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Intellectual Property Rights with regard to Microorganisms and other 'Living Beings'

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Microorganisms are commonly described as any living organism that a human cannot see with his or her naked eye, and requires the aid of a microscope to observe. Mankind has used microorganisms for its own purposes for a very long time, with the most common example being microorganisms being used in the preparation of various food items like bread and alcohol. While the grant of patent protection being granted to such organisms is also not a new practice, there is growing concern that new scientific developments in the biotechnology fields can cause more harm than good. This paper begins with a short description of microorganisms, their use throughout history, and the earliest patent protections offered to them. It then goes on to examine the development of patent protection granted to living things in 3 separate jurisdictions, the United States of America, the European Union, and India, along with discussions regarding the judicial involvement in this process and the differences caused due to differing objectives that each of these sought to achieve. Also examined are two important international treaties that are involved in this entire process, the TRIPS Agreement under the WTO, and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for Patent Procedure. Finally, this paper examines the moral argument against granting patents on life, especially the "slippery slope" argument that says that granting patents on lower life forms today can lead to demands for the same protections on more complex organisms in the future. This is then compared to the regulations regarding animal testing and how distinctions have already been made on lower and higher life forms, and that the same can be used as a template will deciding on patent issues.

Keywords: *patent, microorganisms, Budapest treaty, TRIPS agreement, animal testing.*

INTRODUCTION

In a general sense, microbiology can be described as "the study of organisms too small to be clearly seen with the unaided human eye",[1] and microorganisms as "organisms with a diameter of 1mm or less, which can be divided into 6 main types: Archaea, Bacteria, Protista, Fungi, Viruses, and Microbial Mergers."[2] These organisms may be as small as a single cell, but may also include cell clusters. It is thought that single-celled microorganisms were the first living beings to appear on this planet around 3.5 billion years ago.[3] The diversity of microorganisms is staggering, with some being airborne and ubiquitous, while others are so restricted in their habitats that they can only be found on a particular body part of a single species of beetle.[4] The field of study in biology has existed among human civilisation for almost as long as any other form of knowledge, and this has now led to the dawn of the biological revolution. This has led to the creation of a very lucrative industry out of the task of biology and biologists to have ultimate control over the creation and alteration of life,[5] which has meant that many biologists now have to work in both laboratories and in corporations.[6] A side effect of this is that there is a growing need for greater investment in the various costly research and development projects that biologists have to undertake, and this consequently means that there is a need to offer protection to these new technologies as it is unlikely that anyone will be willing to invest their time and money in the creation of a product they could not make profits off of, and it is in this context that the protection of the latest creations in the form of micro-organisms has to be considered. [7]

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[1] S. K. Soni, *Microbes: A Source of Energy for 21St Century* (New India Publishing Agency 2007)
[2] *Ibid*
[3] *Ibid*
[4] C R Benjamin, W C Haynes, & C W Hesseltine, 'Micro-Organisms: What They Are, Where They Grow, What They Do' (1964) 995 ARS USDA <https://naldc.nal.usda.gov/download/32293/PDF >
[5] William Stockton, 'On the Brink of Altering Life'(*The New York Times*, 17 February 1980) <https://www.nytimes.com/1980/02/17/archives/on-the-brink-of-altering-life-altering-life.html?searchResultPosition=1> accessed 14 January 2022
[6] Robert Reinhold, 'Bacteria Tycoons Start a Real Growth Industry'(*The New York Times,* 3 February 1980) <https://www.nytimes.com/1980/02/03/archives/bacteria-tycoons-start-a-real-growth-industry-marketing.html?searchResultPosition=1> accessed 14 January 2022
[7] Stanley D Schlosser, 'Patenting Biological Inventions' (1981) 12 U Tol L Rev 925

Micro-organisms have been used by humans for various purposes for a very long time, with the most common example being the use of yeast in the fermentation process. The patent protection offered to microorganisms is also not a new development, as it has been done in Belgium and Finland as early as the 1830s and 1840s.[8] Today, microorganisms are used for a multitude of purposes, ranging from the pharmaceutical industry to the defence sector. In order to allow the proper development of the industry and encourage research into this important aspect of biology, proper protection must be offered to the creation of new and cutting-edge technology in this sector.

PATENTING MICROORGANISMS

Improvements in technology, especially in the microbiology field have meant that there are often new inventions in the field that require protection which can be received through patents. This has meant that despite concerns about the morality of granting patents on life, many jurisdictions have been granting patents on microorganisms, and further, important international treaties have been created that also deal with these issues on a global scale. However, different jurisdictions have different objectives while resolving challenges to the patents on life, which is exemplified in judicial pronouncements.[9]

LEGAL POSITION IN THE UNITED STATES

The Constitution of the United States gives the United States Congress the authority to encourage the progress of science and the arts "by securing for limited times to inventors the exclusive rights to their discoveries",[10] and under this power, Congress enacted the Patent Act in 1952, which provided for a fairly broad definition of patentable subjects, which would include "any new and useful process, machine, manufacture, or composition of matter". If the inventor is successful in showing that his invention will fall under the category of one of these subject-matter categories, he is also required to fulfill further statutory requirements, including

[8] Philip M. Weber, 'Patenting of Microorganisms' (2006) 5 NRDD, 13
[9] Srividhya Ragavan, 'Patent Judicial Wisdom' (2008) 20 NLSIR, 165
[10] Constitution of the United States, 1790, art 1 s 1 cl 8 8

that the invention must have "utility" and that it is "novel"[11]. Aside from these requirements, it must also be seen that the invention is non-obvious and described in writing to allow a person skilled in the field to use the invention.

One of the first issues regarding the patentability of an industrial process that uses microorganisms arose in *Guaranty Trust Co. v Union Solvents Corp*.[12], in which the district court held that the patent was not being given to the bacteria per se but to the fermentation process involving the bacteria. In 1974, *In re* Mancy[13] addressed the initial patentability of processes involving microorganisms, and the Court of Customs and Patent Appeals (CCPA) held that no claim was being granted to the microorganism itself, but that does not mean that the process that involved the microorganism was not patentable. The court also said that the microorganism was a "product of nature" and hence no claim can be granted to it. This led to a policy in the Patent and Trademark Office that denied patents on micro-organic product inventions until Congress provided legislations that dealt with such claims.[14]

The revolution in the patenting of microorganisms came with two important cases, *In re* Bergy[15] and *Diamond v Chakrabarty*[16], the former relating to a process of producing a known antibiotic and a previously unknown microorganism called *Streptomyces vellosus*, and the latter relating to the field of genetic engineering where a new microorganism had been created by transmitting a number of compatible plasmids into a single bacterial cell, which could then aid in fighting crude oil spills. The PTO and the Board of Appeals in both cases did not allow patenting of the microorganism itself, on the ground that it would cover a living thing. The CCPA reversed the decision in both cases and held that the claims defined subject matter under Section 101 of the Patent Act. The Supreme Court in the Diamond v Chakrabarty[17] case described the invention concerned and observed that the issue before the court was relating to statutory interpretation, that is, whether Chakrabarty's microorganism could be considered to

[11] United States Code, 1976, s 102
[12] *Guaranty Trust Co. v Union Solvents Corp.* [1931] 54 F.2d 400
[13] *In reMancy*, [1974] 499 F.2d 1289
[14] James Carroll, 'Bergy, Flook, and Microorganisms as Patentable Products' (1980) 29 CULR, 485
[15] *In re Bergy* [1977] 563 F.2d 1031
[16] *Diamond v Chakrabarty* [1980] 447 [U.S] 303
[17] *Ibid*

be a "manufacture" or "composition of matter" under Section 101. The majority decision was to interpret these terms as expansive, and that Congress' intention was that the patent laws be given the widest possible scope. It was observed that while Section 101 does have limits, as described in*Parker v Flook*[18]which had held that laws of nature, physical phenomenon, and abstract ideas would not be patentable, US patent law allows for the patenting of "anything under the sun that is made by man."[19] Chakrabarty's microorganism would not fall under the categories that have been excluded, as it would have to be considered non-naturally occurring manufacture or composition of matter being a product of human ingenuity, as a new bacterium has been created with markedly different properties and characteristics than any other available in nature.

The United States led the way in giving a liberal understanding to the patent system, especially through *Chakrabarty's*[20]case where the US Supreme Court had an opportunity to steer the system. By the time the case reached the Supreme Court after its journey through the patent system, the prevalent attitude with regard to biotechnology had changed from one of regulation to that of promotion, with concerns that not taking such steps would lead to the US losing its lead in the field to countries in Europe who were actively promoting such research.[21] The decision of the Court that any result of human creativity, whether it be biotic or abiotic, allowed for the beginning of a new era in biotechnology advances, as it encouraged investment through the creation of economic potential in the industry.[22] Looking at the moral and ethical considerations involved in this process, which were brought up in *Animal Legal Defense Fund v Quigg*[23], the Federal Circuit reasoned that under the United States Constitution *locus standi* is given to parties who suffer actual personal injury or a threat to personal injury,[24]

[18] *Parker v Flook* [1978] 437 [U.S] 584
[19] *Chakrabarty* (n 16)
[20] *Ibid*
[21] 'Brief on Behalf of Genentech Inc as amicus curiae'(*Ip Mall*)
<https://ipmall.info/sites/default/files/hosted_resources/chisum_cases/briefs/15_Diamond/15_diamond_8.htm>
last accessed on 14 January 2022
[22] Geri J. Yonover, 'What Math (Not) Chakrabarty Wrought: From The Mouse That Roared To Hello Dolly And Beyond'(1998) 32 VULR 349, 358
[23] *Animal Legal Defense Fund v Quigg* [1991] 932 F.2d 920
[24] Constitution of the United States, 1790, art 3 s 2

and since the appellants (a non-profit organisation of farmers) could not show that any individual rights were being infringed upon by the patent challenged, the suit could be dismissed on the basis of lack of standing.[25] This allowed the US to brush under the carpet the moral questions involved and focus on promoting the growth of the industry.

LEGAL POSITION IN EUROPE

The European patent system can be described as both disciplined and inclusive with regard to the grant of patents to biotechnologies and various other related technologies. The European Patent Office (EPO) does not even reject the patent claims of naturally occurring products as is common in the United States. The EPO's stand is basically that while no patent can be granted for finding a substance hitherto unknown that occurs in nature, the same can be made patentable if it is shown to have some technical effect.[26] The various provisions regarding municipal patent laws of various European countries have been incorporated in two major documents: the European Patent Convention[27] ("EPC") and the Biotechnology Directive of 1998 ("The Directive"). The EPC prescribes 4 conditions for the successful patenting of a product, and they are that the product should be patentable, that it should show novelty and consist of an inventive step, and that it must show industrial usage.[28] The Directive of 1998 also conforms to these criteria, and it actually specifies under Article 3.2 that biological material which has undergone a considerable amount of human processing and intervention can be patented even if its initial existence was inherent in nature. One of the important characteristics of the EPC is the inclusion of the "public order and morality" clause under Article 53(a), which denies the grant of patent protection to any invention considered against "*ordre public*" and morality. This provision regarding "*ordre public*" provides the general public with the ability to challenge specific patents on the ground that granting them would be

[25] Animal Legal Defense Fund (n 23)
[26] 'Guidelines for Examination in the European Patent Office' (*European Patent Office*, 1March 2021) <https://documents.epo.org/projects/babylon/eponet.nsf/0/C4B20952A0A7EF6BC125868B002A5C61/$File/epo_guidelines_for_examination_2021_hyperlinked_en.pdf > accessed 14 January 2022
[27] Donna M. Gitter, 'International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and their Fair-Use Exemption' (2001) 76 NYULR 6
[28] Convention on Grant of European Patents, 1977, art 52

morally offensive.[29] The EPC also states that European patents shall not be granted in cases of "plant or animal varieties or essentially biological processes for the production of plants or animals", but that "this provision shall not apply to microbiological processes or the products thereof".[30]

One of the important decisions that showcase the attributes of the European Patent Office is the Harvard/Onco mouse case. The inventor in this case had successfully patented the Onco mouse, a transgenic organism that had undergone sufficient human and technical intervention which led to its mutation, and as it was receptive to breast cancer, it could assist in early diagnosis. The patent application was initially rejected on the ground that the subject matter would be "a variety of animals", and hence could not be patented. On appeal against this decision, where multiple parties also enjoined briefs before the appellate body where the question was raised whether invention could be patented. Eventually, it was ruled by the EPO in 1994 that the patent could be granted. This case highlights the willingness of the patent system in Europe to grant patents to biological products that have undergone a sufficient amount of human engineering. In 1995, a patent was also granted for a DNA sequence that had encoded a human protein that pregnant women produced, and which could assist in pregnancy. It was found that the subject matter in question was more than a mere discovery as "it had been isolated from its surroundings and a process had been developed to obtain it." This case led to limitations on the applicability of the "products of nature" doctrine.

The US Supreme Court decision in *Chakrabarty* influenced decisions on the same subject matter in Europe as well, but the latter has taken a different approach to the moral questions raised. The European Patent Office, for example, had to take into considerations protests by various organisations before considering the Harvard OncoMouse patent, as it involved a comparatively higher life form.[31] The EPO has then clarified the "morality" requirement as

[29] David G. Scalise & Daniel Nugent, 'Patenting Living Matter in the European Community" (1993) 16 (4) FlL.J, 990<https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1358&context=ilj> accessed 14 January 2022
[30] Convention on Grant of European Patents, 1977, art 52(b)
[31] Donna .M. Gitter, 'Led Astray By The Moral Compass: Incorporating Morality Into European Union Biotechnology Patent Law', (2001)19 (1) BJIL 1, 29

provided under the European Patent Convention[32] would be violated if "the public regards the invention as so abhorrent that the grant of patent rights be inconceivable". This has led to the existence of some subjectivity within the patent system in Europe and has been argued to have prevented Europe from having the strong biotechnology regime that the US has, but the fact remains that the Courts in Europe have not shied away from adjudicating on moral issues of importance at the cost of economic benefit.[33]

BUDAPEST TREATY

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or the Budapest Treaty was signed in Budapest, Hungary in 1977 and is administered by the World Intellectual Property Organisation. As of January 2022, 85countries are party to this treaty.[34] All countries that are party to the Paris Convention for the Protection of Industrial Property of 1883 can accede to this Treaty. Furthermore, the African Regional Industrial Property Organisation, the Eurasian Patent Organisation (EAPO), and the European Patent Organisation (EPO) have filed a declaration of acceptance under Article 19(1)(a) of the Treaty.

This treaty aims to simplify the disclosure requirements of national patent laws through the recognition of a single microorganism depository.[35]Normally, for meeting the legal requirement of "sufficiency of disclosure", patent applications must have a description of the subject matter of the invention in such a manner that a person skilled in the art can reproduce the same. However, in cases of an invention of a microorganism, it would be near impossible to describe it completely.[36]Under this Treaty, if any party needs to deposit a sample of microorganisms for patent purposes under the laws of the Contracting State, then such a party can do so with any "International Depository Authority (IDA)", and the Contracting State

[32] Convention on Grant of European Patents (n 28)
[33] Donna.M. Gitter (n 27)
[34] 'WIPO Administered Treaties' (*WIPO IP Portal*) <https://wipolex.wipo.int/en/treaties/ShowResults?search_what=C&treaty_id=7> accessed 9 January 2022
[35] Stephen A. Bent, Richard L. Schwaab, David G. Conlin & Donald D. Jeffry, *Intellectual Property Rights In Biotechnology Worldwide* (Stockton Press, 1987)
[36] *Introduction To Intellectual Property* (2nd edn, Wolters Kluwer 2017)

must recognise the same, irrespective of whether such authority is situated outside the territory of such State.[37]. Deposits made in an IDA have to be in accordance with the rules prescribed under the Treaty on or before the filing of the complete patent application. The Treaty also prescribes the requisite conditions that a facility should adhere to in order to be declared an IDA[38], and provides that depositories can gain international depository status if it is situated within the national territory of any member state which can assure that such depository will continue to exist and carry out the tasks assigned to it.[39]However, substantive regulations regarding the use of deposited microbes fall under the authority of national patent law.[40]

TRIPS AGREEMENT

The Agreement on Trade-Related Aspects of Intellectual Property Rights is described as an international agreement, to which all the members of the WTO are the party, which prescribes minimum standards for the regulation of the intellectual property rights provided by different governments as applied to nationals of other WTO member nations.[41]The Agreement provides that, subject to certain conditions, patents have to be made available in all fields of technology, with regard to any invention.[42]However, similar to the European Patent Convention, it provides that inventions can be excluded from patentability to "protect *ordre public*".[43] Further, it categorically states that while member states can exclude "plants and animals" from patentability, the same exception cannot be extended towards "microorganisms" and "non-biological and microbiological processes."[44] While TRIPS allows member States to exclude plants and animals from patent protection, the lack of a common and internationally accepted

[37] Budapest Treaty on the International Recognition of Microorganisms for the Purpose of Patent Protection, 1977, art 3(1) (a)
[38] Budapest Treaty on the International Recognition of Microorganisms for the Purpose of Patent Protection, 1977, art 7
[39] Budapest Treaty on the International Recognition of Microorganisms for the Purpose of Patent Protection, 1977, art 6
[40] Michael F. Mulcare, 'International Patent Protection: A First Step towards Curing AIDS' (1992) 15 STLJ 648
[41] 'Overview: The TRIPS Agreement' (*WTO*) <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 10 January 2022
[42] TRIPS Agreement, 1995, art 27
[43] TRIPS Agreement, 1995, art 27(2)
[44] TRIPS Agreement, 1995, art 27(3) (b)

definition of the term "microorganism" leads to a general lack of clarity on the subject, with even jurisdictions with a comparatively long tradition of granting biotechnological patents differing in their interpretation of this subject matter.[45]

LEGAL POSITION IN INDIA

Patents in India are governed under the Patent Act of India, 1970, which defines an invention as a new and useful "manner of manufacture or a substance produced by manufacture".[46] The Act does not define the terms "manner of manufacture" or "substances". This led to the Patent Office interpreting the same to imply that something can only be patentable if it is a tangible non-living substance. Section 3(j) of the Act provided that plants and animals in whole, or in parts of the same, which would include seed varieties and biological processes for the production of plants and animals are also not patentable. However, with India's membership in the TRIPS Agreement and the duties of members states provided therein, the Patent Act was amended in 2002, to allow for the patenting of microorganisms, as long as they satisfied other specific conditions.[47]

However, even before the 2002 Amendment that allowed for patents on microorganisms, the judiciary had interpreted the un-amended Act to allow for a patent on a living organism. The Hon'ble Calcutta High Court had decided the case of *Dimminaco A G v Controller of Patent Designs & Ors*[48], in which the patent office had refused to grant a Swiss company a process patent for the preparation of a live vaccine for Bursitis, on the ground that it contained a living organism and was not patentable under the Patent Act provision.[49] The contention of the Patent Office was that the process of creating a vaccine using a living organism could not be considered a process resulting in an article or substance, and it can also not be considered a manner of manufacture, and that as the vaccine used a process on a microorganism it should

[45] Jonathan Curci, 'The New Challenges to the International Patentability of Biotechnology: Legal Relations between the WTO Treaty on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity', (2005) 2 (1) BYUILMR 1
[46] Patent Act, 1970, s 2(1) (j)
[47] Patents (Amendment) Act, 2002
[48] *Dimminaco A G v Controller of Patent Designs & Ors* [2002] IPLR 255 Cal
[49] *Ibid*

only be considered a natural process. The High Court pointed out that the Patent Act had not defined the term "manufacture" anywhere, and proceeded to consult various dictionaries for its meaning. The Court eventually concluded that the process for manufacturing the vaccine, in this case, was a new process and the same could be patented under the Act under Section 5 read with Section 2(1)(i). The Court also relied on the vendability test to determine the question of patentability of a process and concluded that since the claim process, in this case, led to a vendible product, the same could be granted a patent, as it would be considered a substance after going through the manufacturing process.[50] It is important to note here that the patent granted was a process patent over the process of manufacture, which allowed for patenting of the process which would then result in a living matter as a product and not over the living matter itself. The Court also reserved its right to decide other similar cases on a factual basis, observing that the claim for the grant of a patent in regards to something that may be considered an invention could only be decided after careful consideration of the facts of each individual case.

The 2002 Amendment simplified the definition of 'invention' and provided that the only requirement of patentability is that a product is new, non-obvious, and useful.[51] However, the addition of Section 3(j)[52], which does not allow patents to be granted to essentially biological processes that lead to the production of plants and animals, or plants and animals on the whole or in part other than microorganisms could lead to a future patent application being rejected as the subject is not considered a microorganism simply because it is a non-microscopic organism. Hence, there is a need for a clear definition of the term "microorganism". It has also been argued that the decision of the Calcutta High Court in *Dimminaco AG*[53]was also due to the influence of *Chakrabarty,* as it was the former that opened up biotechnology patents in India. However, the context in which this protection was granted warrants examination. India's generic drug industry and its biotechnology potential had been noticed just before this decision of the court came out, especially in the role it played in

[50] Dimminaco AG (n 50)
[51] Patent (Amendment) Act, 2002, s 3(f)
[52] Patent (Amendment) Act, 2002, s 4(e)
[53] Dimminaco AG (n 50)

combating the South African AIDS crisis. However, India, being a developing country, has had to balance the protection of national welfare and encouraging trade, and hence could not completely follow the US example. In the famous *Roche v Cipla*[54]judgment of a single-judge bench of the Delhi High Court, an interim injunction prayed for by the plaintiff, a patent holder with respect to a particular drug used in treating cancer, was not granted against the defendant, who was involved in making a generic (and much cheaper) version of the same drug. The Court held that aside from a credible challenge against the patent that the defendant had put forth, the fact that the drug was involved in critical treatments for cancer patients, and that the grant of an injunction could jeopardise such treatment, meant that interim injunction could not be granted, establishing that the access to crucial resources for the welfare of the public will remain an important consideration in Indian patent law.[55] The amendments that have been brought on to the Patent Act have led to an overall liberalisation which has, in turn, resulted in a great increase in the number of patent applications filed and granted in the biotechnology field. The 2019-20 Annual Report of the Patent Office says that the number of biotechnology patents granted has increased steadily from 185 in 2015-16 to 357 in 2019-2020,[56] which is a staggering increase considering that the same number was at 71 in 2004-05.[57]

RESOLVING THE HIGHER AND LOWER ORGANISMS QUESTION

The debate over the grant of patents, or "ownership", over life and the moral and ethical basis of the same continues to rage. The arguments that support the grant of such patents point towards commercial realities, the fact that many patents on living things, including microorganisms, have already been given, and the unquestionable benefit that such products can bring to humankind, be it in the form of better medicines, or more efficient technologies.[58] However, while considering the creation of a system to encourage such a protection system, it

[54] *Roche v Cipla* [2008] 148 [DLT] 598
[55] *Ibid*
[56] 'Annual Report 2019-2020' (*Intellectual Property India,* 2020) <https://ipindia.gov.in/writereaddata/Portal/Images/pdf/IP_India_English_29.08.21_Final_.pdf > accessed 15 January 2022
[57] 'Annual Report 2004-2005' (*Intellectual Property India*, 2005) <https://ipindia.gov.in/writereaddata/Portal/IPOAnnualReport/1_82_1_1_41_1_annual-report-04-05.pdf > accessed 15 January 2022
[58] Thomas D Kiley, *Learning to Live with the Living Invention* (Asia Pacific Lawyer Association 1979)

is also important to review the arguments against the grant of such patents. Concerns have been raised that in the future when scientific development has led to improvements in the biotechnology field, scientists could have the ability to create truly novel, and higher, organisms, and the moral considerations of granting patents to such organisms would be very distinct from those involved in providing similar protection in case of microorganisms and other lower organisms.[59] While bacteria are given no moral or legal rights, more complex organisms are, including plants and animals like cats, dogs, and non-human primates, though to different extents.[60]

The major moral argument against the granting of patents on life stems from the inherent distinction that people make between living and non-living things and the fears of a "slippery slope" that granting of ownership over living things could lead to. The 'doctrine of vitalism', which believes that organisms are endowed with life that gives them a unique standing in the world can be considered to be a progenitor of such moral qualms.[61] However, this doctrine has been rejected, considering the fact that life has been seen to be nothing but complex, yet understandable physiochemical processes.[62] This, however, does not help with the "slippery slope" argument, which stems from fears that while today patents are granted on microorganisms and other "lower" life forms, scientific advancement could soon mean that more complex organisms, suited to specific requirements, could be made in the labs, including engineered humans, and since the line that differentiates the two is blurry, it is better not to grant patents on life at all. However, the author contends here that this is simply not the case, and the difference between the "lower" and "higher" life forms have been made in the past and to good effect, as exemplified by the distinction made in animal testing regulations all over the world.

The stated objective of patent law in all jurisdictions is to encourage innovation and promote development. The United States Constitution provides Congress the power "to promote the

[59] Burke K Zimmerman, 'The Case against Patents for Living Organisms' (1979) 7 APLAQJ 278
[60] *Ibid*
[61] Shyamkrishna Balganesh, 'Patenting of Organisms: The Distinction between Lower and Higher Life Forms' (2000) 12 SA 144
[62] In re Bergy (n 15)

progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries"[63], and it is under this provision that the US patent law is authorised. Patents are a trade-off made by granting inventors the exclusive right over their invention, in exchange for the information about the concerned invention to allow for the growth of the body of human knowledge. The principle behind animal testing is also similar. While there can be no moral basis for causing pain to, or killing, a living creature without reason, it will be hard to convince the general public that animal testing can result in significantly useful results to humans (or even the animals themselves) is not worth the sacrifice. However, the considerations are not the same for all animals, and this is clearly visible in various legislations that deal with animal testing regulations. The Animal Welfare Act[64] (AWA) is a federal US law that, along with the regulations made under it,[65]provides for the minimum standards of care and treatment that must be provided for certain animals that are to be used in, among other things, experimental research. However, under its protections are only available to dogs, cats, non-human primates, guinea pigs, hamsters, rabbits, or other warm-blooded animals, but "excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research".[66] This means that 95% of the animals that are experimented on fall outside of the purview of this legislation.[67]Other than this, the Public Health Service, which oversees the Food and Drug Administration and the Centre for Disease Control and Prevention (the two federal agencies that conduct the most animal tests), has a policy that covers all vertebrate animals used for research purposes in laboratories that are affiliated with the PHS.

Similarly, in India, the Prevention of Cruelty to Animals Act, 1960, provides for the protections available to animals, which are defined as "any living creature other than a human being".[68]

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[63] Constitution of the United States (n 10)
[64] Animal Welfare Act, 1966
[65] *Ibid*
[66] Animal Welfare Act, 1966, s 21 32(g)
[67] 'Federal Laws and Agencies Involved With Animal Testing' (*Animal Legal Defense Fund*) <https://aldf.org/article/federal-laws-and-agencies-involved-with-animal-testing/#:~:text=The%20Animal%20Welfare%20Act%3A,minimal%20protections%20for%20the%20rest.> accessed 16 January 2022
[68] Prevention of Cruelty to Animals Act, 1960, s 2(a)

However, it also provides that the act does not make unlawful the "performance of experiments (including experiments involving operations) on animals for the purpose of advancement by the new discovery of physiological knowledge or of knowledge which will be useful for saving or for prolonging life or alleviating suffering or for combating any disease, whether of human beings, animals or plants".[69] Under the Act, the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)[70] has been created, which has, in turn, promulgated the Breeding of and Experiments on Animals (Control & Supervision) Rules, 1998 to regulate the experimentation on animals. These regulations provide for different requirements that have to be fulfilled before beginning with a research project involving rats, mice, guinea pigs, or rabbits, in comparison with projects that use canines, bovines, or non-human primates.[71] The differing standards applied to different animals clearly show that distinction can and has been made on the amount of care required while conducting experiments on them. These distinctions can also be used while answering the moral questions of patents granted on life. This would mean that while patents on lower organisms like microorganisms, or to an extent, mice and rats need not be given grave consideration, patents on higher organisms, like canines or bovines, should be thoroughly inspected to make sure that the benefit accrued from such patents can justify the costs.

[69] Prevention of Cruelty to Animals Act, 1960, s 14
[70] Prevention of Cruelty to Animals Act, 1960, s 15
[71] Shiranee Pereira, Prema Veeraraghavan, Sonya Ghosh, Maneka Gandhi, 'Animal experimentation and ethics in India: the CPCSEA makes a difference' (2004) 32 ATLA 411