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## **EFFECTIVE ADOPTION OF SYNTHETIC BIOLOGY IN INDIA NEEDS SERIOUS PATENT REFORM**

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### **ABSTRACT**

Synthetic biology (SB) is an emerging trans-disciplinary field that has given a new dimension to biological aspects of science. Emerging science and technology fields are increasingly expected to provide solutions to societal grand challenges. At the same time, it is important to protect the innovation as intellectual property system helps to transform ideas to potential applications. It is important that innovators develop the strategy for their innovations that aligns with patentable subject matter of the respective jurisdiction in advance. However, SB raises issues relating to the scope of patent law to confer effective protection. Scrutiny of such issues aims to understand the different parameters that can stimulate the growth as well as success of SB related technologies and minimise the associated risk. This report highlights the bottleneck for patent protection and aims to provide an unbiased overview of the major issues, and recommendations.

**Keywords:** Synthetic biology, SB, intellectual property, patent, emerging technology, patentable subject matter

## Introduction

In the last few decades, technology has provided some remarkable tools to accelerate, not merely speed up, this process, and these tools have tremendous potential of becoming even more versatile. In the context of SB, which has been defined as an emerging discipline that uses engineering principles to design and assemble biological components, is being signalled as offering solutions to the most urgent challenges faced by humanity, including climate change, agriculture, pharmaceuticals, food, environmental degradation, population growth, and access to sustainable energy.<sup>1</sup> Although, the emergence of new technologies regularly raises the question of whether the patent system, which was historically designed mainly to protect mechanical inventions, and then extended to chemical products and processes, is suitable to protect inventions in the field of SB. More importantly, it also raises the concern whether the patent system would be able to promote the advancement of these new technologies. Although, intellectual property (IP) comprises of different forms such as patents, copyrights, trademarks, designs, the author focuses on patents as the major IP tool as they are the prime trade currency for commercialisation.<sup>2</sup> This article attempts to identify key challenges for patent protection with special reference to India and proposes possible action items to protect and maximize the value of the innovation.

## Discussion

SB is characterised by a focus on translational, application-oriented research, with a view to bringing scientific advancements to the market.<sup>3</sup> Our ability to engineer biology to do useful things underpins the industrial revolution. There are perhaps at least three general approaches to SB.<sup>4</sup> The first approach aims to modify existing organisms in order to achieve desired functionalities, such as the production of certain metabolites.<sup>5</sup> This approach is similar to genetic engineering, but applies the increasing knowledge of genome circuitry and aims to develop efficient standardized practices. The second approach starts by using building blocks, such as nucleotides, to synthesize genes or even whole genomes, thereby generating a 'synthetic organism'.<sup>4</sup> The last approach aims to reduce the complexity of naturally existing organisms by deleting redundant genes or sequence part, which are mostly required for adaptation to diverse environments. The resulting 'minimal genome' organisms can be used for the generation of 'streamlined' microorganisms that are perfectly adapted and highly efficient for a specific task.<sup>4</sup>

However, SB raises unique social, legal and regulatory questions that need to be addressed if the full benefits of the science are to be realised. With regard to the promotion of innovation, some crucial characteristics of SB might be listed in comparison to 'classical' biotechnology. The first of these is interdisciplinarity. SB combines approaches from various disciplines, such as biotechnology, chemistry, physics, nanotechnology, computing and engineering.<sup>6</sup> This requires patent professionals to be proficient in all of the technical domains involved.

India is yet to formally come up with its national strategy on SB for both policy and regulatory. In the absence of India undertaking a proactive approach, there is ample chance that we will end up having the same contentious debates as those on genetically modified organisms.

India established the Department of Biotechnology during the late 1980s to harness the emerging science to the benefit of the society. However, there has been a long-standing lack of clarity and consensus among scientists, policymakers, industry, law, and civil society on how needs to deal with SB related technology for the social welfare.

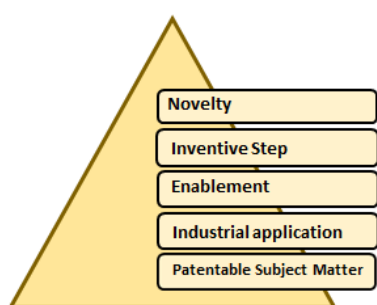
Patents are territorial rights. The exclusive rights are only applicable in the country or region in which a patent has been filed and granted. The basic criteria for patent protection have been depicted in figure 1 which is more or less same across multiple geographies, but patentable subject matter varies. Section 3 and Section 4 of the Patent Act deals with the list of exclusions that are non-patentable subject matters in India (table 1).<sup>7</sup> The much debated and broadly worded Section 3 excludes several inventions from patentability and has long been considered the greatest deterrent for innovators. The section is commonly relied upon by examiners to object to or reject patent applications. Also, it has become challengeable for the patent examiners to deal with SB or other emerging technology related innovations by existing patent system which was historically designed and last amended on 2005.

India patent Act Section 3 (c) states that the mere discovery of naturally occurring substances is not patentable.<sup>7</sup> To that light, synthetic DNA sequences are therefore more easily patentable than DNA sequences derived from natural sources. Genetic sequence constructed using synthetic biological techniques, thus, not be products of nature would remain patentable. However, the ethical justification of DNA synthesis may be debatable (Section 3 (b)). Moreover section 3 (d) excludes the inventions pertaining to new form of the existing substance if there is no enhancement of efficacy.<sup>7</sup> If the synthetic DNA sequence possess similar efficacy of naturally occurring gene/DNA sequence then it is not patentable. There should be enhancement

of efficacy to be patentable. What percentage of efficacy will be considered increase in efficacy is not clear. How different does something have to be considered different? How different can something be and still be considered the same? There are no clear guidelines for dealing these issues.

One of the revolutionary applications of SB is the development of CRISPR-Cas 9 technology, a simple and effective gene editing tool that can find, cut and replace DNA at a specific location.<sup>8</sup> Most of the objections and rejections made for CRISPR-Cas 9 patent applications under section 3 (c), (d), (e), (i) and (j) of Indian patent Act.<sup>9</sup> For example, some of the inventions were concluded as mere discovery of something that exists in nature mere discovery of new form, new property of existing substance, aggregation of the properties of the components, process for producing such substance aggregation. Many inventions were barred as those refer to treatment of the impaired cells by altering cell function and/or if it is directed to eukaryotic cell.<sup>9</sup>

Software infrastructure in the SB laboratory deserves special attention. Software patents are a problem because patent laws in jurisdictions around the world are not clear on this aspect. India patent system (Section 3(k)) bars software related innovation but copyright is allowed. Currently, synthetic biologists use multifaceted software, artificial intelligence tools for circuit design and implementation, circuit optimisation, DNA and RNA design, protein design, target identification, integrated workflows etc. The objection exists as default for most of the computer-related inventions in India.<sup>9</sup> The decision in such cases is not consistent with different examiners forming their own views in terms of the requirement. One possible recommendation would be that innovators focus on the key features and seeks protection on the methodology used to reach the claimed innovative concept not the software per se. The composition claim can be framed for the invention accordingly in which the computer programme/software code is one of the features.



**Figure 1: Basic criteria for patent protection**

SL#	Non-Patentable subject matter
1	Section 3 (a) Inventions those are frivolous and contrary to natural laws
2	Section 3 (b) Inventions which go against public morality
3	Section 3(c) the mere discovery of something that exists in nature
4	Section 3 (d) the mere discovery of a new form of already existing known substance without enhancement of the known efficacy
5	Section 3 (e) A mere admixture resulting only in the aggregation of the properties
6	Section 3 (f) The mere arrangement or re-arrangement or duplication of known devices each functioning independently
7	Section 3 (h) A method of agriculture or horticulture
8	Section 3 (i) Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human or animals to render them free of disease
9	Section 3 (j) Plants and animals in whole or any part including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals

10	Section 3 (k) A mathematical or business method or a computer programme per se or algorithms
11	Section 3 (l) A literary, dramatic, musical or artistic work or any other aesthetic creation
12	Section 3 (m) A mere scheme or rule or method of performing mental act or method
13	Section 3 (n) A presentation of information
14	Section 3 (o) Topography of integrated circuits
15	Section 3 (p) traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components
16	Section 4 Atomic energy related inventions

**Table 1: India Non-Patentable subject matter**

## Conclusion

Globally SB has advanced rapidly in the last decade; however, in India it is in nascent stages. We're seeing a proliferation of patents in this field, with the potential for significant impact on health, agriculture, the environment and the economy.<sup>10</sup> If governments are serious about the progress of biological research, they will have to consider the implications of patenting of SB. It is necessary to reconstruct the section 3 to promote the innovation related to emerging technologies. One of the immediate action items is the communication among diverse sectors including scientific communities, policymakers, IP professionals and patent examiner to come up with a road map and guidelines for treating SB and other emerging fields. It is the time to re-evaluate, revise the existing policy in light of emerging technologies. It is crucial to make sure that Patent examiner gets adequate trainings and guidelines for SB or other related areas. Scientist and IP professional need to focus on human intervention, redesigning part and

highlight the features of the invented technology. They should describe how the invented technology would be beneficial for social welfare over existing technologies by pinpointing the potential industrial revolution. Given the potential of SB in biomedicine, agriculture, energy and other sectors it is important that SB gets the priority it deserves.

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