Sociotechnical alignment in biomedicine:
the 3D bioprinting market beyond technology convergence

Abstract
The nature of hybrid technologies has been frequently interpreted with the concept of technology convergence. However, this concept tends to highlight only technical aspects of technology and market evolution. In order to provide a more comprehensive picture, the concept of sociotechnical alignment is explored here.
The field of 3D bioprinting (the production of biological structures with automated, computer-controlled bioprinters) is focused on here. In the emergent global bioprinting market, companies have relied on three core technologies (tissue engineering, additive manufacture, and software development) and continue to receive inputs from other technologies.
On the biological side, bioprinting has benefited from new approaches such as the use of induced pluripotent stem cells. On the engineering side, it has been possible to use relatively cheap technologies such as open-source processing Arduino boards. On the software side, the proliferation of open source packages has strengthened the possibilities of bioprinting. The combination between these and other technology fringes involves a process of sociotechnical alignment whereby technical, scientific, and political issues are always at play.
As a result, different companies have been able to realize different market strategies, having varied geographical reach. However, the first movements towards extensive globalization can also be noticed. In this way, the current diversity of the bioprinting market may be jeopardized in the years to come.

Keywords: sociotechnical alignment; technology convergence; 3D bioprinting; induced pluripotent stem cells; Arduino; open source software

1 THE TOPIC

It is widely realized that the name “mobile phone” (or “cell phone”) is far from doing justice to what the device really is. It can be used as a calculator, an internet browser, a digital diary, a data storage device, among other applications which include, for sure, that of a telephone. This kind of combination of different technologies, which creates not only sophisticated machines but also thriving markets, has frequently been described with the concept of technology convergence. To be sure, a blend of technologies requires remarkable technical achievements. However, is that all that is required? When technologies converge, are there other sorts of (non-technical) convergence which happen "in the background" and are equally decisive? This paper addresses this issue from the viewpoint of a "highly converged" biomedical technology: 3D bioprinting.

The combination of technologies became highly targeted by analysts in the 1980s and 90s, thanks mainly to the "overlaps among robotics, computing, and information and telecommunication technologies" (Caviggioli, 2016). Since the late 1990s, technological blends have become a hallmark of information technologies, a process which led to the recent interconnection of digital devices and the dawn of so-called internet of things (Adams et al., 2018, Borés et al., 2003). Nowadays, convergence can be noticed in a growing range of economic activities and technological fields (Curran, 2013, Caviggioli, 2016). This certainly includes the domain of pharmaceuticals and biomedicine with the creation of fields such as biotechnology, nutraceuticals, and cosmeceuticals (Caviggioli, 2016).

In biomedicine, technology convergence has generated lasting and impactful effects. It has led to the expansion of existing domains, such as the expansion of genetic sequencing as a result of the combination between last-generation sequencers and data processing technologies (Hood, 1990, Stein, 2010). Convergence has also helped create new scientific domains, which happened, for example, when genomics and data analysis technologies joined hands to form bioinformatics, which is "now often highlighted as a knowledge management strategy for achieving CT [converging technologies]" (Fuller, 2009). Finally, technology convergence has enabled the creation of new markets, as exemplified by the combination between diagnostic tools and software, spawning the now flourishing market of medical diagnosis software (Gutierrez, 2005).

In 1963, in a paper written by Rosenberg (1963), the term *convergence* was initially applied to technological domains. Several analysts have followed this usage thereafter. The term, in the meaning it has gained, points to the creation of new "[…] technologies stemming from at least two previously disparate techno-scientific domains […]" (Jeong, 2014). The phenomenon has also been described as "[…] a blurring of boundaries between at least two hitherto disjoint areas of science, technology, markets or industries […]" (Curran, 2013). As explained by Cavigiolli (2016), the expression used by different authors has displayed some variation: convergence, merging, cross-fertilization, hybridization, and fusion.

These technical and economic factors and concepts are taken into account in this paper. However, the main goal is to argue that, in addition to such factors, it is crucial to consider the social relations and political processes that accompany, and frequently underpin, the scientific and technical viability of technology convergence. This is particularly decisive in biomedical markets, which have been largely permeated by social concerns and power relations.

The idea of economic processes backed by social relations is surely not new. Some concepts such as "sociotechnical regimes" (Belmin et al., 2018) or "sociotechnical systems" (Geels, 2004) have been proposed to account for it. In this paper, we have recourse to the idea of *sociotechnical alignment* proposed by Molina (1995, 1997), which points to "[…] the process of creation, adoption, accommodation (adaptation) and close or loose interaction (interrelation) of technical and social factors and actors […]" (Molina, 1997).

Molina's proposal reverberates old concepts such as embeddedness, initially formulated by Polanyi (1944) and subsequently developed by Granovetter (1985). It is also close to more recent interpretations, such as Fuller's (2009) sociological view of technology convergence, and Santos' (2002) geographical concept of technical phenomenon, which encompasses "[…] all technological manifestations, including the technologies of action themselves."

The present analysis focuses on the example of 3D bioprinting, a technology that aims to generate bioactive (and potentially therapeutic) tissues, constructs, and organoids, through a layer-by-layer deposition of bioinks containing cells, with the use of software-controlled devices called bioprinters (Ahadian and Khademhosseini, 2018, Choudhury et al., 2018, Mandrycky et al., 2016, Mironov et al., 2008). Bioprinting is highlighted here because, as it will be explained, its advent was made possible by a typical process of sociotechnical alignment. Furthermore, the bioprinting market is still at its initial stages of formation and globalization (Choudhury et al., 2018), which makes it possible to identify the commercial potentialities brought about by sociotechnical alignment.

This paper is structured as follows. Initially, our research methods are described. We move on to introduce the main features of bioprinting and begin to explain why, more than just convergence, manifestations of alignment can be identified. Subsequently, an analysis of the dimensions of alignment is provided, including its technical, social, geographical, political, and regulatory aspects. The final section summarizes the main points and brings some concluding remarks.

2 Research methods

This paper derives from a research project conducted through a collaboration between researchers based in three English universities. The project is aimed to identify and interpret the social and regulatory challenges posed by some cutting-edge biomedical technologies, including 3D bioprinting. Four main research methods have been mobilised:

First, the main features and challenges of bioprinting have been identified through a comprehensive literature review, encompassing both technical and social/ethical aspects.

Second, an analysis of the bioprinting market has been conducted. In order to identify companies exploring the field, three sources have been utilized: the 3DMetNet website[1]; the aforementioned literature review; and the interviews with bioprinting companies (see below). Once a company was identified, its website was consulted in order for us to confirm that its activities are directly or indirectly related to bioprinting, as well as collect further information such as year of foundation, number of employees, headquarters, types of products, and so on. Included in our analysis were both the (still rare) companies selling bioprinted products such as organoids and the (more numerous) companies whose products can be specifically used in bioprinting production, market or research: bioprinters, bioinks, and scaffolds. Excluded from our analysis were companies whose websites could not be found or were inactive. Companies whose activities were fully dedicated to animal health or plant biology were also excluded. Eventually, we included 84 companies, as summarized in Table 1.

[1] https://www.3dmednet.com/

Table 1 appears here

The third research method used in this study was an online survey whose conduct was reviewed and approved by the ethics committee of an English university. All the companies we identified (as previously explained) were sent an invitation by email or via the contact form of their website (or both ways when both means were available). The invitation message contained a link to an online anonymous form exploring several aspects of the company's organization, products, research activities, and funding. The whole process, from invitations to the final processing of the survey data, lasted from August to November 2020[2]. Eventually, 23 companies participated in the survey, as summarized in Table 2.

Table 2 appears here

Finally, qualitative interviews with professionals involved in bioprinting were conducted. Initially, with approval from the ethics committee of an English university, interviews were conducted in Brazil (where local professionals were interviewed) and Italy (where some European professionals were interviewed). At a subsequent moment, with approval from an ethics committee of another English university, other (face-to-face or online) interviews were conducted. In addition to people based in bioprinting companies, we interviewed academic researchers and regulators involved or interested in bioprinting, which allowed us to understand the field's regulatory and scientific challenges. The interviews explored technical, scientific, and regulatory challenges of bioprinting, and, in the case of entrepreneurs, also focused on their companies' features, history, and relations. Table 3 summarizes the interview process, which began in November 2018 and was completed in November 2020.

[2] In December 2020, some preliminary data was published (and shared with the participating companies) on the research project's website.

Table 3 appears here

Drawing on this qualitative information and these quantitative data, this paper provides an interpretation of the current configuration of the global bioprinting market. This surely leads us to consider the phenomenon of technology governance but also introduces more comprehensive aspects which subsequently usher us into the idea of sociotechnical alignment.

3 THE EMERGING GLOBAL BIOPRINTING MARKET

3.1 Market features

Analysts mobilizing the concept of technology convergence tend to emphasize the benefits of the phenomenon, the biggest of which is technology development, said to be quicker and more robust in converging technologies (No and Park, 2010, Karvonen and Kässi, 2013). Furthermore, consumers are said to benefit from convergence insofar as new and improved products reach the market thanks to such convergence (Adams et al., 2018).

Due to these advantages and positive externalities, "[…] R&D managers and researchers have formulated their own strategies for technology convergence" (Jeong, 2014). Moreover, it is stressed that national government programmes have been created in an attempt to make some targeted technologies, such as nanotechnology and biotechnology, converge (Roco and William Sims, 2002). The list of countries and regions making such investments include the United States (Wolbring, 2008), the European Union (Nordmann, 2004), and South Korea and Japan (Kim, 2017).

However, technological development seldom runs so smoothly. Frequently, the combination of technologies happens through processes marked by disputes and exclusions. When one speaks of sociotechnical alignment, those problems are constantly born in mind. "For this reason, the term 'alignment' is well supplemented by those of 'misalignment' and 'realignment' which express, on the one hand, situations of tension and disharmony and, on the other, changes or reaccommodations […]” (Molina, 1997).

This paper is aimed to unravel both the alignments and misalignments of bioprinting. In spite of being a relatively recent technology, whose contemporary form only emerged in the 21st century, bioprinting has enabled the constitution of a new global market (Choudhury et al., 2018). In order to have a clearer idea of the geographical distribution of the companies shown in Table 1, let us consider the following map.

Map 1 appears here

Even though companies are concentrated mainly in the United States and Western Europe (as represented by the white dots), and even though no company could be identified in the African continent, Map 1 shows that they are now present in several world regions. Most of them have modest innovative power and offer simple bioprinters and bioinks. Of the 23 companies that participated in our online survey, 11 have ten or less employees. We are dealing with young companies, as can be seen in Chart 1.

Chart 1 appears here

It can be seen that the vast majority of companies now exploring bioprinting have been created in the 21st century. In fact, the few companies created before the year 2000 began in other fields and have recently decided to also explore bioprinting. Indeed, operating in parallel fields seems to be a normal strategy of current bioprinting-related companies. Our online survey gives us a good idea of this phenomenon, as shown in Chart 2.

Chart 2 appears here

Of the 23 companies that participated in the survey, only three declared to be exclusively dedicated to bioprinting. There were ten respondents declaring to be mostly dedicated to bioprinting, with the same number declaring to have some involvement. Therefore, most of these companies in a sense incorporate the process of sociotechnical alignment by combining different technological areas in their activities. For example, in a company that produces bioprinters in parallel with non-bioprinting software, the advances obtained in software development can at some point be incorporated into the algorithms of the software embedded in the bioprinter.

In terms of clients, the role played by academic groups is clear, as seen in Chart 3.

Chart 3 appears here

While academic groups appear as the main group of clients, hospitals constitute the rarest client, with only one company declaring to sell products to a hospital.

3.2 Basic convergences

In bioprinting, convergence gains a lexical form in the technology's name, which also happen in domains such as bioinformatics, neurogenetics, and other hybrid disciplines. Bioprinting's formation has relied on three main technological pillars.

First, there is the area of tissue engineering where scientists have acquired the ability to use gels to deposit cells in predetermined patterns. In these environments, which are sometimes held together by solid supports called scaffolds, cells can interact and form tissue-like structures. Bioprinting could not exist without the knowledge and techniques developed in this "traditional solid scaffold-based tissue engineering" (Mironov et al., 2008).

Second, advances in the areas of additive manufacturing (3D printing) have made it possible to produce three-dimensional structures through an automated layer-by-layer deposition of materials. These advances have helped constitute bioprinting (Ahadian and Khademhosseini, 2018), enabling the deposition of gels containing live cells (bioinks), so that "the walls of the tissue to be printed" can be "carefully modelled" (Abudayyeh et al., 2018).

Finally, this automation would not be possible without advances in computing sciences and software development. As we showed elsewhere (Authors, 2019), software has been increasingly used in bioprinting, being mobilized at several moments of the printing process, including modelling, control of bioprinters, analysis of bioprinted tissues, and others.

These three core technologies (tissue engineering, additive manufacturing, and software development) have been aligned to give shape to what is currently understood as bioprinting. This process has some dimensions relevant for understanding the potential evolution of the field, three of which are scrutinized below.

4 SOCIOTECHNICAL ALIGNMENT AND ITS DIMENSIONS

The aim of this paper is to propose a comprehensive analysis of the emerging global bioprinting market in the light of the concept of sociotechnical alignment. Initially, technical and scientific aspects will be stressed but, as it will be seen, their proper analysis suggests the existence of underlying socio-political processes.

4.1 First dimension: technology

As claimed by Molina, in the study of a market "the emerging character of the technology is a major factor"; it should be considered that such technology may be surrounded by uncertainties and thus "the process of its industrial diffusion is likely to take years" (Molina, 1997). Molina was studying the then emerging sector of microprocessors but his conclusions can, with adjustments, be applied to the current state of bioprinting.

Even though the latter is surrounded by considerable doubts, especially in regards to its clinical applications, which are still quite modest, there have been efforts to make the technology more sophisticated and robust. Interestingly, such efforts frequently involve the assimilation of inputs from technologies different from the three core technologies that make up bioprinting. In this section, which is aimed to analyse the technical side of sociotechnical alignment, three of such recent technological incorporations will be considered.

First, the biological section of bioprinting has been potentialized by the possibility of bioprinting so-called induced pluripotent stem cells (iPSCs). These are stem cells (capable of turning into any other cell of the human body) which are not collected from embryos or other sources such as bone marrow; instead, iPSCs are generated from adult somatic cells (generally skin or blood cells) and transformed into stem cells through a series of laboratory reactions. It is acknowledged that iPSCs have opened up new biomedical research pathways because they have the flexibility of any stem cell but can be used without some of the ethical dilemmas posed by embryonic stem cells (Zheng, 2016).

Scientists spent years trying to find ways to bioprint iPSCs, which initially proved too fragile to resist the bioprinting process. In 2020, the French researcher interviewed in our study was beginning to use iPSCs in bioprinting. She explained that technical challenges are being overcome to realize this kind of application:

> I've been in some conferences talking about biofabrication and bioprinting, and some people are actually working with IPS already, so it might be difficult but maybe not unfeasible […] I actually think it's going to be a great resource. I'm quite sure we can bioprint them. It all depends on which condition we bioprint them.

In our analysis of the bioprinting literature, we found, by using text mining techniques and looking at the abstracts of papers, two 2016 bioprinting studies where iPSCs were used. For the year 2019, this number rose to ten. Even though this still represents a small proportion of the bioprinting studies published (less than three percent for 2019), the increase is relevant because of the scientific avenues being thus opened up. For example, in one of the studies identified, Fantini and colleagues (2019) implemented "the combination of iPSCs and 3D bioprinting technologies to model a neural tissue" , which enabled "the generation of a more complex and realistic neural tissue 3D model for the study of neurodegenerative diseases" .

Furthermore, the discovery of those new research pathways increases the academic demand for bioprinters, thus reinforcing the bioprinting market.

Second, the construction of bioprinters has becomes less costly as a consequence of an expanding use of Arduino boards. A bioprinter, like any other electronic machine, has its motions and operations controlled by a central processing board, which in this case is responsible for transforming the information received from the computer into printing movements. In the past, constructors of bioprinters acquired central boards from IT companies. Nowadays, the international, open source Arduino community has been designing and producing low-cost boards which can be easily bought on the internet. On the community's website[3], it is claimed:

> Over the years Arduino has been the brain of thousands of projects, from everyday objects to complex scientific instruments. A worldwide community of makers – students, hobbyists, artists, programmers, and professionals – has gathered around this open-source platform […].

One of the Italian academic bioprinting groups we visited has designed its own bioprinters. They have used Arduino, as well as Raspberry (a similar kind of open source board), whenever relatively simple bioprinters are built up. According to the group's PI: "Arduino is for more cheaper printers but there is a lot of evolution of Arduino or the electronic board that you can use."

Interestingly, some bioprinting companies are now also using Arduino boards. This has happened, for example, in a Brazilian company, whose founder (interviewed in 2019) appreciates the low prices of the board:

> Yeah, the Arduino board […] We buy most things on the internet. And if we have some money left, we would import it through Ali Express or other Chinese providers. But then we'd have to buy more items to make it worth doing.

In this case, therefore, the blend of technologies involves not only the open source board but also the internet and the purchase conveniences it offers.

Some information about the use of Arduino and similar boards was collected in our online survey, as shown in Chart 4.

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[3] https://www.arduino.cc/en/Guide/Introduction

Chart 4 appears here

Three kinds of use of open source are depicted in Chart 4: companies using Arduino and other similar boards; companies using only Arduino; companies using only other open source boards. In the survey, eight companies declared to be in one of these categories, which is the same number of companies that declared not to use any open source board. Therefore, the practice seems to be at least considerable among bioprinting-related companies. However, this use of Arduino boards leads to the production of relatively simple bioprinters, a strategy that has been viable for some companies, as explained below.

Third, in terms of software, both researchers and companies have benefited from a proliferation of software packages that have not been specifically designed for bioprinting but can be adjusted to bioprinting needs, as we explained elsewhere (Authors, 2019). Even though both proprietary and open source packages have been used, the latter have been particularly important in this phenomenon. It is important to notice that open source software has been decisive for academic researchers but for companies as well. For example, Swedish Cellink has been one the most successful globalized bioprinting companies and was a pioneer in the commercialization of bioinks (Choudhury et al., 2018). Cellink has used an open source software called Slic3r (pronounced "slicer") which is responsible for the interface between computer and bioprinter. In Brazil, one of the academic bioprinting groups we visited has a bioprinter produced by Cellink. Interviewed in 2018, the researcher responsible for the purchase explained: "Actually, Cellink doesn't have any software [developed within the company] […] By the way, it delivers Slic3r to you, with the installation CD, but Slic3r is free."

If open source software is important for a robust company such as Cellink, it can only be key for small companies as well. In our fieldwork, we visited a small company producing bioprinters which is using another software developed by an open source community. According to one of the company's founders:

> We've got an open source software, called Pronterface, which is responsible for the interface between the computer – the design – and the bioprinter […] Pronterface is an open source software, used in several other printers in additive manufacture, and you can make it more complex depending on your needs […] It identifies one syringe, or it identifies two, or it identifies three. It controls the temperature, the table, the syringes, the [printing] motions, everything.

Therefore, societal alignment surely comprises technological shifts whereby a certain domain assimilates inputs from other domains. We have seen that in addition to its three core technologies, the bioprinting domain has been open to new inputs from technological fields such as induced pluripotent stem cells, open source central boards, and open source software. Such transformations are surely taking place in academic groups, which frequently become technology pioneers, but have also been fostered by companies. For sure, the incorporation of technologies by bioprinting companies may be followed by difficulties, and it is not unlikely that some decisions may be given up on in the years to come. For, as explained by Molina (1997): "Implementation underlines precisely the fact that the initial transfer of technology does not necessarily imply appropriation and effective usage. The process is rather one of mutual adaptation and development between the incoming technology and the user organisation or environment."

This gradual adaptation is a key dimension of sociotechnical alignment. It is always accompanied by another kind of adaptation which has to do with personal or institutional relations, as analysed below.

4.2 Second dimension: relations

In order for technologies to be successfully combined, social alliances must be successfully established. According to Fuller (2009), technical convergence can only be realized when the different domains "[…] see their interests as more closely aligned, so that they come to orient their patterns of work to each other." Even for authors who were less concerned than Fuller about social and ethical issues, it is clear that convergence involves a great deal of negotiations and relations. Bozeman and colleagues (2001) argued that the human aspects involved in the development of a technology are not restricted to common notions of human capital but also encompass the social relations and tacit knowledge held by scientists. And various authors have stressed the relevance of institutional contexts and intra-organization relations for the development of converging technologies (Stokols, 2008, Klein, 1996, Jeong, 2014). However, how these relations play out in emerging markets and biomedical technologies is yet to be understood.

Most of today's bioprinting-related companies possess few employees and modest funding. In this condition, much of their success ends up depending on the personal relations and social networking of managers and employees. For example, a high manager of a British company (interviewed in 2019), can capitalize on his previous experiences and contacts after several years of work in biotech and pharma companies. He explained that his bioprinting company is seeking to enhance its market position.

> […] but in a small start-up company, the technology is only one part of it. It's how do you engage and work with the target market, how do you communicate your value proposition, how do you differentiate from what other people are offering in the marketplace, and how do you manage those relationships and interactions?

One of the Brazilian companies we visited is developing a new product. The company's founder began to develop the product during a post-doctoral project at a university. When the project was completed, and after the foundation of the company, the contact was kept with the post-doctoral supervisor and another professor based in that university. Because the product requires a special bioink, a new contact was sought with a research group based in another university. In this way, thanks to the academic and personal relations of the company's manager, it has been possible to develop this product which, if eventually patented, will be owned by the company and the two universities. Therefore, a personal and academic trajectory can turn into an asset for a company of relatively modest innovative capacity.

One of the European companies we interviewed (in 2020) is located in a business incubator. The company's manager spoke of some of the advantages of such location.

> It enables us to continue our research collaboration and product development with the university at the same time, while developing other things in the pipeline […] A lot of the other people that are working in and around us are very much in the biomedical space […] we work quite closely with quite a few of the academics and other people here to develop new things.

The location is not ideal for the conduct of more ambitious projects, due to the modest infrastructure available, but the opportunity to share the space with other researchers and emerging companies has been important for this young company. In this way, sociotechnical alignment also involves the interplay of interests and projects that, at certain moments, come to be aligned.

The examples reviewed above have to do with relations that reach low degrees of institutional formality. When companies manage to reach bigger sizes and establish more systematic organizations, more formal collaborations are frequently established or signed. Indeed, several bioprinting-related companies have sought to improve their innovative capacity, and assimilate new technological inputs, by means of research partnerships. In order to understand this phenomenon, we collected, on the companies' websites, information about current research collaborations. In this way, it was possible to design Social network 1.

Social network 1 appears here

Information about research collaborations was available on the website of 38 companies only. Each research collaboration between a bioprinting-related company (green circles) and other players (orange circles) was considered as a link. Four aspects deserve to be highlighted in Social network 1.

First, the core of the network is formed by universities and research institutions, which have then been the main research partners of bioprinting-related companies[4]. Second, some dynamic bioprinting companies (such as Swedish Cellink, German EnvisionTec, and Swiss regenHU) appear close to the network's centre, having

[4] Of the 23 companies that participated in our online survey, three declared to derive from a university (spin-out) and eight declared to be partially derived from a university.

collaborations with several players; the exception here is German GeSim, which occupies a marginal position, perhaps because its website fails to accurately report all the company's collaborations. Third, in spite of having a relatively modest commercial weight, some companies (such as British Biogelx and Swedish FluiCell) manage to be centrally positioned, showing that the establishment of many partnerships is possible for less dynamic companies as well. Fourth, some fields that might be expected to have close relations with bioprinting, such as medical devices and information technologies (IT), appear far from the network's centre.

This last aspect, which seems particularly intriguing, can be further analysed by considering the case of software. In our internet survey, 14 of the 23 participating companies declared to be developing software. We asked where such development occurs, and the outcome is seen in Chart 5.

Chart 5 appears here

Therefore, the vast majority of the respondents (13) are developing software and plug-ins within the company. However, as verified in our qualitative interviews, this involves the development of simple products, generally aimed to provide users of bioprinters with a simple interface to control the printing parameters. Because so far such basic software packages have been sufficient for these companies' clients, none of them has been seriously devoted to developing more sophisticated packages. A whole field then remains open for future collaborations to develop further enhancements of the bioprinting technology.

Nevertheless, even if companies have not had partnerships which are consolidated to the point of being disclosed on their websites, there still may be some informal collaboration going on "in the background," in more informal ways. Therefore, the interplay between misalignment and alignment is complex and requires a constant adaptation of strategies and relations. "The exploitation of any technically based advantage of an emerging technology involves a cultural behavioural process of perception and goal alignment among all relevant players in its realm of application" (Molina, 1997). Another aspect that complexifies this picture is the political context where companies belong, as seen in the next section.

4.3 Third dimension: political economy

In the constant task of dealing with a converged technology and its future combinations, companies have some leeway to make decisions and be creative. However, they are at the same time subjected to pressures and restrictions. In this section, two of such constraints will be emphasized: regulatory issues and the interplay of forces on the bioprinting market.

As for regulations, it is important to note that there has been no country or transnational agency with regulations or guidelines specifically designed for bioprinting (Authors, 2017). On the one hand, this circumstance creates some market opportunities. For example, as bioprinters have not been defined, in regulations, in the formal category of medical device, they are commercialized as research instruments. As a consequence, companies need not obtain strict certifications and follow well-defined manufacture practices. As explained by the manager of a Brazilian company:

> […] the printer is used only for research, isn't it? As long as it's only for research, the one who must be concerned with ethical issues is the researcher who buys the printer, in terms of what kind of cell you're going to use, if you need approval from the hospital to use the cell you're going to use […] When they receive the printer, it's up to the researcher, to the department, or maybe the university, to look at it.

On the other hand, however, this situation restricts the companies' scope of action. As we showed elsewhere (Authors, 2020), a few researchers interested in bioprinting are based in hospitals. However, it is difficult for these research groups to acquire bioprinters, as nobody is sure about the standards and requirements to be complied with by hospitals when purchasing such devices with a view to therapeutic applications. In this way, the absence of clear regulations is one of the factors explaining why companies have been unable to access hospitals, as seen in Chart 3. In another Brazilian company, simple bioprinters have been manufactured. According to the company's manager (interviewed in 2019), the strategy would be different if specific regulations were in place:

> I would think about the area of regenerative medicine, which is a richer field. I could develop cardiac segments (let's imagine), cartilaginous segments, bone segments […] So, yes, I would lean towards the medical field if the regulations had been created […]

In this situation, companies are not encouraged to promote further technological combinations, which will be required when bioprinting eventually reaches a phase of clinical applications. As nobody knows whether and when specific regulations will be created, companies continue to operate under such uncertainties. As argued by Borés and colleagues (2003), the list of uncertainties to be coped with by innovative companies include "uncertainties about policies and regulation."

In terms of the market position of bioprinting companies, it is interesting to consider that there is still some leeway for the application of varied strategies and business models. In our online survey, we asked about the participants' market reach, as well as the location of their main competitors. In order to analyse the responses, we defined the following four situations:

1. National market/competition: companies whose main clients/competitors are located in the same country where they have their headquarters
2. Regional market/competition: companies whose main clients/competitors are located in their countries and at least one neighbour country
3. Strategic market/competition: companies whose main clients/competitors are located in both the United States and Western Europe
4. Global market/competition: companies whose main clients/competitors are located in the United States, Western Europe, and at least one other world region

Therefore, our typology imparts a special value to the United States and Europe, because these have been the areas where most companies have been created and managed (see Map 1), in addition to being the areas holding the most dynamic companies. The outcomes of the responses given in our survey are displayed in Table 4.

Table 4 appears here

Interestingly, five companies (three of them in the United States, one in Singapore, and one in South America) declared to have their main clients in their home country. In addition, these three American companies also declared that their main competitors are in their country. Therefore, we are dealing with a technology field where it is still possible, even in very dynamic countries, to have national strategies. Generally, those strategies are based in the manufacturing of simple bioprinters, with clients found in universities, frequently by means of personal and informal relations, as already explained.

However, two of the companies having a national market declare to be at the same time subjected to a strategic competition. In other words, while these companies are mainly exploring their national markets, they compete with companies located in the United States and Western Europe. Nowadays, such competition can be faced because, at times, the bioprinters of local companies are much cheaper than those sold by globalized companies. For example, the price of the bioprinters commercialized in Brazil by the most famous American companies are in average six times higher than that of the bioprinters produced by the Brazilian companies we visited. This is so because, in the absence of standards for manufacturing, small companies can be flexible in terms of materials, in addition to using open source software and open source central boards, as explained above. Moreover, because bioprinters are not medical devices and therefore cannot be imported with tax exemptions, the exchange rate imposes financial sacrifices on groups willing to import the products of prestigious foreign manufacturers such as Cellink or EnvisionTec. These economic factors help explain the existence of small bioprinting companies in countries as different as Turkey, India, Bulgaria, and Israel.

However, most companies in Table 4 declared to have a strategic market reach and be engaged in a strategic competition. If the bioprinting market eventually gains monopolistic features, these companies, or ate least some of them, are likely to impose an overwhelming dominance. From a scientific point of view, they are already leaders, as attested by the case of American Organovo, which has pioneered some bioprinting research areas, in addition to having a strong patent position (Rodríguez-Salvador et al., 2017). Elsewhere (Authors, 2019) we showed that bioprinting has already been the target of an increasing number of patent applications.

In the pharmaceutical sector, regulatory harmonization was to a considerable degree promoted by the industry, which created favourable conditions for the dominance of multinational companies (Petryna, 2009). In bioprinting, if the current regulatory uncertainties are dealt with under the pressure from emerging multinational leaders, then the process of sociotechnical alignment might be marked by hierarchies between actors with different resources at their command. For, indeed, there are "[…] forms in which alignment is enforced by one party over another through sheer use of power" (Molina, 1997).

The manager of a small British bioprinting-related company (interviewed in 2019) was asked whether the company might be sold at some point:

> Potentially. There are a lot of people out there like Johnson & Johnson that would be interested in this kind of proposition […] It would either be pharmaceutical or an existing medical device company that wants the technology to reduce their own costs and bring it in-house for their manufacture.

It remains to be seen, then, for how long the bioprinting market will keep its current diversity, and for how long the current strategies of localized companies continues to prove possible.

5 Final considerations

Generally, authors speaking of technology convergence focus on the connections made possible when technologies come together. Alternatively, in the approach advanced here, it has been pointed out since the beginning that alignments are as important as misalignments that remain to be tackled in the future.

In the usage proposed by Dilger and Mattes (2018), it can be said that “flows” are as important as “particular disconnections, immobilities, and blockages of flows.”

One finding that needs to be stressed at this point is that misalignments are not always detrimental to market evolution; sometimes, they create market. It was seen, for example, how the current regulatory uncertainties surrounding bioprinting end up defining a flexible environment where small companies can have their costs reduced and their range of options enlarged. It was also seen that the current discontinuities of the global market end up forming gaps which can be filled by the strategies of small companies.

However, the current misalignments also bring about some challenges and difficulties. We showed, for example, that current regulatory uncertainties keep bioprinting companies away from having solid relations with hospitals. The business model of most companies limits their scientific ambitions, creating a situation in which they have rare relations with IT, medical devices, and other companies that could help them enlarge the scope of technologies they incorporate. As a result, most of the technological innovations of bioprinting continue to be realized in universities. As illustrated in Social network 1, universities lie at the core of the research landscape, and the most dynamic bioprinting companies try to orbit around them. On this issue, we can then echo what was claimed by Jeong (2014): “[…] industrial firms are more likely to create converging technology in collaboration with universities than when they conduct R&D activities alone.”

At the moment, the bioprinting market is considerably diverse, with robust and promising companies coexisting with small and modest ones. For the latter, personal relations and more or less informal collaborations have been decisive. In the future, if specific policies are formulated for the field, it is important to take these characteristics into account. For the elaboration of initiatives for technological development is more effective when one understands how technologies mingle in the domain at issue (Nemet and Johnson, 2012).

The evolution of regulations and standards will be key for the future configuration of the bioprinting market, especially because new frameworks will be necessary when bioprinting assumes new features. So far bioprinting has been dependent on what Salter and colleagues (2017) described as “science-based model of innovation” whereby innovative efforts are mainly made via traditional forms of academic projects and evidence gathering. When bioprinting becomes more embedded in what the authors call "practice-based models of biomedical innovation," whereby research is combined with the delivery of health care, new regulations and standards are likely to emerge. Depending on how the process unfolds and how sociotechnical alignment is realized in the years to come, the shifts of the market can be drastic and even devastating for companies with little financial power.

It is known that recent decades have been marked by an "[…] increasingly dominant role of transnational, often very powerful organisations and actors in the formulation and implementation of health interventions" (Dilger and Mattes, 2018). Sociotechnical alignment, in the bioprinting domain, can also become highly shaped by such powers, especially if pharma companies decide to invest heavily in the sector. Therefore, it seems important to seek for future arrangements whereby alignments can be balanced, and misalignments would not imply the unviability of most of the current market strategies.

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