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Reaping the Fruits of Research on Microorganisms: Prospects and Challenges for R&D and Industry in Sri Lanka

Ruwan Fernando



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RESEARCH PAPER

159

REAPING THE FRUITS OF RESEARCH ON MICROORGANISMS: PROSPECTS AND CHALLENGES FOR R&D AND INDUSTRY IN SRI LANKA

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15 JULY 2022

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ABSTRACT

When the Intellectual Property Bill designed to secure compliance with the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") was challenged in the Supreme Court of Sri Lanka, the Court determined that the patenting of naturally occurring microorganisms by right holders would result in the increase of the prices of diagnoses and cures. The Supreme Court found that in the absence in the Bill of mitigatory measures -as allowed by the TRIPS Agreement- and of a working definition of the term "microorganism", there was a violation of the right to equal protection under Article 12 (1) of the Constitution. In the circumstance, the patent protection for microorganisms was narrowed down to transgenic microorganisms.

The policy makers do not appear to have disregarded the positive impact of the Supreme Court determination by making the necessary statutory provisions and policy changes to facilitate the patent applications on transgenic microorganisms, while ensuring that local researchers are not restrained from gaining access to naturally occurring microorganisms for research and development.

Cuando la Ley de Propiedad Intelectual, que fue diseñada para garantizar el cumplimiento del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual Relacionados con el Comercio (Acuerdo sobre los ADPIC), fue impugnada ante el Tribunal Supremo de Sri Lanka, éste determinó que la concesión de patentes sobre microorganismos naturales por parte de los titulares de los derechos daría lugar a un aumento de los precios de los diagnósticos y las curas. El Tribunal Supremo determinó que, en ausencia de medidas de mitigación incorporadas en el Acuerdo sobre los ADPIC en el proyecto de ley y la no inclusión de ninguna definición de trabajo al término "microorganismo" en el proyecto de ley, sería una violación del derecho a la igualdad de protección en virtud del artículo 12 (1) de la Constitución. En esta circunstancia, la protección de las patentes de microorganismos se redujo a los microorganismos transgénicos.

Los responsables políticos no parecen haber ignorado el impacto positivo de la decisión del Tribunal Supremo al adoptar las disposiciones legales y los cambios políticos necesarios para facilitar las solicitudes de patentes sobre microorganismos transgénicos en cumplimiento del Acuerdo sobre los ADPIC y otros acuerdos internacionales, al tiempo que garantizan que los investigadores locales no se vean limitados a la hora de acceder a los microorganismos de origen natural para su investigación y desarrollo.

Lorsque le projet de loi sur la propriété intellectuelle, qui visait à garantir la conformité avec l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce ("Accord sur les ADPIC"), a été contesté devant la Cour suprême du Sri Lanka, celle-ci a estimé que le brevetage des micro-organismes naturellement présents dans l'environnement par les titulaires de droits entraînerait une augmentation des prix des diagnostics et des traitements. La Cour suprême a déterminé qu'en l'absence de mesures de mitigation incorporées dans l'Accord sur les ADPIC et la non-inclusion d'une définition pratique du terme " micro-organisme " dans le projet de loi, il y avait une violation du droit à une

protection égale en vertu de l'article 12 (1) de la Constitution. Dans ces circonstances, la protection par brevet des micro-organismes a été restreinte aux micro-organismes transgéniques.

Les responsables politiques ne semblent pas avoir négligé l'impact positif de la décision de la Cour suprême en adoptant les dispositions légales et les changements politiques nécessaires pour faciliter les demandes de brevets sur les micro-organismes transgéniques conformément à l'accord sur les ADPIC et à d'autres accords internationaux, tout en veillant à ce que les chercheurs locaux ne soient pas empêchés d'accéder aux micro-organismes naturellement présents pour la recherche et le développement.

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1. INTRODUCTION

The issue of patent protection for microorganisms drew a great deal of attention in Sri Lanka when three petitioners challenged the Intellectual Property Bill, which was designed to secure compliance with the TRIPS Agreement, on the ground that the certain patent provisions of the Bill were inconsistent with Article 12 (1) of the Constitution of Sri Lanka.² Article 12 (1) of the Constitution guarantees that all citizens are equal before the law and are entitled to equal protection by the law.³

The patent provisions of the Bill were challenged as being inconsistent with Article 12 (1) of the Constitution on two grounds. The first ground concerned the negative impact of the patent protection on the prices of pharmaceutical drugs. The petitioners argued that the failure of the State to include mitigatory measures, consistent with Article 31 of the TRIPS Agreement and reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") such as compulsory licensing and parallel importing of pharmaceutical drugs to meet the national health emergencies, was inconsistent with Article 12 (1) of the Constitution.⁴

The other ground of challenge was that the provision that allows for the patenting of microorganisms without any limitations to the protection conferred is inconsistent with Article 12 (1) of the Sri Lankan Constitution.⁵ The petitioners contended that in the absence of a definition of the term "microorganism", it would be possible for a variety of pathogens to be patented paving the way for a patent holder to carry out research for the purpose of diagnosis and finding cures, which will increase the prices of diagnoses and cures.⁶ The petitioners also argued that product patents for food, medicines and drugs should be prohibited to ensure the equal protection of the public by the law and persuaded the Court to limit the protection to "transgenic microorganisms".

The Supreme Court of Sri Lanka accepted both arguments and held that Article 12 (1) of the Sri Lankan Constitution not only guarantees equality before the law, but also provides for equal protection by the law. Thus, the Supreme Court determined that (i) the failure of the State to include those mitigatory measures is inconsistent with Article 12 (1) of the Constitution; and (ii) the non-inclusion of the necessary definition to the term "microorganism" would pave the way for a variety of pathogens to be patented, which in effect will increase the prices of diagnoses and cures, is inconsistent with Article 12 (1) of the Constitution which guarantees equal rights and equal protection to citizens.⁷

The State, however, corrected the clauses that the Supreme Court found inconsistent with the Constitution by incorporating mitigatory measures such as compulsory licenses and parallel importation in respect of pharmaceutical products and public health concerns.⁸ The patent protection of microorganisms was thus, restricted to "transgenic microorganisms".

² S. C. determination of the Intellectual Property Bill on 09.06.2003 in relation to Petitions Nos. 14/2003, 15/2003 & 16/2003, 1074.

³ Ibid.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.

⁷ Ibid.

⁸ Intellectual Property Act, s. 86 (1) (iv) & (2).

The current Act therefore specifies that only “transgenic microorganisms” requiring direct human intervention as defined in the Act are patent eligible.⁹

This raises first, the important question of whether it would be compatible with the TRIPS Agreement to limit the grant of patents only to transgenic microorganisms and if so, under what conditions. This also raises the related question of whether the Supreme Court determination provides a useful policy option to policymakers in Sri Lanka to use the flexibilities incorporated in the TRIPS Agreement to promote and support the local innovations. Secondly, the patent protection for transgenic microorganisms also raises the important question of facilitating the patent procedure for the deposit of microorganisms in an internationally recognised depository authority irrespective of where the depository authority is located, in order to fulfill the disclosure and best mode requirement.

1.1 The Purpose of the Paper

The purpose of this paper is to examine the TRIPS compatibility of restricting patents to transgenic microorganisms in the context of patent law/policy measures that suit the national development needs of Sri Lanka as a developing country in protecting and promoting local inventions and innovations on microorganisms.

The paper considers first, the patentability criteria of microorganisms in the light of the provisions of the TRIPS Agreement. Secondly, it considers the scientific definition of microorganisms and the importance of inventions on microorganisms in the field of health and combating major epidemic diseases. Thirdly, it will consider whether a statutory definition of the term “microorganism” is necessary and if so, whether such a legal definition must be a guideline or a directive. Fourthly, it will consider the importance of statutory provisions to facilitate the deposit of microorganisms in an internationally recognized deposit authority for the patent procedure in order to fulfil the disclosure and the best mode requirement. Finally, it considers what patent law/policy measures are needed to promote local innovations related to microorganisms by adapting the patent law to local conditions in a manner consistent with the TRIPS Agreement.

⁹ Ibid., s. 212.

2. THE TRIPS AGREEMENT AND MICROORGANISMS

Article 27.1 of the TRIPS Agreement defines the minimum patentable subject matter and the subject matter that may be excluded from patentability. It reads as follows:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Thus, the term “invention” in Article 27.1 of the TRIPS Agreement, while undefined, imposes an obligation on member countries to ensure that the patentability involves satisfying a two-step test: (1) the technological advance claimed in the patent application is (a) an “invention” and if so, is it a patentable subject matter and (2) if so, is that “invention” (i) novel; (ii) involves an inventive step; and (iii) industrially applicable?

Although the TRIPS Agreement does not specifically refer to biotechnology under Article 27.1, patents shall be available without discrimination as to the field of technology¹⁰ which may include biotechnology as well. Accordingly, biotechnological inventions involving living organisms (life forms) under the TRIPS Agreement, form part of a patentable subject matter in some form or another in almost all member countries.

Under the provisions of paragraphs 2 and 3 of Article 27 of the TRIPS Agreement, the members may exclude from patentability two types of inventions, namely:

1. The prevention within their territory of the commercial exploitation of which is necessary to protect the order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.¹¹

2. a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; b) plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.¹²

Under Article 27.3 (b) of the TRIPS Agreement, microorganisms are patentable subject matter, provided that the requirements of patentability are met (novelty, inventive step and industrial applicability). The TRIPS Agreement does not define the term “microorganism”, nor the general patentability criteria, rather it leaves to the World Trade Organization (WTO)

¹⁰ TRIPS Agreement, Article 27.1.

¹¹ TRIPS Agreement, Article 27.2.

¹² TRIPS Agreement, Article 27.3.

members the discretion to do so. Members can also adopt appropriate measures, including pre- and post-grant TRIPS flexibilities to promote innovative and flexible uses of the intellectual property (IP) in a manner that would be consistent with the provisions of the TRIPS Agreement. Thus, the WTO members under the TRIPS Agreement are at liberty to define and exclude the subject matter in their domestic laws in a manner not inconsistent with the provisions of the TRIPS Agreement.

Garrison (2006) argues that given that the patent system has proved to be a beneficial institution in terms of encouraging innovation, patent holders ought to be accorded more extensive and more secure rights to tackle the “free rider” problem.¹³ Garrison, however, concedes that while exceptions to those rights must be minimised as far as possible, the extent of the rights provided to patent holders ought to be confined to the minimum to encourage the desired degree of innovation.¹⁴ Garrison suggests that this can be done either through a limitation of the rights initially accorded, or through commensurate exceptions.¹⁵ Therefore, Garrison suggests that the best approach is to take into account the interests of patent holders and the interests of society at large, focusing on providing better incentives for innovation, and also greater benefits for society in the long run.¹⁶

Garrison thus, suggests that exclusive patent rights should be neither too extensive nor too meagre. The approach suggested by Garrison is likely to protect local biotechnological inventions while promoting local “incremental biotechnological innovations” which are largely derived from the existing technologies.

In contrast, the 2011 Guide issued by the UNCTAD suggests that high level IP protection does not necessarily lead to more innovation and investment, particularly in developing countries and that they must use TRIPS flexibilities to shape the broad scope of exclusive rights both before a patent is even issued and after a patent has been granted.¹⁷ According to UNCTAD, pre-grant flexibilities such as patentable subject matter and patentability criteria constitute a generally applicable proactive tool, whereas post-grant flexibilities such as compulsory licences and parallel imports are usually limited to particular cases where the government considers an existing monopoly right to be too broad.¹⁸

Sri Lanka has declared in its biotechnology policy statements that its goals are to foster and promote local innovations of researchers and local industry. Sri Lanka is thus required to interpret the exceptions to patent rights in a manner that would suit its biotechnology patent laws/policies in order to promote local biotechnological innovations and minimise the implications of such exceptions on the legitimate interests of stakeholders.

Therefore, the policymakers should consider the suitability of the pre and post-grant TRIPS exceptions to be incorporated in the national legislation to ensure that biotechnology patent rights are not granted or used inappropriately by the patent owners against the national and stakeholder interests. The determination of the Supreme Court in restricting the patent protection to transgenic microorganisms is a clear recognition that the broad scope of patent protection would be detrimental to the interests of a developing country such as Sri Lanka in sectors of vital importance such as health, agriculture and energy food security.

¹³ Garrison C. “Exceptions to Patent Rights in Developing Countries” (2006) UNCTAD-ICTSD Issue Paper No. 17, Geneva, 2006, 21.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ UNCTAD, “Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide”, (2011), 13.

¹⁸ Ibid.

This policy objective seeks to prevent the abuse of patent rights by the right holders by limiting the broad scope of patents derived from natural substances so that the appropriate balance can be maintained between the right holders and the interests of stakeholders such as users of the technological knowledge and the holders of the biodiversity and associated traditional knowledge holders.

2.1 The Scientific Definition of Microorganisms

The term “microorganism” describes an organism that is too small to be seen with the naked eye without using a microscope.¹⁹ Microorganisms are generally regarded as living organisms that are microscopical in size and relatively simple, usually unicellular, in structure, including algae, bacteria, viruses and protozoa and unicellular algae, and microscopic fungi.²⁰ They are considered to be a category of life different from the kingdoms of plants and animals. Cells and tissues of higher plants and animals are the subjects of microbiology, but they are not microorganisms. Microorganisms are classified into 3 categories, namely, single-celled organisms, unicellular organisms and noncellular organisms.²¹

1. A single-cell organism consists of one cell and
2. A unicellular organism consists of multiple cells and fall into two categories namely,
 - (a) Prokaryotes (organisms without a cell nucleus such as bacteria); and
 - (b) Eukaryotes (organisms with a cell nucleus such as fungi, microscopic plants (blue algae), protozoa, moulds and microscopic animals);²²
3. Noncellular organisms (organisms lacking a cellular structure with no organised nucleus) are usually viruses, dependent on other cells for their production.²³

The main feature of a microorganism is that it is capable of being replicated or transferring genetic material *viz*, its DNA, either in culture or by DNA recombinant technology by direct human intervention so as to produce new organisms. The advantage of microorganisms for the purpose of patent protection is that microorganisms can be manipulated in the laboratory by transforming them into organisms by direct human intervention in their genetic composition so as to produce genetically modified organisms that express characteristics not attainable normally by microorganisms under natural circumstances.

2.2 Commercial Potential of Microorganisms

Microorganisms are used in different fields for the production of useful commercial products and processes which may fall within the definition of “invention” in section 62 of the IP Act of Sri Lanka. For example, the microbial production of antibiotics, vaccines, amino acids,

¹⁹ *Compact Oxford Dictionary Thesaurus* (Indian Edition, 2006), 563.

²⁰ John Adds, Erica Larkcom & Ruth Miller, *Microorganisms and Biotechnology*, (1st ed. Nelson 1998) 1.

²¹ *Ibid.*

²² William Bains, *Biotechnology*, (Reprinted ed. Oxford 1993) 210.

²³ *Ibid.*

steroids, organic acids, vitamins, foods and beverages, etc. are all valuable commercial products in the field of industrial, pharmaceutical and medical biotechnology. In the field of environmental biotechnology, microorganisms are used for clearing oil-contaminated tankers and oil spill management. In the field of food biotechnology, single-cell proteins (SCP) such as mushrooms, which are rich in protein, minerals, fats, carbohydrates are used as food supplements for humans and animals in combating hunger.

2.3 Patent Protection for Microorganisms

In considering the patentability of microorganisms, four different issues can be examined:

1. patentability of microorganisms themselves (microorganisms *per se*);
2. patentability of processes utilising microorganisms;
3. patentability of products produced by microorganisms;
4. patentability of microorganism mutations and of genetic modification techniques.

Microbiological inventions generally involve the use of a new strain of microorganisms to produce a new compound or to produce a known compound more efficiently such as to produce a higher yield or purity.²⁴ The new organism may have been found in nature, such as by a screening of soil samples or may have been produced in the laboratory by artificially induced random mutation (mutation/isolation) or by more specific techniques such as genetic engineering.²⁵ The commercial production of penicillin and streptomycin by fermentation technology in the US paved way for the development of microbiological industry in many other countries made way for the modification of their patent regimes.

2.4 Invention-Discovery Dichotomy

Patents covering microorganisms have been granted in a number of developing countries, including China and the Republic of Korea. In the UK, claims to microorganisms are allowed *inter alia*, as products of microbiological processes. There are different approaches among jurisdictions as to whether patent protection may be granted in respect of naturally occurring microorganisms such as pathogens and microorganisms found for the first time in the natural environment.

The patenting of living materials raises a fundamental question of whether living materials should be defined as “invention” or “creations” or “discoveries,” since both creations and discoveries are excluded from patentability. In general, a discovery can be defined as finding something that was previously unknown, but existed in nature, or as the identification of properties and utilities thus, far unknown.²⁶ It does not go through the application of human endeavour to produce a technical solution to an unresolved technical problem.²⁷

In contrast, an invention does not exist unless three fundamental requirements are fulfilled, namely, that (i) there must be a creative process; (ii) it must be new and (iii) it has a purpose

²⁴ Philip W. Grubb, *Patents for Chemicals and Biotechnology* (4th ed. Oxford 2004), 247.

²⁵ *Ibid.*

²⁶ Michal Cohen, “Patent Protection of Biotechnological Inventions-Economic Perspectives and the EC Directive Analysis”, (2001) Thesis, Erasmus Program in Law & Economics, 5.

²⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.* 161 F.2 d 981 (7th Cir. 1947 (Funk test 1)).

beyond the mere purpose of existence for the sake of existence.²⁸ The purpose must be “doing something”, “having some level of value” or “applicability” viz, utility, the level of which should, however, be beyond the sake of existence.²⁹

As opposed to a discovery, an invention is regarded as the creation of something by the man that did not previously exist and thus, while a discovery extends human knowledge, an invention increases practical abilities.³⁰ These practical abilities are necessarily the result of a human creative process and such creative process determines the level of invention and any new and useful improvement. This interpretation is based on the concept that something found in nature cannot be created or invented.³¹

The line between eligible and ineligible subject matter has traditionally been denoted by the terms “invention” and “discovery” with patent law, thus, being seen to rest on a fundamental distinction between protectable inventions on the one hand and unprotectable discoveries on the other.³² Thus, the invention versus discovery dichotomy has been applied to distinguish between protectable inventions and non-protectable discoveries. The patenting of living materials, thus, raises a fundamental question of whether living materials should be defined as “inventions” or “discoveries,” having in view that discoveries are excluded from patentability.

2.5 Chakrabarty Test for Patenting of Microorganisms

In the landmark case of *Diamond v. Chakrabarty*³³ the US Supreme Court held that a genetically engineered bacterium that was capable of breaking down crude oil, constituted a patentable subject matter as Chakrabarty’s bacterium did not exist in nature, but was rather a man-made product with different characteristics than any naturally occurring microorganisms. Chakrabarty, developed a bacterium (derived from the *Pseudomonas genus*) capable of breaking down crude oil, which he proposed to use in treating oil spills.

The bacteria in question did not produce a useful product, however; it had the useful property that could feed on, and so disperse and dissolve an oil layer. In this case, the respondent filed a patent application relating to a human-made invention, i.e. a genetically engineered bacterium with a property which is not possessed by the non-naturally occurring bacteria.

The patent application included three types of claims: (i) process claim for the method of producing bacteria; (ii) claims for an inoculum comprising a carrier material floating on water and (iii) claim to the bacteria themselves. The patent examiner accepted the first two claims but rejected the third claim on the ground that products of nature and living things are not patentable under the US law. The invention was rejected by the Patent Office on two grounds: (i) microorganisms are products of nature; and (ii) living things are not patentable subject matter under section 101 of the US Patent Act.

²⁸ John R. Rudolph, Gowling, Strathy & Henderson, (eds.), *A Study of Issues Relating to the Patentability of Biotechnological Subject Matter*, Report prepared by Intellectual Property Policy Directorate, Industry Canada, January 31, 1996, Chapter3. C. <http://www.ic.gc.ca/eic/site/ppd-nsf/vwapj/rudolpef/SFILE/rudolpef.pdf>.

²⁹ Ibid.

³⁰ Giuseppe Sena, “Directive on Biotechnological Inventions: Patentability of Discoveries”, 30 IIC, 731. (1999) Vol. 30, No. 7, 731–738.

³¹ John R. Rudolph, Gowling, supra note 114.

³² Justine Pila, “Bound Futures: Patent Law and Modern Biotechnology”, Boston University Thesis (2003), 15–16.

³³ *Diamond v. Chakrabarty* 447 U.S. 303 (1980).

The Patent Office Board of Appeals affirmed the rejection on the ground that living things are not patentable subject matter under section 101 of the US Patent Act. The Court of Customs and Patent Appeals reversed the decision holding that the fact that microorganisms are alive is without legal significance for purposes of patent law. The Court held that an invention derived from bacteria, which was made to dissolve an oil layer in the sea, had added a significant value for the treatment of oil spills and was patentable.³⁴

The Supreme Court subsequently held that a live human-made microorganism is patentable subject matter under section 101 as the respondent's micro-organism constituted a "manufacture" or "composition of matter" within section 101 of the statute.³⁵ The Supreme Court determined that Chakrabarty had produced a new bacterium with markedly different characteristics from any bacteria found in the nature.³⁶ The Court held that although the laws of nature, physical phenomena and abstract ideas have been held not patentable as discoveries (excluded from patentability), the Chakrabarty's micro-organism was a non-naturally occurring manufacture or composition of matter, a product of human ingenuity.³⁷

The Court held that Chakrabarty's bacterium did not exist in nature, but was rather a man-made product with different characteristics than any naturally occurring bacterium. The Court observed that the "claim" was not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity "having a distinctive name, character [and] use".³⁸ Therefore, the discovery is not nature's handiwork, but his own accordingly and it is patentable subject matter under section 101 of US Patents Act.³⁹

The Supreme Court observed that the patentee had produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.⁴⁰ The natural bacterium from the genus *Pseudomonas* did not contain 2 stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway. The addition of these two plasmids by Chakrabarty was the human intervention that ultimately transformed a natural bacterium into an artificial bacterium.

Accordingly, the invention in question was more than a discovery of natural phenomena or a law of nature but rather the end result of an intellectual process that involved in part a discovery or an abstract piece of information, but which ultimately involved the utilisation of other compounds. The court signaled that although the products of nature do not constitute patentable subject matter, they can be patentable where the end results create a fundamentally new product possessing a distinctive name, performed function, quality, character or use.

The Chakrabarty decision is likely to be recognized as a doctrinal test and broad endorsement of patenting living organisms qualifying for patent eligibility— a new product of human ingenuity having a new or useful end result-including distinctive characteristics such as name, quality, performed function, character or utility. The Chakrabarty test, therefore, is not confined to the new and useful features of an invention, but goes beyond that so as to include non-naturally occurring biological materials, whether living or not, with markedly different characteristics from the ones found in nature.

³⁴ Ibid., p. 306.

³⁵ Ibid., at 308–310.

³⁶ Ibid.

³⁷ Ibid. at 310.

³⁸ Ibid. at 309–310.

³⁹ Ibid.

⁴⁰ Ibid., at 131.

Accordingly, a newly discovered microorganism in nature is only a discovery. However, any genetically modified microorganisms such as a transgenic microorganism is patent eligible under the Chakrabarty doctrine. However, an invention which is incapable of industrial applicability does not meet the requirement of utility. Hence, an invention concerning a microorganism that does not describe the utility in the specification may not satisfy the requirement of utility.

3. THE SRI LANKAN INTELLECTUAL PROPERTY ACT (IP ACT) AND MICROORGANISMS

The Intellectual Property Act (IP Act) of Sri Lanka defines an invention as “an idea of an inventor which permits in practice the solution to a specific problem in the field of technology”.⁴¹ The invention for the purposes of this Act may be, or may relate to a product or process not excluded from patentability under section 62 (3) of the IP Act. An invention is patentable if it is new, involves an inventive step and is industrially applicable.⁴² The Sri Lankan Act thus allows patenting of any qualified invention which is not excluded from patentability in the field of technology, provided that it meets the other patent requirements such as novelty, inventive steps and industrial applicability.

Section 62 (3) of the IP Act refers to compulsory and optional exclusions, i.e subject matter which notwithstanding being an invention under section 62, it is not patentable. Under the category of compulsory exclusions,⁴³ the following types of inventions *inter alia* are excluded from patentability:

- (a) Discoveries, scientific theories and mathematical methods;
- (b) Plants, animals and other micro-organism other than transgenic microorganism and an essentially biological process for the production of plants and animals, other than non-biological and microbiological processes.

On the other hand, under the optional exclusion in the IP Act, the Intellectual Property Office has discretion to exclude the following types of inventions from patentability:

- (c) Any invention, the prevention within Sri Lanka of the commercial exploitation of which is necessary to protect the public order, morality, including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment.⁴⁴

Under the category of compulsory exclusions therefore, no animal, plant or micro-organism except a transgenic micro-organism and essentially biological process for the production of plants and animals other than non-biological and micro-biological processes, can be patented in Sri Lanka, provided that they satisfy the three criteria mentioned above.

⁴¹ Intellectual Property Act, s. 62 (1).

⁴² *Ibid.*, s. 63.

⁴³ *Ibid.*, s. 62 (3) a–e.

⁴⁴ Intellectual Property Act, s. 62 (3) (f).

3.1 Is the Definition of the Term “Microorganism” Necessary?

The question of whether the term “microorganism” should be defined legally either in a generic manner or not is debatable as there appears there was much reluctance on the part of the IP Act drafters to define the term “microorganism”. This may be due to the fact that there is no universally accepted legal term for “microorganism”. For example, it is not defined in the European Union Biotechnology Directive⁴⁵ or the European Patent Convention (EPC).⁴⁶

In the Plant Genetic Systems case,⁴⁷ however, the Board of Appeal of the European Patent Office (EPO) considered what is meant by that term. The Board held that the term “microorganism” includes not only bacteria and yeasts, fungi, algae, protozoa, plasmids and viruses, but also animal and plant cells i.e. all generally unicellular organisms with dimensions beneath the limits of human vision which can be propagated and manipulated in a laboratory.⁴⁸ However, the developed countries such as the US, EU and developing countries such as India and Brazil grant patent protection for microorganisms without any definitive term, but spell out the scope of protection that suit their local conditions. It is submitted that the approach in Sri Lanka is only to spell out the scope of the term “microorganism” rather than to define the term “microorganism”.

Although the phrase “transgenic microorganism” is not defined in Sri Lanka, the term “transgenic” as defined in the Act shall mean “an organism that expresses a characteristic, not attainable normally by the species under natural circumstances, but which has been added by means of direct human intervention in its genetic composition”.⁴⁹

This means that for the “transgenic microorganisms” to be patentable, there must be a direct human intervention in the genetic composition of the microorganisms, thereby transforming the naturally occurring microorganisms into a transgenic microorganism that express characteristics, not normally attainable under natural circumstances.⁵⁰

Thus, microorganisms that can be protected in Sri Lanka are those whose genetic material has been altered using genetic engineering techniques (generally known as recombinant DNA technology). Thus, for example, an invention relating to a genetically-engineered bacterial cell whose DNA content has been altered by the direct intervention of man by some technical process (genetic engineering) which could be used to dissolve oil layers in the sea may qualify as a patentable subject matter.

3.2 Policy Approach

The policy approach adopted by Sri Lanka is, therefore, to narrow down the patent protection to genetically modified microorganisms.

Under the Sri Lankan IP Act, as noted, transgenic microorganisms, microbiological and non-biological processes are patentable provided that they adhere to the patentability

⁴⁵ Directive of the European Parliament and of the Council of the Legal Protection of Biotechnological Inventions (1998) 98/44/EC.

⁴⁶ European Convention on the Grant of European Patents (EPC) as amended (1973).

⁴⁷ T 0356/93 (Plant Cells/Plant Genetic Systems) of 21.02.1995 OJ EPO 1995, 545.

⁴⁸ Ibid., point. 34.

⁴⁹ Intellectual Property Act, s. 212.

⁵⁰ Ibid.

requirements.⁵¹ But *per se* claims for non-transgenic microorganisms are not allowed, even if there is a direct human intervention involved in making the invention. Claims to microorganisms *per se* have been allowed for example, in the UK on the ground that they are products of microbiological processes even when they are merely isolated from their natural surroundings, but having regard to their culture, characterisation and the finding of a utility, such claims are regarded as an invention distinct from a discovery.⁵²

Hence, the patentable subject matter does not extend to microorganisms *per se* in Sri Lanka on the ground that they are products of microbiological processes. It can be argued that a microorganism that has been isolated from natural surroundings or obtained by artificially induced random mutation (except where it involves a transgenic process) may not qualify for patent protection in Sri Lanka. Thus, live attenuated vaccines like most viral vaccines which have been inactivated by a technical process (except by a transgenic process) such as most bacterial vaccines and some viral vaccines would also disqualify from patent protection.

⁵¹ Ibid., s. 62 (3) (b).

⁵² Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Intellectual Property Office (IPO) (April 2009), paragraphs 118–119.

4. DISCLOSURE REQUIREMENT (DISCLOSURE OF THE INVENTION TO THE PUBLIC)

The TRIPS Agreement provides that Member States shall require an applicant for a patent to disclose the invention in a sufficiently clear and complete manner so that the invention may be carried out by a person skilled in the art.⁵³ The TRIPS Agreement also provides some flexibility to satisfy the disclosure requirement, in particular, it provides that the applicant *may* be required to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application⁵⁴ and to provide information concerning the applicant's corresponding foreign applications and grants.⁵⁵

Section 71 of the IP Act requires that the following three elements be disclosed and satisfied for the grant of a patent: (i) written description (invention to be disclosed in written form adequately in a manner sufficiently clear and complete); (ii) enablement (method for performing the invention must be described for the invention to be evaluated and carried out by a person having ordinary skill in the relevant technology); and (iii) best mode (the best method of carrying out the invention known to the inventor at the time of filing the application).

4.1 *Disclosure Requirement and Deposit of Microorganism*

One of the requirements for patentability is that the invention has to be disclosed, normally in a written description which allows other inventors to develop and obtain patent protection for later improvements and subservient inventions that build on the applicant's teachings.⁵⁶

When an invention involves a microorganism or the use of a microorganism, disclosure is not possible in a written form and, hence, it has to be deposited with a Recognised Depository Institution so that such material will be available to the public. The depositing of a microorganism in a Culture Collection Centre for testing and examination may fulfil the disclosure requirement of the patent law and allow third parties to obtain samples of strains from the depository for further research and working on the invention.

Biological material eligible for deposit can be those materials that are capable of direct or indirect self-replication, such as bacteria, fungi, including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds.⁵⁷ Furthermore, viruses, vectors, cells, organelles, and other non-living material existing in and reproducible from a living cell may be deposited by means of a deposit of the host cell capable of reproducing the non-living material.⁵⁸ The depositing of the microorganism in an International Depository Authority (IDA) is regarded as having satisfied the written description requirement as prescribed in the Budapest Treaty, as explained below.⁵⁹

⁵³ TRIPS Agreement, Article 29.

⁵⁴ *Ibid.*, Article 29.1.

⁵⁵ *Ibid.*, Article 29.2.

⁵⁶ Donald S. Chisum, Tyler T. Ochoa, Shubha Chosh and Mary LaFrance, (eds.), *Intellectual Property*, (LexisNexis 3rd ed. 2015) 111.

⁵⁷ US Deposit Rules 37 CFR 1.801-1.809.

⁵⁸ *Ibid.*

⁵⁹ Budapest Treaty for the International Deposits of Microorganisms for the Purpose of Patent Protection (1977).

5. THE BUDAPEST TREATY AND DEPOSIT REQUIREMENT

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure⁶⁰ is an international convention governing the recognition of the deposit of microorganisms in officially approved culture collections for the purpose of patent procedure. The main feature of the Treaty is that a Contracting State that allows or requires such deposit must recognize, for those purposes, the deposit of a microorganism with any IDA, irrespective of whether such authority is in or outside the territory of the said State.⁶¹

According to Dr. Bussas of the German Collection of Microorganisms and Cell Cultures (DSMZ), the main reason for depositing patent-related material with an IDA is to render it available to entitled parties for trials and examinations; he also notes that a number of industry players deposit significantly more samples than their counterparts in research institutions.⁶² Thus, there is no need to deposit multiple samples of the same biological material in every national centre where patent protection is sought by the applicant. This offers applicants an efficient, streamlined and cost-effective means of meeting the disclosure requirements associated with patenting microorganisms and other biological material.⁶³

5.1 Should Sri Lanka Join the Budapest Treaty?

Sri Lanka is not a party to the Budapest Treaty; it has not so far made the necessary local arrangements to facilitate the depositing of biological material in an IDA. The patent lawyers, scientists, researchers and the National Intellectual Property Office (NIPO) will experience difficulties, for example, when a patent applicant mentions a biological material in the specification which may not be described, the applicant would not be able to satisfy the requirement of sufficiency of description and the disclosure of the best method of performing the invention as required by section 71 (3) of the Intellectual Property Act.

Apart from the discussed Budapest Treaty advantages, the Treaty does not require any substantive change to the national patent legislation because it does not define the term “microorganism” or the patentability requirements. Until Sri Lanka is able to establish its own IDA, it can nominate any IDA out of the 45 IDAs currently in operation recognised under the Budapest Treaty, so that patent-related samples of biological material can be deposited and stored in such IDAs thereby fulfilling the disclosure requirement under section 71 (3) of the IP Act. This arrangement will not only fulfil the requirements of patentability, but it may also allow the researchers, inventors, scientists access to samples of such biological material for further research and development of innovations related to microorganisms.

⁶⁰ Ibid.

⁶¹ WIPO, Summary of Budapest Treaty on the International Recognition of the of Microorganisms for the Purposes of Patent Procedure. www.wipo.int.

⁶² WIPO Online Magazine, 4/2015 (August). https://www.wipo.int/wipo_magazine/en/2015/04/.

⁶³ Ibid.

6. LEGAL RECOGNITION OF DEPOSIT REQUIREMENTS

The biological deposit is not a requirement in the IP Act of Sri Lanka as a part of the disclosure requirements of the specification. However, the biological deposit may be necessary for any patent applicant to practice the invention without access to microorganisms which are obtainable from nature.

The deposit requirement of microorganisms has been recognized as having fulfilled the disclosure requirement by case law in other jurisdictions. For instance, in *re Argoudelis*,⁶⁴ it was held that the availability of the biological products via a public depository provided an acceptable means of meeting the written description and the enablement requirements under section 112 of the US patent law.

Furthermore, in *re Wands*,⁶⁵ it was held that a deposit can also satisfy the best mode requirement of section 112 of the US patent law, and that a deposit is not strictly necessary where the written description requirement can be met in ways other than by making a deposit. In *Amgen v. Chugai Pharmaceuticals Co.*,⁶⁶ it was argued that in the field of biological materials, a biological deposit should be required so that the public has access to exactly what the patent applicant contemplates as the best mode. The Court however held that depositing biological material was not necessary where the best mode of preparing a cell line necessary to practice the invention was disclosed and enabled in the specification.⁶⁷

The question of whether an invention that involves a microorganism which is capable of being carried out by a person having ordinary skill in the relevant art without a deposit must be decided on the facts of the particular case. The biological deposit may be necessary to practice the invention where the written specification alone is not sufficient to describe how to make and use the invention in a reproducible manner.

An applicant in Sri Lanka may argue, for example, that where the written specification is sufficient to give directions to enable the invention to be performed by a person having ordinary skill in the relevant technology, the depositing of the microorganism in an international depository authority may not be necessary. However, this argument may be rejected by the examiner in terms of section 71 (3) of the IP Act of Sri Lanka. If the biological material has been deposited by the applicant prior to the date of filing of the application, it may not be possible for the applicant to rectify the deficiency of the application and fulfil the sufficient disclosure and best mode requirement.

Rule 31 of the Implementing Regulations of the European Patent Convention refers to the deposit of biological material. It states that if an invention involves the use of microorganisms which are not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83.⁶⁸ Accordingly, a sample of the biological material has to be deposited with a recognised depository institution on the same terms as those laid down in the Budapest Treaty not later

⁶⁴ *In re Argoudelis* 434 F. 2nd 1390, 168 USPQ 99 (C.C.P.A. 1970).

⁶⁵ *In re Wands*, 858 F.2d. 731, 8 USPQ 2nd 1400 (Fed. Cir, 1988).

⁶⁶ *Amgen, Inc., v. Chugai Pharmaceutical Co., Ltd* 706 F. Supp. 94 (D. Mass. 1989).

⁶⁷ *Ibid.* para 81.

⁶⁸ EU Implementing Regulations to the Convention on the Grant of European Patents 2006, Rule 31 (1).

than the date of filing of the application.⁶⁹ The application should also provide such relevant information as is available to the applicant on the characteristics of the biological material.⁷⁰

A similar requirement is found in the Indian Patent Act.⁷¹ The deposit requirement was included in the Indian Act after India ratified the Budapest Treaty⁷² for facilitating the deposit of biological material. In addition to other requirements, the complete specification must contain a reference to the deposit of the biological material in the IDA, if applicable.⁷³

The Indian Patents Act provides, in effect, that if the applicant mentions biological material in the specification which may not be described in such a way as to satisfy the disclosure and best mode of performing the invention, and if such material is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty subject to other conditions.⁷⁴ Hence, the invention shall only be regarded as having been disclosed if a culture of the microorganism has been deposited with a recognised depository institution.⁷⁵

The question, however, is whether the deposited material needs to be made available to the public at the time of filing or whether it is enough to do so before the grant of the patent. In India, the deposit of the material shall be made not later than the date of filing the application in India and a reference thereof shall be made in the specification within the prescribed period.⁷⁶ Thus, access to the material is available in the depository institution only after the date of the application of the patent in India or if a priority at the institution.⁷⁷

In *re Lundak*,⁷⁸ in contrast, the US Federal Court held that deposits could be made at any time prior to the issue of the patent and thus, it need not be made prior to or while filing the application. Accordingly, the depositing of the biological material made after filing, but prior to the issuance of the patent, meets the statutory requirement of section 112 of the US Patents Act.

The author is of the view that the Indian approach is more likely to be recognised in Sri Lanka subject to the following conditions:

1. a sample of the biological material shall be deposited in a depository institution which is able to furnish a sample of such biological material, not later than the date of filing of the patent application in Sri Lanka;
2. the name and address of the depository institution, the accession number and date of the deposit should be given in the specification of the application within the prescribed period;
3. where the biological material has been deposited by a person other than the applicant, a statement shall be filed identifying the name and address of the depositor;

⁶⁹ Ibid., Rule 31 (a).

⁷⁰ Ibid., Rule 31 (b).

⁷¹ The Patents Act, 1970 as amended by Act No. 15 of 2005. section 10(4).

⁷² Budapest Treaty, note 146.

⁷³ Patents Act, Section 10 (4) proviso (ii).

⁷⁴ Ibid.

⁷⁵ T 0223/92 (*HIF-Gamma/GENETECH*) of 20.07.1993, www.epo.org/law-practices-case-law/appeals/recent/.

⁷⁶ Patents Act, s.10 (4) (A) .

⁷⁷ Ibid.

⁷⁸ *In re Robert L. Lundak*, 773 F. 2nd 1216, (227 USPQ 90 (Fed. Cir. 1985).

4. access to biological material will be available in the depository institution only after the date of the application for patent in Sri Lanka or if a priority is claimed after the date of the priority.

The policy makers should seriously consider the advantages of the Budapest Treaty and begin the process of becoming a member of the Treaty, while making the necessary statutory changes for facilitating the deposit of microorganisms as a substitute of the requirement of written description. Sri Lanka missed a great opportunity by not including the deposit requirement in the IP Act, thereby denying the patent applicants the possibility of fulfilling the disclosure requirement and the best mode of performing the invention in relation to microbiological inventions.

7. CONCLUSION

In the light of the above discussion, it is submitted that although the TRIPS Agreement makes it mandatory to make available patents for microorganisms, it is left to the WTO Members the freedom to use the flexibilities contained in the Agreement. The Sri Lankan Supreme Court determination provides useful policy guidance to policy makers to adapt the patent law to local conditions and design the patent law in a manner that suits its biotechnology policy objectives, including to prevent the abuse by patent holders against the interest of other stakeholders including researchers and competitors.

Naturally occurring microorganisms will not qualify for patenting protection, even if isolated. Man-made genetically modified microorganisms which express organisms that are not normally found or naturally occurring, are patentable subject matter in accordance with the IP Act of Sri Lanka, provided they meet the prescribed patentability criteria and disclosure requirement.

The policy objective recognised by the Supreme Court should be fully implemented to promote local innovation related to microorganisms. It is TRIPS compliant to limit the grant of patents for transgenic microorganisms subject to the provisions of the IP Act of Sri Lanka. This approach facilitates the promotion of local biotechnology industry and the commercialization of medicines at affordable prices to the people of Sri Lanka. Furthermore, this approach prevents the grant of frivolous patents that do not satisfy the strict patentability criteria.

The deposit requirements should be introduced by ratifying the Budapest Convention and introducing the necessary statutory provisions to facilitate compliance with the written description requirement under section 71 of the IP Act, including the best mode of performing the invention.

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