3D PRINTING – AN ANALYSIS OF LIABILITIES AND POTENTIAL BENEFITS WITHIN THE INDIAN LEGAL FRAMEWORK

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The present has begun to be revolutionised with the advent of 3D printing – technologically as well as socially. We are steadily gravitating away from the two-dimensional world of printing to a world of marvel, where 3D printed drugs, food products, hardware and even biological organs are no longer things of mere imagination. However, great innovation is accompanied by equally great regulatory challenges and debate. Printing with biological and non-biological materials results in a spectrum of policy challenges when compared to traditional ink-jet printing. For instance, the ambit of the existing legal framework governing organs and tissues in India is restricted to transplantation from another human being. Further, the legal framework on medical devices and drugs do not contemplate the possibility of additively manufactured devices and drugs. Additionally, 3D printing also throws the conventional province of patent law into disarray since it does not provide any clarity on whether the infringement will be assessed based on the CAD file or the 3D printed product. Likewise, the ease with which these products are manufactured turns the chain of product manufacturing into a complex web consisting of several potential defaulters. This paper strives to highlight some of these regulatory concerns and offers a framework wherein challenges will be translated into solutions, thus, balancing regulation with innovation.

I. INTRODUCTION

According to the economist Joseph Schumpeter, industries mutate and continually shed the skin of their old economic structures to explosively usher

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in new ones.[1] Schumpeter termed this phenomenon 'creative destruction'.[2] Since then, markets have regularly faced disruptive technological innovations which threaten the old manner of functioning. The two-dimensional world of duplication is now set to encounter the next exponential technology in the form of additive manufacturing or 3D printing.[3] Invented by engineer Chuck Hull in 1986,[4] a 3D printer allows for the transformation of a computerised two-dimensional blueprint into a tangible object. The blueprint of the product, also called a Computer Aided Design ('CAD file'), is created using software which deconstructs the image into a series of two dimensional cross-sectional slices.[5] The CAD file is sent to the 3D printer that creates objects by forming layers, which is termed additive manufacturing or 3D printing.[6] Similarly, a 3D scanner has the ability to scan an object and create a CAD file.[7]

Since the 1990s, the reach of 3D printing has been expanding from a niche sector to a wider audience, marking the next technological revolution. It is now used for the creation of printed organs, prosthetics, space technology, education, patented designs, drugs, weapons along with other commonly used household objects.[8] Recognising the value of additive manufacturing, NASA conducted the first 3D printing calibration test in space on November 17, 2014.[9] There has also been a remarkable expansion in the area of bioprinting[10] using this technology.

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1 Thomas C. Leonard, *Redeemed by History: Review Essay on Thomas K. McCraw, Prophet of Innovation: Joseph Schumpeter and Creative Destruction*, 17(1) History of Economic Ideas 189 (2009), available at https://www.princeton.edu/~tleonard/papers/McCraw.pdf (Last visited on June 24, 2018).

2 Sharon Reier ('Reier'), *Half a Century Later, Economist's 'Creative Destruction' Theory Is Apt for the Internet Age : Schumpeter: The Prophet of Bust and Boom,*The New York Times, June 10, 2000, available at https://www.nytimes.com/2000/06/10/your-money/half-a-century-later-economists-creative-destruction-theory-is.html (Last visited on June 24, 2018).

3 Jasper L. Tran*, 3D-Printed Food*, 17 Minn. J. L. Sci. & Tech. 855 (2016).

4 Nicole D. Berkowtiz, *3D Printing Liability*, 92(4) Washington University L. Rev. 1037 (2015).

5 Bing Wu, Roberta L. Klatzky & George Stetten, *Visualizing 3D Objects From 2D Cross Sectional Images Displayed In-Situ Versus Ex-Situ*, (Unpublished, HHS Author Manuscript) (on file with author), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2862280/ (Last visited on June 24, 2018).

6 Atlantic Council, Thomas Campbell, Christopher Williams, Olga Ivanova & Banning Garrett, *Could 3D Printing Change the World? Technologies, Potential, and Implications of Additive Manufacturing*, Strategic Foresight Report, (October, 2011) available at http://www.atlanticcouncil.org/images/-files/publication_pdfs/403/101711_ACUS_3DPrinting.PDF (Last visited on August 6, 2018).

7 Reier, *supra* note 2.

8 Kira, *Exclusive: Winsun China Builds World's First 3D Printed Villa and Tallest 3D Printed Apartment Building*, January 15, 2015, available at http://www.3ders.org/articles/20150118-winsun-builds-world-first-3d-printed-villa-and-tallest-3d-printed-building-in-china.html (Last visited on January 31, 2017).

9 Bill Hubscher, *Open for Business: 3-D Printer Creates First Object in Space on International SpaceStation*, November 24, 2014, available at https://www.nasa.gov/content/open-for-business-3-d-printer-creates-first-object-in-space-on-international-space-station (Last visited on January 31, 2018).

10 Mathew Varkey & Anthony Atala, *Organ Bioprinting- A Closer Look at Ethics and Policies*, 5 Wake Forest J. L. & Pol'y 275, 276 (2015).

In fact, on December 3, 2016, Google Grant with IIT Bombay launched a project in the field of prosthetics, to manufacture the conventional rubber-based Jaipur Foot using 3D printing.[11] Today, 3D printing is used to cater to the global need for prosthetics especially in the developing countries, where lack of access and affordability continue to act as obstructions.

3D printing as a technology has great potential because of its ability to swiftly produce cost-effective and customised products. The potential of customisation also makes 3D printing at home the answer to complaints against mass production post the cold war era.[12] However, there are also adverse effects of additive manufacturing that legislators need to be mindful of. The extant legislations such as those which seek to prevent the unlawful use of firearms, would be rendered anachronistic in their current form as they may not be elastic enough to accommodate violations using 3D printed technology. Medical laws too do not envisage 3D printed organs, for instance, in cases of transplantations, and therefore lack rules to regulate them. As 3D printing becomes more commonplace, the failure of our laws to keep up becomes more evident. In terms of intellectual property, for instance, a study by an analyst group (Granter) suggests that companies may lose nearly USD100 billion due to the alleged IP violations by 3D printing.[13] These are merely some of the legal regimes which will need to refashion themselves, in order to usher in this technology and use it to its optimum potential.

In this paper, we present an analysis of the possible problems that 3D printing can cause. Further, we also examine the solutions to these problems while seeking to reframe certain legislations in the Indian context, in order to keep up with this technology. Part II of the paper discusses the complexities surrounding this technology in the context of India's medical laws. In the medical field, additive manufacturing has translated into bioprinting, customised prosthetics, surgical implants, and swifter transplantations. In Part III of the paper, we examine relevant provisions of laws pertaining to product liability in India, and place 3D printing in that context. In Part IV of the paper, the impact of 3D printing on the patent regime of India is examined. Part V delineates the law pertaining to intermediaries, as CAD files are circulated predominantly using internet intermediaries. India's intermediary laws therefore play a crucial role in ushering in additive manufacturing technology. In Part VI of the paper, we provide an analysis of the possible solutions to problems common to these different laws posed by additive

[11] Malathy Iyer, *Jaipur Gets a Leg-Up, 3D Printed Version Ready*, December 5, 2016, available at http://timesofindia.indiatimes.com/city/mumbai/Jaipur-foot-gets-a-leg-up-3D-printed-version-ready/articleshow/55798866.cms (Last visited on January 31, 2017).

[12] Caitlin Werrell & Francesco Femia, *The 3D Printing Revolution, Climate Change and National Security: An Opportunity for U.S. Leadership*, Center for Climate and Security, December 5, 2012, available at https://climateandsecurity.org/2012/12/05/the-3d-printing-revolution-climate-change-and-national-security-an-opportunity-for-u-s-leadership/ (Last visited on December 1, 2018).

[13] 3ders.org, *Gartner: 3D Printing to Result in $100 Billion IP Losses Per Year*, October 14, 2013, available at http://www.3ders.org/articles/20131014-gartner-3d-printing-to-result-in-100-billion-ip-losses-per-year.html (Last visited on August 6, 2018).

manufacturing. In Part VII, we conclude by emphasising the relevance of additive manufacturing in the context of developing countries, by examining the 3D4D challenge.

II. 3D PRINTING – A PANACEA?

While 3D printing affects a number of industries, its impact is particularly significant in the field of medicine. In fact, it is expected to 'revolutionise' the entire system of healthcare.[14] In 2015 it was noted that within 500 days of the introduction of 3D printing, all the hearing aids manufactured in the United States were being produced by such printers.[15] Creating hearing-aids is merely one avenue in which 3D printers may be used, as they are now being used to produce customised drugs, make implants and fixtures for direct use in operating rooms, and create organs.[16] In addition to creating these customised medical products faster, 3D printing allows for accuracy, reliability and repeated performance.[17] Further, it also allows for improved collaboration by providing access to downloadable files for replicating designs.[18] In this part, we discuss the impact of 3D printing in terms of bioprinting, printing prosthetics and fixtures, and printing drugs.

A. BIOPRINTING

Nearly 20,000 people die every year in India due to the non-availability of organs.[19] One of the root causes of this problem is the difficulty in finding the right match for organ donation. This is because the tissue often gets rejected by the host's body in the traditional organ regenerative system.[20] In this system, stem cells are first isolated, thereafter seeded onto a porous biodegradable platform and cultured using a bioreactor before implantation.[21] It becomes impossible to create complex structures using this system because of non-uniformity throughout the porous platform at the stage of seeding.[22]

This problem of tissue rejection can be eliminated by using the organ from the patient's body. This process of bioprinting involves designing of a blueprint of the cell structure of this organ followed by isolating stem cells and

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14 C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39(10) Pharmacy & Therapeutics 704 (2014), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189697/ (Last visited on June 24, 2018).

15 Richard D'Aveni, *The 3D Printing Revolution*, Harvard Business Review, May, 2015, 40, available at https://hbr.org/2015/05/the-3-d-printing-revolution (Last visited on June 24, 2018).

16 Ventola, *supra* note 14.

17 *Id*.

18 *Id*.

19 Times of India, *About Organ Donation*, available at http://timesofindia.indiatimes.com/aboutorgandonation.-cms (Last visited on January 31, 2017).

20 *Id*.

21 *Id*.

22 Ventola, *supra* note 14.

segregating them based on organ specificity.[23] These are then printed by loading cells, which form the bio-ink,[24] into the printer.[25] The cellular pattern is controlled and customised as per need using laser printers.[26]

This creates a specific tissue by adding layers of cells for organ regeneration.[27] Thus, 3D printing helps overcome the limitation of the traditional system by providing precise cell placement and freedom of fabrication through controlled speed and resolution.[28] The first instance of bio-printed cell structure was Organovo's creation of blood vessels using only primary human cells.[29] However, concerns were raised regarding the 3D printed organ market formed by Organovo because of the excessive cost incurred to produce such a market.[30] In its defense, Organovo has stated their advanced bio ink process does not require printing of all the details of an organ – they get completely formed naturally once the right cells are placed roughly in the correct place.[31] Thus, the cost of production is only incurred till the stage of placing the cells.

India also recently saw the development of its first artificial liver tissue created using 3D printing technology.[32] The artificial liver mimics a human liver both structurally and functionally.[33] Although proving to be a technological leap, there is a major problem associated with bioprinting – the non-availability of functional vasculature. A functional vasculature, i.e. an arrangement of blood vessels required to carry oxygen, nutrients and remove waste,[34] is necessary to maintain the metabolic functions of the bio-printed organs.[35] Thus, numerous biotech companies are investing in research for growing complete human organs with fabricated microvascular systems.[36]

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23 Prachi Patel, *The Path to Printed Body Parts*, 2(9) ACS Cent. Sci. 581 (2016) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5043457/# (Last visited on January 31, 2017).

24 Varkey&Atala, *supra* note 10.

25 *Id*.

26 *Id*.

27 *Id*.

28 Ventola, *supra* note 14.

29 Organovo.com, *History,* available at http://organovo.com/about/history/ (Last visited on August 6, 2018).

30 Dave Bullock, *Sir, Your Liver is Ready: Behind the Scenes of Bioprinting*, November 7, 2010, available at https://www.wired.com/2010/07/gallery-bio-printing/ (Last visited on January 31, 2017).

31 John J. Manappallil, Basic Dental Materials, 418 (2003).

32 Himanshu Goenka, *Indian Biotech Startup, Pandorum Technologies, Develops 3D-Printed Liver Tissue,* December 24, 2015, available at http://www.ibtimes.com/indian-biotech-startup-pandorum-technologies-develops-3d-printed-liver-tissue-2239183 (Last visited on January 31, 2017).

33 *Id*.

34 Varkey & Atala, *supra* note 10.

35 *Id*.

36 *Id*.

B. PRINTING PROSTHETICS AND OTHER DEVICES

Aside from organ printing, 3D printing has remoulded traditional prosthetics by negating the need for modifying implants through surgeries because of a uniform size requirement.[37] First, a 3D model is created by replicating the limb or the skull using a 3D scanner. The model, in turn, is printed into a prosthetic of the required size and fit.[38] Further, 3D printers also have the capability to print patient matched devices to cater to the unique needs of specific patients.[39] These are created based on a template model of the patient's anatomy using medical imaging. The most common method of printing medical devices is powder bed fusion, which works with a variety of material such as titanium and nylon.[40] The leading case study of Kaiba Gionfriddo who was diagnosed with a fatal disease at the age of eight months, which led to the collapse of her windpipe, emphasises the significance of this technology.[41] Kaiba was given a 3D printed device, serving the purpose of a wind pipe, which instantly helped her survive.[42]

C. DRUG PRINTING

3D printed drugs have transmuted the idea of personalised drug dosing. An optimal medical dosage may be created based on the pharmacogenetics profile and characteristics such as age and sex.[43] This has also led to customisation of complex drugs. The case study of Spritam is a classic example of this crucial benefit of additive manufacturing. In March, 2016, Aprecia Pharmaceuticals a US based company, announced the availability of Spritam,[44] – a drug used in the treatment of epilepsy.[45] It had successfully secured the approval of the US Food and Drug Administration ('FDA').[46] Aprecia uses ZipDose technology which revolves around Powder-liquid 3D printing to create porous structures that rapidly disintegrate when coming into contact with liquids.[47] This creates a very efficient way of delivering high doses of medication. Aprecia developed its ZipDose Technology

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[37] U.S. Food & Drug Administration, *Medical Applications of 3D Printing,* December 21, 2017, available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/3DPrintingofMedicalDevices/ucm500539.html (Last visited on January 31, 2018).

[38] Patel, *supra* note 23.

[39] U.S. Food & Drug Administration, *supra* note 37.

[40] *Id*.

[41] David Sher, *Can Organs Be 3D Bioprinted? A Stem Cell Trachea Will Tell,* 3D Printing Industry, February 6, 2014, available at http://3dprintingindustry.com/news/can-organs-3d-bioprinted-stem-cell-trachea-will-tell-23249/ (Last visited on January 31, 2017).

[42] *Id*.

[43] Varkey & Atala, *supra* note 10.

[44] Aprecia Pharmaceuticals, *First FDA-Approved Medicine Manufactured using 3D Printed Technology now Available*, March 22, 2016, available at https://www.aprecia.com/pdf/ApreciaSPRITAM-LaunchPressRelease__FINAL.PDF (Last visited on January 31, 2018).

[45] Jennifer Hicks, *FDA Approved 3D Printed Drug Available In The US*, Forbes, March 22, 2016, available at http://www.forbes.com/sites/jenniferhicks/2017/03/22/fda-approved-3d-printed-drug-available-in-the-us/#4a1dc24d13d0 (Last visited on January 31, 2018).

[46] Bullock, *supra* note 30.

[47] *Id*.

platform using the 3D printing technology that originated at Massachusetts Institute of Technology.[48] Using this technology, Aprecia is developing formulations of medicines that rapidly disintegrate with a sip of liquid, even at high dose loads.[49] Today Spritam continues to be the only 3D printed drug which has secured FDA's approval.[50]

3D printers provide doctors with information regarding the patient's anatomical structure with specific details that were earlier not provided by 2D representations. Surgeons are able to undertake accurate diagnosis and provide better treatment when equipped with a patient's in-depth anatomical model.[51] The wide-ranging benefits include avoidance of exposure of tissues for a long duration due to scans generated at a click, and evasion of trial and error methods to produce better outcomes.[52] Further, personalised surgeries help save time by providing customised information regarding the patient.[53]

At this juncture, it is essential to understand the mechanisms in force in India to regulate the medical activities discussed above – including the Transplantation of Human Organs and Tissues Act, 1994, the Medical Devices Rules 2017, and the National Regulatory Authority and its powers.

D. REGULATORY MECHANISMS

In India, medical laws can be divided into twelve categories concerning various aspects such as periodic reports and returns,[54] licenses/certifications,[55] etc. Considering the impact of 3D printing will predominantly lie in the area of producing organs, devices or equipment and finally drugs, the following portion discusses Indian statutes pertaining to these.

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48 *Id*.

49 *Id*.

50 Robinson Meyer, *3-D Printed Drugs Are Here*, The Atlantic, August 19, 2015, available at http://www.theatlantic.com/technology/archive/2015/08/3d-printing-pills-spritam-drug-industry/401177/ (Last visited on January 31st, 2017).

51 Ventola, *supra* note 14.

52 *Id*.

53 *Doctors in Belgium Use Mcor Paper-Based 3D Printing to Dramatically Reduce Surgical Time*, available at http://mcortechnologies.com/doctors-in-belgium-use-mcor-paper-based-3d-printing-to-dramatically-reduce-surgical-time/ (Last visited on August 6, 2018). ("With each procedure, we easily win an hour in the operating room, and that's a major benefit for the patient," says Professor RaphaelOlszewski, a surgeon and head of the university's oral and maxillofacial surgery research lab (OMFS Lab, UCL)).

54 *See* Income Tax Act, 1961; Value Added Tax Act, 2005; Employees' State Insurance Act, 1948.

55 For example, registration under Societies Registration Act, 1860, inspection for electrical installation/substation, drug licence for medical store, NOC from local municipal office for any bye law, licence for storage of petrol/diesel, etc.

1. Transplantation of Human Organs and Tissues Act, 1994

The Transplantation of Human Organs and Tissues Act, 1994 ('the Act') hinges on the concept of 'transplantation' as defined in §2(p) of the Act. It is defined as "grafting of any human organ from any living person or deceased person to some other living person for therapeutic purposes".[56] This understanding of 'transplantation' guides the other provisions of the Act. An illustration of the same can be seen in§3 of the Act which prescribes the requirement for taking the authorisation of a living donor before removing any organs for transplantation.[57] This assumes that organs will be sourced from *another* person living or dead, thereby negating the possibility of creating organs by additive manufacturing.[58] Similarly, §9 of the Act provides for restrictions on removal and transplantation in the context of removing the organ from the donor's body.[59] It does not contemplate removal of organs or tissues from the bodies of the patients themselves. Another illustration of it is §10 of the Act, which discusses the registration of hospitals which engage in "removal, storage or transplanting of any human organ or tissue or both".[60] In this provision too, registration for hospitals which bioprint organs is not mandated, keeping them outside the purview of regulation. Evidently, the entire scheme of the Act, which hinges on this definition of transplantation, needs to accommodate bioprinting.

2. Medical Devices Rules, 2017

In the case of medical devices printed using 3D printers, the Medical Devices Rules, 2017 ('the Rules') will be applicable and implemented from 2018. According to the Rules, a medical device means:

> "(A) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i), (B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii), (C) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act; Explanation: For the purpose of these rules, substances used for in vitro diagnosis shall be referred as in vitro diagnostic medical device."[61]

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56 Transplantation of Human Organs and Tissues Act, 1994, §2(p).
57 *Id.*, §3.
58 *Id.*, §2(p).
59 *Id.*, §9.
60 *Id.*, §10.
61 Medical Devices Rules, 2017, Rule 2.

Therefore, these Rules divide devices into various classes and focus on the quality and safety control of these devices.[62] 3D printed devices may be included under these Rules as the Central Government has the power to issue notification in the Official Gazette under §3 of the Drugs and Cosmetics Act, 1940. It can be anticipated that once additive manufacturing becomes commonplace, the Central Government will bring out the appropriate notification under this to include additive manufacturing within its fold.

3. The National Regulatory Authority: Production of Medicinal Drugs

National Regulatory Authorities ensure that medical products which are released for public distribution, such as pharmaceuticals, are screened appropriately.[63] India's regulatory body, the Central Drugs Standard Control Organization, under the Directorate General for Health Services, of the Ministry of Health and Family Welfare ensures that medical products comply with the acceptable norms and adhere to safety regulations till they reach the end consumer. In addition to this body, the Drugs and Cosmetics Act, 1940, lays down the standard of manufacturing drugs in its second schedule.[64] Understandably this Act has not envisaged the possibility of additively manufactured drugs, and therefore, the special standards if any, that such drugs need to comply with have not been discussed. It is important that the National Regulatory Authority and the Indian Food and Drug Administration come up with a policy regarding additive manufacturing similar to the manner in which the FDA has dealt with it. The FDA, in 2016, issued draft guidance on the Technical Considerations for Additive Manufactured Devices to advise manufacturers who are producing devices through 3D printing techniques.[65] Such active participation – by the Indian Food and Drug Administration or even the National Regulatory Authority which are responsible for regulating quality of pharmaceuticals and food products – is lacking and thereby increasing the obscurity in the area of regulation in additive manufacturing.

Remarkably, in the Indian context dialogue regarding additive manufacturing is at its nascent stages. This is especially exhibited in the fact that neither in the National Health Policy, nor in the Draft Pharmaceutical Policy,[66] does one

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62 *Id*.

63 National Regulatory Authorities, available at http://www.who.int/immunization_standards/national_regulato-ry_authorities/role/en/ (Last visited on August 5, 2018).

64 Dr. Surinder Singh, *Drug Regulations in India*, Central Drugs Standard Control Organization, April 24, 2009, available at http://pharmexcil.org/data/uploads/Drug%20Regulations%20in%20India%-20Dr%20Surinder%20Singh.pdf (Last visited on November 3, 2017).

65 Technical Consideration for Additive Manufactured Medical Devices: Guidance for Industry and Food and Drug Administration Staff, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulation-andGuidance/GuidanceDocuments/UCM499809.pdf (Last visited on October 22, 2018).

66 Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Draft Pharmaceutical Policy, 2017, available at https://drive.google.com/file/d/0B5aL-duyigKaTTdvLUQzazh4My00UU5XaENnVEJPRjhhNEt3/-view (Last visited on November 3, 2017).

find any mention of 3D printed drugs or prosthetics or other devices. Considering the Council for Scientific and Industrial Research ('CSIR') has often pioneered research in such fields,[67] it could also take up the initiative of ushering in a public discourse on additive manufacturing. Aside from the CSIR, the Ministry of Health and Family Welfare is also empowered to release notifications regarding subjects within its mandate, and thus could use its powers to do the same to analyse 3D printing in the Indian context.[68] In the past, the Ministry has released notifications on the Mental Healthcare (Rights of Persons with Mental Illness) Rules, 2018 and tobacco control laws, and also notified the Transplantation of Human Organs Rules, 1995.[69]

III. PRODUCT LIABILITY LAW CONCERNS

An all-pervasive problem in using 3D printers is the confusion pertaining to pinning product liability. Product liability is defined as the liability for damage or injury caused by a product.[70] It may be imposed on any or all the parties in the "manufacturing and supply chain" of such product.[71] There are mainly three theories of product liability – warranty, negligence and strict liability.[72] Warranty is a claim made or implied regarding the quantity or the quality of the product based on contractual law.[73] Negligence is a claim based on the defect of a product occurring due to the negligence of the defendant. The same concept is applied in strict liability without the need to prove the fault of the defendant.[74] 3D printing bears revolutionary implications for industry and consumers in terms of the liability involved. This part of the paper examines the theories and concerns regarding the law relating to product liability in the Indian scenario.

A. PRODUCT LIABILITY LAW IN INDIA

Product liability law in India has been constantly evolving and cannot be restricted to a specific statute. It finds its roots in a variety of legislations – mainly the Sale of Goods Act, 1930 ('SGA'), Consumer Protection Act, 1986 ('CPA'); and other statutes relating to specific goods such as the Drugs and

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67 For instance, it was CSIR which had taken initiative for the creation of the Traditional Knowledge Digital Library, taking inspiration from China and South Korea. For more information, *see* Abha Nadkarni & Shardha Rajam, *Capitalising the Benefits of Traditional Knowledge Digital Library in Favour of Indigenous Communities*, 9(1-2) NUJS Law Review 183.

68 Ministry of Health and Family Welfare, Notifications, available at https://mohfw.gov.in/node/2795 (Last visited on October 22, 2018).

69 *Id*.

70 Legal Information Institute, *Product Liability Law: An Overview*, available at https://www.law.cornell.-edu/wex/products_liability (Last visited on January 31, 2017).

71 Nadkarni & Rajam, *supra* note 67.

72 *Id*.

73 *Id*.

74 *Id*.

Cosmetics Act, 1940, and the Food and Safety Standards Act, 2016.[75] We discuss product liability against the backdrop of these legislations and the law of torts.

1. Sale of Goods Act, 1930

The SGA governs the sales of goods in the field of contractual law. The goods covered under the SGA are all kinds of movable property excluding claims and money.[76] Any right under SGA arises only when the essentials of a contract of sale are fulfilled. There are three essentials - *first*, the transfer of the goods has to take place,[77] *second*, such transfer should be from the seller to the buyer[78] and *finally*, the transfer should be for a price.[79] Product liability under the SGA can be understood from §§12 and 16 of the Act. According to §12 which discusses 'condition and warranty', a condition is a specification essential to the main purpose of the contract whereas warranty is a specification collateral to the same.[80] Breaches of conditions as well as warranties give rise to the claim for damages.[81] However, breach of condition provides an added right to repudiate the contract of sale which is not available in cases of warranty.[82]

In order to give rise to a claim, the conditions or warranties should be specifically written in the contract. However, §16(1) provides for an implied condition (which may not necessarily be in a written form) to the reasonable fitness of the goods when the buyer expressly or impliedly conveys to the seller, a) the particular purpose of the goods and b) there exists reliance on the seller's skill or judgment.[83] If a seller deals in a specific product, the goods are required to be of a merchantable quality and damages are provided for all latent defects. However, such implied condition is excluded when a good is sold under patent or trade name.

Despite the reliance on these obligations of the seller, the principle of 'caveat emptor' is reflected in the SGA.[84] No damage is provided when there is an apparent defect that is discovered by reasonable care.[85]

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75 Karnika Seth, *Product Liability in India*, available at https://www.sethassociates.com/wpcontent/up-loads/Product-liability-in-India.sethassociates2.pdf (Last visited on January 31, 2017).

76 The Sale of Goods Act, 1930, § 2(7).

77 *Id*., § 4(3).

78 *Id*.

79 *Id*., § 4(1).

80 *Id*., §§ 12(2) & 3.

81 *Id*.

82 *Id*., § 4(1).

83 *Id*., §16(1).

84 *See* Ranbirsingh Shankarsingh Thakur v. Hindusthan General Electric Corpn. Ltd., 1970 SCC OnLine Bom 136 : AIR 1971 Bom 97.

85 *Id*.

2. Consumer Protection Act, 1986

With the underlying objective of an enhanced protection of consumer interests,[86] the scheme of CPA provides for various redressal mechanisms in cases of 'defect' in goods. The constituents of 'defect' in goods can be understood from a combined reading of §§2(1)(f) and 2(1)(i) of the Act. Defect as per §2(1)(f) means

> "any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force under any contract, express or implied or as is claimed by the trader in any manner whatsoever in relation to any goods".[87]

Further, as per §2(1)(i), the definition of 'goods' is the same as provided under the Sale of Goods Act, 1930.[88]

Various provisions of the CPA specify that a 'complainant' can approach the appropriate forum with allegations of 'defect'.[89] However, the definition of 'complainant' excludes a person who purchases the goods for resale or 'commercial purposes'[90] The Supreme Court has defined 'commercial purpose' as when goods are purchased with a view of carrying out a large-scale activity for the "purpose of earning of profit".[91]

Product liability is usually categorized into strict liability and no fault liability. Strict liability is a standard of liability in which a person is legally responsible despite absence of fault on his part.[92] Even though there has not been any precedent by the Supreme Court to show that the liability under CPA is strict rather than fault based,[93] there is evidence to suggest that the Act is not premised on fault liability entirely. The only provision requiring proof of negligence is §14 of the CPA providing for compensation.[94] The Orissa State Commission, in a case concerning auto parts, ordered for repair of goods despite absence of any defect which was 'intentional'.[95] Therefore, negligence as a defence for liability may not stand in Consumer Forums.

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86 The Consumer Protection Act, 1986, Preamble.

87 *Id*., §2(1)(f).

88 *Id*., §2(1)(i); Goods are defined as "every kind of movable property other than actionable claims and money; and includes stock and shares, growing crops, grass, and things attached to or forming part of the land which are agreed to be severed before sale or under the contract of sale".

89 For e.g., The Consumer Protection Act, 1986, §§11, 12, etc.

90 The Consumer Protection Act, §2(1)(c)(vi).

91 Laxmi Engg. Works v. P.S.G. Industrial Institute, (1995) 3 SCC 583 : AIR 1995 SC 1428.

92 Ramaswamy Iyer, The Law of Torts (A. Lakshmikanth & Ramaswamy Iyer, 10th ed. 2007).

93 Seth, *supra* note 75.

94 The Consumer Protection Act, 1986, §14.

95 Abhaya Kumar Panda v. Bajaj Auto Ltd., (1991) 2 CPJ 644.

3. The Law of Torts

One of the founding cases of product liability in torts is *Donoghue* v. *Stevenson*.[96] It laid down that liability for defect in a product may be claimed even in the absence of contractual obligations between the parties.[97] In these cases, a claim based on *negligence* is formed because of the principle of 'duty of care', which a manufacturer owes to the ultimate consumer arising out of the 'neighbour principle'.[98] The principle highlights a duty of care towards neighbours, extending it beyond the affected immediate party. In India, the law of torts is not codified, and is based on jurisprudence from other countries – mainly English judicial decisions.[99] However, their application in the Indian context has been evolving continuously.[100]

Product liability in the field of tort law is not restricted to negligence. It goes to the root of the social and economic need to protect consumers through another principle of strict liability, which is explained herein below. This liability in torts was first established by the Supreme Court of Californiain *Greenman* v. *Yuba Power Products*.[101] The principle was developed to place the burden on manufacturers which sell such products in the market rather than the costs being borne by powerless consumers.[102] Strict liability "relieves the plaintiff of proof inherent in pursuing negligence".[103] This was adopted by various states in the United States through §402A of the Restatement Second of Torts.[104]

In India, an adapted version of 'strict liability' is the running theme of different product specific statutes such as Essential Commodities Act, 1955, the Drugs and Cosmetics Act, 1940 and Food Safety and Standards Act, 2006 inasmuch as these acts do not envisage mental culpability in their provisions. §10C of the Essential Commodities Act provides that mental culpability will always be presumed on part of the accused.[105] However, the standard of proof is "beyond reasonable doubt"[106] which means that the accused can show that he had acted with

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96 Donoghue v. Stevenson, (1932) UKHL 100.

97 *Id*.

98 *Id*.

99 *Id*.

100 *See* Central Inland Water Transport Corpn. Ltd. v. Brojo Nath Ganguly, (1986) 3 SCC 156 : AIR 1986 SC 1571; Nitin Walia v. Union of India, 2000 SCC OnLine Del 799 : AIR 2001 Del 140.

101 Greenman v. Yuba Power Products, Inc., (1963) 59 Cal.2d 57; Jay Laxmi Salt Works (P) Ltd. v. State of Gujarat, (1994) 4 SCC 1.

102 *Id*.

103 Cronin v. J.B.E. Olson Corp., 8 Cal.3d 121.

104 American Law Institute, Restatement (Second) of Torts, 1965, §402A(1). It states:

> "one who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."

105 Essential Commodities Act, 1955, §10C.

106 *Id*.

due diligence as per the provisions of the Act but it usually proves to be a weak defence.[107] The underlying weakness of these defences is that it leads to a situation where the accused accepts the offence and merely argues an excuse to exonerate oneself.[108] Further, §27 of the Drugs and Cosmetics Act imposes penal provisions on defaulters even in absence of any intention.[109] Similarly, the legislature has omitted to provide such requirement in the Food Safety Standards Act.

The specific exclusion of mental culpability in these enactments as well as certain provisions CPA indicates that when a person does not come within the ambit of the definition of a 'consumer' under CPA or within the ambit of the specific products of the above mentioned statutes, he will attempt to seek relief through negligence under the law of torts in a civil court.[110] Thus, product liability law in India is shaped by CPA, SGA & law of torts along with specific legislations such as food and drug related ones.

B. IMPLICATIONS OF 3D PRINTING ON PRODUCT LIABILITY LAW

1. Breach of Warranty

Warranties are simply assurances regarding the standard of the product in a particular transaction.[111] All terms and conditions in a contract, including warranties, are formed against the background of the bargaining power between the parties entering into the contract.[112] There are various provisions in the Indian Contract Act, 1872, to ensure that parties are on an equal footing. An illustration of the approach is evinced through§19A of the Act wherein any contract induced by undue influence is voidable at the option of the party whose consent was taken under circumstances of dominance of position.[113] Moreover, Indian courts have regularly considered the question of validity of an agreement if the "bargain was neither fair nor equitable nor just nor conscionable".[114]

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[107] David Oughton & John Lowry, Text Book on Consumer Law 368 (1997).

[108] *Id*.

[109] Drugs and Cosmetics Act, 1940, §27.

[110] Gowree Gokhale, Huzefa Tavawalla & Debargha Basu, *Civil Litigation System*, available at http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Product_Liability_-_issues_and_concerns.pdf (Last visited on August 5, 2018).

[111] Murali Neelakantan, Kaushalya Shetty & Nidhi Killawa, *Extended Warranty Contracts: Insurance in the Garb of Warranties?*, available at https://www.khaitanco.com/PublicationsDocs/Extended-Warranty-Contracts-Insurance-in-the-Garb-of-Warranties.pdf (Last visited on October 28, 2018).

[112] Barkley Clark & Christopher Smith, The Law of Product Warranties, (2002).

[113] Indian Contract Act, 1872, §16. It states, "A contract is said to be induced by 'undue influence' where the relations subsisting between the parties are such that one of the parties is in a position to dominate the will of the other and uses that position to obtain an unfair advantage over the other".

[114] *Ramakrishna Naidu* v. *Palaniappa Chettiar*, 1962 SCC OnLine Mad 59 : AIR 1963 Mad 17.

These existing legal obligations of fair and conscionable bargain will ensure that the effect of 3D printing on claims of breach of warranty is not severe. In fact, the impact of 3D printing on warranty claims may prove to be beneficial for the consumers when seen from the perspective of the timeline of the need for development consumer legislations. In pre-Industrial Revolution marketplace, neither the buyers nor the sellers had leverage in warranty negotiations owing to the equivalent expertise.[115]The situation underwent a significant change with rapid industrialisation post World War II. There was concentration of economic power in the hands of a few corporate houses against the individual consumers-forming the backdrop of consumer legislations across the world.[116] 3D Printing again shifts the scale of bargaining power owing to the concept of 'prosumer' –giving the consumer the ability to customise and thereby making the consumer a 'prosumer' – someone with agency in the production process.[117] With 3D printers becoming increasingly accessible, the roles of sellers and buyers can be fulfilled by individuals instead of big industrial houses. The transformation of their roles will place both the parties on an equal footing. Thus, it is suggested that warranty clauses, and consequently, claims will become more equitable with the advent of 3D Printing.

2. Negligence

All negligence claims in product liability arise out of a cause of action which needs to be substantiated with evidence to prove the fault on part of the defendant. The burden of providing evidence is easier to fulfil in claims relating to 3D Products. These products are created out of a stored computerised design.[118] The storage ensures that there exists a digital record of the product with defects.[119] If the buyers are given access to these stored designs, they will be provided with the opportunity to identify the defects and claim negligence accordingly. Thus, 3D Printing reduces the difficulty in acquiring proof for negligence claims.

Another notable impact revolves around the future of 3D printing which involves an increase in the number of individual sellers, as discussed above. These sellers occasionally sell 3D printed products from their homes. They do not have the resources to inspect and recall products unlike large-scale manufacturers

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115 Nicole D. Berkowtiz, ,*3D Printing Liability* , 92(4) Washington University L. Rev. 1037(2015).

116 *Id*.

117 Susan Gunelius, *The Shift from CONsumers to PROsumers*, Forbes, July 3, 2010, available at https://www.forbes.com/sites/work-in-progress/2010/07/03/the-shift-from-consumers-to-prosumers/#335eb72933df (Last visited on August 3, 2017).

118 *See* discussion in Part I of the paper.

119 *See* Max Marder, *Leave 3D Printing Alone*, January 27, 2014, available at http://www.huffingtonpost.com/the-morningside-post/leave-3d-printing-alone_b_4666660.html, *archived at* http://perma.cc/3SQA-MHM5 (Last visited on August 5, 2018) ("A 3D printer interprets computer aided design (CAD) files — three-dimensional schematics used by engineers since the 1980s — and builds objects up layer- by-layer out of plastic, metal, or in principle any other material.").

who are in a position to undertake preventive measures.[120] Therefore, 3D Printing will prompt a situation where an expanded number of negligence claims reach the court owing to the inability of these individual sellers to avoid design defects.

3. Strict Liability

When an injury occurs through a 3D printed product, the consumer may attempt to seek remedy against one or many of the following; (A) defective digital file or code, (B) defective 3D Printer, (C) error of printing, and (D) the individual who created and sold the product.[121] However, the injured consumer may not find recourse under the principle of strict liability. This complex chain of sale involving these parties, which exists in the process of 3D printing, takes away from the traditional manufacturer-consumer supply set up.

Concerning (A), goods or products as defined in the Sales of Goods Act refer to tangible and movable products.[122] The definition encompasses 3D printed products as they are movable and tangible. However, questions arise regarding applicability of the product liability laws with respect to CAD Models and Codes. It has been held in the case of *Tata Consultancy Services* v. *State of Andhra Pradesh*[123] ('TCS') that once software is uploaded on a medium such as a CD or a floppy, it becomes canned software. These are in the form of electronic data. There is therefore sufficient judicial precedent, including the TCS case, to indicate that such canned software is a 'marketable commodity'[124] that is a 'good' which satisfies wants and needs.[125] However, it is not clear whether non-canned electronic data will also be included in the definition. Thus, there exists a clear obstacle in imposing liability on the digital designer owing to the tangible-intangible barrier.

The burden of proof in cases of strict liability is discouraging, especially when seeking remedies against the manufacturer in a situation such as (B) – that of the 'defective 3D printer'. To overcome this, the plaintiff may seek a remedy against the company that manufactured the 3D Printer. In such a scenario, there needs to be sufficient proof to suggest that the printer was defective in the first place, that such defect existed when the manufacturer introduced the product

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[120] Nicole D. Berkowitz, *Strict Liability for Individuals? The Impact of 3-D Printing on Products Liability Law*, 92 Wash. U. L. Rev. 1019 (2015).

[121] Kennedys,*3-D Printed Products, Product Liability and Insurance Implications*, June 2, 2014, available at http://www.kennedyslaw.com/article/3dprintedproducts/http://www.kennedyslaw.com/article/3dprintedproduct/ (Last visited on January 31, 2017).

[122] The Sale of Goods Act, 1930, §2; the definition in Consumer Protection Act, 1986 also refers to the Sale of Goods Act, 1930 definition.

[123] Tata Consultancy Services v. State of A.P., (2005) 1 SCC 308 : AIR 2005 SC 371 : (2004) 137 STC 620.

[124] *Id*.

[125] Gramophone Co. of India Ltd. v. Collector of Customs, (2000) 1 SCC 549 : (1999) 114 ELT 770; Tata Consultancy Services v. State of A.P., (2005) 1 SCC 308 : AIR 2005 SC 371 : (2004) 137 STC 620.

in the market,[126] and the injury was caused due to that defect in the product. These questions of fact do not arise in a traditional manufacturer-supplier chain but increase the evidentiary burden in the complex chain of creating a 3D printed product. It also poses the legal question of whether the neighbour principle can be extended to this situation. Consequently, whether the manufacturer of a printer could be made liable for a defect suffered due to the product printed by another party using that printer remains to be answered.

Further, under (C) when there has been an error while printing the product, a consumer may attempt to sue the store that printed the 3D Product. However, the store merely provided access to 3D printers qualifying for a service instead of goods; thus, taking the issue out of the regime of product liability.

Finally, the potential defendant under (D)– 'the hobbyist inventor'[127]– may also escape strict liability. Such liability is only imposed on those "engaged in the business of selling or otherwise distributing products who sells".[128] Thus, there exists ambiguity regarding the classification of the hobbyist as an occasional or commercial seller. Such categorization depends on three assessments. *First*, the relationship between the defective product and the general business of the inventor, *second*, the frequency and quantity of similar sales and *third*, engagement in mass advertising.[129] Thus, if (D) occasionally sells the products or does so at a small scale without advertising, he does not qualify as someone 'engaged in business'.

3D printing has the potential to democratise product creation.[130] It allows ordinary individuals to become creators of sophisticated products. This democratisation takes away from the underlying reasoning of strict liability. It is concluded that imposing liability on big corporate houses is based on the idea of benefit derived out of placing liability on sellers and manufacturers of products. The conclusion is based on two premises: a) the manufacturers and sellers of products are large-scale companies i.e. enterprises[131] and b) it is socially beneficial to impose liability on enterprises.[132]

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[126] Ranbirsingh Shankarsingh Thakur v. Hindusthan General Electric Corpn. Ltd., 1970 SCC OnLine Bom 136 : AIR 1971 Bom 97.

[127] Shen Wong, *When Classical Doctrines of Products Liability Encounter 3D Printing: New Challenges in the New Landscape,* 16 Houston Buss. & Tax L. J. 104 (2016), available athttp://hbtlj.org/articlearchive/v16i1/-16HousBusTaxLJ104.pdf (Last visited on December 1, 2018); Tabrez. Y. Ibrahim, *3D Printing: Digital Infringement and Digital Regulation,* 14(1) Nw J. Tech. & Intell. Prop. 37 (2016)*,* available at http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1247&context=njtip (Last visited on January 31, 2017).

[128] American Law Institute, Restatement (Third) of Torts, 2012, §1.

[129] Nora Freeman Engstorm, *3-D Printing and Product Liability: Identifying the Obstacles*, 162(35) Univ. Pa L. Rev. Online 35 (2013), available at http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=-1121&context=penn_law_review_online (Last visited on January 31, 2017).

[130] *Id*.

[131] The Competition Act, 2002, §2(h) (definition of 'Enterprises').

[132] *Id*.

In cases of defects in the field of medicine, the provision of human tissues or bloods is regarded as a 'service'. Even though CPA does provide jurisdiction to consumer forums for shortcomings in services, there is ambiguity for their inclusion under the concept of strict liability. Foreign courts have concluded that strict liability is not the appropriate remedy for the shortcomings in such services.[133] A case in point is *Donovant* v. *Idant Laboratories*[134] where the federal district court of Pennsylvania rejected the claim of 'sperm' being a product in the process of 'sperm donation'.

Thus, the legislators have to revisit the domains of product law liability as the proliferation of 3D printing occurs in the legal sphere. They may have to come with an expanded definition to prevent 3D printed products from escaping product liability and formulate regulations to govern the occasional sellers of 3D printed products.

IV. PLACING 3D PRINTING WITHIN INDIA'S PATENT LAW REGIME

3D printing has caused ripples in the intellectual property rights regime of several jurisdictions, particularly in light of the law pertaining to patents. In fact, it is estimated that 3D printing will result in the global loss of at least USD 100 billion per year by the end of 2018.[135] In addition to this quantifiable loss, there is also the intangible cost of inventors' subsequent distrust in the patent regime. 3D printers are a major cause of concern due to their ability to manufacture in the microcosm. When patented products are being printed at home, enforcement of the patent becomes nearly impossible. In this part of the paper, we discuss 3D printing and the nature of problems it poses to the patent regime in India.

A. PATENT CONCERNS WITH 3D PRINTING

The lure of 3D printing lies in its ability to allow consumers to take power from traditional manufacturers and supply chains to 'manufacture' at home.[136] However, this very usurpation of power has its adverse consequences in terms of pinning liability and causing losses to patent holders. Issues in patent law

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[133] Angela R. Vicari, *3D Printing: New Life Sciences Technology and Old Product Liability Claims*, Arnold & Porter, August 1, 2016, available at https://www.arnoldporter.com/en/perspectives/publications/2016/08/2016-_08_01_3d_printing_new_life_sciences_13117.

[134] Donovan v. Idant Laboratories, 625 F.Supp.2d.256.

[135] Gartner, *Gartner Reveals Top Predictions for IT Organizations and Users for 2014 and Beyond*, October 8, 2013, available at http://www.gartner.com/newsroom/id/2603215 (Last visited on January 31, 2017).

[136] Maya M. Eckstein,*The Intriguing New Legal Questions Raised by 3D printing* , February 4, 2016, available at http://www.insidecounsel.com/2016/02/04/the-intriguing-new-legal-questions-raised-by-3d-pr (Last visited on January 31st, 2017); Maya M. Eckstein, *Let's Look Closer at 3D Printing and IP Issues*, February 9,2016, available at http://www.insidecounsel.com/2017/02/09/lets-look-closer-at-3d-printing-and-ip-issues (Last visited on January 31, 2017).

with respect to 3D printers may be of two distinct types – they may be *first*, regarding replication of patented products, and *second*, getting patents for 3D printed products/processes.

1. Using 3D Printers to Replicate Patented Products

Simply put, each printed copy of an invention is a lost potential sale to the patent holder.[137] According to §48 of The Patents Act, 1970, ('1970 Act'), a patent holder has the right to prevent third parties from making, using or selling any patented product without their consent.[138] As is evident, unlike copyright, patent goes a step further and prohibits mere usage too, and not just sale. Therefore, making patented products utilising 3D printer and thereafter using these products, would inevitably be considered as infringement under the 1970 Act.

The primary problem with additive manufacturing can be traced back to the existence of websites such as Thingiverse and Shapeways which permit a 'Do-It-Yourself community' ('DIYers') to create and make available designs for free.[139] When ideas are in the form of CAD files, deliberate and unintentional patent violations alike are facilitated as they are transferred easily. This ease of availability, combined with the plunging cost of 3D printers, encourage the DIYers to generate patented goods in the form of useful designs.[140] Therefore, the CAD file versions of patented goods become freely available, thereby encouraging infringement.

Aside from their free availability, such an online sharing model also protects infringers with anonymity. The incentive for creating and distributing CAD files seems to be rooted in a desire to cultivate interest amongst hobbyists and enthusiasts, rather than commercial exploitation. Therefore, websites allow for anonymous downloads and seem unperturbed by the lack of profits.

In addition to not requiring identity proofs for downloading CAD files, it is also uncertain how many users who download the CAD file go ahead and make the patented product.[141] The answer to this question becomes relevant as according to the 1970 Act, rights of the patent holder includes the right to prevent others from making that product. However, it is impossible to determine how many users make the patented product once they download the CAD file. At present, whether merely downloading the CAD file of a patented product could be

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[137] Timothy Holbrook, *How 3-D Printing Threatens Our Patent System*, January 6, 2016, available at https://www.scientificamerican.com/article/how-3-d-printing-threatens-our-patent-system1/ (Last visited on January 31, 2017).

[138] The Patents Act, 1970, §48.

[139] Davis Doherty, *Downloading Infringement: Patent Law As A Roadblock To The 3d Printing Revolution*, 26(1) Harv. J. L. & Tech. 353 (2012), available at http://jolt.law.harvard.edu/articles/pdf/v26/26HarvJL-Tech353.pdf (Last visited on July, 2017).

[140] *Id*.

[141] *Id*.

regarded as an infringement is still debated, and therefore it is difficult to pin liability based merely on downloads.

2. Using 3D Printed Products/Process to Obtain Patents

Aside from these issues, it is also imperative to understand whether all 3D printed goods can be patented. It cannot be assumed that all goods can be. To be patentable under the 1970 Act, an invention must fulfil the conditions mentioned under §2(j) as well as pass the filters enlisted in §3.[142] Therefore, it must be novel, have an inventive step, and must be capable of industrial application. Additionally, it must not be part of the exceptions mentioned in §3 of the 1970 Act. In the context of 3D printing, this could lead to considerable confusion. For instance, bioprinted organs may not be capable of being patented as such organs may be seen as 'naturally occurring'. However, with the United States Supreme Court's decision in the case of *Association for Molecular Pathology* v. *Myriad Genetics*,[143] it could be assumed that 3D printed organs could be patented, whereas the naturally occurring material could not be. Nevertheless, in the Indian context, the decision could be different. §3(j) of the 1970 Act prohibits patents in "plants and animals in whole or any part thereof".[144] To create a 3D printed organ of an animal, biomaterial of that/an animal would necessarily have to be used, and would squarely fall within the phrase 'any part thereof' as under §3(j). A 3D printed organ of an animal therefore, may be incapable of being patented, even though it is not naturally occurring and involves considerable degree of human interference.

Therefore, with the advent of 3D printing, India's patent regime will need to re-mould itself to escape anachronism. In the next part, we discuss the manner of pinning liability.

B. ASSESSING LIABILITY

Infringement may be of three types – direct, indirect, and contributory infringement.[145] Direct infringement is the most common form and occurs when a product that is substantially close to a patented product or invention is marketed, sold, or used commercially without the permission of the owner of the patent.[146] Indirect infringement is understood to be either deceitful or accidental infringement. When a person knowingly aids the infringement of a patent, he may

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[142] The Patents Act, 1970, §§ 2(j) & 3.

[143] Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 576. In this landmark case on gene patenting, the United States Supreme Court decided that merely isolating genes which are naturally occurring without any modification is not patentable.

[144] The Patents Act, 1970, §3(j).

[145] Upcounsel, Types of Patent Infringement: Everything You Need to Know, available at https://www.upcounsel.com/types-of-patent-infringement (Last visited on October 23, 2018).

[146] Deepa Goel & Shomini Parashar, IPR, Biosafety and Bioethics 94 (2013).

be held liable for indirect infringement.[147] Additionally, if such material is unknowingly sold or supplied, then such person may be held liable for contributory infringement.[148] In case of 3D printing, it is easy to imagine a situation, where person A designs a CAD file which infringes on a patent, and thereafter uploads it on Shapeways.[149] Subsequently, person B downloads the file to print the object. In the present situation, the liability of A, Shapeways, and B need to be discussed in terms of direct, indirect, and contributory infringement. A thorough analysis of this hypothetical will expose the associated problems.

In the aforementioned hypothetical, A cannot be held directly liable as A has not sold or offered to sell his design. Further, he has not made or used the patented invention – he has merely made the CAD file and uploaded it on Shapeways. B on the other hand, can be held directly liable for making the patented object, once he downloads the CAD file and prints it. To determine A's liability, indirect and contributory infringement considerations may be helpful. A's action of aiding 'another's direct infringement',[150] can be held wrongful under the doctrine of indirect infringement, if done with specific intent. The appropriate theory of indirect infringement would depend on the facts of each particular case. According to Davis Doherty, indirect infringement would be applicable if A's design is exactly the same as the patented invention, whereas contributory infringement may be applicable if A's design permitted B to print replacement parts for reconstruction, rather than repair.[151] Further, if in the above hypothetical neither A nor Shapeways know of such an infringement, they could be held responsible under contributory infringement. Most importantly, in order to hold an inducer liable for indirect infringement or contributory infringement, the direct infringement must necessarily have occurred.[152]

In the Indian scenario, a major problem with respect to pinning liability on A and Shapeways is the small number of case laws on contributory and indirect infringement theories. Borrowing from judicial precedents in the United States, contributory infringement may be pinned based on the 'active inducement' test or the 'substantial non infringing purpose' test. With respect to 3D printing in India, the substantial non infringing use test may not prove to be very helpful, as there may be a vast variety of potential non-infringing use. The delineation of what constitutes contributory infringement in order to assess the applicable theory of infringement may be required. At this juncture however, the recent Intermediary Guidelines, 2011 may prove useful. In the next part, we examine the provisions with respect to intermediary liability under the Intermediary Guidelines, 2011.

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147 Bijal Vakil, *Indirect Infringement - A Successful Defense in Patent Infringement Cases*, available at https://www.whitecase.com/publications/article/indirect-infringement-successful-defense-patent-infringement-cases (Last visited on July 31, 2017).

148 *Id*.

149 This example is taken from Davis Doherty, *supra* note 139, and discussed in the Indian context.

150 *See generally* Water Techs Corp v. Calco, Ltd., 850 F. 2d 660, 668 (Fed. Cir. 1988).

151 *Id*.

152 Zenith Laboratories v. Bristol Myers-Squibb, Co.19 F.3d 1418 (Fed. Cir. 1994).

V. MAKING 3D PRINTING COMMONPLACE: THE ROLE OF INTERNET INTERMEDIARIES

Although invented in the 1980s, 3D printing grew in popularity only in the internet age. With CAD files and 3D printers becoming more easily available, printing gradually evolved from a hobby for tech enthusiasts to a broader audience. Today, designs for objects which may be 3D printed, are generally hosted on file sharing websites such as Thingiverse, Shapeways, 123D and GrabCad.[153] Most of these websites include peer improvisation of the designs hosted, while also informing the user regarding how many times the design has been downloaded.[154] Some of these websites have sophisticated arrangements to maximize user satisfaction. For instance, Thingiverse is now owned by MakerBot,[155] a global leader in the additive manufacturing industry, consequently allowing users to take advantages of a symbiotic relationship. Designs hosted on the Thingiverse website can now be used to create the product in the MakerBot printer, which is better suited for the files.[156]

Considering the central role of intermediaries in the spread of 3D printing, it therefore becomes crucial to study the law governing them in order to adjudge the legal consequences of 3D printing. In India, the Information Technology Act, 2000 ('IT Act') and the Information Technology (Amendment) Act, 2008, along with Intermediary Guidelines, 2011, ('Guidelines') govern the liability of intermediaries. The subsequent parts analyse these laws in order to assess intermediary liability with respect to additive manufacturing.

A. THE INFORMATION TECHNOLOGY ACT, 2000, AND THE INFORMATION TECHNOLOGY (AMENDMENT) ACT, 2008

In this part, the applicability of the IT Act, along with its liability regime is discussed.

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[153] Dinusha Mendis & Davide Secchi, *A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour*, Centre for Intellectual Property Policy and Management, Intellectual Property Office, March, 2015, available at https://assets.publishing.service.gov.uk/government/uploads/system/-uploads/attachment_data/file/549045/Study-I.pdf (Last visited on August 5, 2018).

[154] *Id*.

[155] Thingiverse, *About Makerbot*, available at https://www.thingiverse.com/MakerBot/about (Last visited on October 23, 2018).

[156] MakerBot, *Thingiverse*, available at http://www.makerbot.com/thingiverse/ (Last visited on August 5, 2018).

1. Applicability of the IT Act

According to §1(2) of the IT Act, the Act will be applicable to "any offence or contravention thereunder committed outside India by any person".[157]This has been interpreted to mean that the provisions of the IT Act would be applicable even if the offence or contravention is committed outside India if the contravention involved a computer system located in India. If the foreign intermediary has no computers or systems located in India, remedy in tort law or copyright law may yet be availed.

However, the interpretation of this provision may not necessarily be straightjacketed. Almost all the online file sharing platforms dedicated to 3D printing are established in the United States of America, and thus, are governed by its laws.[158] Interestingly, nearly all of these websites provide for the company's right to ignore conflict of laws provisions, and sufficient bargaining power to determine the governing law. For instance, according to the terms and conditions of GrabCad, users will not be governed by the United Nations Conventions on Contracts for the International Sale of Goods.[159] Platforms such as Thingiverse and 123D require their users to wave their 'moral rights or other rights with respect to attribution of authorship of their content upon registration'. However, most users do not examine the terms of such 'wrap' contracts before availing the services provided by such websites.[160]

Since there have been no cases regarding the liability of service providers in the context of 3D printing, questions regarding jurisdiction, applicable law and enforcement mechanisms remain to be answered. However, the Indian judiciary has been faced with the question regarding jurisdiction on prior occasion. In the case of *Myspace Inc.* v. *Super Cassettes Industries Ltd*.,[161] the Delhi High Court clarified that MySpace – although operating from the United States – could be held liable under the Indian laws regarding intermediary liability.[162] Therefore, despite the fact that MySpace operated primarily outside of India, provisions of the IT Act continued to apply.[163]

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157 Information Technology Act, 2000, §1(2).

158 For 123D *see* Autodesk, *Legal Notices & Trademarks*, §2.1 available at http://usa.autodesk.com/adsk/-servlet/item?siteID=123112&id=21310328 ; For *GrabCad, see* GRABCAD COMMUNITY, *GrabCAD® Website Terms of Use*, available at http://grabcad.com/terms; for Thingiverse, *see* Thingverse, *Important Information- Terms, Privacy & Rights*, §3.3 & 6, available at http://www.thingiverse.com/legal(Last visited on October 22, 2018).

159 GrabCAD, *Terms of Service*, available at https://blog.grabcad.com/wpcontent/uploads/2015/07/GrabCAD_-Terms_of_Service_PREVIOUS_VERSION.pdf (Last visited on October 22, 2018).

160 L.E. Trakman, *The Boundaries of Contract Law in Cyberspace*, 2 Int'l Bus. L. J. 159, 164 (2009).

161 Myspace Inc. v. Super Cassettes Industries Ltd., 2016 SCC OnLine Del 6382.

162 Anubha Sinha, *Super Cassettes v. MySpace (Redux)*, Centre for Internet & Society, January 16, 2017, available at https://cis-india.odsvrg/a2k/blogs/super-cassettes-v-myspace. (Last visited on October 22, 2018).

163 Myspace Inc. v. Super Cassettes Industries Ltd., 2016 SCC OnLine Del 6382.

In the case of 3D printing therefore, it is possible that the judiciary finds such CAD file hosting websites liable under Indian law. Since the Supreme Court has not decided on the liability of foreign intermediaries till now, the different facets of the question regarding governing law remain unexplored.

2. Who is an Intermediary?

According to §2(w) of the IT Act, an intermediary with respect to any particular electronic message means "any person who on behalf of another person receives, stores, or transmits that message or provides any service with respect to that message"[164]. At the international level, internet intermediaries have been defined by the OECD and UNESCO. According to them, internet intermediaries include amongst other things, web hosting providers and participative networking platforms that do not themselves create or own the content being published.[165] Therefore, web-based hosts for sharing CAD files such as Shapeways and Thingiverse come within this definition.

3. Obligations of Intermediaries

Once CAD file hosting websites have been considered as intermediaries, it is necessary to examine the nature of obligations upon them, as per the information technology laws of India. According to the Information Technology (Amendment) Act, 2008, intermediaries cannot be held liable for any third party content which was hosted on such intermediary, if the function of the intermediary was circumscribed to providing access to the server, or did not include initiation/selection of the receiver, or did not include modifying the information contained in the transmission.[166] Finally, the intermediary must observe due diligence and follow other guidelines laid down by the Government. Therefore, intermediaries which act merely as conduits to allow entities/persons to use its network would not be held responsible for the material.

In India, there have been few cases with respect to pinning liability on intermediaries. In the case of *Super Cassettes Industries Ltd.* v. *Myspace Inc.*,[167] for instance, the Delhi High Court discussed the secondary liability of intermediaries for infringement by 'permitting a place to be used to communicate a copyrighted work to the public' under §51(ii) of the Copyright Act. 1957. The Court held MySpace to the threshold of 'actual knowledge' as was established in the European Union, stating that actual knowledge is the requirement of contributory infringement.[168]

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[164] Information Technology Act, 2000, §2(w).

[165] OECD, *The Economic and Social Role of Internet Intermediaries*, April, 2010, available at https://www.oecd.org/internet/ieconomy/44949023.pdf (Last visited on October 31, 2017).

[166] The Information Technology (Amendment) Act, 2008, §79.

[167] Super Cassettes Industries Ltd. v. Myspace Inc., 2011 SCC OnLine Del 3131.

[168] *Id.*

The recent Delhi High Court (Division Bench) judgment in this case however, represents a dawn of India's intermediary liability laws – which had been regressively interpreted by Justice Manmohan Singh's decision in 2012.[169] The Division Bench overturned the single judge's decision,[170] and held that MySpace did not have 'actual knowledge' or even constructive knowledge as it could not be assumed that MySpace had checked all the content before uploading such content on the website. The sheer volume of information hosted on its platform obstructed this exercise.[171]

At a policy level, it is of the utmost importance that intermediaries do not become strictly liable for the content hosted on their platforms. This is to prevent a chilling effect on free speech by curbing the manner in which intermediaries could function. It cannot be assumed or even necessary that an intermediary goes through all the content hosted on its platform.

B. THE INFORMATION TECHNOLOGY (INTERMEDIARY GUIDELINES), 2011

Aside from the IT Act, the Guidelines also impose certain duties on the intermediaries. According to Rule 3 of the Guidelines, intermediaries need to carry out due diligence, and necessarily warn users not to upload any information which 'infringes any patent, trademark, copyright or other proprietary rights'.[172] Such warning must be by way of publication of rules and regulations, and user based agreements for access/usage of the intermediary's computer resource. In addition to this, the intermediary must act swiftly once such information has been brought to its knowledge by an affected person.[173] According to Rule 3(4), this information must mandatorily be in writing or through email with an electronic signature. Thereafter, the intermediary within thirty-six hours of receiving the information must inform its users of such non-compliance and also has the right to terminate the access rights of the users to the computer resource. The intermediary must also preserve such information for at least ninety days to aid the investigation process.

Although the Guidelines are detailed, their rigorous language has resulted in a stifling of free speech. In the discussion below, some of the criticisms of these Guidelines are analysed to assess the loopholes they might present to the spread of 3D printing.

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169 *Id*.

170 Myspace Inc. v. Super Cassettes Industries Ltd., 2016 SCC OnLine Del 6382.

171 *Id*., *see* Smitha Krishna Prasad, Rakhi Jindal & Vivek Kathpalia, *Intermediaries - Messengers or Guardians? How India and US Deal with the Role and Liability of Intermediaries*, available at http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Articles/Intermediaries__Messengers_or_Guardians.pdf (Last visited on October 31, 2017).

172 Information Technology (Intermediary Guidelines), 2011, Rule 3.

173 *Id*., Rule 3(4).

C. CRITICISM OF THE GUIDELINES

The criticisms of the Guidelines have primarily hinged on their teleology. While their objective was to promote and safeguard the free usage of the internet, the provisions regarding takedowns and private administration of injunctions have resulted in censoring free speech.[174] In the context of 3D printing, such strict provisions result in the lack of availability of free CAD files, thereby constricting the very nature of 3D printing. Considering 3D printing's primary purpose is to disseminate in a more affordable manner, strict guidelines discourage entrepreneurship in the field of 3D printing. As these Guidelines impose liability on intermediaries, intermediaries too have a tendency to over-comply.[175]According to a report[176] out of the seven intermediaries who received notices to takedown six over complied. This is also because most Indian intermediaries do not have the legal competence to argue based on the merits of the notice.[177] This also shows that intermediaries often mechanically comply with the takedown notice, especially in a situation where there exists information asymmetry between the takedown authority and the intermediary.[178] Moreover, the third party who has provided the information to the intermediary is not informed about the takedown.[179] Natural justice principles such as that of *audi alteram partem* have not been provided for with respect to the information-provider's rights. Furthermore, there is no duty of the intermediary to provide reasons regarding the takedown of any material.[180] Considering the small number of Indian CAD file sharing websites, it is imperative that the Guidelines be interpreted in a manner so as to encourage rather than censor businesses.[181]

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[174] Rishabh Dara, *Intermediary Liability in India: Chilling Effects on Free Expression on the Internet 2011*, Centre for Internet and Society, available at https://cis-india.org/internet-governance/intermediary-liability-in-india.pdf (Last visited on August 8, 2017).

[175] Gautam Bhatia, *The Chilling Effect in India*, Indian Constitutional Law & Philosophy Blog, December 5, 2013, available at https://indconlawphil.wordpress.com/2013/12/05/the-chilling-effect-in-india/ (Last visited on August 5, 2018). (The chilling effect doctrine, with respect to the right to freedom of speech and expression, is concerned with excessive self-censorship. An individual may indulge in excessive self censorship and refrain from disseminating a perfectly legitimate expression, if he fears that on expressing himself: (i) liability will be incorrectly imposed on him, or the law will adversely affect him; (ii) cost of legal defence will be very high (iii) doubts the legitimacy of the expression and faces high damages if found incorrect. On the internet, since expressions have to flow through various intermediaries, any chilling effect on the intermediaries also has an indirect chilling effect on the creators and seekers of expressions. By inducing fear into any cog in the machine, one can halt the whole apparatus).

[176] Dara, *supra* note 174.

[177] Super Cassettes Industries Ltd. v. Myspace Inc., 2011 SCC OnLine Del 3131.

[178] *Id*.

[179] David Rizk, *New Indian internet Intermediary Regulations Pose Serious Threats to Net Users' Freedom of Expression,* Electronic Frontier Foundation, available at https://www.eff.org/deeplinks/2011/06/new-indian-internet-intermediary-regulations-pose (Last visited on January 26, 2017).

[180] Centre for Internet and Society*, India Weighing Looser Web Rules*, available at http://cis-india.org/news/looser-web-rules (Last visited on January 27, 2017).

[181] Feedspot, *Top 40 CAD Blogs and Websites for CAD Designers and Users*, available at https://blog.feedspot.com/cad_blogs/ (Last visited on July 7, 2018).

There is also ambiguity with respect to interpreting certain provisions of the Guidelines. For example, what constitutes 'action' under §79 has been debated. Although the Government has come up with a clarification in March, 2013,[182] whether such action has to be taken as per the domestic laws of the intermediary, or as per foreign laws has not been clarified. Finally, despite the Supreme Court's decision in *Shreya Singhal* v. *Union of India*,[183] as per the Intermediaries Guidelines, intermediaries must necessarily include terms of service which proscribe legal and illegal content.[184] It has been recommended that proscribing legal content essentially results in a chilling effect on free speech.[185]

In the European Union courts have had the opportunity to discuss intermediary liability in case of counterfeit goods displayed on the intermediary's website. In the case of *Loreal* v. *eBay International AG*,[186] for instance 'fakes' of Loreal products were offered for sale on the website, thereby violating the trademark of Loreal. In order to assess whether eBay had any secondary liability, the CJEU held that according to Article 14 of the E-Commerce Directive, hosting platforms were exempt from liability as long as the intermediary did not play an 'active role'.[187] Essentially, a neutral role exempts the intermediary from liability and is therefore necessary to avail of Article 14.

Nevertheless, in seeking to encourage businesses and protect free speech, it is necessary to be mindful of the fallouts of unbridled speech. For instance in March, 2018, the European Commission issued a recommendation to address concerns regarding infringements of intellectual property rights, consumer protection, etc.[188] One of the prime takeaways of this recommendation in the Indian context, is the special attention given to small companies to discuss best practices and technological solutions. As aforementioned, considering that CAD files are hosted in India by small to medium sized companies, it is necessary to be mindful of their special concerns.

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[182] Government of India, Ministry of Communications and Information Technology, Department of Electronics & Information Technology, Clarification on The Information Technology (Intermediary Guidelines) Rules, 2011 under §79 of the Information Technology Act, 2000, March 18, 2013, available at http://meity.gov.in/writereaddata/files/Clarification%2079rules%281%29.pdf (Last visited on August 10, 2017).

[183] Shreya Singhal v. Union of India, (2015) 5 SCC 1: AIR 2015 SC 1523.

[184] Divij Joshi, *Indian Intermediary Liability Regime: Compliance with Manila Principles on Intermediary Liability*, Centre for Internet & Society, available at https://cis-india.org/internet-governance/files/indian-intermediary-liability-regime (Last visited on August 6, 2018).

[185] *Id*.

[186] Loreal v. Ebay International Ag, (C-324/09) EU:C:2011:474 (July 12, 2011)

[187] *Id*.

[188] European Commission, *Commission Recommendation on Measures to Effectively Tackle Illegal Content Online*, available at https://ec.europa.eu/digital-single-market/en/news/commission-recommendation-measures-effectively-tackle-illegal-content-online (Last visited on July 7, 2018).

D. PLACING 3D PRINTING IN THE INTERMEDIARY CONTEXT

Although severely criticised as overly harsh, these rules may serve well to protect patent infringements from 3D printing. Although according to the rules, the internet intermediary may be held responsible for infringement by third party users, some intermediaries are able to divert this monetary liability to users. For instance, Shapeways holds the uploader responsible for all legal costs accrued due to the uploaded file.[189] It is therefore imperative that Indian courts scrutinise the contract provisions and user agreements before adjudging liability and imposing penalties.

As evinced in the foregoing discussion, the Indian legal framework regarding intermediary liability (although nascent), may be capable of dealing with the adverse effects of 3D printing. With developments such as *Super Cassettes Industries Ltd*. v. *Myspace Inc*.,[190] it is very well possible that India's intermediary provisions, read with other laws such as the Copyright Act and tort law, can face the challenges introduced by 3D printing. The manner of determining liability in other jurisdictions too may be examined if the situation so arises.

VI. SOLUTIONS

To many, additive manufacturing opens up a Pandora's Box of legal issues – from pinning liability to creating appropriate enforcement mechanisms. However, as is evident from the prior discussion, 3D printing could solve some of the most deep-rooted problems the world faces today – that of accessibility and affordability. Today 3D printing is used in space technology, in the field of medicine and healthcare, architecture and construction, and engineering, aside from food, fashion and music.[191] For example, in conflict-ridden Sudan, 3D printing continues to a symbol of accessibility, as the 3D printing lab Not Impossible caters to the need of the growing amputees in the region.[192] This part of the paper analyses the different methods to counter the detrimental consequences of this disruptive innovation. Aside from the four broad solutions offered, other suggestions with respect to the intermediary guidelines, and in the medico-legal field, must be considered in order to receive additive manufacturing in India. Some of these suggestions have already been made in the different parts of the paper.

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[189] Eckstein, *supra* note 136.

[190] Super Cassettes Industries Ltd. v. Myspace Inc., 2011 SCC OnLine Del 3131.

[191] Statista, *Leading Uses of 3D Printing Between 2015-2018*, available at https://www.statista.com/statistics/-560271/worldwide-survey-3d-printing-uses/ (Last visited on July 7, 2018).

[192] World Federation of Engineering Organizations *Engineering for Change*, available at http://www.-wfeo.org/3d-printers-may-poised-take-developing-countries/ (Last visited on July 7, 2018).

A. PATENTABILITY OF CAD FILES

One of the main problems arising out of 3D printing is the question of liability. With respect to patent law concerns examined in Part IV of the paper, it is imperative to consider at what stage and how a patent has been infringed. To overcome this difficulty, it has been proposed that the CAD files of patented objects be regarded as patentable themselves.[193] Such a solution tackles the problem head on – if CAD files are patented, it is not necessary to keep track of who is in fact making the product once they download the file as the very act of download would be infringement. Downloading CAD file therefore, needs to be interpreted within the term 'making' as under §48 of the Patents Act, 1970.[194] Furthermore, the sale of the CAD file has greater potential for replicating the patented product than a single manifestation of such file by printing it. Each CAD file may thus be printed repeatedly by different end users.

However, commentators who have analysed this solution understand that patent law requires a physical manifestation of the invention.[195] Therefore, pinning direct infringement on the CAD file itself would perhaps not fit within the present legal framework. It may be questioned why CAD files should be on a separate platform, if moulds of a patented product are not patentable themselves. It is crucial to understand that as opposed to CAD files, moulds do not generally create a completely operable end product and thereby do not infringe. Further, if tangibility is a requirement for patent infringement, one can negate that criterion by keeping in mind the context of the legislation. It is difficult to imagine legislators envisaging the extent of software technology when the Act came into force in 1970. In the peculiar case of 3D printing, the physicality of an object must not be regarded as a prerequisite to constitute an infringement, as a user of the CAD file does not use the file as an end within itself – in fact, the CAD file symbolises the end product which is patented.[196] Thus, the CAD file intrinsically represents the patented object and seeks to appropriate the economic value of the invention. Considering it has the same objective as the tangible copy of the patented product, the requirement of tangibility can be relaxed.[197]

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193 Timothy Holbrook & Lucas Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 UC Davis Law Review 1319 (2018).

194 *Id*.

195 *Id*.

196 *Id*.

197 Timothy R. Holbrook, *Territoriality and Tangibility After Transocean*, 61 Emory L.J. 1087, 1106 (2012). (Similar principle has been adopted by the Federal Circuit in Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc. (617 F.3d 1296). It is the first case to find infringement based on documents and not physical manifestation of the invention. This was further reiterated in Pfaff v. Wells Electronics (525 U.S. at 68)).

B. BARCODING AND OTHER MEANS OF RECOGNITION

Recently, Microsoft has come up with embedded ID tags for 3D printed products, in order to identify the products printed by 3D printers.[198] A unique bar code may be assigned to products printed by each printer, which thereafter become easier to track and regulate. This is vital for assessment of primary liability in cases of infringement, as well as product liability in case of the tort of negligence.[199] Most importantly, criminal liability may be pinned in a more reliable fashion once such an identification mechanism is firmly established.[200]Therefore, before 3D printing begins to be widely used in India, it is imperative that certain categories of printers mandatorily embed an identification tag within the products printed. However, it must be recognised that for certain products, such as bioprinted organs, the barcoding mechanism may not be appropriate. This mechanism therefore may be used generally, and but would have exceptions.

C. DATABASE SOFTWARE

It is also possible to create software which detect whether the product being produced infringes any known intellectual property rights.[201] Such a database may be fed into the 3D printers in order to inform the user of the intellectual property rights existing in the product sought to be printed. Although it serves as a deterrent, it continues to be problematic with respect to the ability to maintain and update the software itself. In fact, Intellectual Property Ventures has already filed a patent for software which detects such intellectual property rights to detect whether the product produced is infringing.[202]

D. RESTRICTING USAGE OF SOME TYPES OF MATERIAL

It has also been advocated that the government monitor the materials to be used for 3D printing.[203] For instance, considering the potential use of 3D printers in the market for nuclear materials, perhaps a regulation to restrict

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[198] Simon Martin, *InfraStructs: the ID Tag System for 3D Prints*, July 23, 2013, available at https://www.solidsmack.com/3d-cad-technology/infrastructs-embedded-id-tags-in-3d-printed-objects-eliminate-need-for-rfid-and-barcodes/ (Last visited on October 29, 2017).

[199] Signe Brewster, *Microsoft Working on Barcode-like ID Tags for Tracking 3D Printed Objects*, available at https://gigaom.com/2013/07/23/microsoft-working-on-barcode-like-id-tags-for-tracking-3d-printed-objects/ (Last visited on November 2, 2017).

[200] *See* BBC, *Working Gun Made with 3D Printer*, May 6, 2013, available at http://www.bbc.com/news/science-environment-22421185 (Last visited on October 31, 2017) (This is especially true since creation of weapons via 3D printers is not impossible).

[201] Clare Scott, *European Parliament Report Examines Intellectual Property and Civil Liability Issues in 3D Printing*, December 8, 2017, available at https://3dprint.com/196783/ip-civil-liability-3d-printing/ (Last visited on October 22, 2018).

[202] Kruttika Vijay, *3D Printing: Are We Ready?*, November 9, 2012,available at https://spicyip.com/2012/11/3d-printing-are-we-ready.html (Last visited on October 22, 2018),

[203] De Clercq Advocaten Notarissen, *The Legal Aspects of 3D Printing from a European Perspective*, November, 2015, available at https://www.declercq.com/assets/uploads/old/images/stories/pdf/

materials would be more advantages than an entirely unchecked marketplace.[204] Such a practice could vastly reduce the potential damage which can be caused by 3D printing weapons such as guns, or even chemical/biological threats. Another material whose use may be regulated is biological material, in order to ensure that printed organs do not enter the black market.

E. PLACING 3D PRINTING WITHIN THE OPEN ACCESS MOVEMENT

With the advent of 3D printing, scholars and legal professionals seem to be clamouring to reduce the losses in terms of intellectual property rights. At this juncture –when patent laws as well as the internet intermediary regime seem to evolving – the global access movement becomes indispensable to the discussion.

The Open Access movement seeks to make research output available without barriers such as cost, in order to increase awareness allow easier access. Although at present, the Open Access movement predominantly involves academic material such as peer reviewed journals, etc., it is imperative that CAD files also join in this milieu. The fundamental difference between 3D printing and traditional manufacturing processes lies in their accessibility. Today, 3D printing is used by several conflict-ridden zones such as Sudan, as well as developing countries such as Nepal and Cambodia.[205]Considering its benefits, such as reduced costs, custom designs, as well as increased ease of replacing parts, has made 3D printing a go-to technology for creating prosthetics.

Therefore, it must be ensured that enforcement of laws – especially those relating to intellectual property rights and intermediary liability – does not become repressive. The purpose of 3D printing needs to be the lens through which infringements and violations are viewed.

VII. CONCLUSION

As additive manufacturing increasingly becomes part of our lives, the 3D4D challenge can be used to understand the true extent of the technology's potential advantages. The 3D4D or the *3D printing for development* was a challenge organised by the charity Techfortrade in 2012, inviting participants to suggest workable solutions for problems faced by developing countries i.e. the global

white%20-paper%20legal%20aspect%20of%203d%20printing%20-%20de%20clercq.pdf (Last visited on October 29, 2017).

[204] Robert Kelley, *Is Three-dimensional (3D) Printing a Nuclear Proliferation Tool?*, 54 Non-Proliferation Papers, February, 2017, available at https://www.sipri.org/sites/default/files/EUNPC_no_54.pdf (Last visited on November 3, 2017).

[205] Angie MacDonald,*Changing Lives in Developing Countries with 3D Printed Prosthetics*, November 23, 2016, available at https://ultimaker.com/en/stories/30886-changing-lives-in-developing-countries-with-3d-printed-prosthetics (Last visited on July 7, 2018).

south.[206] The rationale behind viewing 3D printing as a one stop solution is that it does away with the accoutrements required in traditional manufacturing processes, such as economies of scale, assembly lines, customisation, infrastructural needs such as cutting and casting tools, etc. Objects to be printed generally just require molten plastic as ink, while the CAD files can be shared across the globe, freely. The sheer range of products which can be made – whether it be mechanical spare parts, or toys – using ubiquitous recycled plastic, has motivated individuals to view 3D printing as a panacea for community problems. Remarkably, inventors are now creating 3D printers which can print themselves, essentially serving as factories-in-a-box and brings manufacturing to the microcosm. 3D printing thus changes the objective from economies of scale to economies of scope – i.e. localisation of production.[207]

3D printing, in order to be a workable solution for problems, must begin with a bottoms-up approach.[208] The 3D4D Challenge helps understand the true potential of using 3D printing technology – so much so that today, a 3D printer can print itself, thereby creating multiple copies.[209] 3D printers are also becoming increasingly cheap – the cheapest one in India costs about USD 320.[210]

In July, 2014, SpaceX launched a rocket with 3D printed components into space, remarkably testing the technology's boundaries.[211] However, as scholars would later understand, this was an inspiring exhibition of the true capacity of 3D printing technology. With offerings of the ilk of prosthetics, art, drugs, organs, etc., additive manufacturing has already entered our world, and cannot be dismissed as too far futuristic or insignificant.

Beginning with the discussion on the nature of additive manufacturing, in order to introduce the various methods and materials involved in the technology, we studied the technology's impact in the field of medicine. Within this part, we recommended certain changes in the extant regime, and the manner in which it needs to be altered to escort 3D printing technology. These recommendations are sector-specific. After analysing the medico-legal system, we discussed

[206] Thomas Birtchnell & William Hoyle, 3D Printing for Development in the Global South - The 3D4D Challenge (2014), available at http://ro.uow.edu.au/cgi/viewcontent.cgi?article=2298&context-=sspapers (Last visited on August 28, 2017). (Several projects have been initiated bearing these principles in mind. Projects have been started by the Climate Connected Benefit Society (which has created solar lamps printed from soda bottles), the Fripp Design and Research (which works towards the lack of prostheses for children and adults in developing countries), and Protoprint (which has distributed a waste recycler and printer to empower a women's waste-picker union in India) have attempted to solve problems commonly faced by communities in developing countries).

[207] Robert Kelley, *supra* note 204.

[208] Birtchnell& Hoyle, *supra* note 206.

[209] *Id*.

[210] *Id*.

[211] Lou Del Bello, *A Fully 3D-Printed Rocket is Not as Crazy as it Seems. Investors Agree*, March 28, 2018, available at https://futurism.com/relativity-3d-printed-rocket (Last visited on October 22, 2018).

the product liability system in various jurisdictions and compared it with India's. Within this part, the SGA, CPA, and the law of torts were analysed in order to delineate the potential problems additive manufacturing technology introduces. Furthermore, implications in the matter of warranty, negligence as well as strict liability were examined.

The next part of the paper dealt with patent law systems, beginning with the legacy of primary, secondary and contributory infringement in copyright law. The patent regimes of the United States and India were reviewed and compared in order to assess each jurisdiction's capacity to receive additive manufacturing technology. The intermediary liability mechanisms were discussed subsequently, and we find that the IT Guidelines may very well be suitable to include 3D printing, barring a few minor changes.

Finally, we provided four broad solutions in addition to the sector-specific recommendations as aforementioned. These would minimise the problems associated with each of the subjects of law discussed – the medico-legal field, the product liability system, and the patent law regime. These would also help in liability in case of intermediaries.

3D printing – much like the internet – could vastly improve life as we know it, and irrevocably change it. Although severely criticised by scholars as opening up perplexing legal issues, the benefits of the technology are tough to dismiss. Most importantly, the legal problems brought forth by this technology are not insurmountable – in fact, companies such as Microsoft have already attempted to overcome some of these obstacles by striking at their root – identification of the printed products. With barcoding of 3D printed products considered to be a legitimate suggestion, governments as well as corporations and individuals are improvising at a rapid pace. As technology plunges society into constant dynamism, it is up to the legal regime to rise up to the challenge that is 3D printing.