

# Asian Patent Lawyer's Annual

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# 3D bio-printing patents



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*Mr. D.P.S. Parmar, from LexOrbis, considers Indian positions and prospects of 3D bio-printing patents.*

**B**io-printing refers to the 3D printing technology for printing living tissues, growing new organs, and specially growing a human kidney instead of harvesting or transplanting. With this technique it is now possible to grow other human organs like muscles, blood vessels, bladders, and so on. However, when we talk about relationship between 3D bio-printing and patent rights in India, it might just become another complex issue where technology and morality collides.

## Patentability Issues

Ironically, the patentability of living higher organisms and parts thereof is viewed differently for ethical reasons or otherwise. It is kept beyond the scope of patent eligible subject matter under section 2(1) (j) read with exceptions introduced under Patent Act, 2000 (amendments) stipulated in Patents Act, 1970 Section 3(J) specifically crafted for these exceptions, which read as “*plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;*” Nevertheless, pacemakers, artificial limbs, hearing aids etc. remained patentable for the obvious reason that these inventions qualify as new product or process criteria under section 2(1)(J). However, the newly developed organs using 3D Additive printing technology raised few eyebrows and would be a bit complicated for IPO to accept as patentable for reasons such as its similarity with naturally occurring organs and/or for ethical reasons under section 3 (b). This section reads: “*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*”

## Scope of Exception – Section 3

It is true that explicit exceptions of ‘*plants animals and part thereof*’ under section 3(j) keep such inventions beyond the scope of patent eligibility where such claim is directed to plants and animals or parts thereof *per se*. However, in the second part of section 3(j) the process for their production if it is not “*essentially biological processes for production or propagation of plants and animals*”, is acceptable as patent eligible subject matter. This leaves enough room for obtaining patents on processes which are not essentially biological such as 3D printing

using bio-inks to create three dimensional objects suitable for substitution of non-functional/damaged human body parts. In fact, 3D printing creates three dimensional objects by building up layers of biological material using bio-inks for creation of identical human cells, tissues to human organs structures.

## Essentially biological process after Monsanto

In the Monsanto case [146 of 2013] for a ‘*recombinant DNA molecule for enhancing stress tolerance in plants, recombinant plants and methods thereof*’, IPAB set aside the findings of the Controller that the process disclosed was essentially a biological process and ruled that:

“30. Let us see amended Claim 1 [claim 16 amended]. It relates to a method that requires several steps that together provide claimed solution. The method here is best considered as a series of individual steps. **It is a method that includes an act of human intervention on a plant cell and producing in that plant cell some change. Therefore, the respondent erred in finding this method as essentially biological process and excluded under section 3(j).** We set aside his findings to that extent.”

## 3D printing and section 3(j)

The question which remained unanswered is ‘can 3D produce three dimensional objects suitable for substitution of non-functional/damaged human body parts step aside the exclusions meant under section 3(j) and qualify as patentable being a product of non-essential biological process?’ Moreover, if we see part of section 3(j) where it is merely stating that, “*essentially biological processes for production or propagation of plants and animals*” leaving the part thereof. From this we can safely conclude that legislative intent is clear that process for productions ‘part thereof’ is not covered by the exclusions under section 3 (j). Meaning, thereby, that Patent Act, 1970, as amended, is clearly in favor of patentability of the bio-printed products such as tissues and organs etc. and even the bio-printing processes for their production are patent eligible.

## Human intervention and essentially biological processes

Coming back to human intervention aspect and in order to get patent on bio-printing related inventions [product

or process] emphasis should be on the man-made characteristics, quality and alterations rather than on naturally occurring methods or matters [section 3 (c)]. Bio-printed organs can be viewed as distinct from naturally occurring organs and how they are essentially developed biologically in the body or what is occurring in nature from products of human ingenuity. It is clear that inventors create and design the bio-printing process *in-vitro* in human controlled conditions and therefore it cannot be treated as a naturally occurring product just because of their similarity with naturally occurring human tissue or organs etc. Similarly, it can also not be equated with merely isolated or removed naturally occurring human tissues or organs etc. by grafting for transplanting. It is true that bio-printing attempts to replicate naturally occurring tissues or organs but there is nothing natural in the man-made method by which 3D printers build layers upon layers of living cells to design and construct the desired tissue, blood vessels, or organs.

### Way forward

Bio-printing inventions would of course change the landscape of patenting in the field of life science. Bio-printing patents in India can be possible if the claims are drafted to emphasize the man-made and non-essentially biological process/non-naturally occurring /distinct from naturally occurring process/product aspects present in this disruptive technology to revolutionize the patient care industry. Patent eligibility of 3D bio-printing technology is yet to be tested in the IPO and courts. Until then we may safely look positively that bio-printed processes and products can be patented in India. In this context, lead inventions of Proctor and Gamble, L'Oréal [Bio-printing of human skin] and Bangalore-based Indian bio-tech star-up Pandorum Technologies [Artificial 3D bio-printed liver tissues]

among about 20 others worldwide biotech companies would be worth watching for snapshot of new possibilities in this emerging area of 3D bio-printing technology in medical science.



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Mr. Parmar has vast experience and expertise in intellectual property law. He had worked with the Indian Patent Office for over 27 years and had played very active and vital roles both at administrative and policy levels. He represented India at various rounds of discussions organized by the WIPO and attended follow programs at the European and Japanese Patent Office. He has been instrumental in writing some path breaking and insightful decisions on Indian Patent law issues including those that established legal positions on excluded subject matters under Section 3(d), 3(i) and 3(k), divisional applications, compulsory license, to name a few. He was instrumental in recognition of Indian Patent Office as 15th ISA and IPEA under the Patent Cooperation Treaty (PCT).

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