Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI SILICON VALLEY BANGALORE SINGAPORE MUMBAI BKC NEW DELHI MUNICH NEW YORK

3D Printing: Ctrl+P the Future

A Multi-Industry Strategic, Legal, Tax & Ethical Analysis

April 2020

3D Printing: Ctrl+P the Future

A Multi-Industry Strategic, Legal, Tax & Ethical Analysis

April 2020

ndaconnect@nishithdesai.com

DMS Code: 558895,1:

About NDA

We are an India Centric Global law firm **(www.nishithdesai.com)** with four offices in India and the only law firm with license to practice Indian law from our Munich, Singapore, Palo Alto and New York offices. We are a firm of specialists and the go-to firm for companies that want to conduct business in India, navigate its complex business regulations and grow. Over 70% of our clients are foreign multinationals and over 84.5% are repeat clients.

Our reputation is well regarded for handling complex high value transactions and cross border litigation; that prestige extends to engaging and mentoring the start-up community that we passionately support and encourage. We also enjoy global recognition for our research with an ability to anticipate and address challenges from a strategic, legal and tax perspective in an integrated way. In fact, the framework and standards for the Asset Management industry within India was pioneered by us in the early 1990s, and we continue remain respected industry experts.

We are a research based law firm and have just set up a first-of-its kind IOT-driven Blue Sky Thinking & Research Campus named Imaginarium AliGunjan (near Mumbai, India), dedicated to exploring the future of law & society. We are consistently ranked at the top as Asia's most innovative law practice by Financial Times. NDA is renowned for its advanced predictive legal practice and constantly conducts original research into emerging areas of the law such as Blockchain, Artificial Intelligence, Designer Babies, Flying Cars, Autonomous vehicles, IOT, AI & Robotics, Medical Devices, Genetic Engineering amongst others and enjoy high credibility in respect of our independent research and assist number of ministries in their policy and regulatory work.

The safety and security of our client's information and confidentiality is of paramount importance to us. To this end, we are hugely invested in the latest security systems and technology of military grade. We are a socially conscious law firm and do extensive pro-bono and public policy work. We have significant diversity with female employees in the range of about 49% and many in leadership positions.

Accolades

A brief chronicle our firm's global acclaim for its achievements and prowess through the years –

- **Legal500:** Tier 1 for Tax, Investment Funds, Labour & Employment, TMT and Corporate M&A *2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013, 2012*
- **Chambers and Partners Asia Pacific:** Band 1 for Employment, Lifesciences, Tax and TMT *2020, 2019, 2018, 2017, 2016, 2015*
- **IFLR1000:** Tier 1 for Private Equity and Project Development: Telecommunications Networks. *2020, 2019, 2018, 2017, 2014*
- **AsiaLaw Asia-Pacific Guide 2020:** Tier 1 (Outstanding) for TMT, Labour & Employment, Private Equity, Regulatory and Tax
- **FT Innovative Lawyers Asia Pacific 2019 Awards:** NDA ranked 2nd in the Most Innovative Law Firm category (Asia-Pacific Headquartered)
- **RSG-Financial Times:** India's Most Innovative Law Firm *2019, 2017, 2016, 2015, 2014*
- **Benchmark Litigation Asia-Pacific:** Tier 1 for Government & Regulatory and Tax *2019, 2018*
- **Who's Who Legal 2019:**
  Nishith Desai, Corporate Tax and Private Funds – Thought Leader
  Vikram Shroff, HR and Employment Law- Global Thought Leader
  Vaibhav Parikh, Data Practices - Thought Leader (India)
  Dr. Milind Antani, Pharma & Healthcare – only Indian Lawyer to be recognized for 'Life sciences-Regulatory,' for 5 years consecutively
- **Merger Market 2018:** Fastest growing M&A Law Firm in India
- **Asia Mena Counsel's In-House Community Firms Survey 2018:** The only Indian Firm recognized for Life Sciences
- **IDEX Legal Awards 2015:** Nishith Desai Associates won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm"

Please see the last page of this paper for the most recent research papers by our experts.

Disclaimer

Contact

For any help or assistance please email us on ndaconnect@nishithdesai.com
or visit us at www.nishithdesai.com

Acknowledgements

Dr.Milind Antani
milind.antani@nishithdesai.com

Jaideep Reddy
jaideep.reddy@nishithdesai.com

Darren Punnen
darren.punnen@nishithdesai.com

Shreya Shenolikar
shreya.shenolikar@nishithdesai.com

Contents

1. Introduction

The advent of the three-dimensional printer (**"3DP"**) has been heralded as the 'new industrial revolution' ushering in a new era of manufacturing.[1] With only sixty years passing between the progression of the first electronic printer to the 3DP, the excitement around 3D printing is clearly warranted. The 3D printing industry is growing at a rapid pace and was valued at excess of USD 7 billion[2] in 2017 and is expected to reach a value of USD 35.6 billion by 2023.[3]

3D printing allows corporations to cut costs by decentralizing manufacturing and streamlining supply chains. Further, consumers with access to the technology will be empowered to 'print' products from their own homes, eliminating the need to rush to shops to purchase items they require for their everyday lives. 3D printing is likely to have a major impact on all industries with manufacturing processes, including pharmaceuticals, aviation, food and fashion. However, as is the case with all disruptive technology, the regulation of 3D printing is a challenge that lawmakers, and regulators across sectors will have to contend with. Due to the diverse set of applications of 3D printing technology, the regulation should be comprehensive enough to apply in different instances while still having room for evolving with the technology.

Technology Overview & State of The Art in Industry

'Three-dimensional printing', or 'additive manufacturing', refers to the process by which CAD files are transformed into physical articles. There are many different types of 3DPs, each using slightly different materials. However, the overall procedure applies generally to all 3DP versions. The CAD file, an all-encompassing three-dimensional electronic 'blueprint' with the schematics of the article to be printed, is created manually using dedicated software or through three-dimensional scanning devices. The file is then uploaded to a 3DP which creates the physical object through a layering process, where layers of the relevant material are continually deposited and built up in the printer, slowly building the structure, until the final product emerges.[4] There are currently seven different categories of three-dimensional printing processes.[5]

The technology has already started to make waves in various industries. Within the medical field, researchers at the National University of Singapore have developed a way to print customizable tablets, combining multiple drugs and crafting the medication to best meet the needs of individual patients.[6] Customized medication is not only helpful in improving treatment outcomes but can also increase patient adherence e.g. by allowing the patient to take only one table a day. Outside medicine, a Dutch company has started printing the world's first inhabitable 3D homes near the city of Eindhoven, Netherlands.[7] 3D printing is also currently employed by Finnair to build parts for aircraft, Adidas to create soles for shoes and Williams F1 for parts in their formula one racecars. 3D-printed guns have been made in

1. Robert Bogue, *'3D Printing: The Dawn of a New Era in Manufacturing'*, available at: https://www.researchgate.net/publication/263059946_3D_printing_The_dawn_of_a_new_era_in_manufacturing (last accessed April 1, 2020).
2. TJ McCue, *'Wohlers Report 2018: 3D Printer Industry Tops $7 Billion'*, available at https://www.forbes.com/sites/tjmccue/2018/06/04/wohlers-report-2018-3d-printer-industry-rises-21-percent-to-over-7-billion/#2cfa19402d1a
3. *'3D Printing Market: Growth, Trends and Forecasts (2020-2025)'*, available at: https://www.mordorintelligence.com/industry-reports/3d-printing-market.
4. *'3D Printing and IP Law'*, available at http://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html
5. *'Types of 3D Printing Technology'*, available at: https://all3dp.com/1/types-of-3d-printers-3d-printing-technology/
6. *'3D Printing and IP Law'*, available at http://www.wipo.int/wipo_magazine/en/2017/01/article_0006.html
7. Victor Tangermann, *'A Dutch City Is Creating the First Habitable, 3D Printed Houses'*, available at: https://futurism.com/3d-printing-habitable-houses/

both Australia and the US.[8] Thus, with so many applications, the potential of 3D printing is unprecedented and will be closely monitored by consumers, manufacturers and regulators for years to come.

> As a result, it is vital to anticipate issues that may arise from the technology, and examine whether the current legal framework is equipped to adequately accommodate the disruptive technology, as well as where the law should evolve to allow for the ever-growing space.

This paper will assess how the law in India, as it currently stands, regulates 3D printing. This paper provides an overview of how existing law regulates Computer Aided Design (**"CAD"**) files and 3D printed objects. This includes an examination of how CAD files and 3D printed objects are protected under existing Intellectual Property (**"IP"**) law and how they may be taxed. The paper also examines the effects of 3D printing in the food, pharmaceutical and defense industry and the proposing changes in the existing regulatory framework governing these industries to account for 3D printing technology. Finally, the paper also deals with product liability issues that may arise in respect of 3D printed goods and deals with some of the ethical implications of 3D printing technical.

8. Tom Barnes, '*3D printed guns seized by Australian police during raid*'available at https://www.independent.co.uk/news/world/australasia/guns-3d-printed-australia-seized-police-raid-queensland-a8454486.html
Doug Criss and Kimberly Berryman, '*More than 1,000 people have already downloaded plans to 3-D print an AR-15*', available at https://edition-m.cnn.com/2018/07/30/us/pennsylvania-3d-guns-trnd/index.html?r=https%3A%2F%2Fwww.google.co.in%2F

2. Business Models

In order to understand the legal implications of 3D printing technology, it is equally important to understand the various commercial models within which the 3D printing technology would be utilized. Some of the broad business models, or the evolution of current business models that may arise with the infusion of the technology, are discussed below:

I. Sale or Licensing of Cad Files

> Given that the manufacturing activity for any product manufacturer would be decentralized, the primary asset for any business that adopts 3D printing technology would be the CAD file, where the CAD file would be monetized by being licensed or sold to third parties.

Distributing CAD files instead of the articles themselves saves the company distributing the CAD file costs associated with manufacturing, labour, handling, shipping and shrinkage & inventory loss to name a few.

A. Sale of CAD files

The sale of a CAD file would involve complete transfer of the rights of the CAD file to the purchaser, thereby allowing the purchaser to print the product contained within the CAD file multiple times, modify it further, or even sell it further with or without improvements.[9]

Commercially, the sale of CAD files would be feasible in custom service arrangements, where a purchaser engages a business to develop a product specifically for the purchaser's requirements. Pursuant to the sale, the ownership in the CAD file would transfer to the purchaser and the seller would not be able to sell the CAD file to another individual/entity.

The sale of CAD files could further be divided on the basis of end users. The end user could be either an intermediary or the consumers themselves. Sale to intermediaries would generally be utilized where there is some value addition that is required before a 3D printed product can be used by a consumer. For instance, in the food industry, a 3D printed food article may still require cooking or assembly before service.[10] Sale to intermediaries may also take place in the case of products that require technical assembly before they can be sold. On the other hand, sale to consumers would be feasible in sectors that are not heavily regulated (e.g. furniture) and where there is no service element involved.

B. Licensing of CAD files

In a licensing arrangement, the CAD file would be provided to the consumer or intermediary for single use, multiple uses or use for a specific period of time. In an intermediary scenario, the CAD file could be licensed by a brand owner to a franchisee, to produce and sell the brand owner's products for the duration of the franchise arrangement.

II. 3D Printing as a Service

3D printing could also be provided as a service. For instance, 3DPs can be installed in production centers and can be used to manufacture a wide variety of products.[11] As a production center, a business could produce 3D printed products

9. Thierry Rayna and Ludmila Striukova, *'From rapid prototyping to home fabrication: How 3D printing is changing business model innovation'*, available at https://www.sciencedirect.com/science/article/pii/S0040162515002425

10. 'How 3D Printing is changing the food industry', available at https://www.outsource2india.com/eso/mechanical/articles/3d-printing-impact-food-industry.asp

11. Thierry Rayna and Ludmila Striukova, '*From rapid prototyping to home fabrication: How 3D printing is changing business model innovation*', available at https://www.sciencedirect.com/science/article/pii/S0040162515002425

for various companies on demand, and supply the same to customers. This would reduce the need for companies to maintain inventory and warehousing thereby reducing expenses incurred in logistics.

3DPs can also be set up the way photocopy centers operate today. Persons who do not have 3DPs at home can print products (using CAD files present with them) from local stores that provide 3D printing services.[12]

12. Companies have already begun offering online 3D printing services where customers can upload a CAD file and the 3D printed product will be printed by the service provider and shipped back to them - https://www.sculpteo.com/en/services/rapid-prototyping/ and https://www.think3d.in/3d-printing-service-india/.

3. Intellectual Property

Given the nature of the technology, IP protection would be one of the primary legal touchpoints that needs to be addressed.

> 3D printing is set to revolutionize traditional manufacturing processes by allowing design, trademark and patent holders to license out CAD files containing their IP and let the receiver of the CAD file manufacture the IP protected article.

However, in the absence of proper IP protection for CAD files or infrastructure with the IP holder to protect the download and dissemination of the CAD file, the rights of IP holders could be jeopardized.

As 3D printing technology enters the mainstream, the IP framework will need to evolve to ensure that the IP rights of the CAD file owners are sufficiently protected. This would encourage creators to commercialize their CAD files and consequently provide consumers with a wide variety of CAD files to print the products they need.

Therefore, a robust IP framework and enforcement mechanism should be geared towards protecting the biggest asset of the 3D printing process – the CAD file.

In this chapter, we have provided an overview of the IP framework in India followed by an analysis of how each IP would regulate CAD files and 3D printed objects.

I. Introduction to IP framework in India

India recognizes the following types of Intellectual Property:

i. Patents for inventions.

ii. Trade marks for marks that can be 'graphically represented' and used to distinguish a proprietor's goods and services from others.

iii. Copyright for literary, dramatic, musical or artistic works, cinematograph films, sound recordings and computer programs.

iv. Design registrations for features of shape, color or configurations applied to a good.

India is also signatory to the Agreement on Trade Related Intellectual Property Rights (**"TRIPS"**) and has complied with its obligations under the TRIPS by incorporating them in statute. A more detailed overview of the IP regime can be found in our separate research paper titled 'Intellectual Property Law in India'.[13]

It is crucial to clarify the IP regime to account for 3D printing. This is because 3DPs can be used by any person to print, sell and distribute articles without the consent or knowledge of the IP holder. Individuals can also scan the original articles and sell 3D printed counterfeits for cheaper. However, CAD file holders may legitimately operate if they are able to duly obtain rights in connection with from the IP holders in connection with the file.

The first line of defense for IP protection in the 3D printing space would be at the source i.e. the CAD file. As with online piracy, if third parties manage to obtain a CAD file illegally, it becomes difficult for proprietors to enforce their legal rights with respect to their IP. Thus,

> it is vital for IP holders to prevent infringement by tackling the issue at its very inception i.e., before people have access to CAD files.

13. Intellectual Property Law in India, available at: http://nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Intellectual_Property-Law_in_India-Web.pdf

II. Intellectual Property Law and 3D Printing

A. Trademarks

Trademarks are protected in India by both statute and common law. The Trade Marks Act, 1999 (**"TM Act"**) allows for the registration of marks that can be graphically represented and are capable of distinguishing a proprietor's products or services from others. A trademark is registered in respect of a certain category of goods or services. The underlying function of a trademark is to give an indication to potential purchasers as to the manufacturer or quality of the goods or services.[14] Once a trademark is registered, the holder of the registration has the exclusive privilege to use that registered mark in the course of trade in their specified categories of goods and services and to sue others for infringement. Under the TM Act, a trademark is infringed when a person other that the proprietor of that mark uses in the course of trade, a mark which is identical with, or deceptively similar to the registered trademark in relation to the relevant goods or services.[15] However, even holders of unregistered marks who can establish goodwill may have a right in 'passing off' to prevent others from using the mark.

> CAD files may include digital versions of a holder's trademark, and the unauthorized use of such trademark may constitute infringement or passing off if done in the course of trade.

For example, a CAD file may comprise of a model of a popular Nike shoe with its trademark, the Nike swoosh, emblazoned to the shoe. Here, the CAD file may be perceived as a 'digital counterfeit' since anyone with access to the file and a 3D printer would be able to print out the article, a seemingly perfect iteration of the product. The trademark holder hence stands to lose out on the goodwill and reputation associated with the trademark. Creators of the CAD file may also be liable for secondary infringement under the TM Act. Secondary infringement occurs when a person materially contributes or induces the direct infringer to commit the infringement. However, for secondary infringement to be established, primary infringement must be proven.

B. Copyrights

The Copyright Act, 1957 (**"Copyright Act"**) in conjunction with the Copyright Rules, 1958 (**"Copyright Rules"**) form the legislative framework that governs copyright protection in India. Under the Copyright Act, copyright subsists in original literary, dramatic, musical or artistic works, cinematograph films, and sound recordings regardless of whether they are registered with the Copyright Office.[16] Software code is generally treated as "literary work" under copyright law, while CAD files may be treated as "artistic works" since they may amount to a "drawing (including a diagram, map, chart or plan)".[17] Additionally, the 3D printed object may also amount to an "artistic work" if it is a "sculpture", "engraving" or "any other work of artistic craftsmanship". An infringement of copyright occurs when any person does any acts which are the exclusive rights of the copyright holder e.g., reproduction or import.[18]

It is worth noting that the Copyright Act expressly protects digital copies of the copyrighted work.

> A copyright grants an exclusive right to the copyright holder to reproduce the work in any material form including storing it in the electronic medium.[19]

14. *Godfrey Phillips India Ltd. vs Girnar Food & Beverages Pvt. Ltd* 1997 (2) Arb LR 559 Delhi.
15. Section 29 of the Trademarks Act, 1999.
16. Section 13 of the Copyright Act, 1957.
17. Section 2(c) and (o) of the Copyright Act, 1957.
18.
19. Section 14(c)(1) of the Copyright Act, 1957.

As a result, the current copyright regime is likely to sufficiently protect the right of the copyright holder against unauthorized transmission of CAD files containing their artistic works.

Separately, the Copyright Act also lists a range of acts that would not constitute infringement, including fair dealing with the work for private or personal use, including research.[20]

To the extent discussed above, the Copyright Act would govern the right of the copyright holder holders to transfer CAD files to suppliers and distributors. This exclusive right allows the copyright holder of the CAD file to grant licenses in respect of the CAD file with restrictions on the manner of use of such CAD file. The licensees of the CAD file can also be restricted from adapting the copyrighted work in any way.

> Copyright holders should ensure that adequate mechanisms for protecting their CAD files are in place. This is because CAD files can be surreptitiously transmitted online without the knowledge of the copyright holder.

C. Patents

The Patents Act, 1970 (**"Patents Act"**) is the legislation governing patents in India. A patent may be granted for an invention, which is defined as "a new product or process involving an inventive step and capable of industrial application".[21] A patent confers the exclusive right to the patent holder to prevent third parties from carrying on the following acts in respect of the patented invention, over which the patent holder has exclusive rights: making, using, offering for sale, selling or importing.[22]

3DPs may facilitate easier infringement of patents since CAD files can be easily distributed online and the resulting products can be printed at multiple locations with limited visibility of the patent holder. Further, the position on whether distributing of CAD files would amount to infringement of a patent is unclear and depends on whether making or selling digital iterations of the patented product (through the medium of CAD files) constitutes direct infringement of the patent holder's rights. Alternatively, one may consider asserting a right of contributory infringement under common law.

D. Design

Certain kinds of designs are protected under the Designs Act, 2000 (**"Designs Act"**).

> A 'design' is defined by the Designs Act as *"only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by an industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye",*

but do not include, among other things, "any mode or principle of construction", "anything which is in substance a mere mechanical device", or "any artistic work" under the Copyright Act.[23] Therefore, many 3D printed objects which are "mere mechanical devices" under the Designs Act or "artistic works" under the Copyright Act (discussed above) would get excluded from the Designs Act. Additionally, many CAD files, being drawings, are also likely to get excluded from the Designs Act, since drawings are artistic works under the Copyright Act (as discussed above).

20. Section 52 of the Copyright Act, 1957.
21. Section 2(1)(j) of the Patents Act, 1970.
22. Section 48 of the Patents Act, 1970.
23. Section 2(d) of the Designs Act, 2000.

For a design to be protected, it should be registered with the Controller-General of Patents, Designs and Trade Marks. A design is registered in relation to a class of goods where the design is protected only in relation to the goods with respect to which registration has been granted. Once a design is registered, the registration holder has the exclusive right to apply the design to any article in any class in which the design has been registered.

Broadly speaking, under the Designs Act, piracy of a design occurs: (a) when the design is applied to the relevant good (in respect of which the registration has been granted) for the purpose of sale without the authorization of the holder; (b) when a good in respect of which a design has been registered has been imported or marketed for the purpose of sale without authorization of the holder.[24]

III. Treatment of Intermediaries

CAD files would mostly likely be transmitted over the internet using websites that provide hosting services e.g. online marketplaces. Therefore, it is pertinent to under how intermediaries such as social media networks and sites that provide hosting services for CAD files would be regulated.

Intermediaries in India are regulated under the Information Technology Act, 2000 (**"IT Act"**). Under the IT Act, the general principle is that intermediaries would not be held liable for infringing content uploaded on their platforms provided the following conditions are fulfilled:.

1. The function of the intermediary is limited to providing access to the system; or
2. The intermediary does not initiate, select the receiver of or select / modify the information contained in a transmission; and
3. The intermediary observes due diligence discharging their duty and observes other guidelines the Central Government may prescribe.[25]

Section 3 of the Information Technology (Intermediary Guidelines) Rules, 2011 sets out detailed due diligence requirements for intermediaries.

> "An important due diligence obligation is that intermediaries are required to promptly take down infringing content in the event if they receive any order to this effect by a court or government agency."

24. Section 22 of the Designs Act, 2000.

25. Section 79(2) of the Information Technology Act, 2000.

4. Industrial Implications of 3D Printing Technology

3D printing technology would clearly have a huge impact across all sectors that involve manufacturing. Companies will be able to focus their attention on innovation and development of their product and minimize some resources on considerations such as manufacturing and distribution. The cost of production of goods will decrease as the cost of shipping and handling will be negligible for transmitting a CAD file. These savings would flow on to importers in addition to savings on import duties, as the importing process may be more economical. This business model is comparable to sale of e-books rather than the physical copy of the book. E-books often tend to be cheaper than their physical counterpart as there are no costs incurred in manufacturing and shipping. However, the impact of this technology would vary. The key differentiation in this respect is the extent to which the raw material is in the control of the manufacturer. For example, 3D printing technology may be less disruptive and have a largely positive impact on the pharmaceutical industry as the bulk drug substance is entirely in the control of the manufacturer and cannot be replicated using a 3D printer. On the other hand, in the defense industry, the impact of 3D printing is mixed. While 3D printing will allow for greater customization with respect to manufacture of spare parts for weapons systems and reduce waste by eliminating the need to maintain a large inventory, it can also lead to unregulated proliferation of small arms among the masses. In the following section, we have examined the impact of 3D printing on industries that are tightly regulated i.e. pharmaceutical, food and defense. We not only examine the preparedness of the existing laws to regulate 3D printing and 3D printed goods, but also analyze how those laws can be modified or interpreted to allow 3D printing technology to flourish.

I. Food Industry

A. 3D-printing food & overview of the current technology

Machine-made food is no longer just a fun prop in science fiction novels. Using 3DPs like Foodini and Biozoon, consumers can now print out a burger.[26] 3D printed food is seen as a welcome development in the culinary and technology space, as the technology today provides unprecedented control over the shape, color, texture and nutritional content of food.[27]

Different models of 3DPs use different techniques to achieve print food. The *Foodini*, for instance, utilizes capsules into which fresh ingredients are loaded, and then pumped out through the nozzle ('extruder') by arranging layer after layer of the ingredients until the desired result is achieved. The machine, however, does not cook the food, which has to be subsequently heated, baked or fried. *Foodini* also allows users to upload recipes onto it, as well as images and shapes in which they would like their food to be printed. In Cambridge, Dovetailed's 3D printer uses a molecular gastronomic technique of spherification to print fruit.[28] Dovetailed's 3D printer can print fruits that taste like one fruit but looks like another – for example, one that looks like a raspberry but tastes like a strawberry. Closer to home, India has developed its own commercially available

26. Tom Rawstorne, *The Future of Cooking? PRINT Your Dinner: Don't Scoff - But Now 3D printers Can Make Food*, available at http://www.dailymail.co.uk/sciencetech/article-2530195/The-future-cooking-PRINT-dinner-Dont-scoff-3D-printers-make-food.html.

27. *'3D Printed Food – Just Because We Can, Doesn't Always Mean We Should'*, available at https://www.forbes.com/sites/deloitte/2018/05/29/3d-printed-food-just-because-we-can-doesnt-always-mean-we-should/#6b35875b2e93.

28. Michael Molitch-Hou, 'The 3D Fruit Printer and the Raspberry That Tasted Like a Strawberry', available at https://3dprintingindustry.com/news/3d-fruit-printer-raspberry-tasted-like-strawberry-27713/

3D printer, the Chocobot which can print out chocolate in unique shapes.[29]

> Despite the advantages of customized food and nutrition, 3D printed food is fraught with challenges such as food safety, product liability, and long-term effect on the human body.[30]

Below, we have examined the extent to which the current food laws are equipped to deal with the challenges presented by 3D printed food.

B. Is 3D printed food "food"?

Despite the manufacturing process of 3D printed food being different, the output is still food, and thus, the relevant statutes in regard to regular food should also apply to 3D printed food. The Food Safety and Standards Act, 2006 (**"FSSA"**) is the primary legislation governing the food industry in India. The FSSA establishes the Food Safety and Standards Authority of India (**"FSSAI"**) as the regulatory body that monitors the manufacture, processing, storage, distribution, sale and import of food to ensure the availability of safe and healthy food for human consumption.

The definition of 'food' in the FSSA appears to be wide enough to include 3D printed food.[31]

> More specifically, 3D printed food could also fall within the category of 'novel food', which is defined in the FSSA as *"an article of food for which standards have not been specified but is not unsafe; provided that such food does not contain any of the foods and ingredients prohibited under this Act and the regulations made thereunder."*[32]

Pursuant to Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016 (**"FSSA Regulations 2016"**), a novel food:

a. may not have a history of human consumption;

b. is a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.[33]

Since 3D printing of food is innovative and does not have a history of safe use, it could currently fall under this definition of novel food. The Food Authority may, at any time, direct a food business operator manufacturing and selling such special type of article of food, to provide details regarding the history of use of the novel or modified ingredients added and their safety evaluation.[34]

This would be over and above the standard regulations that apply to the manufacture, import, sale and/or distribution of food under the FSSA, such as the requirement for every food business to obtain a license to manufacture, import and distribute food products.[35] These requirements are generally applicable to commercial settings such

29. Scott J Grunewald, *'Coming This Month: India's First 3d Chocolate Printer For Less Than $1,000'*, available at https://3dprintingindustry.com/news/coming-month-indias-first-3d-chocolate-printer-less-1000-31004/

30. Jasper L. Tran, 3D-Printed Food, 17 Minn. J.L. Sci. & Tech. 855 (2016), available at: https://scholarship.law.umn.edu/mjlst/vol17/iss2/7

31. Section 2(j) of the Food Safety and Standards Act, 2006.

32. Section 22(4) of the Food Safety and Standards Act 2006.

33. Regulation 13(1)(a) and (c) of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016.

34. Regulation 20 of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016.

35. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011

as a) manufacturers/importers/distributors of the 'ink'; and b) intermediaries who produce/cater the food for sale using 3DPs. These regulations should not apply to end consumers who print food for private consumption.[36]

C. Customized nutrition

3D printed food has the potential to allow hospitals and healthcare practitioners to customize nutrition to their patients' individual dietary needs based on information about their height, weight, body mass index, daily schedule and caloric deficit for the day.[37] For instance, a hospital in Netherlands is serving a five course 3D printed meal[38] which is easier to swallow for elderly patients, while retaining more minerals and vitamins as compared to overcooked food. Hospitals are also considering adding medication to this 3D printed food itself.

3D printed food that is specifically customized for nutritional purposes, or for use as health or dietary supplements, would be required to comply with the requirements of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016. Under these regulations, food business operators, will need prior approval of the FSSAI before making any health claims regarding novel foods, including 3D printed food.[39]

> "The approval of the FSSAI will be given based on scientific evidence."

36. Chapter 2, Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011

37. Bianca Bosker, '*3D Printers Could Actually Make Donuts Healthy*', available at https://www.huffingtonpost.in/entry/3d-printed-food_n_3148598

38. *'Dutch hospital in Zwolle to serve 3D printed meals packed with extra nutrients to patients'*, available at https://www.3ders.org/articles/20160905-dutch-hospital-in-zwolle-to-serve-3d-printed-meals-packed-with-extra-nutrients-to-patients.html

39. Regulation 4(9)(ii) of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016.

D. Labelling and product liability

Product liability arises under the FSSA primarily with respect to adulteration.

> "An adulterant is defined under the FSSA as a *"material which is or could be employed for making the food unsafe or sub-standard or misbranded or containing extraneous matter"*.[40]"

Adulteration, intentional or otherwise, could occur at three stages – a) when the ink is being prepared, b) certain toxins or other substances found in the printer itself being mixed into the food; and c) when the food is being printed. The FSSA not only prohibits the adulteration of food but also prescribes a penalty for such contravention.[41] In the first two instances, liability could be attributed to the manufacturer of the ink or the 3DP, while in the third case, it is likely to be on the entity that prepares the food.

Therefore, it becomes imperative for manufacturers of the 3DP and its ink, as well as commercial producers of food using 3DPs to ensure that adulterants do not find their way into the final food being served to a consumer.

The FSSA and the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 also have specific labeling requirements applicable to manufacturers of food. In the case of 3D printed food, entities manufacturing the 'ink' (basic ingredients which the 3DP would use to print out the food) as well the entities using the 3DP to print out the food (provided such printing is done for commercial purposes). Labeling requirements would include accurate declarations of the ingredients and nutritional value, along with declaration of allergens that may be found within the food products. Failure to comply with the labelling requirements which leads to the food product being unsafe for a consumer, or causing

40. Section 3(a) of the Food Safety and Standards Act, 2006.

41. Section 57 of the Food Safety and Standards Act, 2006.

injury, may attract liability for the manufacturer of the ink under the FSSA.

E. Conclusion

At least as of now, 3D printing food ingredients is not within the realm of mainstream consideration. The ingredients have to be brought fresh and the 3D printer acts more like an assembly line than an automatic cooking process. While the technology of 3D-printing food holds great potential, the question that needs to be addressed is whether the food regulatory system in India is prepared for the legal implications associated with 3D printed food. Moreover, even though the speed, cost and quality of 3D printed food is improving at a rapid pace, 3D printing technology may take some time to find a sustainable market. When 3D printed food becomes more mainstream, special regulations may need to be put in place to regulate 3D printed food.

II. Pharmaceutical and Medical Device Industry

3D printing has the potential to revolutionize the rapidly growing Indian pharmaceutical industry. 3D printing drugs can resolve supply chain inefficiencies, allow healthcare practitioners to customize drugs to their patients' needs and reduce waste by allowing pharmaceutical companies to manufacture exactly to demand.

> 3D printing could be the key catalyst to push further growth of the pharmaceutical industry in India by localizing manufacture and distribution of drugs and medical devices, thereby resolving the supply chain inefficiencies that hinder the growth of the pharma industry.

3D printing can also make clinical testing of drugs and medical devices simpler and cheaper by allowing companies to make changes to drug composition or the specifications of medical devices just by changing the CAD file.

This section will discuss the possible implications of 3D printing on the pharmaceutical sector, specifically with regard to clinical trials, import, manufacture and the supply chain mechanics of drugs and medical devices in India. It will also analyze whether the existing regulatory framework is adequate for the regulation of drugs and medical devices and also examine what areas of the law might require changes to accommodate 3D printed drugs and medical devices.

A. State of the Art

3D printed drugs are no longer a thing of the future - Spritam, an anti-epilepsy drug using levetiracetam as its Active Pharmaceutical Ingredient (**"API"**) has already been granted approval by the Food and Drugs Administration of the United States of America (**"FDA"**).[42] Spritam is manufactured using technology which employs 3D printing to create a porous design that allows the medication to dissolve quickly in the mouth.[43] While levetiracetam has been used to treat epilepsy for over 15 years, 3D printing has made it possible to improve the design of the medication and also to increase the dosage per tablet to 1,000 mg without affecting its solubility.[44] FDA has approved over 100 3D printed medical devices including those that were patient-matched devices tailored to fit a patient's anatomy.

42. Haopeng Wang, *'Will 3D Printing Revolutionize the Pharmaceutical Industry'*, available at https://www.cpaglobal.com/cpa-global-blog/will-3d-printing-revolutionise-the-pharmaceutical-industry

43. *'Making Medicine Using 3D Printing'*, available at https://www.spritam.com/#/patient/zipdose-technology/making-medicine-using-3d-printing

44. Matt Johnson, *'The Benefits of Additive Manufacturing Applies to 3D Printed Pills and Medication'*, available at https://www.embodi3d.com/blogs/entry/343-the-benefits-of-additive-manufacturing-applies-to-3d-printed-pills-and-medication/

3D printing has applications that could increase the standards for patient care exponentially. It allows doctors to print drugs with dosages customized for each patient and surgeons to practice complex surgery beforehand by 3D printing prototypes of the patients' organs. In South Texas last year, conjoined twins who were fused below the waist were separated successfully after surgeons were able to practice the surgery beforehand using virtual computer simulations and generating 3D models of the conjoined twins' anatomy.[45] It also allows for drugs to be manufactured locally thereby saving on transportation costs and can make it easier for patients in remote areas to access high quality medication.

B. Implications of 3D Printing on the Pharmaceutical and Medical Device Industry

i. Overview of the Regulatory Framework of Drugs and Medical Devices

The Drugs and Cosmetics Act 1940 (**"D&C Act"**) along with the Drugs & Cosmetics Rules 1945 (**"D&C Rules"**) and the Medical Device Rules 2017 (**"MDR"**) is the primary legislative framework regulating drugs and medical devices in India. The Central Drugs Standard Control Authority (**"CDSCO"**) is the regulator appointed under the D&C Act and is primarily responsible for regulating clinical trials and the import of drugs while state licensing authorities are responsible for regulating the manufacture and sale of drugs and medical devices. The D&C Rules and the MDR require persons engaged in conducting clinical trials, manufacturing, importing and selling drugs and medical devices respectively to obtain licenses to do so.

Under the D&C Act, a drug is defined as all medicines and substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes including substances intended to be used as substances in a drug such as gelatin capsules.[46] Currently, only certain medical devices that have been notified by the MoHFW are regulated as 'notified medical devices' under the ambit of the D&C Act and the MDR.

For obtaining and renewing their licenses under the D&C Rules and MDR, importers, manufacturers, wholesalers and retailers are expected to maintain their facilities as per the standards prescribed in the D&C Rules and MDR. Given these requirements, it is unlikely that 3D printing of drugs and medical devices would be possible at the consumer level However, 3D printing may instead assist and replace conventional manufacturing capabilities at the commercial level.

> "Under India's existing legal framework, 3D printing of drugs and medical devices is not prohibited, provided the manufacturer possesses the requisite approvals from the regulator for manufacture of the drug or medical device."

A question that arises is whether 3D printed drugs need to be specifically approved due to a change in the manufacturing process. In India, 'new drugs' are required to undergo clinical trials with a view to proving their safety and efficacy for use in Indian patients. A 'new drug' is a drug that has not been used to a significant extent in India, or one that may have already been approved, but is proposed to be introduced into the Indian market with different dosage forms or routes of administration (among other changes) than what has been previously approved for marketing. Therefore, where a 3D printed drug proposes to change the dosage

45. *'Formerly conjoined twins moving home to the Valley'*, available at http://www.driscollchildrens.org/about-us/formerly-conjoined-twins-moving-home-to-the-valley

46. Section 3(b) Drugs and Cosmetics Act 1940.

form of a drug, such drugs may be required to undergo clinical trials in accordance with the requirements of the D&C Rules prior to being manufactured for sale in India. However, a mere change in the manufacturing process from traditional manufacturing to 3D printing, should not require specific approval from the CDSCO provided the composition of the drug remains the same.

In the case of medical devices, change in the manufacturing process, equipment or testing is considered to be a major design change if the change affects the quality of the device.[47] The manufacturer or importer of the medical device is required to obtain permission from the relevant authorities before carrying out the change, Therefore, the manufacturers and importers of the approved medical device may be required to obtain prior approval from the regulator in the event they wish to 3D print a medical device which was earlier being manufactured through other means.

The implications of 3D printing on the pharmaceutical industry can be examined along each stage of the supply chain.

ii. 3D Printing and its use in Clinical Trials

3D printing can drastically cut costs of manufacturing or importing drugs for the purposes of clinical trials/investigations. Generally, manufacturing or importing new drugs for test purposes can be cumbersome as it involves the installation or complex machinery (in the case of manufacture), or shipping time (in case of import).

3D printing of drugs does not require the installation of complex machinery and allows easier customization of the test drug. The CAD files can be modified easily to change drug composition and therefore conducting clinical trials of different iterations of a drug requires limited manufacturing alterations. Therefore, in the initial testing stages, where the drug/ medical device is not being tested on humans, 3D printed drugs can help expedite the research process. These gains would also carry over to the human clinical trial stage.

> “Clinical trials for drugs and clinical investigations/clinical performance evaluations for medical devices are compulsorily required to be carried out for new drugs, and for medical devices that are a first of their kind.”

However, given the definition of ‘new drug’, new iterations of the drug/medical device would each require a separate approval for testing from the CDSCO, as each new iteration of the test substance may be considered a new drug.

iii. Import

The D&C Act currently envisages import of drugs and medical devices in its physical form. 3D printing would allow complete schematics of drugs to be imported electronically without any physical movement of goods. Within the legal framework, it is debatable whether downloading CAD files of drugs will amount to “import”, or whether the printing activity within India would be separately construed as ‘manufacture’ under the D&C Act. The D&C Act defines “to import” as *“to bring into India.”*[48] The relevant question then shifts to whether a CAD file amounts to a drug or medical device. The definition of a drug does not include digital components. However, the legal position with respect to a medical device is slightly different.

> “While the definition of a medical device does not explicitly include software, the parameters outlined to determine whether a medical device is an in-vitro medical device state that the *“software*

47. Sixth Schedule of the Medical Device Rules, 2017.

48. Section 2(g) of the Drugs and Cosmetics Act 1940.

which drives a device, or influences the use of a device, falls in the same class"[49] as the medical device.

"

Therefore, the software, when used in conjunction with operating a medical device, should be included within the definition of medical devices.

For the purposes of determining whether a CAD file is included in the definition of "software" for the purposes of MDR, it must be ascertained whether a CAD file drives a device, or influences the use of a device. Depending upon whether there are alternate means of manufacturing the device, a CAD file might be a necessary pre-requisite to the existence of such medical device and therefore can be said to drive the device. In such a case import of a CAD file can mean import of a medical device and may require a license under MDR. However, given the current legal framework, only medical devices that have been notified are included within the regulation of the D&C Act and MDR, it calls to question whether a CAD file is regulated at all, until it is notified as a medical device.

Further, the CAD file plays no role in either driving or influencing the device after 3D printing the device. A literal interpretation of the statement also indicates that the terms "drive" and "influence" were to apply after existence of the device in the first place. An interpretation to the contrary would imply that when equipment used to manufacture medical devices is imported, such import would also require an import license under the MDR, which is not the case. Functionally, CAD files are closer to equipment used to manufacture medical devices than software used to drive or influence a device.

As a consequence, the import of CAD files for medical devices today may not require a license under MDR. In any case, import of CAD files for drugs should not require an import license as the definition of drug at no point involves any digital component.

49. Part II, Medical Device Rules 2017.

It must be noted that regardless of whether importing CAD files requires a license, manufacture of a drug or medical device using such CAD file but without the requisite legal compliance will attract penalty under the provisions of the D&C Act.

iv. Manufacture

Theoretically, 3D printing should allow the consumer to manufacture drugs in the comfort of their own home. However, given that the actual bulk drug substance is entirely in control of the manufacturer, 3D printing is less likely to decentralize manufacturing in the pharmaceutical industry. Further, the D&C Rules and MDR require mandatory licenses to manufacture drugs and medical devices. In fact, the act of labeling itself would amount to manufacture under the D&C Act, requiring a license. Different licenses are required for manufacturing drugs depending upon the schedule in which the drug is classified with a separate license required for each facility in which such drug or device is manufactured.

The D&C Rules also stipulate the Good Manufacturing Practices (**"GMP"**) that need to be followed in the case of drugs, with separate requirements for Ayurveda, Siddha and Unani drugs.[50] The MDR also prescribes Quality Management System (**"QMS"**) that lay down the requirements for documentation, management responsibilities, resource management and monitoring for medical device manufacture. Violation of the GMP or the QMS can attract penalties and lead to cancellation of license.

The main reason that drug manufacturing cannot be localized is that the key component of the drug is its API, also known as bulk drug in India. The ingredient in the bulk drug is in the exclusive knowledge and control of the manufacturer and currently it is not possible to procure the API without the permission of the manufacturer, as it is not possible to 3D print the API itself. Therefore, the supply of "ink" for the printer is controlled by the manufacturer of the drug.

50. Schedules M, M-II and M-III of the Drugs and Cosmetic Rules 1945.

Commercially, it could be possible to sell the API as opposed to the finished drug which would allow the patient or their caretaker to manufacture the drug in their homes. Alternate distribution models involving licensed pharmacies and hospitals can also be considered. While this would drastically reduce the cost and consequently the price of the drug, the current regulatory framework in India does not permit manufacture of drugs without a license or in facilities that are not GMP compliant.

> The definition of "manufacturing" under the D&C Act *"includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution."*[51]

Patients 3D printing the drug are likely to fall under the first part of the definition as 3D printing the drugs is part of making the finished drug. However, as they are manufacturing the drug for consumption and not for sale, the definition of manufacturing should not strictly apply to them. As the manufacture of drugs using 3D printing becomes more popular, the legal position on manufacture would hopefully be made clearer.

There is also an emerging technology developed by Lee Cronin known as the 'Chemputer'. Cronin's ambition is to create a printer that can allow individuals to print pharmaceuticals at home. The "ink" for the printer would be simple reagents from which more complex molecules are formed.[52] The chemputer in the long term could dismantle supply chains and would allow for drugs to be manufactured at the site of need. At the same time, there should be certain protective measures set in place for such devices as they could be an avenue for counterfeiters in non-GMP setups to make drugs without the permission of the manufacturer, thereby causing a public health issue.

The D&C Act, however, is well equipped to deal with counterfeit drugs. Manufacture of drugs without a license is an offence under the D&C Act.[53] The D&C Act also stipulates that manufacture, import or sale of spurious drugs or those not of standard quality is punishable.[54] The Indian Penal Code also has separate provision criminalizing making or selling an adulterated drug.[55] The combined effect of the provisions is that the quality of drugs is maintained and those manufacturing spurious or adulterated drugs are penalized regardless of any IP violations.

v. Distribution/Sale

In the current scenario, 3D printing is less likely to disrupt drug distribution networks, given that Active Pharmaceutical Ingredients (APIs) should continue to be under the control of the drug manufacturer. However, 3D printing does have the potential to decentralize drug manufacture and reduce supply chain inefficiencies.

Currently, the distribution of drugs and notified medical devices can only be carried out by licensed entities who have obtained permissions to stock and sell drugs on a wholesale or retail basis. Each facility where drugs are stored requires a different permit and are open to inspection by the CDSCO. Additionally, inventory moves slower in the pharmaceutical industry as compared to other sectors. As a consequence, pharmaceutical companies overproduce often at the cost of disposing of unfit inventory. A decentralized form drug distribution could fix a lot of the problems Indian drug distributors face.

51. Section 3(f) of the Drugs and Cosmetics Act 1940.
52. Tim Adams, 'The 'chemputer' that could print out any drug', available at https://www.theguardian.com/science/2012/jul/21/chemputer-that-prints-out-drugs
53. Section 18 of the Drugs and Cosmetics Act 1940.
54. Section 13 of the Drugs and Cosmetics Act 1940.
55. Sections 274, 275 and 276 of the Indian Penal Code 1860.

3D printing makes manufacturing much simpler to decentralize. Rather than keeping finished drugs ready, pharmaceutical companies could keep only a fixed amount of API ready and manufacture finished drugs depending on the demand for it. The versatility of manufacturing equipment could also allow drug manufacturers to manufacture 'orphan drugs' i.e. those drugs which are not perennially in demand cheaply as they do not need to invest in elaborate manufacturing facilities for such drugs.

Decentralization of manufacturing also allows for customized dosages of drugs as per patient requirements. To take full advantage of this benefit, pharmaceutical companies are likely to ship API either to licensed pharmacists, hospitals or patients themselves. However, such entities should be permitted to manufacture drugs in order for the model to work. Currently, the definition of manufacturing states that the term "does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business."[56] This exception may allow pharmacies to manufacture drugs in a limited capacity. However, this exception would not extend to hospitals. The law regulating distribution of pharmaceutical products may need a re-visit, in order to fully exploit the capabilities and efficiencies that 3D printing technology has to offer.

C. 3D Printed Medical Devices

Medical devices such as orthopedic and cranial implants, surgical instruments, external prosthetics and dental restorations can be customized for patients using 3DPs. The MDR sets in place licensing requirements for manufacturers and importers. The MDR also specifies requirements for conducting clinical investigations for medical devices before granting permission to companies to market such devices. The clinical investigation requirements are more relaxed in case of medical devices with an already approved predicate device. The Medical Devices Rules, 2017 carve out exemptions for custom-made devices made on the basis of a doctor's prescription. Given that the use of 3D printing technology in medical devices is largely geared towards its ease in customization to the specific needs of the patient, it may be possible for manufacturers and importers of such devices to avail of such exemption.

III. Defense Industry

Globally, countries are beginning to realize the latent potential of 3D printing technology in the defense sector. The European Union has released the report of a study commissioned with the aim of eventually deploying 3D printing technology in defense specific scenarios[57] while the United States of America has already successfully operationalized 3D printing technology to print spare parts for nuclear submarines which are no longer manufactured by the original manufacturer.[58] Defense manufacturers are also looking to creating 3D printed missiles with Raytheon, a US based Defense Company, having already created nearly every component of a guided weapon using 3D printing.[59] Even in India, Hindustan Aeronautics Limited, an Indian state-owned aerospace and defense company, is using 3D printing to print components for the indigenously developed Hindustan Turbofan Engine-25.[60] Similarly, Gas Turbine Research Establishment, a Defense Research and Development Organization laboratory is

56. Section 2(f) of the Drugs and Cosmetics Act 1940.

57. *'EDA 3D-printing report and final video now available'*, available at https://eda.europa.eu/info-hub/press-centre/latest-news/2018/07/12/eda-3d-printing-report-and-final-video-now-available

58. *'3D Opportunity in the Department of Defense: Additive Manufacturing Fires Up'*, available at https://www2.deloitte.com/content/dam/insights/us/articles/additive-manufacturing-defense-3d-printing/DUP_1064-3D-Opportunity-DoD_MASTER1.pdf

59. Lt. Gen. Prakash Katoch, *'Military Applications of 3D Printing: Where are We?'* http://www.indiandefencereview.com/news/military-applications-of-3d-printing-where-are-we/

60. Prakash Paneerselvam, *'Additive Manufacturing in Aerospace and Defence Sector: Strategy of India'*, available at https://idsa.in/system/files/jds/jds-12-1-2018-additive-manufacturing.pdf

using 3D printing to build prototype engines for India's aircraft program.[61]

The reason countries are turning to 3D printing technology for their defense systems is because 3D printing can revolutionize weapons manufacturing by cutting down maintenance costs of weapons systems. Maintenance of complex weapons systems often require high levels of customization, and production of parts in remote locations in low volumes on tight deadlines.[62] Armies also need to anticipate demand for such spare parts and an inaccurate estimation can lead to excess inventory and waste.

> 3D printing allows for a high level of customization while simultaneously cutting down on manufacturing costs and inventory waste as parts can be manufactured on site based on real-time demand.

In the defense sector, 3D printing can bring about high levels of efficiencies with minimum risk of abuse as long as the CAD files are kept confidential. Even if CAD schematics of parts are leaked, the average citizen is unlikely to 3D print airplane engines or spare parts for nuclear submarines.

However, while spare parts of weapons systems are of no interest to the average citizen, the schematics of 3D printable guns might be useful to many. In May 2013, Defense Distributed, an open source firm, designed and uploaded the schematics for 'Liberator' a 3D printable single shot handgun which was downloaded over a 100,000 times before the United States Department of State demanded that it be taken down.[63] The assembled guns are made entirely of plastic except for a nail to serve as a firing pin and a six ounce piece of steel whose sole purpose is to make the gun detectable to metal scanners, which is a requirement under US law.[64] The liberator is essentially a 'ghost gun' in that if the metal parts are removed, it can pass undetected through airport security and because it has no serial number it is untraceable. While currently, most people cannot afford to purchase a 3D printer sophisticated enough to print the gun, this may not be the case once the technology becomes more affordable.

Since the incident with Defense Distributed, the State Department of the United States has come to a settlement allowing Cody Wilson, the ex-head of Defense Distributed, to publish the schematics of the gun online but hours before the blueprints were to be published, a Federal judge blocked the publication.[65] The threat of CAD files containing schematics 3D printed guns has been allayed for a while. However, it may not be long before such files are as easily available on the internet as pirated music is.

The manufacture, possession and sale of arms and ammunition is tightly regulated in India. Arms and ammunition can only be manufactured under a valid license issued by the Department for Promotion of Industry and Internal Trade under the Industries (Development and Regulation) Act, 1951.[66]

The sale of firearms is also strictly regulated under the Arms Act 1959 along with the Arms Rules 2016 (**"Arms Laws"**). No person can possess or sell arms without licenses from the Central Government[67] and it is completely

61. Prakash Paneerselvam, '*Additive Manufacturing in Aerospace and Defence Sector: Strategy of India*', available at https://idsa.in/system/files/jds/jds-12-1-2018-additive-manufacturing.pdf

62. '*3D Opportunity in the Department of Defense: Additive Manufacturing Fires Up*', available at https://www2.deloitte.com/content/dam/insights/us/articles/additive-manufacturing-defense-3d-printing/DUP_1064-3D-Opportunity-DoD_MASTER1.pdf

63. Andy Greenberg, '*3D-Printed Gun's Blueprints Downloaded 100,000 Times In Two Days (With Some Help From Kim Dotcom)*', available at https://www.forbes.com/sites/andygreenberg/2013/05/08/3d-printed-guns-blueprints-downloaded-100000-times-in-two-days-with-some-help-from-kim-dotcom/#3be57cb710b8.

64. Marrian Zhou, '*3D-printed gun controversy: Everything you need to know*', available at https://www.cnet.com/news/the-3d-printed-gun-controversy-everything-you-need-to-know/

65. German Lopez, '*Federal court blocks release of 3D-printed gun blueprints*', available at https://www.vox.com/2018/8/1/17638872/3d-printed-guns-court-restraining-order.

66. Serial No. 37 Schedule I Industries (Development and Regulation) Act, 1951.

67. Section 3 of the Arms Act, 1959.

forbidden for individuals to carry automatic weapons.[68] Certain classes of persons such as ex-military officers, persons of the Coorg race and members of recognized Rifle Associations are exempt from the Arms Laws.[69] In other cases, a license will only be granted if the applicant can show a genuine reason to possess a firearm such as personal protection, security, target shooting or crop protection and the process to obtain a license can take months if not years.[70]

Despite strict gun control laws, arms trafficking continues to take place in India. In 2014, 55,453 arms were seized under the Arms Laws.[71] Out of these 32,319 arms were unlicensed, improvised, crude or country arms. 3D printing technology may exacerbate arms trafficking. The biggest threat posed by 3D printed guns is that they are untraceable due to the easy movement of CAD files. 3D printed guns need not contain any metal and therefore cannot be detected by metal detectors. Additionally, they do not contain an identification number linked to the owner of the gun and therefore are 'ghost guns'.

> One effective way to prevent illegal proliferation of guns is to prevent individuals from uploading CAD files of 3D printable guns in the first place.

For instance, the Community Standards of Facebook prohibit users from uploading schematics of guns that can be 3D printed. Websites will need to develop sophisticated systems to recognize uploads containing CAD files for 3D printable guns without requiring human involvement.

68. Section 14 of the Arms Act, 1959.

69. Exemptions and Withdrawals from the Arms Act, 1959, available at https://mha.gov.in/sites/default/files/NotifiExemptions_030913_0.pdf.

70. *'India — Gun Facts, Figures and the Law'*, available at https://www.gunpolicy.org/firearms/region/india.

71. National Crime Records Bureau, available at http://www.ncrb.gov.in/StatPublications/CII/CII2014/Table%2024.1.pdf.

IV. Liability in 3D Printed Articles

A. Civil Liability

With 3D printing technology, the consumer is the manufacturer. The raw materials used by the consumer are the CAD file and the "ink", while the 3D printer is the device used for manufacturing the desired product. Given that traditional legal definitions do not take into account the paradigm of 3D printing, it is unclear who will be liable in case the 3D printed product is defective. Liability can be entirely on the part of the maker of the CAD file, the maker of the 3D printer, the manufacturer of the "ink" used or the consumers themselves. The liability can also be apportioned between either or all of the above parties depending on the facts and circumstances of the case. So far, Indian courts, to our knowledge, have not had the opportunity to lay down principles for apportionment of liability in case of a 3D printed product. Broadly speaking, product liability in India is governed through the following legislations: (a) Indian Contract Act, 1872, which will be applied based on the parties' contractual relationship; (b) Consumer Protection Act 1986 **("CPA")** to be replaced soon with the Consumer Protection Act, 2019 **("CPA 2019")**; (c) Sale of Goods Act 1930; (d) law of torts; and, (e) special statutes relating to specific goods e.g. food, pharmaceuticals etc. Issues under the Consumer Protection Acts are discussed below.

i. Consumer Protection Act, 1986

In the 3D printing context, the CPA 1986 recognizes two primary grounds for liability viz., defects in goods and unfair trade practices. A defect is a *"fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard"* required under law, contract, or representation by a trader.[72] 'Unfair trade practice' means, broadly speaking, an unfair or deceptive practice (of which there are illustrations in the CPA) used for promoting the good. The CPA

72. Section 2(1)(f) of the Consumer Protection Act, 1986.

contemplates that the "trader" of a good shall be liable for defects in the quality of goods.[73] A trader can include any entity along the supply chain including the manufacturer, seller or distributor of the goods.[74] A "manufacturer" under the Act is any person who manufactures the good or any part of the good or assembles the parts manufactured by others.[75] It also includes any entity that puts their own mark on a good manufactured by others.[76]

To the extent that 3D printing is used as another method for manufacturing products, product liability laws will apply the way they currently do. However, the allocation of liability becomes complex when the consumer prints the good. The person printing the goods is likely to be included in the definition of "manufacturer" as defined in the CPA; therefore, it is possible that in the instance the object printed is defective, and the consumer does not have a remedy against the 'manufacturer' under the CPA since the consumer is herself the manufacturer. Therefore, it will become necessary to examine whether the consumer has recourse against the seller/ developer of the CAD file, manufacturer of the material used to print the product i.e. the "printer ink", and/or manufacturer of the 3D printer.

In the context of CAD files or CAD software, it may also be necessary to analyze whether there is a 'deficiency' of 'service' and not just a 'defect' in the 'goods'.

It must be noted that standards prescribed by the CPA are in addition to existing contractual agreements. Therefore, license and sale agreements with respect to CAD files, 3DPs, and 3DP material will become relevant as well.

ii. Consumer Protection Act, 2019

The CPA 2019, unlike its predecessor, contains specific provisions to apportion liability in product liability claims. However, the CPA 2019 was not yet brought into force as of March 2020 (making the CPA the applicable law). Under the CPA 2019, the consumer may bring a product liability action against the manufacturer, product service provider or a product seller.

In the case of 3D printing, two pre-manufactured components are the 3DP and the substance used for printing. Additionally, there is also the software component i.e. the maker and seller of the CAD file.

The consumer under CPA 2019 is arguably in a more advantageous position compared to the CPA due to the clarity introduced for product liability.

It may be noted, however, that one of the exceptions to product liability that is if the product in question was intended to be used as a component or material in another product (such as the 'ink' in the 3DP) and the necessary warnings or instructions were given by the product manufacturer to this effect, then the product manufacturer would not be held liable if the harm was caused by use of the end product.

B. Criminal liability

3D printing, if used improperly, may fall foul of various provisions under the Indian Penal Code 1860 (**"IPC"**). Some of the most pertinent provisions are outlined hereafter.

However, a general principle that runs through the IPC is the concept of *mens* rea or 'criminal intent'. Therefore, manufacturers and distributors of 3DPs, and authors and sellers of CAD files, should ensure that their intent that the machines and files not be used for criminal purposes is clearly communicated.

i. Counterfeiting currency and stamps

3D printing may lead to a greater threat of counterfeiting and can be used to create and circulate fake currency. As the technology advances, it may be increasingly difficult to distinguish between counterfeit and genuine

73. Section 2(1)(c) of the Consumer Protection Act, 1986.
74. Section 2(1)(q) of the Consumer Protection Act, 1986.
75. Section 2(1)(j) of the Consumer Protection Act, 1986.
76. Section 2(1)(j) of the Consumer Protection Act, 1986.

currency. The IPC criminalizes various conduct relating to counterfeit currency (bank notes and coins) and government stamps.[77]

> A person is defined to carry on 'counterfeiting' if she *"causes one thing to resemble another thing, intending by means of that resemblance to practice deception, or knowing it to be likely that deception will thereby be practiced".*[78]

The IPC also criminalizes making, buying, mending, selling, or disposing of instruments used or intended to be used for counterfeiting

ii. Offences relating to documents and to property marks

3D printing can aid the making of a seal, plate or other instrument for the purposes of committing forgery of property marks, valuable security, wills or other documents which is criminalized under the IPC.[79]

iii. Cheating

3D printing can also make it easier for people to falsely represent 3D-printed goods as something they are not and in doing so deceive someone else in a manner causing them harm.

> *The IPC defines 'cheating' as "any act of deception that fraudulently or dishonestly induces the deceived person to deliver any property or acquires their consent to retain property, or intentionally induces a person to act or refrain from acting in a certain way, which causes damage or harm to that person in body, mind, reputation or property."*

77. Sections 230-263A, 489A-489E of the Indian Penal Code, 1860.
78. Section 28 of the Indian Penal Code, 1860.
79. Chapter XVII, Sections 467 and 472 of the Indian Penal Code, 1860.

5. Tax Implications of 3D Printing

3D printing technology will fundamentally challenge existing tax regimes. It is expected to drastically alter the configuration of the supply chain, especially for manufacturing-based industries, by shifting the site of value-creation closer to the customer. This will create implications for value-based taxes, such as Value Added Taxes (**"VAT"**), and in India the Goods and Services Tax (**"GST"**). It will also require multinationals to re-think their group transfer pricing policies and profit allocations.

> *One of the gating tax considerations for 3D printing will be the treatment of IP in various business models, as the IP in the CAD file is likely to be the most valuable asset for businesses engaging in 3D printing.*

This will raise issues related to taxation of licensing and sale of IP, which are already widely debated in a pre-3D printing world. Further, ownership of equipment, such as a 3D printer, physically located in a different country could potentially create a Permanent Establishment (**"PE"**) of the owner in that country, and profits derived by the owner from use of the printer could be liable to tax in that country.

The actual tax implications of 3D printing will be driven by the specific commercial model in which the 3D printing technology is utilized. Discussed below are broad tax issues that need to be kept in mind by a business engaging in 3D printing:

I. Direct Taxes

Taxation of income in India is governed by the Income Tax Act, 1961 (**"ITA"**), as amended annually by the Finance Acts. Under the ITA, tax residents of India are subject to tax in India on their worldwide income, whereas non-residents are taxed only on their Indian-sourced income i.e. income that accrues or arises in India, is deemed to accrue or arise in India, or which is received or is deemed to be received in India.[80] Residence under the ITA is determined on a year to year basis. A company is said to be resident[81] in India if it is incorporated in India, or its place of effective management (**"POEM"**) during the year is located in India.[82]

Section 9 of the ITA deems certain income of non-residents to be Indian-sourced income. Under section 9(1), "capital gains" are considered to have their source in India and are taxable in India if they arise directly or indirectly, through the transfer of a capital asset situated in India. The rate at which such capital gains are taxed depends on the type of asset involved, the period for which it has been held prior to its transfer, and the nature of the taxpayer. The "business income" of a non-resident is taxable in India only if it accrues or arises, directly or indirectly, through or from any business connection (**"BC"**) in India. 'Business connection' is defined inclusively under the ITA and has been interpreted expansively by Indian courts. In case a foreign company has a BC in India under the ITA, its business profits are taxable in India at 40%[83] on the net profits, unless the income qualifies for specific rates such as royalties or fees for technical services (**"FTS"**) which are taxable at 10% on the gross amount received.[84]

Section 90(2) is a beneficial provision which states that where the taxpayer is situated in a country with which India has a double tax avoidance agreement (**"DTAA"**), the provisions of the DTAA apply to the extent they are more beneficial to the taxpayer compared to the

80. Section 5(2), of the Income Tax Act, 1961.

81. Section 6(3), of the Income Tax Act, 1961.

82. POEM has been defined to mean a place where key management and commercial decisions that are necessary for the conduct of business of an entity as a whole are, in substance made.

83. All tax rates indicated herein are exclusive of applicable surcharge and cess under the ITA.

84. Section 115A of the Income Tax Act, 1961.

ITA. In particular, PE is defined narrowly under DTAAs compared to the definition of BC under the ITA. Consequently, business income of a non-resident that can avail of a DTAA would be taxed in India only if the non-resident has a PE in India (based on the narrower definition), as opposed to treatment under the ITA which taxes such business income where the non-resident has a BC in India (the creation of which is more likely due to the wide definition and interpretation of the term). With the recent entry into force of the General Anti Avoidance Rule under the ITA from April 1, 2017, and of the Multilateral Instrument from October 1, 2019, an additional qualification to availing of tax benefits has been added from a substance and anti-tax-avoidance point of view.

Taxation of income of non-residents in the 3D printing business raises two primary issues for consideration: (a) Characterization of income, i.e., whether income earned from use or sale of a CAD file is royalty or business income or capital gains, and whether fees from providing 3D printing as a service are 'fees for technical services'; and (b) Classification as a PE, i.e., a non-resident taxpayer may have a taxable presence in India resulting in Indian tax liabilities due to the presence of a fixed place of business in India such as 3D printers / storage space for printer ink, etc.

A. Characterization of income

The characterization of income becomes important due to differences in the way different types of income are taxed. As mentioned, the business income of a non-resident is taxed in India on net basis[85] at a rate up to 40% and only in case of existence of a PE / BC of the non-resident. However, certain streams of payment are taxed at 10% of the gross amount under the ITA (such as royalty, FTS etc.) when there is no PE / BC. This can impact companies' cost of doing business in India. Further, where the characterization of income is not in line with international practice, a potential risk of double taxation can arise (due to non-availability of credit in the residence country of taxes paid in India).

85. After netting off allowable deductions.

i. Sale of CAD File

As mentioned in Section II on Business Models, the primary asset for a business that adopts 3D printing technology would be the CAD file, and its monetization would lie in its sale or license. The question of characterization of proceeds from the sale brings up the debate on taxation of copyright versus copyrighted article. At the core of the debate is the question whether payments for purchase of a CAD file amount to purchase of the copyright in the file, making the payments taxable as royalty; or is simply the purchase of a good (tangible or intangible) making the payments taxable as business income. Indian courts have expressed divergent views.

In the context of applicability of sales tax, the Supreme Court had held that copyright in a computer programme remains with the originator of the programme, but the moment copies are made and marketed, they become 'goods' qualifying for sales tax.[86] Although this decision was rendered in the context of the sales tax law of the state of Andhra Pradesh, it has been relied on in income tax cases such as *DIT v. Ericsson A.B.*[87] *and Motorola Inc. v. DCIT*[88] to uphold the distinction between 'copyright' and 'copyrighted article' as articulated by the Supreme Court and to deny characterization of the payment as royalty where a copyrighted article is being purchased. This distinction is supported by the approach of the OECD[89] where the character of payments received in transactions involving the transfer of software depends on the nature of the rights that the transferee acquires under the particular arrangement regarding the use and exploitation of the program.

The determination under the ITA, however, as to whether certain income is royalty, is complicated as the definition of 'royalty'

86. Tata Consultancy Services v. State of AP [2004] 271 ITR 401 (SC).

87. [2012] 343 ITR 470 (Delhi).

88. [2005] 147 Taxman 39 (Delhi) (SB).

89. Organization for Economic Co-operation and Development.

under the ITA[90] is wider than internationally prevalent definitions. Royalty under the ITA includes consideration for license of computer software where no transfer of underlying IP is involved, payments for access to or use of scientific or technical equipment even if no control or possession over the equipment is transferred, even payment of royalty between two non-residents can be taxed as royalty sourced in India if the acquirer uses the information for carrying out a business or profession in India. Due to this wide definition, Indian courts have often held the payment for copyrighted articles to be taxable as royalty.

To the contrary, definitions of 'royalty' under DTAAs are relatively narrower. Hence, non-residents that are tax residents of jurisdictions with which Indian has a DTAA, can claim the favourable treaty position where available to argue that the sale proceeds of CAD files do not qualify as 'royalty' under the applicable DTAA and is business income, which in turn is not taxable in India if the non-resident does not have a PE / BC in India.

Based on principles developed by case law, the current position of the law may be summarized as below:

- Where the ITA applies or the non-resident is from a non-treaty jurisdiction, the Indian payer is likely to be under an obligation to withhold tax on payments for purchase of the CAD file from a non-resident, as if such payments are royalty. This is due to the wide definition of royalty coupled with the narrow exceptions to it in the ITA. A large body of case law rejecting the distinction between copyrighted article and copyright restricts the scope to establish that the payment is not in the nature of royalty;
- Where the definition of royalty in a DTAA is narrow, there may be scope for the taxpayer to pursue the argument based on 'copyrighted article'. However, judicial decisions are split, and the law is unsettled on this issue.

ii. Licensing of a CAD File

Payment for license of a CAD file is likely to be regarded as royalty under the ITA. It would fall under the very first specification in the definition of royalty under the ITA: *"transfer of all or any rights (including the granting of a licence) in respect of a patent, invention, model, design, secret formula or process or trade mark or similar property."* The payment is also likely to qualify as royalty under the applicable DTAA, although the determination would need to be made based on the terms of the applicable DTAA.

iii. 3D Printing as a Service

3D printing could be provided as a service, either as a production center to streamline logistics or as a standalone service for consumers without 3D printing capabilities. Both models, production center and provision of 3D printing services to customers, have been explained in Section II on Business Models.

Service fee earned for providing 3D printing as a service could be taxed as FTS in India (at 10% on the gross amount), if it qualifies the definition. The phrase 'fees for technical services' is defined in the ITA as:[91]

90. Section 9(1)(vi), Explanation 2, of the ITA – *"For the purposes of this clause, "royalty" means consideration (including any lump sum consideration but excluding any consideration which would be the income of the recipient chargeable under the head "Capital gains") for—*
(i) the transfer of all or any rights (including the granting of a licence) in respect of a patent, invention, model, design, secret formula or process or trade mark or similar property;
(ii) the imparting of any information concerning the working of, or the use of, a patent, invention, model, design, secret formula or process or trade mark or similar property;
(iii) the use of any patent, invention, model, design, secret formula or process or trade mark or similar property;
(iv) the imparting of any information concerning technical, industrial, commercial or scientific knowledge, experience or skill;
(iva) the use or right to use any industrial, commercial or scientific equipment but not including the amounts referred to in section 44BB;
(v) the transfer of all or any rights (including the granting of a licence) in respect of any copyright, literary, artistic or scientific work including films or video tapes for use in connection with television or tapes for use in connection with radio broadcasting, but not including consideration for the sale, distribution or exhibition of cinematographic films; or
(vi) the rendering of any services in connection with the activities referred to in sub-clauses (i) to (iv), (iva) and (v)."

91. Section 9(1)(vii), Explanation 2, of the Income Tax Act, 1961.

> *"any consideration (including any lump sum consideration) for the rendering of any managerial, technical or consultancy services (including the provision of services of technical or other personnel) but does not include consideration for any construction, assembly, mining or like project undertaken by the recipient or consideration which would be income of the recipient chargeable under the head "Salaries"."*

The phrase and the definition have been subject to a lot of judicial interpretation, and Indian courts and tribunals have put forth the following principles:

- **The phrase 'fees for technical services' envisages human intervention:** Courts have held that the import of the word 'technical' in the statutory definition is unclear. Since it is preceded by 'managerial' and succeeded by 'consultancy', the rule of *noscitur a sociis* requires that the meaning of 'technical' takes colour from the other two words. Dictionary meanings of 'managerial' and 'consultancy' indicate the involvement of a human element, since both types of services are rendered by humans. 'Technical' should also be construed as involving a human element or a human interface; and would not include services provided by machines or robots.[92]
- **Technology or technical knowledge should be made available to others:** Tribunal decisions have held that 'fees for technical services' envisage a situation where the technology or technical knowledge involved is made available to the service recipient; and not simply where using a technical system, a service is rendered to others.[93]
- **Mere use of technology does not make service 'technical':** The Mumbai Tribunal has held that where no specific skill is required to provide services, they could not be 'managerial, technical or consultancy' services simply because services involved use of technology.[94]
- **Payments for using standard facilities are not included:** High Courts have observed that the definition contemplates the provision of specified services to a payer for a fee, and not mere collection of fees for using a standard facility that all who are willing to pay the fees can use.[95]

The withholding tax on FTS earned by a non-resident is 10% under the ITA. These rates are subject to available relief under an applicable DTAA. While many DTAAs entered by India define FTS (or fees for included services) in a manner similar to the definition under the ITA, some DTAAs depart from this pattern and hence the provisions of the specific DTAA will be important to analyze in a given set of facts.

Based on the current position of law on FTS, 3D printing services could be regarded as FTS where the service includes customization based on the specific requirements of the customer (as this would involve a human element of designing the CAD file). It is unlikely to be regarded as FTS where a customer simply places an order for creating a print of a standard design or object, in which case such income would be characterized as business income.

92. *CIT v. Bharati Cellular Ltd.* [2008] 175 Taxman 573 (Delhi) – Supreme Court upheld the observation in appeal but reversed finding on facts in *CIT v. Bharti Cellular Ltd.* [2011] 330 ITR 239 (SC) [High Court observation also followed by the Supreme Court in *GVK Industries Ltd. v. ITO* [2015] 371 ITR 453 (SC) and in *CIT v. Kotak Securities Ltd.* [2016] 383 ITR 1 (SC)]; *CIT v. Chief Manager, State Bank of India* [2012] 21 taxmann.com 506 (Punj. & Har.)

93. *ITO (TDS) v. Hindustan Zinc Ltd.* [2013] 40 taxmann.com 42 (Jodh. - Trib.); *DCIT v. Parasrampuria Synthetics Ltd.* [2008] 20 SOT 248 (Delhi - Trib.); *Jaipur Vidyut Vitran Nigam Ltd. v. DCIT* [2009] 123 TTJ 888 (Jp. - Trib.)

94. *ITO v. Fino Fintech Foundation* [2016] 159 ITD 743 (Mum.-Trib.)

95. *Skycell Communications Ltd. v. DCIT* [2001] 251 ITR 53, *PCIT v. Madhyanchal Vidyut Vitran Nigam Ltd.* [2017] 293 CTR (All.)

B. Potential Permanent Establishment Issues

Historically, the concept of PEs has been based on the physical nexus of the business of a non-resident with the source state. However, with the growth of the digital economy and consequent shift in business models from brick and mortar establishments to virtual setups, physical nexus is no longer seen as a sufficient criterion by most governments to establish taxable nexus.

Countries like India with consumer-centric economies have been trying to expand the scope of PEs to include virtual PEs. While many measures are introduced under domestic laws, concerted international effort is also under way to reform the way taxable nexus is understood under international tax law, led by the OECD's Base Erosion and Profit Shifting (**"BEPS"**) initiative. Action 1 of the BEPS Action Plan seeks to address issues plaguing taxation of the digital economy. Many suggestions made under Action 1 have already been adopted in many countries through unilateral domestic legislation. In India, this has included measures such as the introduction of Significant Economic Presence[96] of a non-resident in India forming a Business Connection – which is a nexus criterion based on the number of transactions or users in India. Recently, the OECD has proposed a unified approach to taxing the digital economy to provide a direction to countries in terms of suggested measures to curb divergent and aggressive unilateral measures.[97] The proposal is pending finalization, and in any case, it currently leaves open several questions for further research and debate, and thus is expected to take some time before certainty is achieved on this count internationally. Even after an approach is identified, DTAAs between countries will need to be revised to incorporate the new standard.

i. Virtual PE under Indian law

Indian jurisprudence on PEs has already developed precedent on virtual PEs based on existing DTAA provisions, at times digressing from traditional PE principles. In one such line of decisions, Indian courts have opined on servers or equipment constituting PEs of non-residents in India.

The Kolkata Tribunal has held that a website or search engine would not by itself constitute a PE of the non-resident in India, if the server it is hosted on is not physically located in India.[98] In a separate line of cases concerning travel reservation companies, the Delhi Tribunal concluded on the existence of a PE in India through several physical factors such as computers provided by the non-resident taxpayer to travel agents in India to incentivise subscription to the company's system and to facilitate the booking process.[99] In a recent decision, the Authority for Advance Rulings (**"AAR"**) held that an interface processor placed at the customer's location to facilitate payment authorizations and settlements, although owned by the non-resident's subsidiary in India, led to the constitution of a PE of the non-resident in India. This was based on the conclusion that the functions carried out by the processor were core functions of the non-resident, and all risk mitigation functions in relation to the processors were performed by the non-resident and all decisions with respect to processors were taken by it.[100]

In this context, PE risks for 3D printing businesses need to be evaluated, based on the type of business model adopted. Where a non-resident has a 3D printing facility in India for consumers to print the product, the facility could constitute a PE. This could involve a physical space in India at the disposal of the non-resident where 3D printing is undertaken or could involve situations where 3D printers

96. Explanation 2A of the Income Tax Act, 1961.

97. *'Secretariat Proposal for a "Unified Approach" under Pillar One'*, available at https://www.oecd.org/tax/beps/public-consultation-document-secretariat-proposal-unified-approach-pillar-one.pdf.

98. *ITO v. Right Florists (P.) Ltd. [2013] 25 ITR(T) 639 (Kolkata - Trib.)*

99. *Amadeus Global Travel Distribution SA v. DCIT (2008) 113 TTJ 767 (Del); and Galileo International Inc. v. DCIT (2008) 114 TTJ 289 (Del)*

100. *In re MasterCard Asia Pacific Pte. Ltd.* [2018] 406 ITR 43 (AAR – New Delhi)

are supplied by the non-residents to users in India. A place for storing printing equipment or printer ink / material at the disposal of the non-resident can also create a PE risk, based on the terms of the specific DTAA involved.

II. Indirect Taxes

Prior to July 1, 2017, a series of central and state taxes were levied at various stages of the supply chain. These included taxes such as central excise duty on manufacture, central sales tax on inter-state sale, sales tax / value added tax on intra-state sale, and service tax on the provision of services. Moreover, credit for input taxes paid was not uniformly available across central and state levies, thereby leading to a cascading effect of taxes.

With the introduction of the GST, India now has a unified indirect tax system. The GST has subsumed and broadly replaced the following taxes:

Central Indirect Taxes	State Indirect Taxes
▪ Central Excise Duty ▪ Additional Excise Duty ▪ Additional Customs Duty (CVD) ▪ Excise Duty levied under the Medicinal and Toilet Preparations (Excise Duties) Act, 1955 ▪ Special Additional Duty of Customs ▪ Service Tax ▪ Central Surcharges and Cesses so far as they relate to the supply of goods and services	▪ State VAT / Sales Tax ▪ Entertainment and Amusement Tax (except when levied by local bodies) ▪ Central Sales Tax (levied by Centre and collected by State) ▪ Luxury Tax ▪ Octroi and Entry Tax ▪ Purchase Tax ▪ Taxes on lottery, betting and gambling ▪ Taxes on advertisement ▪ State surcharges and Cesses so far as they relate to the supply of goods and services

Any 3D printing product, including but not limited to 3D printers, printer ink, other equipment or raw material, passing through the supply chain either domestically or across Indian borders is likely to be subject to GST and/or customs duty, at the rate applicable to the particular product description. Since the GST also applies to supply of services, provision of 3D printing as a service is also likely to incur GST.

A. Goods and Services Tax

The GST regime is comprised of three major statutes: the Central Goods and Services Tax Act, 2017 (**"CGST Act"**) which provides for the taxing powers of the Central Government; individual State / Union Territory Goods and Services Tax Acts (**"SGST Act"** and **"UTGST Act"**, respectively) which provide for the taxing powers of each State / Union Territory; and the Integrated Goods and Services Tax Act, 2017 (**"IGST Act"**) which grants exclusive rights to the Centre to tax inter-state commerce.

Under the GST regime the "supply" of goods, or services, or both, is treated as the taxable event, with different taxes applying to inter-state supply and intra-state supply. Every inter-state supply of goods or services is liable to IGST under the IGST Act, while every intra-state supply of goods or services is liable to both CGST under the CGST Act, and SGST / UTGST under the applicable SGST Act / UTGST Act. Supply is treated as either inter-state, or intrastate, depending on the location of the supplier, and the "place of supply" determined in accordance with the provisions of the IGST Act.

GST is levied at the following rates: Nil, 5%, 12%, 18% and 28% depending on the rate schedule applicable to the supply in question. Most goods and services are taxed at 18%. To prevent the

cascading effect of taxes, a uniform input tax credit system is available in respect of input supplies of goods or services used or intended to be used in the provision of output supplies of goods or services or both. GST is a consumption tax and is typically passed on to the consumer of the good / service as part of the price.

As a general rule, the import of goods or services or both into India qualifies as a taxable interstate supply chargeable to IGST, while the export of goods or services or both from India is treated as a zero-rated supply not chargeable to tax under the GST regime.

With the introduction of the GST in India, the scope of VAT (i.e. imposed by a State) and CENVAT (imposed by the Central government) has been significantly curtailed. From July 1, 2017, VAT and CENVAT may be levied only on petroleum crude, high speed diesel, motor spirit (commonly known as petrol), natural gas, aviation turbine fuel and alcoholic liquor for human consumption.

B. Customs Duty

Customs duty is a Central Government duty levied on goods that are imported into India and exported from India. The Customs Act, 1962 provides for the levy and collection of duty on imports and exports, import / export procedures, prohibitions on importation and exportation of goods, penalties, offences, etc. The rates at which customs duty is levied are specified in the Customs Tariff Act, 1975.

While export duties are levied occasionally to mop up excess profitability in international prices of goods in respect of which domestic prices may be low at the given time, levy of import duties is quite wide. Prior to the introduction of GST in India, import duties were generally categorized into basic customs duty, additional customs duties, countervailing duty, safeguard duty and anti-dumping duty. With the introduction of GST, the customs framework has been significantly revamped. Import of goods is now subject to IGST at the rate prescribed for inter-state supply of the goods concerned, in addition to basic customs duty, while most other duties have been abolished, or significantly curtailed. While the standard rate of customs duty for import of goods is 28.84% (including IGST and education cess), the actual rate may vary according to the product description.

6. Ethical Issues in 3D Printing

As with all disruptive technology, 3D printing raises ethical concerns, particularly on models relating to bioprinting.

3D printed organs can be programed to be more advanced than normal human organs, thereby making human enhancement a realistic possibility. The ethical concerns in this regard are much like gene editing. Asymmetrical access to the benefits of bio-printed organs and medicines can exacerbate the divide between the rich and the poor. Assuming all human enhancement through bio-printing is permitted, the rich can manipulate their organs to live longer and healthier lives than their fellow citizens.

I. 3D Printed Organs

Over half a million people die in India every year due to paucity of a replacement organ.[101] 3D printed organs can possibly eliminate the need to source organs from live and deceased donors. It is particularly difficult for patients to find a match and then to harvest, store and transport organs so that they remain viable throughout the transplantation process. Referred to as bio-printing, customized 3D printed organs can be created for patients saving thousands of lives every year. In India, the Transplantation of Human Organs Act 1994 (**"THOA"**) governs the retrieval, storage and transplantation process for organs. It is highly regulated and seeks to ensure that donors make fully informed decisions about donating organs as well as to prevent commercial trade in organs. Many countries have provisions in place that prevent organ trading.

> "Sale of 3D printed organs is technically trade in human organs. However, the ethical reasons that countries rely on to prohibit organ trade in status quo do not apply to 3D printed organs."

Therefore, it may be likely that in future 3D printed organs will be regulated much like blood and plasma is regulated currently.

> "The ethical issues in bioprinting, however, arise when we consider whether bio-printed organs may be a way for humans to circumvent the restrictions on germ-line gene editing and 'print' better and more functional organs for themselves. Concentration of this technology in the hands of the few can also lead to an increasing divide between the rich and poor."

Where the persons who can afford this technology are able to live for a century or more while others must remain content with shorter lifespans.

II. New Dimensions to Piracy

3D printing literally gives a 3rd dimension to piracy! The debates that have been ranging in academic circles thus far on the moral basis for IPR in context of pharmaceutical products, movies, books and music will spill over into all sectors. This is particularly true for works that are protected by way of copyright. Just the way online piracy helped increase access to copyrighted works such as books, music and movies, 3DPs can increase access to material things. Due to the increase in access to the internet in the 1990s (and to a certain extent due to piracy) many people were able to access educational material they would not have had access to otherwise. This could be true for 3D printed objects in the future. Due the simplicity

101. Aastha Ahuja, *'Lack Of Organ Donation In India: Here Is Why Half A Million People Die Annually In India Due To Unavailability Of Organs'*, available at https://sites.ndtv.com/moretogive/lack-organ-donation-india-half-million-people-die-annually-india-due-unavailability-organs-2107/.

of printing out items protected by IP, 3D printing could increase access to everyday items for everyone no matter where they are located. On the flipside, this would require IP holders to come up with innovative business models to protect their interest.

III. The limits to 3D printing

The allure of 3D printing is that it is able to decentralize manufacturing at the consumer level. Additionally, as the technology progresses, most items should be capable of being 3D printed provided consumers are willing to assemble these items. Given this, in the event 3DPs become more common, it would completely change existing production models across industry requiring countries to possibly reorganize their entire economy to accommodate this change in production means. In some cases, we may even witness large scale lay-offs of employees engaged in the fast-moving consumer goods section. The implications of encouraging 3D printing technology will give rise to long battled issues of labor versus technology and the steps that should be taken to ensure that everyone benefits from the 3D printing revolution.

7. Conclusion

3D printing has vastly different effects on different industries. 3D printing technology is expected to have an overwhelmingly positive impact on the pharmaceutical and food industry in the future while potentially presenting new challenges to IP rights due to ease of dissemination of CAD files and 3DPs.

Nonetheless, 3D printing technology is still in its nascent stage as 3DPs are currently not affordable for regular households. However, as technology improves and the cost of 3DPs decreases, we may expect most 3DPs to be as accessible as personal computers are today. In remote or low-income areas, 3DPs may be available in libraries and internet cafés the way photocopy machines are present today. 3D printing has the most impact in remote areas where traditional transport routes such as roads and railways are not well developed. 3D printing can also help reduce waste and the associated environmental impact by reducing the use of single use plastic in packaging. 3D printing also helps in cutting down the carbon footprint of the good as the good does not need to be shipped across long distances anymore.

> Success or failure of the 3D printing model of business will depend largely on how well CAD files can be protected. 3D printing can effectively wipe out the manufacturing sector for simpler articles such as bottles and cutlery. However, for more complex objects such as phones, guns and medical equipment, 3D printing actually allows manufacturers to customize products for the benefit of their consumers.

The 3D printing sector is developing at a fast pace with new developments being made every few weeks. Already, Four-Dimensional (4D) Printing technology has begun development. In 4D printing, the 3D printed object transforms on the application of external stimuli such as temperature, light or time.[102]

Currently, there is ambiguity in India on the application of existing laws to the changes in business models that 3D printing can bring about. Despite there being some doubt about how regulators will react to the challenges brought about by 3D printing, one thing is certain; 3D printing will give the phrase 'internet of things' a whole new meaning.

102. '*4D Printing: A technology coming from the future*', available at https://www.sculpteo.com/blog/2017/10/25/4d-printing-a-technology-coming-from-the-future/.

The following research papers and much more are available on our Knowledge Site: www.nishithdesai.com

Private Equity and Private Debt Investments in India

May 2019

International Commercial Arbitration: Law and Recent Developments in India

May 2019

Are we ready for Designer Babies?

June 2019

India Opens Skies for Drones

August 2019

Digital Health in India

November 2019

Impact Investing Simplified

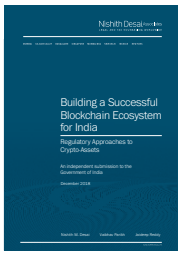
July 2019

IP Centric Deals: Key legal, tax and structuring considerations from Indian law perspective

February 2019

Fund Formation: Attracting Global Investors

February 2019



Building a Successful Blockchain Ecosystem for India

December 2018

NDA Insights

TITLE	TYPE	DATE
Delhi Tribunal: Hitachi Singapore's Liaison Office in India is a Permanent Establishment, Scope of Exclusion Under Singapore Treaty Restrictive	Tax	November 2019
CBDT issues clarification around availment of additional depreciation and MAT credit for companies availing lower rate of tax	Tax	October 2019
Bombay High Court quashes 197 order rejecting Mauritius tax treaty benefits	Tax	May 2019
Investment Arbitration & India – 2019 Year in review	Dispute	January2020
Changing landscape of confidentiality in international arbitration	Dispute	January2020
The Arbitration and Conciliation Amendment Act, 2019 – A new dawn or sinking into a morass?	Dispute	January2020
Why, how, and to what extent AI could enter the decision-making boardroom?	TMT	January2020
Privacy in India - Wheels in motion for an epic 2020	TMT	December 2019
Court orders Global Take Down of Content Uploaded from India	TMT	November 2019
Graveyard Shift in India: Employers in Bangalore / Karnataka Permitted to Engage Women Employees at Night in Factories	HR	December 2019
India's Provident Fund law: proposed amendments and new circular helps employers see light at the tunnel's end	HR	August 2019
Crèche Facility By Employers in India: Rules Notified for Bangalore	HR	August 2019
Pharma Year-End Wrap: Signs of exciting times ahead?	Pharma	December 2019
Medical Device Revamp: Regulatory Pathway or Regulatory Maze?	Pharma	November 2019
Prohibition of E-Cigarettes: End of ENDS?	Pharma	September 2019

Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparallel mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to *Intellectual Property*.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our Lab Reports dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical eco-system that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at **research@nishithdesai.com**

Nishith Desai Associates

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India

tel +91 22 6669 5000
fax +91 22 6669 5001

SILICON VALLEY

220 California Avenue, Suite 201
Palo Alto, CA 94306-1636, USA

tel +1 650 325 7100
fax +1 650 325 7300

BANGALORE

Prestige Loka, G01, 7/1 Brunton Rd
Bangalore 560 025, India

tel +91 80 6693 5000
fax +91 80 6693 5001

SINGAPORE

Level 30, Six Battery Road
Singapore 049 909

tel +65 6550 9856

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra–Kurla Complex
Mumbai 400 051, India

tel +91 22 6159 5000
fax +91 22 6159 5001

NEW DELHI

C–5, Defence Colony
New Delhi 110 024, India

tel +91 11 4906 5000
fax +91 11 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich, Germany

tel +49 89 203 006 268
fax +49 89 203 006 450

NEW YORK

1185 Avenue of the Americas,
Suite 326 New York, NY 10036, USA

tel +1 212 464 7050