3D printing: unleashing the magic

Martina Ferracane argues that policy makers should engage in a proactive regulatory dialogue and implement a framework to aid the development of a technology that is set to shake and reshape our reality

"Every once in a while a revolutionary product comes along that changes everything"

Steve Jobs

Not quite science fiction

The 'replicator' was a futuristic gadget proposed in the '60s in the Star Trek series. The machine could rearrange subatomic particles to form any object, from food to spare parts to repair the ship. The show plot took place around the 2260's, but 3D printing has made the replicator a reality already today. This technique enables the creation of three-dimensional objects starting from a digital model. The 3D design is sliced digitally and successive ultra-thin layers of material (which can be as diverse as metal or ceramic) are deposited one on top of the other until the three-dimensional object is created.

This process of 'additive' manufacturing is a diametric contrast to the traditional manufacturing processes, which are fundamentally subtracting material and typically produce waste while casting, moulding, forming, machining and joining a part. Given the nature of additive manufacturing, there are barely any economies of scale, making it particularly well positioned for customisation of products to fit the specific characteristics or preferences of an individual.

As the range of materials suitable for printing expands and the technology keeps advancing, 3D printing is positioning itself as a *"viable alternative to conventional manufacturing processes in an increasing number of applications"* - as reported recently by McKinsey. Several products are already being manufactured and customised through 3D printing, while the prototyping of food, drugs and even human organs is moving at a staggering pace.

The magic of 3D printing

3D printing allows to bring the customers in direct contact with the companies, taking manufacturing into a whole new era of customisation. Beyond expressing a preference between a set of predetermined options (colours, sizes or add-ons), the customisation of the vast majority of the products manufactured today has normally been out of scene. In fact, a tweak in most of the products manufactured with standard manufacturing would imply a big readjustment in the manufacturing facilities. However, additive manufacturing allows the companies to accommodate

Policy makers should engage in a proactive regulatory dialogue and implement a framework under which 3D printing can achieve the status of a legitimate form of production a specific size or configuration request by simply modifying the digital file of the product. As a result, 'mass customisation' becomes commercially viable.

The possibilities in this area are numberless. They go from online customisation of basic products such as lamps or shoes to printing of human organs using the patient's stem cells, through personalisation of drugs based on the genetic data of the individual or the creation of smooth food for people with impaired mastication.

The rapid uptake of 3D printing in the shoe market makes a clear case for the potential to create new value through customisation. Several shoe companies, including Nike, Feetz, and United Nude, are now using 3D printing technology to give customers shoes that are custom made for them. The process starts by creating an accurate 3D model of the person's feet through the use of 3D scanning technique.

Today, this can be done economically through mobile apps-thereby also offering the possibility for the customer to became an integral part of the manufacturing process by providing his/her own data. This information is then combined with details about the customer's height, weight, and activities they engage in. After inputting all the data, the customers receive a personalised pair of shoes tailored exactly for them.

The same transformation is set to happen for other products, such as jewellery, dresses, car dashboards, parts for jet engines, replacement parts for synthesisers, electronic parts, or drugs. Other interesting examples of functional customisation can already be found in the medical sector, where, for instance, the Belgian company Materialise is printing customised prosthesis.

Beyond allowing for mass customisation, the flexibility of additive manufacturing makes it possible to create objects of great intricacy in their internal structure, which would not be feasible to manufacture with standards techniques. In this way, limitless opportunities are opening up for new designs which add strength to the object, while reducing the amount of material needed to produce a functional product (savings can be as high as 90% of material). General Electric, for instance, is printing jet engine brackets that weigh 84 percent less than their predecessors and nozzles which are five times more durable and two thirds lighter than before, allowing for savings in fuel costs estimated to be up to $1.6 million per airplane per year.

Another example presenting the revolutionising potential of this technology to create complex structures - and perhaps the greatest application of 3D printing - is bio-printing. It consists in the layer by layer deposition of cells into a 3D gel to create functional three-dimensional tissue and organ constructs. When it comes to transplants, waiting lists are often deadly long. Not only is there an insufficient number of organ donations, but the transplant recipient's immune system is most likely to reject the organ-and therefore careful attention has to be dedicate to finding a donor whose immune system might fit the recipient. By printing the organ, however, most of the problems associated with donations can be bypassed. The time it takes for the entire process of printing an organ is relatively short compared to the time spent waiting for the right donor. Moreover, the use of the patient's own stem cells as a basis for the print eliminates the risk of rejection.

A 3D bioprinter deposits multiple types of kidney cells—cultivated from cells taken by a biopsy—while simultaneously building a scaffold out of biodegradable material. The finished product is then incubated. The scaffold, once transplanted into a patient, would slowly biodegrade as the functional tissue grows.

Researchers are currently looking mainly into 3D printing of specific living parts, such as kidneys, ears, blood vessels, skin and bones. However, the research is likely to spread to other areas shortly. Today, every 30 seconds a patient who could have been saved with tissue replacement dies instead. By cutting organ donors waiting lists to zero, 3D printing would produce an incredible value for the society.

This overview shows how diverse the applications of 3D printing for direct product manufacturing can be. McKinsey estimates that 3D printing of final products can cover up to 50% of products in relevant categories by 2025, with up to 80% value increase per product when the consumers decide to use themselves a 3D printer. Beyond final product manufacturing, this technology is also facilitating the production process through tool and mould manufacturing and promoting product innovation through rapid prototyping.

Setting the priorities right

Both technical and regulatory barriers are slowing down the diffusion of 3D printing today. Technical limitations comprise mainly slow build speed, limited object size, limited details or resolution, and high costs for materials and printers. However, rapid progress is being made in all these areas.

The Department of Energy's Oak Ridge National Laboratory and machine tool manufacturer CINCINNATI® Incorporated recently announced a partnership for creating a 3D printer with 200 to 500 times the speed, and 10 times the size, of most current printers. Carbon3D has also recently pulled in $100 million in new funding to bring to the market a 3D printer which allows to print functional parts at 100 times the speed of existing printers. Moreover, several patents for technologies such as laser sintering will expire soon, thereby spurring additional competition among manufacturers of 3D printers. This will, in turn, drive new players also in the market for printing materials, providing a downward push to the prices.

The major challenges for widespread adoption of this technology are rather stemming from the strong legal uncertainty surrounding these technologies. For 3D printing to achieve its full potential and to prevent the creation of a fragmented market, a series of interventions should move up in the policy makers' agenda.

Intellectual property rights (IPR) issues are those most likely to arise in the short term. The border between what entails a violation of IPR and what instead falls under the fair use definition is not clear today. It appears unquestionable that if an object owned by the user breaks, its owner can make use of 3D scanning and 3D printing to repair it.

On the other hand, if the file used to 3D print the spare part is downloaded from the web, it can be considered as owned by the company that makes the part and it therefore might entail an IPR violation. It would also be hard to define who is liable in case of a copyright infringement. It could be the person who downloads the file, the platform which shares it or the company which performs the print. The situation gets more complex if the user buys online a file which was uploaded unlawfully, believing that the provider of the file was actually the rightful one.

Shedding light on these issues is paramount for the commercialisation of 3D printed objects and will become more of an issue as the activity moves from the hobbyist community to mass production. In the lack of policy guidance, several 3D printing manufacturers are dealing with the issue today by refusing to print objects which clearly entail an IPR violation and are asking the users to agree to a contractual clause which relieves them from any responsibility.

In addition, striking the right balance will be complicated by the fact that the digital files downloaded from the web are often tweaked to such an extent that they become new objects, and therefore simply uploading the file does not entail that the object will be printed in the same format in which it is uploaded. Given the international nature of platforms for sharing files for 3D printing, it will be required a global response to these issues, and the current IPR regime is certainly not optimally suited for such an approach.

Another challenge requiring policy attention relates to the imposition of tariffs and other duties. Leveraging on the argument that downloadable files (music, film, games) can be made into a physical object (burnt on a cd/dvd), the WTO tends to treat these files as goods (and therefore governed by GATT) rather than software (which would be

3D printing is a technology that has *"the potential to revolutionize the way we make almost everything"*

Barack Obama

governed by GATS). This argument is hardly applicable to 3D printing files. In fact, contrary to the case of a digital song, the file cannot be directly 'consumed'. Only if the file will actually be printed and the print will be functional, there is a case for imposing a control in terms of tariffs and tax collection. Moreover, the same argument presented above complicates the situation. Are duties on a digital file defendable if that file can actually be easily tweaked and turned into a different object?

Conformity standards and testing (including legal liability) of 3D printed objects also urge a regulatory discussion. First of all, additive manufacturing makes necessary to rethink the general rules on the certification process of 3D printed products. As each product is slightly different from the other, it is hard to implement the same rules applied to the current standardised manufacturing system.

The diffusion of mass customisation in the medical sector represents a clear example in this regard. Today, thousands of 3D printed invasive and/or implementable medical devices are being implanted. These devices include artificial limbs, cranial implants and other prostheses and implants manufactured by means of additive manufacturing technology. However, 3D printed medical devices are not explicitly regulated today and the situation does not change under the recent European Commission proposal for the Directive on medical devices.

As a result, all 3D printed medical devices would likely fall under the category of custom-made devices. If this were the case, the regulatory burden on this new technology would remain low, as manufacturers would only be asked to ensure that their devices are safe and perform as intended. The lack of clear and safe framework to regulate 3D printed medical devices would delay their adoption and hamper the possibility to build trust in this technology.

On the other hand, the standard certification process for devices classified as medium or high risk does not fit with the nature of 3D printed devices. In fact, in the case of printed devices, the quality of the finished products relies heavily on pre-manufacturing steps of the patient-specific medical imaging and the design of the device. Appropriate quality requirements should therefore encompass, other than the printing process itself, also the evaluation of the imaging and the digital design phase. Regulating input materials and machinery will not be enough to ensure the safety of the final product and might actually create counterproductive burdens.

In addition to certification issues, there is the problem of legal liability. Today, most of the products are subject to strict production standards and testing, with manufacturers held liable in case of accidents arising from product malfunctioning or inappropriate break. However, if a product is downloaded from the web and then 3D printed at home or in a print shop, it is not clear who would be liable in case of accidents. It could be the designer, the website which shared the file, the supplier of printing material, the manufacturer of the 3D printer or the person who performs the printing.

Finally, there are other key health issues which should also be addressed. For instance, they comprise the necessity to control the safety of certain materials (especially when they are used to create objects that will get in contact with food) and the emission of ultra-fine particles during the printing process.

All these issues are being overlooked today by European policy makers. A proactive regulatory discussion will allow to rethink the nature of digital products and the concepts of IPR, taxation, product certification and legal liability in the digital age, while ensuring a global action in support of innovation. In case of inaction, our current regulatory framework would work de facto as a barrier to innovation.

Disrupt or be disrupted

From a wider economic and societal perspective, 3D printing fits within a wave of technological innovations that recently hit the market and which are set to shake and reshape our reality. While 3D printing alone will not disrupt our entire economy, we are likely to see a radical transformation of entire sectors in response to widespread adoption of this technology. In some cases, this will result from the close interaction of 3D printing with other technologies. For instance, in the pharmaceutical industry, 3D printing and advancements in genomics are supporting the rise of personalised medicine.

For what concerns the manufacturing sector, a hybrid solution between additive and traditional manufacturing, is the most probable outcome. In some cases, the different techniques will co-exist, with 3D printing supporting certain phases of the production process, such as prototyping, production of moulds and tooling, direct manufacturing of spare parts, as well as on-the-spot 3D printing of broken machinery parts.

In other cases, the adoption of 3D printing might disrupt the entire value chain of a company. This is the case for all those products whose customisation is made commercially viable by the use of 3D printing. As the traditional steps of the manufacturing process are replaced by direct manufacturing of the product, the concept of global value chain becomes obsolete. Therefore, as the manufacturing process becomes leaner and the companies start looking for a new and more specialised workforce, they might find more convenient to re-shore their production-thereby also facilitating a closer engagement with their customers.

Finally, plummeting costs for setting up the production system for additive manufacture will enable more and smaller companies to cost-effectively manufacture products on demand and in small batches, supporting the rise of urban start-ups engaged in manufacturing.

Summing up and on why we should look beyond GDP

Even if the direct cost of producing a product with 3D printing might be higher, the restructuring of the production process and the adoption of new business models allow for the total cost of production to be lower. By switching to additive manufacturing, the companies can achieve savings by limiting the waste of material, reshoring the production and thereby decimating transportation costs, and reducing inventory and facility costs.

At the same time, more value for consumers is created with personalised and customised products, while limitless opportunities are opening up for manufacturing of products with intricate internal structures. With the technology developing at a staggering pace, additive manufacturing is becoming commercially viable for a wide range of products.

Policy makers should engage in a proactive regulatory dialogue and implement a framework under which 3D printing can achieve the status of a legitimate form of production. Striking the right balance between ensuring the safety of this technology and avoid stifling the innovation will not be an easy task.

However, a cross-border proactive collaboration to ensure a global regulatory framework would be a much welcome first step and would prevent the rise of a fragmented market resulting from the adoption of national solutions to issues which are intrinsically global. Clear regulation would enhance confidence in this technology and create the conditions for it to spread safely.

Digital fabrication has the potential to transform radically the functioning of certain sectors, spur innovation and produce great value for consumers. The manufacturing sector is likely to experience a re-configuration of the (global) value chain model into a new lean model in which a digital file is directly manufactured into a functional object.

This change will require a smaller but more qualified workforce, therefore creating the conditions for reshoring of manufacturing and the rise of urban start-ups. Being close to the customers, in fact, allows the companies to respond better to their preferences, while decimating transportation costs. In turn, the nature of global trade flows will also be impacted, as fewer intermediate and finished goods will be traded.

These developments alone will not change how our economy works today. However, together with the rise of the sharing economy, the open-source movement, the open data applications and other innovations, 3D printing at home (also referred to as 'home fabrication') feeds into a wider economic and societal transformation which is challenging our model of market exchange.

These innovations are allowing consumers all around the world to benefit from an easy access to nearly free services and products, while more value is also created by customising the service or product to the individual preferences. Our conventional metric for measuring economic performance and wealth today - the Gross Domestic Product (GDP) indicator - fails to reflect the value resulting from these new applications.

Most of these activities take place outside the marketplace or promote access to a product rather than ownership, resulting therefore in GDP shrinking rather than accounting for the new value being created. This argument feeds the wider discussion around how to measure wealth in the digital age.

Digitisation and digitalisation are creating huge gains for people in all parts of the world, most of which is not accounted in GDP. While this metric was never considered perfect, with the digital age it might actually become misleading. Is it finally time to move beyond it? ■

Martina F Ferracane is a Policy Analyst at ECIPE. Her work focuses on EU sectoral policies, especially in the areas of international trade, healthcare and innovation