawings can be difficult to locate. At a higher level, a potential problem might be the ability to change existing methods of production, as the manufacturing industry is generally conservative and relies on conventional methods (Case 3). In addition, AM has a limited scope for many applications in the spare parts business and there

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3 is a need to develop a truly AM global manufacturing network (Case 1 and 4). For instance,
4 usually part of the manufacturing business is externalized by companies; on this regard, the
5 offer of AM services is limited in comparison to conventional methods on a global scale.
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8 Notwithstanding these shortcomings, the expectations are high towards having more
9 applications that take full advantage of the benefits of AM (i.e. availability, reduction of cost in
10 low volume production, and improvement in lead-time).
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13 B. Current Use of AM Technology in Spare Part Applications

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15 While the respondents agreed that the role of AM today remains relatively small, there
16 was consensus in terms of willingness to explore the use of AM in the production of spare parts
17 in the coming years. They also noted that AM is more useful for those spare parts that are often
18 sold in low quantities. Respondents predicted that perhaps in the future, the biggest benefit of
19 AM will be in the production of components that are either rarely in use or/and components that
20 have very long delivery timescales.
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23 The interviews revealed a trend towards the digitization of existing inventories to develop
24 more flexible and scalable e-commerce platforms around the right-holder service business
25 (Case 1, 2, 3 & 4). Summarizing the perspective of the right holders, the main objectives of
26 pursuing a digital spare parts strategy include:
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- 29 1) Improving the availability of original spare parts to suppliers, as well as customers, using
30 a digital platform as a single contact point;
- 31 2) Facilitating the process of finding product information, which can contain the CAD data
32 of the product and other technical or non-technical specifications;
- 33 3) Facilitating the pricing and purchasing process through an easy to use internet platform;
- 34 4) Centralizing digital data of spare parts to have a more comprehensive view of the
35 company's spare part business.
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39 The majority of respondents affirmed that AM is currently in the testing phase in many
40 application areas. Some also mentioned that they already have existing products or spare parts
41 manufactured using AM that are commercially available and in use (Case 1). In order for this
42 path to continue, businesses should start developing wide varieties of spare parts to diversify
43 the needs in terms of production volume (Case 3 & 4).
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46 C. Steps towards Making AM Spare Parts a Mainstream

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48 To encourage the use of AM in spare parts, respondents highlighted the need for further
49 technological research on AM, support for innovation policy activities, as well as spearheading
50 business strategies for digital spare parts. The discussions threw light over the fact that the
51 research projects of the interviewed OEMs are usually a combination of technical feasibility
52 studies and business development plans. The technical research feasibility studies typically are
53 closer to exploratory research in OEMs and the research is typically done using external actors
54 (e.g. consultancy, research institutions and public funding for innovation activities). The
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3 definition of strategy or business development plans is usually handled internally by the OEMs
4 (e.g. with internal sourcing actors and service business development) (Case 1).
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7 One respondent emphasized that the spare part business is highly dependent on
8 availability (Case 3). In other words, how quickly a company responds and delivers the parts is
9 a key issue. Both from a company and customer perspective, it is very important to deliver and
10 receive the part as soon as possible in order to repair the system. As such, pricing might
11 become a secondary importance in some operations. This may mean that the cost factor, which
12 hinders AM applications in many cases (Eyers and Potter, 2015), could be easily overcome by
13 reduced machine downtime, making AM a highly competitive alternative to quickly produce a
14 repaired component and providing increased availability. In summary, digitalization of part
15 inventories and the creation of e-commerce platforms and its link to a deployable AM supply
16 chain should be explored further to make digital spare parts a mainstream.
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19 20 **4.2.2. Repairs, Spares and Patents: Challenges and Solutions**

21 22 A. Challenges with Repairing in Patent Law and Implications for AM Developments

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25 The interviews revealed that the respondents acknowledged that in the European
26 context, the distinction between repairing and making in existing patent laws is unclear. At the
27 same time, respondents considered that further developments in AM are likely to increase the
28 importance and possible applications of this doctrine in many industries, boosting the need for
29 clarification. However, what direction to take as for how to add clarity to the issues at stake was
30 considered a quite difficult question to answer on a general level. The respondents cited that
31 there is a lack of harmonization in Europe regarding the interpretation of the repair versus make
32 doctrine, scarce support for national case laws to resolve these issues, and lack of coherency in
33 which the outcome may be unclear or even controversial. It was pointed out that in some cases,
34 the discussion rarely debated on aspects of legitimate repair as opposed to illegitimate
35 reconstruction or making, as they mainly concentrated on issues related to indirect infringement
36 (Case 1, 5, 6 & 7).
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41 Even though all respondents acknowledged this general lack of clarity, most interviewed
42 agreed that there is some common ideology behind the way this doctrine has been interpreted
43 in Europe. On this basis, most respondents welcomed actions in favour of adding clarity and
44 uniformity of interpretations in this area building from these currently existing general guidelines.
45 It seemed agreeable that a better understanding of the issues and legal rules in this field would
46 benefit all parties involved and would encourage the growth for a sustainable spare parts market
47 in Europe. One respondent thought that “unless it is possible to find clear evidence that these
48 grey areas in law are damaging a large proportion of the market, then such grey areas should
49 be untouched to provide companies with more flexibility to operate (Case 1).
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53 The interviews threw light over various tools that could be used to achieve the ultimate
54 goal of adding legal certainty and ultimately benefit the European spare parts market based on
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3 AM. Respondents pointed towards pros and cons of all these possible future solutions. We
4 present these results in the following sections.
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6 B. Navigating the Challenges: Possible Solutions

7 *B1. Increase Patent Activities in Spare Parts Markets*

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10 The interviews revealed that building a clear and structured IPR strategy is a key
11 element for companies that produce complex products composed by multiple parts and covered
12 by multiple IPRs. Some respondents felt that holding a patent on a complex product *per se*
13 would not guarantee sufficient protection to the patent holder in the spare parts market. The
14 main reason being the legal uncertainty surrounding the “repair versus make” doctrine and the
15 principle of patent exhaustion. Even in cases where the patent is efficient to protect the product,
16 it may not be enough to provide protection for the spares even if those spare parts are included
17 in the claims of the patent on the product. The respondents considered that under the current
18 interpretation of the law, most European courts generally do not penalize the third party when
19 there is a replacement of parts. At the same time, however, they thought that this interpretation
20 of the law is correct. One respondent suggested that “If someone buys a bicycle, it is fair
21 enough that he/she should have the consent to fix it if it goes broken” (Case 2), and “only in
22 special situations, the third party should be bound to a condition in which they can only buy
23 spares from the IP holder” (Case 2).
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29 The respondents also pointed out that litigating a product patent based on direct
30 infringement due to the fact that some parts have been replaced is not a good strategy, because
31 there is no harmonization in terms of interpreting the law within Europe, the case law is scarce,
32 and existing judgments tend to favor legitimate repair rather than finding infringement. To be
33 successful, a company should adopt other strategies than litigate on these grounds. For
34 instance, when there is a complex product, it is important to patent both the product *per se* and
35 as many of the valuable components of the product as possible (Case 1, 2, 5 & 6). Most
36 respondents thought that this is a common strategy in most industries nowadays, except for
37 pharmaceuticals (Case 6). Other respondents pointed out that this strategy is not actually
38 associated with the uncertainty of the law about the extent of repair, but rather linked to
39 business revenue (Case 6). It was revealed that if spares are protected via patents, then most
40 are covered under product patents because patents that cover the method of producing spare
41 parts are not a viable business or IP strategy. In most cases it is very difficult to see the
42 production method of spare parts, so trade secrets are generally a better method of protection
43 than patents.
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48 More importantly, the respondents pointed out that in some exceptional cases, a much
49 more effective strategy would be to hold patents only for the spares, without having a patent on
50 the device. However, the strategy of protecting only important spare components without
51 protecting the whole device tends to be industry specific and more suitable for companies that
52 produce highly complicated products (e.g. electronics for the car industry).
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3 The respondents clarified that the purpose of the patents on the spares is different from
4 the purpose of having patents on the device. Patenting the device is carried out to provide
5 additional value to the customer. "We use patents to tell our customers to buy from us because
6 we have a much better device than the others in the market", says one respondent (Case 2). On
7 the other hand, the patenting of spare parts is a strategy to "lock-in" customers to a company's
8 products, thereby limiting the possibilities for them to fix the defects themselves. The
9 respondents acknowledged that they need to carefully decide which spares to patent, and which
10 should not be covered so as to avoid the dissatisfaction of their customers. Having too many
11 patents for spare parts and forcing customers to always buying from them would ultimately lead
12 to high levels of dissatisfaction and could possibly impact on return customers (Case 2).
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16 Some respondents also noted the downsides of covering patents for both devices and
17 spare parts as this would lead to unnecessary time and effort to filing those patents. It was also
18 reported that in most cases, National Patent Offices found patent claims for spare parts to be
19 unclear, because the general context or host device is missing. As such, this may lead to
20 complications in terms of the scope of protection in the pre- and post-grant stage, as well as the
21 enforcement of rights (Case 6).
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25 Finally, another downside of a strategy to protect both components and devices is that
26 such patents might be too "short-term fetched", meaning that they might not catch future
27 developments, as their scope is too narrow or specific (Case 7). Indeed, this type of strategy
28 might also bear problems related to over-protection and unnecessary patents (Case 7).
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31 Some respondents proposed that a possibility to clarify the distinction between legitimate
32 repair and an unauthorized acts would be to limit the scope of patent protection of device
33 products in such way that the IPR would not extend to the spare parts from such a device.
34 Therefore, no infringement would occur if only some of the components are individually re-made
35 (Case 2). However, the majority of respondents argued that if this suggestion were enforced,
36 then the patent on the device would become less effective (Case 7). Moreover, this proposal
37 might actually push companies to increasingly patent also individual components. Overall, this
38 might not be good for third parties for multiple reasons, spanning from the fact that customers
39 are more locked into certain companies' products, to the rise in the number of patents around
40 and all potential problems of patent tickets, blocking patents, as well as patent trolls in multiple
41 industry sectors (Case 6 & 7).
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45 *B2. Harmonizing the Law*

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48 During the survey, some respondents suggested the use of harmonization via legislative
49 actions or case law as an important tool to clarify issues related to the repair versus make
50 doctrine in Europe. The respondents also recommended that passing a new legislation such as
51 a Directive or Regulation in the EU would be important to establish some general principles to
52 follow to interpret the repair versus make doctrine (Case 6) and to provide courts with some
53 baseline to be taken into account (Case 6 & 7).
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3 Other respondents said that harmonized case law at national level or through the
4 forthcoming Unitary Patent Court would be a better option because case laws in general are
5 more flexible and more suitable for technology-centric areas such as AM that is still developing
6 (Case 5). However, some respondents found that the current UPC agreement is complex in
7 terms of what laws the UPC should apply. It was concluded that, unless we have a specific law
8 in place dealing with the issue, the UPC is likely to apply rules and principles that comes from
9 countries with a more established system such as Germany, or the UK where the issue of repair
10 versus make has been discussed to a sufficient level of detail (Case 7).
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14 Some respondents also thought that not having certainty in terms of 'repair versus
15 reconstruction' is *not* necessarily something that will impede the growth of digital spare parts
16 business in the field of AM (Case 5). The general consensus was that adding more clarity
17 would benefit new companies entering the market. Thus, should the EU want to create new
18 opportunities for these new businesses, legislation towards adding clarity would be beneficial
19 (Case 5). This should be the best option also if the EU is to follow a policy of trying to keep
20 manufacturing "in house" (i.e. not out-shoring anymore) (Case 5). To implement this, there
21 should be well grounded economic or policy reasons, balanced with the interests of "old
22 players", i.e. companies (usually large size companies) that have been in this market for a long
23 time.
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27 *B3. Patent Infringement Doctrines and Patent Claims for CAD*

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30 The issues related to direct and indirect patent infringement in the context of AM and
31 spare parts great generated interest among the respondents. An initial point of discussion in
32 terms of direct infringement of a patent in the context of digital spares and AM, revolved around
33 the question of whether the digital and physical product retained the same level of IPR
34 protection in cases when the product created and protected in the first place was the physical
35 entity. The relation between the physical and digital version of the object in terms of IPRs is
36 crucial for the interpretation of the repair versus reconstruct doctrine because it defines the
37 extension of the scope of the IPR.
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41 One respondent highlighted that it is important to clarify whether the IPRs included in the
42 technical functions of the product are embodied in the digital representation of it (Case 7).
43 According to the same respondent, the digital and physical representations of the product
44 should be kept separate from the IP protection (Case 5 & 7). However, other respondents
45 considered that both digital and physical representation should attract the same IPRs to avoid
46 overly complex and difficult licensing schemes (Case 2).
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49 Another open question in the context of direct infringement was related to the fact that
50 even in the case where the functions of the product are reflected in both physical and digital
51 representations of it, with AM such functions may be achieved in a much more efficient manner
52 than how they were achieved with other manufacturing methods. How would, the doctrine of
53 equivalence apply in infringing situations in these cases? (Case 6)
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3 In relation to indirect patent infringement, all respondents agreed that if someone
4 provides a third party with a CAD file of the protected object or a critical component, then he or
5 she could be found liable for secondary liability as indirect infringement. The key issue that was
6 highlighted in this context is whether the CAD file qualifies as the “means” under European
7 patent law. During the discussion, it was pointed out the analogy between CAD files of protected
8 patent products and source code of protected computer-implemented inventions (CII). Both the
9 CAD file and the source code contain a detailed set of instructions in a digital form to produce
10 the invention. Therefore, it could be argued that if someone provides an unauthorized person
11 with the CAD file of a protected product, he could be found liable for indirect infringement of the
12 product patent. However, European courts have so far only interpreted the concept of “means”
13 as something that is physical or tangible rather than digital. In cases regarding software, the
14 liability was only established if the source code had been provided on a CD or in other “physical”
15 media.¹⁰ Regardless, all respondents felt that the CAD file should qualify for “means” even
16 though it is in a digital form, and that the interpretation of “means” as a physical form is outdated
17 especially in an Internet-age.
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23 Most respondents acknowledged the analogy between source code in software and
24 CAD files in products as been a sensible one (Case 1, 2, 5 & 6). However, when it comes to
25 patent law, CII have their own specific legal practice and are regulated by special rules in
26 Europe (i.e. Art 52 of the EPC). Such rules, may not be extended to technologies that do not
27 qualify as computer programmes or software (Case 7). As such, another key question lies on
28 the legal nature of the CAD file which is a digital dataset that might not be considered as a
29 “software. To date, no case has been decided on the legal nature of CAD files, thus the
30 question remains open. One respondent suggested that one way for CAD to qualify as
31 computer programme could be to convert it into a G-code (which is *per se* a computer
32 programme) (Case 6). In such cases, it could be possible to apply the *ad hoc* software legal
33 rules to CAD.
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37 On a related issue, respondents were asked to comment about the possibilities for
38 having CAD-types of claims in patent applications. Most respondents considered this to be an
39 interesting key point and the main concern was the fact that it is not clear how CAD files should
40 be considered from the view of the law. Can the CAD file be considered a technical invention
41 and qualify as patentable subject matter? Or is it just information to produce the invention and
42 therefore not patentable *per se*? Can CAD files fall under the *ad hoc* provision of Article 52 EPC
43 for computer programmes? Most importantly, should have been decided that CAD files qualify
44 for patentable subject matter, how would the doctrine of exhaustion (and thus the interpretation
45 of the repair versus reconstruct doctrine) apply in the digital context? (Haapanen, 2017).
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49 Under current rules, some respondent thought that most national patent offices would
50 not know how to handle patent applications for CAD data. The respondents welcomed further
51 developments in the patent law to address and tackle the issues of the digital world: right now
52 litigators and patent attorneys are facing the challenge of having to scratch the patent law in
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55 ¹⁰ See for instance BGH decision of 21 August 2012 – Case No. X ZR 33/10- *MPEG-2 Video Signal*
56 *Encoding (MPEG-2-Videosignalcodierung)*.
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such a way that it can also be applied to the digital world - this is often very difficult and problematic and AM adds another layer to this challenge. As such, the respondents would like to have more guidance from the EPO, and for such cases to be added in the EPO guidelines. The respondents were clear on that, under current rules, the safest way to protect CAD files is through trade secrets (Case 1, 2 & 5). One company thought that this is unlikely to change even if there are patents linked to CAD files. This is the same way for software related patents where the source code is not disclosed in CII patents (Case 5).

5. Conclusions

This study highlighted that there is a huge potential for using AM to support the spare parts business. However, there are still technical shortcomings of this technology, as well as challenges related to the business structure of the industry and legal considerations in respect to the intellectual property rights at stake. This paper focused specifically on technology, business and patent related issues. The study revealed that a stable functional European market for digital spare parts in the context of AM is growing and it can only be built around the efforts stemming from multiple fronts, including technical, business and legal perspectives. The outcomes of this research and the implication for practice and society requires to take actions by both industrial actors and the regulator in the EU.

On the front of industrial implication, the study showed that AM has the ability to:

- improve the availability of original spare-parts;
- facilitate the process of finding product information, which can contain the CAD data of the product and the technical specifications;
- facilitate the pricing and purchasing process through an easy to use internet platform; and ecommerce services
- centralize product or spare part's digital data (such as, CAD and meta-information of the product) and improve awareness over companies' spare-part businesses.

The overarching outcome of this study revealed that the implementation of AM to produce spare parts, product upgrades or retrofits spare part applications has become the cornerstone in the technology transfer of AM for many OEM operations. This study corroborates and extends our existing knowledge as the findings of the empirical study showed how AM is tightly interlinked with the replace, re-design or repair of components for legacy systems of OEMs. However, regarding the current situation of AM as a manufacturing alternative, the study revealed that digitalization of product and tooling inventories is still a challenge due to the legacy of non-digitalized product and component information. In addition, the fact that a large part of the manufacturing is externalized to third companies represents a bottleneck for AM implementation in the supply chain of spare parts. Regarding the technological and operation shortcomings, although AM technologies are being deployed as a manufacturing alternative, there is no AM network of service suppliers that can compete with conventional methods of manufacturing in a global scale. In addition, cost of production is generally higher mainly due to the high price of raw materials. Ultimately, the technical implementation of AM has a limited

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3 scope for many applications, especially large scale components. The technology is still in its
4 early phase and requires further development in organizational knowledge before it can become
5 a fully trusted method of manufacturing.
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8 On the front of the regulatory framework, the study reveals that issues of patent
9 protection, as well as scope and patent enforcement in respect to AM technology might create
10 major obstacles to the development of business models in the spare parts market. Some of the
11 key areas include:
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- 14 • issues related to the principle of exhaustion of patent rights and, especially, in relation to
15 interpretations of the so called “repair versus reconstruction” doctrine;
- 16 • challenges in relation to interpreting traditional patent infringement doctrines in the digital
17 context portrayed by AM;
- 18 • issues related to protecting the CAD file via patent law.
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21 The study showed that legal uncertainty in this area has been caused by factors such as
22 the lack of harmonization on these issues in Europe, the scarce and contradictory case law that
23 exists, and the fact that the digital CAD element of AM adds towards the complexities of patent
24 law, which has traditionally been interpreted through tangible and physical goods and not digital
25 or virtual representations. The study suggests that to seek progress about the legal uncertainty
26 linked to issue of legitimate repair in patent law, new development should take place outside the
27 law-making framework, at least in the short-term. For instance, new types of IP strategies in the
28 digital spare parts markets, such as the patenting not only of complex devices, but also of
29 individual spare parts, as well as the filing of patent claims for CAD files could be a way forward.
30 Indeed, there should also be new interpretations of the existing legal tools or the introduction of
31 new types of laws, such as new EU Directives or Regulations in the EU, and having novel
32 interpretations of patent infringement doctrines that are more suited for the digital environment.
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37 In conclusion, the development of AM as a manufacturing alternative is an industrial
38 reality. Reliability and manufacturing capabilities of AM machines have evolved in such way that
39 the industry will be dragged to re-think the technology as a real manufacturing alternative,
40 especially, if we look at the step towards digitalization and automation of company supply chain
41 and logistics, which are linked to the digitalization and servitization of manufacturing operations.
42 To capture the values from the opportunities that AM brings about, however, it is crucial that the
43 key business, technical and legal challenges identified in this study are properly addressed and
44 tackled. While the European and global marketplace for digital spare parts is still young, it's not
45 too early for businesses and IP rights holders to take proactive approaches to prepare
46 themselves for the rise of AM technology in this area.
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Helsinki, 27.03.2018

Dear Editor of the **Journal of Manufacturing Technology Management**

Please find attached the revised manuscript ID JMTM-12-2017-0270 titled “Printed Spares: Challenges between Law and Digital Businesses” for your consideration.

We would like to use this opportunity to thank for your review. We feel that these suggested modifications have significantly added value to the paper.

Please find below a full list of the changes indicating the work we have conducted per comment we received. In the revised article you will find our modifications highlighted in yellow.

The current abstract of our manuscript is:

Purpose:

This paper investigates business and intellectual property issues of producing spare parts using Additive Manufacturing (AM) from a digital source. The aim is to raise awareness of the growing digital spare parts market in Europe, to identify the major business and legal challenges that are currently impeding the growth of such markets, and to propose solutions to navigate these emerging issues.

Methodology:

This paper covers the use of literature review, theoretical analysis and case studies of key challenges that manufacturing industries in Europe are facing in the transition towards developing new digital businesses related to AM produced spare parts.

Findings:

The paper sheds light over core factors that may impede the development of new commercial activities related to AM produced digital spares, including business strategies, patent protection and patent infringement. The study reveals that a stable functional European market for digital spares in the context of AM is growing and it can only be built around the efforts stemming from multiple fronts, including technical, business and legal perspectives.

Originality/value:

The study provides valuable knowledge to promote the growth of a stable European digital spare parts market in the context of AM by pinpointing key issues that need to be addressed within the European AM business environment and the European patent system, and

proposing recommendations for business and legal frameworks to foster and accelerate the development of the digital spare parts market.

Keywords: Additive Manufacturing, Spare Parts, Patent Law, Digital Businesses

Paper type: Research paper

Please do not hesitate to contact us, if you have any questions.

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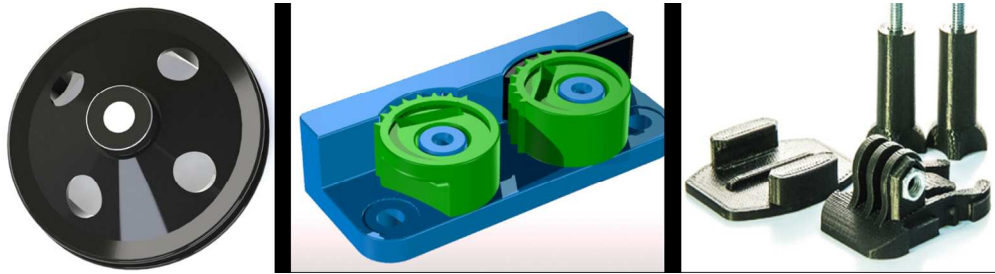
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Editorial revisions integrated

Editor Comments	Authors Actions
More clearly identifying specific research questions. You mention 'aims' on page 2 but what were your exact research questions? Explaining how these research questions were covered in your cases	Thank you for the comment. We added explanations to clarify our specific research questions especially in part 1.
Explaining better how the data that you collected went beyond interviews. In the latter case it would be survey research. This is challenging due to your decision to not include individual case data, but how did for example additional information beyond interviews play a role.	We added a more thorough explanation on the sources of evidence under 4.1.3.
Explaining more where the 'categories' in section 4.2 come from. Why these topics? How much of this structure was also in your interview protocol?	We further explained this both in 4.1.2. and 4.1.3.
Deepening of your analysis. In particular case research can be especially enlightening if it includes comparing and contrasting across your cases. This is not evident in your current submission.	We further deepen our analysis and included more comparison of the cases in 4.1.3.
Clearly stating what the answers to your research questions are, and especially how this adds to what is already known in the scientific literature.	We clarified and better explained how the study answered our research questions both in the part 1. and 5. We have corrected the conclusions section to answer more directly to the research

	questions provided in part 1.
Reviewers Comments	Authors Actions
I suggest not to use notes at the end of the page when the authors cite the different companies of the case studies, but I suggest to write the name of the company in brackets next to the quoted text.	We followed this suggestion and removed the footnotes.
I suggest to create a subparagraph of the conclusion paragraph and develop in a more detailed way a section dedicated to implications for research, practice and society.	We followed this suggestion and added more information in part 5. The conclusions have been divided in two sections with a detailed description of implications for industry and implications for regulatory actors.
<p>The quality of language is enough good. However i suggest to check the language with a native speaker. I underline here some sentences to check for grammatical errors:</p> <ul style="list-style-type: none"> - Page 5 line 34, please check the sentence; - Page 6 line 24, please check the sencece for grammatical errors; - Page 9 line 54, please check the sencece for grammatical errors; - Page 9 Table 1, the acronym OEM is not explained. It will be explained subsequently in page 18, but it is necessary to explain it the first time you cite it in order to have a a better understanding of the meaning; - Page 13, line 10, please check the sencece for grammatical errors; - Page 13, Lines 28, 29, 30, please rephrase the sentences or check them for grammatical errors. <p>What is more, please use always the impersonal form in text. Do not use the terms "we" or "us".</p>	We checked the language throughout the whole paper and especially addressed the points indicated.



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