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Patentability of Biotechnology in India

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ABSTRACT

Biotechnology is a culmination of human intervention and natural processes. Though the evolution of patent law on biotechnology dates back to the seventh century, the global adoption of the patent system started in Venice as the first patent law was enacted in 1494, which regarded as the foundation for the world's patent system. The trend of filing biotechnological patents in India has a steady growth as in 2008-09 the total filing was 1884, 2009-10 the total biotech application is about 2700, however, the highest filing recorded so far is 2774 in 2007. India is one of the bio-diversity rich countries, it would be prudent to protect biotechnological inventions as that would help Indian biotechnology research to compete globally. India needs to reap the due benefits from its rich bio-resources with an enabling provision for patent protection in biotechnological innovations and inventions. This paper author will discuss the biotechnology patenting activity in India, patentability of biological material and patentability of microorganism. This paper also includes case analysis which will reflect about biotech patent jurisprudence in India. At last, it includes a comparative analysis of few international provisions with India provision to get a clear understanding in the topic.

Keywords: *Biotechnology, Patent act, Bio- diversity, biotechnology patent activity.*

I. INTRODUCTION

Biotechnology comprises any technology that uses living entities, in particular animals, plant or microorganism. According to the Organization for Economic Corporation and Development (OECD) – biotechnology includes any technique that uses living organism (or it's part) to make or modify product, to improve plant or animal or to develop microorganism for specific use.³ The biotechnological inventions can be classified broadly into following – (a) invention relating to an organism or material such as living entities of natural or artificial origin (animal, plants and microorganism), biological material and natural occurring substance from livings, (b) inventions relating to the process for the creation of a living organism or product of other biological material and (c) invention relating to the use of such

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³ Patents and innovation: Trends and policy challenges. OECD, Paris, 2004

organism or biological material.⁴

While individual rights on physical property are accepted and recognized in modern society however rights related to intellectual property rights remains a controversial issue till now. Patent in particular has been the center of this universal debate. In the words of Abraham Lincoln “patents were supposed to promote entrepreneurship and industrial development by adding “fule of incentives” to the “fuel of genius”. At the same time patents were treated as a threat that will create monopolies in the market and corporatization of R&D, wherein the rate and direction of innovation are largely guided by commercial motives, devoid of much “fire of genius”⁵

The invention of genetic engineering technology and the consequent growth of modern biotechnology industry had added in new dimensions to the debate. As per one of the lecture given by Nobel prize winner Edward Tatum in 1958 – the basis purpose of genetic engineering seems to control and regulate the functions of the genes in order not to just avoid the structural and metabolic defects but to produce new and better organisms. Accordingly the prospect for its widespread use to develop medicine, enhance the nutritional value of edibles , modifying plants that will be pest resistance since its very inception therefore biotechnology has tremendous prospect for commercial application. This can explain the widespread of privately appropriate new invention in this field. A nd indeed biotechnology industry had seen the highest growth in the patent . In a report of 2006 its states that biotechnology patent have grown at an annual rate of 8.3% a year while the overall growth in the European patent office has been 5.7%⁶ and now in 2020 the number keeps on going up.

⁴ IP India Official, https://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf (Last visited Jan 20 2021)

⁵ Alexanderson, *Inventors I have known*. In: Alger P (ed) *The Human Side of Engineering*. Schenectady, p. 137(1972)

⁶ Khan M, Dernis H *Global Overview of Innovative Activities from the Patent Indicators Perspective*. STI Working paper 2006/3. OECD, p 44 , 2006

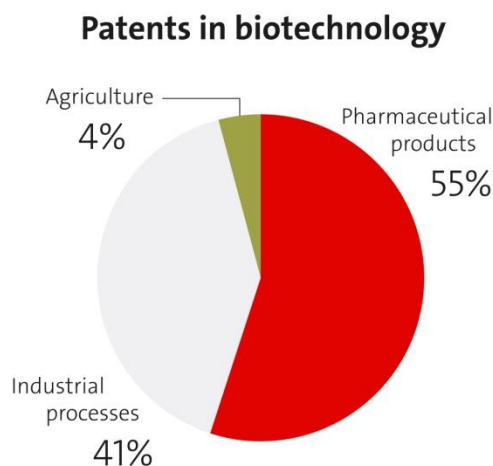


Figure 1⁷

The biotechnology was granted the first time patent in the year 1980, when first Cohen Boyer recombinant DNA patent in 1984, cell line derived from human leukemia patient patented in 1986, genetically engineered corn patented in 1988

II. EVOLUTION OF PATENT IN BIOTECHNOLOGY

The use of patent in protection biological process dates back to the protection of plant variety by US Plant Patent Act 1930. However, many of the countries were against the idea of extending patent in plant varieties because of the social cultural belief where plant was considered as a product of the nature. The pressure from plant breeding industry in Europe, nevertheless resulted in the formation of International Union for the Protection of New Varieties of Plant (UPOV) to protect plant varieties of select plants (largely excluding consumption items), provided they are distinct, uniform and stable (DUS)⁸

Indian Patent practice and jurisprudence with respect to the patenting of biological material are new and still have lacunae in it. Apart from just standard patentability, biotech product is made to cross over other hurdle like mandatory disclosure of biological material, prior approval from biodiversity board which itself have lots of complications.

The Indian patent act does not describe, in an inclusive manner about what things will come under patentability. Rather, section 3 includes a list of inventions considered not patentable. With respect to biotechnology, the Indian Patent Act 1970 as amended till date specifies

⁷ Pie Chart of patenting in different sector, Available at [pie-chart-large.jpg \(4455x4338\) \(epo.org\)](#) (Last visited March 14, 2021)

⁸ Distinctness refers to the unique characteristics compared to what is common knowledge. Uniformity implies possessing of that distinct characteristic by the whole population in a uniform manner. Alongside the uniformity requirement, inheritance of the distinct characteristic of the parent seed is demanded among its progeny to ensure stability. See, for instance, Rangnekar (1999, p 131) for detail.

under section 3(a) to 3(e), 3(h) to 3(j) and 3(p)⁹ inventions that will not be included as a patentable subject matter in India. However, Clause 3(c), 3(d), 3(i), 3(j), 3(p) are important in the context of patentability of biotechnological invention. Clause 3(c) states that “That mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living things or non-living substance occurring in nature”¹⁰ will not be considered as patentable invention. This provision of non-patentability is common to patent law of other countries. The Clause 3(j) states that “plant and animal in whole or any part thereof other than microorganism including seeds, varieties and species and essential biological process for production or propagation of plants and animal as non-patentable invention”¹¹. This provision is different in countries like US, EU & Japan where they grant liberal patent standard and here patent are granted to genetically modified organism including plants. This exception is as per non-patentability is allowed as per TRIPS agreement which provide exception to different countries and allows them to protect varieties as per them.

Invention in biotechnology category filed were mostly of the foreign origin but there was considerable increase in Indian applications, these applications were mostly on the topic of patenting related to topic DNA molecule, vaccines, monoclonal antibodies, recombinant therapeutic molecules, diagnostic kits, stem cells, recombinants hormones, DNA related subjects likes plasmids, vector etc, bioleaching, biotransformation, biological treatment of waste, gene and somatic cell therapy, pluripotent stem cell, recombinant microbes protein such as HIV protein, regulation of cell mediated immune response, recombinant leukemia IL-18 inhibitors, vaccines against cholera and tetanus, peptides based immunotherapy for atherosclerosis, mixed gene therapy, bone generation by gene therapy.

Like other countries India have few predefined restrictions regarding the subject matters claimed as the invention, it must be new, non – obvious, industrially applicable and required sufficient disclosure. When something which is a new compound exists in nature is discovered then one cannot obtain patent because the form of it is not new. Further to translate the discovery into patentable subject matter, the discovered component must be substantially changed through human intervention into a form in which it does not occur in nature or employed in a process resulting in to technical advancement and or economic significance.¹²

Below there are list of few patentable and non-patentable subject matter.

⁹ The patent Act, 1970. Section 3, Acts of parliament

¹⁰ Ibid

¹¹ Ibid

¹² Manual of patent practice and procedure, The patent Office, India, P 22

I) PATENTABLE INVENTIONS¹³

- A. Gene sequence, DNA sequence without having disclosed their functions are not patentable for lack of inventive steps and industrial applications.
- B. Living species having artificial origins such as vaccines are patentable.
- C. Biological material such as rDNA, plasmids are patentable provided they are produced by substantive human intervention.
- D. Modified microorganism & process
- E. Process of isolation and modification.
- F. Cell lines are patentable if artificially produced
- G. Hybridona technology is also patentable.
- H. Treatments of plants
- I. Remediation
- J. Bio probes
- K. Diagnostic/Equipment kits or research tools
- L. Treatments – Water, Air, Environment purification
- M. R-DNA , r-RNA, Antibodies

II) NON PATENTABLE INVENTIONS¹⁴

- A. Discovery of living things or non living things substance in nature- Section 3(c)
- B. Essentially biological process for the production or propagation of plant and animal – Section 3(j)
- C. Any process for the medicinal, surgical, curative, prophalactics, diagnosis or therapeutic or other treatment of human being or animal. – Section 3(i)
- D. New use or new property of known substance – 3(d)
- E. Method of agriculture or horticulture – 3(h)
- F. Traditional Knowledge – Section 3(p)

¹³ The Free DSictionary - <https://legal-dictionary.thefreedictionary.com/Patentable+Inventions> (Last Visited at 12-03-21)

¹⁴ Swidish Intellectual Property Office - <https://www.prv.se/en/patents/applying-for-a-patent/before-the-application/what-cannot-be-patented/> (Last Visited at 12-03-21)

G. Ordre public and morality exception – Section 3(b)

III. ETHICS IN BIOTECHNOLOGY PATENTS

Indian tradition is well known for worshipping animals and plants. They worship cow and plants such as tulsi, neem etc... Perhaps, Indian considers certain plants and animals as a form of God. For an Indian patenting of such plants, animals and other living beings would be sacrilege in India. Owning of living beings is not encouraged in the interest of public order and morality as it was a long-standing tradition in India is not encouraging private property rights over the living and natural things. The Patents Act 2005 addresses ethics in patenting inventions in general by saying that inventions which are against ethical and moral standards are not Patentable.¹⁵ Meanwhile, following the suit of the TRIPS agreement in amendments to its patent law. The Patent Act states that any invention, the exploitation of which is against public order and morality and that may cause serious prejudice to the health of human being, animals or the environments cannot be patented.¹⁶ Further, plant, animals, and essentially biological processes for the production of plants and animals are excluded from patenting on ethical grounds.¹⁷

Under TRIPS, inventions like micro-organisms and such other living inventions produced through microbiological or non-biological or biotechnological processes are patentable.¹⁸ Being a member of TRIPS agreement India does adhere to it, in patenting above inventions. Patenting of such living beings goes against the customary practices and ethical standards in India. However, as it is mandatory on the part of India to grant a patent on inventions which TRIPS do intend to provide patent for, India now encourages patents for micro-organisms and such other living inventions produced through the microbiological or non-biological or biotechnological process through an amendment made to the Patents Act in 2005.

Till now no patent has been granted on living beings unlike in the US and Europe. Therefore, no serious discussion on ethics involved in the patenting of biotechnology inventions has taken place. In future, some serious ethical debates are expected in India on patenting of living beings and of biotechnology inventions in view of its seriousness over ethics and morality. In fact, India began patenting of biotechnology inventions after it was universally settled that living beings could be patented except human beings.

A patent was granted on the living process on the direction of the Calcutta High Court. The

¹⁵ The Patents Act 1970, Chapter II of the Act Inventions not patentable. Acts of parliament

¹⁶ The patent Act, 1970. Section 3(b), Acts of parliament

¹⁷ Ibid., Sub Clause (i)

¹⁸ The TRIPS Agreement 1995. Article 27

court held that there was no bar for patenting living beings or living processes under the patents act. However, no ethical or moral issues involved therein were considered in the case. Ethical objections should not undermine the potential benefits of inventions. We cannot forgo the utility of biotechnology inventions by strictly implementing ethical standards.

IV. PATENTABILITY OF BIOLOGICAL MATERIAL

Mandatory disclosure is required in patent application of source and the origin or geographical location and what all other material used during the invention. – Section 4(d)¹⁹ of Indian Patent Act 2005. In case of patent application involving biological material such as DNA, a recombinant vector, or cells or invention related to genes that may not be described in such a way as to satisfy the enablement and best mode requirements and if such material is not available to the public, submission and/or deposition of biological material to an International Depository Authority (IDA)²⁰ under the Budapest treaty is required if adequate disclosure is not possible - Sec.10 (4) (ii).²¹ The disclosure is mandatory if any specific material imparting the specific property is required to work the invention.

In case the material such as proteins/peptides/amino acids prepared synthetically can substitute the live material to work the invention appropriate submissions may help to overcome the objection. The law also provides for pre-grant opposition and revocation of granted patents of grounds of non-disclosure or wrongful disclosure of source or geographical origin of biological resources and traditional knowledge - Sec. 25(1)²² & Sec. 64²³

The Microbial Type Culture Collection (MTCC) at the Institute of Microbial Technology (IMTECH) in Chandigarh is the IDA in India. However, the scope of this IDA is limited because it is not equipped to accept deposits of “cell lines, cyanobacteria, viruses etc²⁴. Biological deposits of such materials would presumably need to be made in IDAs located outside of India, resulting in increased cost and administrative complexity for domestic biotechnology firms.

National Biodiversity Authority’s prior approval is required for accessing biological material by foreigners/NRIs (Sec. 3) as well as before seeking patent based on biological material and

¹⁹ The patent Act, 1970. Section 4, Acts of parliament

²⁰ “National Agriculturally Important Microbial Culture Collection”, Unit of ICAR-NBAIM by World Intellectual Property Organization (WIPO), Geneva, <https://icar.org.in/hi/content/acquisition-status-international-depository-authority-ida-%E2%80%9Cnational-agriculturally-important>

²¹ Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, p – 3 https://ipindia.gov.in/writereaddata/Portal/News/691_1_Budapest_338_E.pdf

²² Ibid

²³ Ibid

²⁴ Section D: Requirements of International Depository Authorities (IDAs), https://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/section_d.pdf

TK obtained from India Sec 6(1) of Biodiversity Act 2002²⁵

V. PATENTABILITY OF MICRO-ORGANISM

Guidelines were formulated for the examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.

Microbiological inventions include new products, processes, uses and compositions involving biological materials. These inventions cover methods to isolate and obtain new organisms, improve their character, modify them and find their new and improved uses.

Patenting of new micro-organisms is based on their differences with the characteristics & uses of micro-organisms as available in the prior art. Known micro-organisms are restricted to new uses, wherever patent law permits such protection. The same is the case with genetically modified micro-organisms. Genes and gene products are treated similar to chemical compositions.

In the *Dimminaco AG vs. Controller of Patents*²⁶, the Calcutta High Court held in 2002 that a patent on a micro-organism is valid. The court ruled that the Act did not preclude a living end product from being patented. As a result, a large number of patents have been granted to microorganisms since then

Universally, as practised by most patent offices, new micro-organisms isolated for the first time from the natural surrounding can only be patented if they differ in character from the known micro-organisms and find a new or improved use or function. Claims to micro-organisms have been allowed because they are the products of microbiological processes.

VI. RELATIONSHIP BETWEEN PATENT LAW AND CONSERVATION BIOLOGICAL DIVERSITY (CBD)

India enacted the Biological Diversity Act to address the issues of prior informed consent, disclosure and access and benefit-sharing. This Act primarily aims at regulating access to biological resources and associated traditional knowledge to ensure equitable sharing of benefits arising out of their use.

All matters relating to requests for access by foreign individuals, a non-resident Indian, institutions or companies (that are not incorporated or registered in India; or incorporated or registered in India with foreign participation in its share capital or management), and all

²⁵The Biodiversity act 2002, Section 6 ,

²⁶ LAWS(CAL)-2002-1-58, <https://www.the-laws.com/Encyclopedia/Browse/Case?CaseId=502002036000&CaseId=502002036000>

matters relating to the transfer of results of research to any foreigner are dealt with by the NBA. Section 3 provides that all foreign national require approval from NBA for obtaining Biological Resources or knowledge associated with it and Section 4 provides that Indian individuals/entities to seek approval before transferring knowledge/research and material relating to any biological resources (occurring in or obtained from India) to foreign individuals, non-resident Indians, institutions or companies (that are not incorporated or registered in India; or incorporated or registered in India with foreign participation in its share capital or management). NBA may consult the Biodiversity Management Committees (BMC) or any other expert committee constituted for this purpose and thereafter grant approval under Section 19 subject to such terms and conditions it may deem fit.

In case of Collaborative projects (covered by Section 5²⁷ of Biological Diversity Act) that are either approved by the Government or conforms to the policy guidelines formulated by the Government, no further approval is required from NBA.

For flora such as bacterial or fungal strains habitant from reserved and protected forests, notified sanctuaries and national parks are regulated by the Indian Forest Act, 1927²⁸ and Wildlife Protection Act, 1972²⁹. The Indian Forest Act and Forest (Conservation) Act deal with the management of forests and conservation of forest land respectively. Wildlife (Protection) Act is for the protection of wild animals, birds and plants, and aims at protecting, propagating or developing wildlife or its environs through national parks, sanctuaries etc. Also, the Act has a provision to prohibit picking and uprooting etc. of specified plants.

In the Biological Diversity Act, 'Biological resources' mean plants, animals and micro-organisms, their genetic material and by-products with actual or potential use or value. Human genetic material is outside the purview. However, extracts of bacterial and fungal strains and all value-added products are not encompassed in the definition of 'biological resources' and thus do not require the approval of the NBA. The Indian collaborating company of a foreign entity is only required to give prior intimation to the concerned State Biodiversity Board about obtaining such material for commercial purposes. The fees payable for export permits will be regulated by EXIM policies. Please note that additional permission is required from the Director-General of Foreign Trade for import and export of certain biological material.

The Biological Diversity Act forbids an application for any IPR in or outside India without

²⁷ Biodiversity act 2002, Section 5

²⁸ The Indian Forest Act, 1927 <http://nbaindia.org/uploaded/Biodiversityindia/Legal/3.%20Indian%20forest%20act.pdf>

²⁹ Wildlife Protection Act, 1972, http://legislative.gov.in/sites/default/files/A1972-53_0.pdf

prior approval of the NBA. The Gate keeping for this is envisaged at several stages:

1) Section 6(1)³⁰ provides that prior approval of NBA is necessary before applying for any kind of IPRs (in or outside India) based on any research or information on a biological resource obtained from India.

Such approval, however, is not required where IPR rights relating to the protection of plant varieties are applied for [Section 6(3)]. This is because in such cases, it is the Plant Varieties and Farmers' Rights Authority, established under the Protection of Plant Varieties and Farmers' Rights Act, 2001³¹, which grants the right and determines the benefit sharing. This Authority, in turn, endorses the grant of right to the NBA;

2) In case of Patents, one can procure such approval after the publication of the patent application and before the grant of patent.

3) In case of assignment of IP rights to third persons, the persons who have been approved for access to biological resource and associated knowledge may transfer the same by taking approval from the NBA.

While granting such permission, the NBA is most likely to impose benefit sharing conditions such as monetary benefit like royalty, joint ventures, technology transfer product development. The parameters involved for payment of such compensation are the extent of use, sustainability aspect, impact and expected outcome levels, short term and long term benefits etc.

NBA drafted new guidelines on access and benefits sharing particularly on International Regime on Access and Benefit Sharing; Evolving *sui generis* system for the protection of Traditional Knowledge and Amendments to the Biological Diversity Act, 2002³² and Biological Diversity Rules, 2004³³ and opened for a public hearing. The final draft is yet to be released.

VII. CASE LAW BIOTECH PATENT IN INDIA

Dimminaco A.G. v. Controller³⁴: In India, there is no substantial case law development with regard to the biotechnology inventions in India as the industry is in an infant stage. The leading biotechnology patent law decision of the Indian courts is the A.G. v. Controller of

³⁰ The convention on Biodiversity Act 1993

³¹ Protection of Plant Varieties and Farmers' Rights Act, 2001, <https://vikaspedia.in/agriculture/policies-and-schemes/crops-related/protection-of-plant-varieties-and-rights-of-farmers/protection-of-plant-varieties-and-farmers-rights-act-2001>

³² Ibid - 26

³³ The Biological Diversity Rules, 2004, <http://extwprlegs1.fao.org/docs/pdf/ind53983.pdf>

³⁴ Ibid - 23

Patents, Designs & Trade Marks (in 2002), where for the first time, and utility of a biotech invention was demonstrated. The invention related to a process for the preparation of infectious bursitis vaccine. The vaccine was useful for protecting poultry against contagious bursitis infection. Initially, the Patent Office rejected the patent application on the ground that the claim did not constitute an invention. But the utility of the invention was not disputed. Although this decision was issued more than twenty years after the U.S. Supreme Court's decision in *Diamond v. Chakrabarty*³⁵, Indian commentators view it as epoch-making as by this decision, the court overturned a long-standing policy of the Indian Patent Office to refuse such process claims, thus opening the door to biotechnology patenting in India much as the Chakrabarty decision did in the United States.

The Assistant Controller of patent observed that “in India till date, no patent had been granted for any process of preparing a living organism. In the Controller's view if such a process became patentable, “there will be further problems as foreign sophisticated technologies will have to be patented in India. The Assistant Controller also contended that the framers of India's Patents Act, 1970, had relied on the 1959 recommendation of the government commissioned Iyengar Committee that “invention” should be defined narrowly. Appellant Dimminaco countered that the Patent Office had not cited any anticipatory prior art against the claimed process, nor had it questioned the utility of the end-product vaccine. Therefore, the process should be held a patentable “manner of manufacture” coming within the Patent Act's enumerated categories of inventions. After summarizing the parties' respective arguments, the Calcutta High Court considered the scope of “manner of manufacture”³⁶ under section 2(i)(j)³⁷ of the Patents Act, 1970, and noted that the word “manufacture” was not defined in the Patents Act. In such cases, the court explained, the dictionary meaning of “manufacture” or its usage “in the particular trade or business must be accepted. Further, in order to decide whether a particular process of manufacture “ought to be patented or not, “one of the most common tests is the vendibility test. This test is satisfied “if the invention results in the production of some vendible item something which can be passed on from one man to another upon the transactions of purchase and sale claimed method was a patentable invention because the dictionary meaning of the word manufacture does not exclude the process of preparing a vendible commodity which contains a living substance. Where, as in this case, the Patents Act, 1970, provided no definition of “manufacture,” then “the dictionary

³⁵ 447 U.S. 303 (1980)

³⁶ Srividhya Ragavan, Patent Judicial Wisdom, *National Law School of India Review* Vol. 20, No. 2 pp. 165-180, p 170 (2008),

³⁷ The patent Act, 1970. Section 2(i)(j), Acts of parliament

must be accepted. The Assistant Controller had legally erred “by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention.

In overturning the Assistant Controller’s decision, the court held that there was evidence that the Indian Patent Office had already granted a few biotechnology process patents producing a living end product. The Assistant Controller had “not acted on correct principles” by rejecting Dimminaco’s application on the ground that it could not be called a “manner of manufacture” because it involved a living virus in the end-product. The Indian Patent Office appears to have adopted Dimminaco’s teaching that the fact that an invention is living (or produces a living product) does not automatically exclude it from patentability.

The MPPP states that a “living entity of artificial origins such as micro-organism, or vaccines are considered patentable, although higher life forms such as plants or multi-cellular animals, whether of natural or artificial origin, are not. Moreover, biological material such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable provided they are produced by substantive human intervention. In addition, the processes relating to micro-organisms or producing chemical substances using such micro-organisms are patentable.

VIII. CONCLUSION

As stated hereinbefore, the issues that relate to the patenting of biological material are relatively new to India. The standardized practice has yet to be satisfactorily established with respect to patenting or non-patenting of biological inventions. However, if a claim of an invention is related to a novel and inventive and modified genetic material, wherein such genetic material is identified by its protein or amino acid sequences at least in the description and in the claims, such genetic material is capable of industrial application, then the Patent Office generally accepts such invention as patentable. Therefore, the inventions are subject to the fulfilment of the relatively broad criteria. It is noteworthy to mention that the patenting of biological material in India is still decided more often on a case-by-case basis.

One future challenge with the entrepreneurship research is, perhaps, to accommodate the issue of farm-entrepreneurship in the context of UPOV and TRIPS. Also, even if it is established beyond doubt that university patents have been crucial for new biotech start-ups, one may further investigate whether or how patents encourage these neo-entrepreneurs to maintain their innovative spirit in the long run.

Similarly, what could be a satisfactory solution to the benefit sharing debate? Whether -a simple extension of existing intellectual property rights, or monetary or non-monetary compensations would do, or something more novel prescription is warranted? If some form of intellectual property rights is given, what would be the penalty for attempts to infringe on such rights? Given that litigation costs are asymmetrically distributed across countries, whether such an approach would be fruitful. All this would require intense empirical examinations by the scholars of development and public policy, especially in developing countries. While adequate amount of data still poses a constraint one should also not get lost in data and information, losing sight on these larger theoretical questions. Unfortunately, policy research component is not much appreciated in many of the developing countries, and many researchers vent a great deal of energy to make their work either information rich, devoid of theory or opinion rich, with inadequate data. A proper balance would be required.

Furthermore, India being one of the bio-diversity rich countries, it would, thus, be prudent to protect biotechnological inventions as that would help Indian biotechnology research to compete globally. India needs to reap the due benefits from its rich bio-resources with an enabling provision for patent protection in biotechnological innovations and inventions.
