

The pros and cons of life form patenting philosophy essay



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Life form patenting, or rather the patent of synthetically or artificially produced living forms which are not otherwise naturally existing is an issue which has been submerged in controversy since the first such claim application was made. This controversy however, has been more sensationalised than informed. In this paper, thus, an attempt has been made to evaluate the “ pros” and “ cons” of patenting life. To this end, this paper will look at the history of life form patents in the American and European jurisdictions and finally drawing from it asses the likely Indian scenario. Through this examination then it will seek to evaluate the patenting debate from an ethical moral standpoint.

Owing to the constraint of space, the focus and scope of the project is limited to animal life form patents and the paper will not include in its ambit a discussion of patenting plant forms, GMOs or human cloning issues.

To evaluate merits and demerits of any concept, system, principle of fact, it's evolutionary history, the context the debate is couched in needs to be examined in great detail. This is because the debate is relevant and relative to its background history. Therefore, in this paper, before proceeding to consider arguments for and against allowing patents on life forms, it becomes imperative to trace the development of the law in this regard.

Evolution in the United States

The first most important case in this respect of patenting a living form, was the case of *Diamond v. Chakraborty*.^[1]Chakraborty had developed a bacterium that could digest crude oil, an ability not naturally found in any bacteria.^[2]He then filed a patent application in the US, assigning the

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invention to employer General Electric.[3]In his application he filed three types of claims: (1) a process claim for the method of creating the new genetically modified bacterium, (2) “ claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria,” and (3) claims to the living bacterium itself.[4]While the first two claims were granted, the patent examiner had rejected the third on the ground that micro-organisms being “ products of nature” and living objects are not patentable subject matter under Sec 101 of the US Patent Code.[5]On appeal the Patent Office Board of Appeals affirmed the rejection. An appeal was then made to the Court of Customs and Patent Appeals, which stated referring to prior case law that “ the fact that microorganisms [...] are alive [...] is without legal significance’ for purposes of the patent law.”[6]

This decision was upheld by the US Supreme Court in what has since become a landmark decision in biotechnology law. The Court by a 5: 4 majority interpreted the Patent Code broadly to hold that it was wide enough to encompass living organisms as patentable and declared that Sec 101 was meant to include “ anything under the sun that is made by man”.[7]In considering the scope of “ manufacture” and “ composition of matter” under Sec 101 the Court interpreted it to include living matter produced through biotechnology.[8]

It also rejected arguments that micro-organisms could not qualify as patentable subject matter till expressly authorised by the Congress stating that the development of biotechnology was unforeseen at the time of the drafting and further found evidence of the Congress wanting to provide for

such unforeseen technological developments in the broad language of Section 101.[9]

This case set the tone for the floodgate of biotechnology patents which saw a technological revolution within a few years to come. The next stage came with the applications seeking patents in higher life forms.[10] In 1988, a patent was granted on the Harvard Onco-mouse, which claimed “ a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal.”[11] These engineered mice were useful as a dependable animal cancer model for scientists to employ as a test subject in experimental cancer treatments.[12] The implication of this decision was that it brought animals within the purview of patentable subject matter.

Subsequently human gene line has also been patented. The first such patent claim comprised of the cell line taken from the spleen of a person named John Moore, which was valuable for producing antibacterial and cancer fighting proteins; the doctors had identified and isolated the cell line, and applied for patent and it was granted making human cells and genetic material also patentable subject matter.[13] And later following this grant several other similar patents were granted and now at least as regards the US jurisdiction it is a settled fact that human genetic material is unambiguously patentable.[14]

Tracing the European Position

To look at the European history one needs to start with the European patent legislation, the European Patent Convention (EPC) 1973. EPC provides for a <https://assignbuster.com/the-pros-and-cons-of-life-form-patenting-philosophy-essay/>

common patent framework throughout Europe; it provides that patents shall be granted for any invention is susceptible to industrial application, possesses novelty and involves an inventive step.[15]It prohibits patenting of living beings produced through “ essentially biological processes” but it does not prohibit patent on any living beings produced out of a non-biological process.[16]

After the adoption of the EPC, the first case dealing with patenting living beings was the Genentech- I/Polypeptide expression.[17]The invention essentially involved a plasmid, which is a micro-organism which helped control polypeptide expressions in bacteria. The European Patent Appeals Board opined that only essentially biological processes and concomitant products would be excluded under EPC and thus viewing the invention as a product of bio-technological process which did not constitute essential biological process granted patent on it. In Genentech v. Wellcome Foundation[18], however, a contrary decision was reached where the UK Court of Appeal rejected a patent on various claims relating to the production of a substance, human tissue plasminogen activator (t-pa); an invention which was useful in treating thrombosis.[19]The t-pa was produced through recombinant DNA technology and at time it was viewed as being an existing technology which could be applied at least in theory to produce t-pa as to produce growth hormone, insulin etc.[20]Thus it was held that there was no inventive step and the patent was refused.[21]

The finding though was more liberal in Chiron Corporation v. Murex Diagnostics Ltd.[22]where a claim was made for the production of vaccines, polypeptides and antibodies through a biotechnological process which would

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help fight the Hepatitis C virus. Chiron had identified the sequence responsible for causing non-A, non-B Hepatitis (NANBH) and the claims included an immunoassay test method for detecting antibodies against Hepatitis C by screening the blood for the presence of Hepatitis C infection, a vaccine, and a method for cultivating Hepatitis C cells.[23]The invention was considered eligible having successfully met the parameters under the EPC described above, and then it was again reiterated by the Court that biotechnological processes not being excluded under the EPC, it was eligible for a patent being granted. This decision confirmed the position in EC that inventions relating to biotechnological processes were patentable.[24]

The first claim for a patent in animal was again the Harvard Onco-Mouse. [25]In contrast to the relative lack of public controversy in the United States in 1992, the European Patent Office (EPO) grant evoked strong reactions from the animal rights groups.[26]It was argued that “ balancing morality against usefulness is not a fit basis for patenting animals.”[27]The opponents to the patent based their arguments on article 53(a) and 53(b) of the EPC which lists the European exceptions to patentability. Article 53, as mentioned earlier allows for the patenting of biotechnology generally, but states that inventions contrary to the ordre public or morality are excluded from patentability.[28]

When considering the patentability of the onco-mouse, the Technical Board of Appeals favoured granting the patent on technical grounds, but referred a list of moral considerations to the Examination Division before allowing the patent to grant.[29]Among these relevant moral considerations: whether animals were being regarded in the application as objects, the likelihood of <https://assignbuster.com/the-pros-and-cons-of-life-form-patenting-philosophy-essay/>

descendants of transgenic animals escaping into the environment and spreading malignant foreign genes through mating, and whether the claimed patent was drastically interfering with evolution.[30]After considering these issues a patent was granted in 1992, which was also appealed against.

The final opinion was given in 2004 where the Technical Board of Appeals at the European Patent Office held that Rule 23(d) EPC applied to this case, even though Rules 23(b) through 23(e) EPC had only been adopted while challenges to the Harvard Oncomouse patent were still being reviewed.

[31]These rules clarified the application of article 53(a) to genetically modified animals in barring the patent grants on moral grounds. “ Rule 23(d) EPC excludes from patentability inventions relating to processes for modifying the genetic identity of animals (or animals produced by such processes) in which the suffering to the animal is not outweighed by the substantial medical benefit to mankind or animals.”[32]The opinion also confirmed that transgenic nonhuman animals and plants did not invoke the article 53(b) bar on patenting plant and animal “ varieties” and noted that exclusions to patentability if any should be constructed strictly and narrowly while also taking into account the public perception of moral issues.[33]

As regards patenting human genetic material the first such claim in the Relaxin case.[34]The patent subject matter was human H-2 relaxin, a hormone involved in reproduction, and a DNA sequence coding for the hormone. The hormone was released in the body of a pregnant woman during the time of delivery to relax the body and reduce the pain of labour.

[35]It was opposed inter alia on the ground that human genetic material did not constitute patentable subject matter under Art. 52, EPC. This was <https://assignbuster.com/the-pros-and-cons-of-life-form-patenting-philosophy-essay/>

opposed by the Green Party on moral grounds as well.[36]It was argued that patenting human genes would amount to owning property right in the human body was against basic ethical standards. The patent however was granted by overweighing the ethical objections as well as the claim to the patentability of human genetic material; wherein it was held that such patenting did not go against ethics as patenting of genes did not tantamount to patenting a human being and the EPC did not exclude genes in isolated and purified form from being patented.[37]It was stated that “ only in those very limited cases in which there appears to be an overwhelming consensus that the exploitation or publication of an invention would be immoral may an invention be excluded from patentability under Article 53(a)”.[38]

The next significant development in the EC in this context was the adoption of EU Directive on the Legal Protection of the Biotechnological Inventions, 1998 which came into effect in July 2000.[39]While owing to space constraints the Directive cannot be examined in detail, it suffices to say here that it, helped define terms like biological material, essentially biological process etc. and inter alia gave a clear mandate as to inventions which are to be patentable and which not and within that also specifies that while the human body cannot be patented and isolated gene sequence will be patentable.[40]

The Indian Scenario

The Patent Act, 1970 highlights that an invention that satisfies the universally accepted requirements of patentability such as novelty, inventive step and industrial application is patentable.[41]India’s stand on this issue of

Life Patenting is indirectly reflected by the very fact that it's a signatory to the TRIPS agreement.[42] Article 27(1) of TRIPS agreement provides that patent shall be available for any inventions, whether product or processes in all fields of technology provides they are new involve inventive step and are capable of industrial application, hence, providing for both process and product patent.[43]

To fulfill its obligations under the TRIPS, the Patent Act, 1970 has been amended thrice.[44] The second amendment in 2002 brought in changes allowing the patenting of products of chemical, biochemical, biotechnological processes as well as micro-organism. Chemical processes were already patentable under the existing legislation under Section 5, but the amendment added an explanation to the section which states, "chemical processes include biochemical, biotechnological and microbiological processes." [45] Therefore, post this amendment the Indian law now recognizes biochemical, biotechnological, microbiological processes of producing non-natural, human-made, and transgenic living beings like animals, plants, isolating human genetic material etc.

Sec 3 of Indian Patent Act, 1970 which provides exceptions to patentability has also been amended in the light of Art 27(1) of TRIPS agreement; adding clauses like an invention with the primary object being commercial exploitation which would be contrary to public order, morality, or which might cause injury or prejudice to plant or animal health or environment, the mere discovery of a naturally occurring living or non-living thing, plants and animals other than "micro-organisms". The exclusion of "micro-organisms"

from Sec 3 or rather the affirmation of its patentability is an important feature of this amendment.

On account of the enormous growth potential of human genetics, among other life form patents, the Indian Council of Medical Research (ICMR) had issued guidelines, the ICMR Guidelines to regulate research in human genetics and in the absence of a specific legislation to this effect, the Guidelines compliance becomes important.[46]

While in the Indian context, a substantial amount of case law jurisprudence is yet to develop, an indication of the judicial response can be gleaned for the decision of the Calcutta High Court in *Dimminaco A. G v Controller Of Patents and Designs and Others*[47] where patent was granted for the preparation of the “infections Bursitis Vaccine” and the High Court held that there is no statutory bar to accept a manner of manufacture as a patentable item, even if the end product of the manufacture contains living organism.[48] Therefore it can be said with reasonable certainty that India also recognises life form patents.[49]

The Life Form Patenting : The Ethical Debate

Creation and patenting of synthetically produced life form as can be evidenced from the case laws discussed above has tremendous potential to offer in the form of technological development, like creating cheaper bio fuels, a reduction in environmental pollution induced degradation, a solution to several medical problems etc.

However, with this also rises the possibility of heretofore un-thought of

consequences like creation of pathogens, further environmental degradation
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by interference in the genetic line of species like rats etc. In this context, another ethical moral dilemma arises, especially in the context of higher life forms, as organisms no matter how it is produced whether naturally or with the help of bio-technology, retains the capacity for thinking and suffering.

[50]With the newly acquired understanding of life at the most fundamental levels, it is important that we do not regress into previous Pascalian modes of regarding nonhuman organisms as simply machines to be owned, used up, and discarded and patent legislations should therefore reflect a moral obligation not to incentivize the undue suffering of patented organisms.

[51]In the Indian context this is reflected through the framing of Section 3 which excludes from patentability clause (b) that denies patents on “ invention(s) the primary or intended use...of which could be contrary to public order or morality”.[52]

Further patenting and owning genetic materials is often considered by many (including many religious sects) to be tantamount to human slavery; which is then runs counter to the very notions of human dignity, a basic non-derogable guarantee affirmed through numerous documents like the United Nations Universal Declaration of Human Rights (UDHR) 1948[53]. This was an argument which had especially gained currency with the opposition of the Relaxin patent claim.[54]In the John Moore case[55]discussed above, the patient challenged the patent on his cell line arguing that since the patented cells were from his body, therefore they were his property and argued that owning and patenting a part of a human body through patent is a gross violation of human dignity and it struck at the moral roots of humanity.

[56]The Supreme Court rejected Moore’s argument in a very controversial

decision and held that there could not be any property rights over one's body.[57] One of the determining factors in this decision as is reflected in most patent application grants or refusals was an evaluation of the potential benefits from the use of the patent versus ethical moral concerns.[58]

The benefits accruing from biotechnology and genetic research which is incentivised through grant of relevant patents is all but obvious. It would not help with the continues shortage of human organs by stem cell research assisting in the development of genetically compatible organs, it would also minimise chances of xeno-transplantation or the transplantation, implantation or infusion into a human recipient of cells, tissues or organs from a non-human source which is often rejected by the host's immune system;[59] genetic research would also help developing treatments for diseases and in discovering new pharmaceuticals for a wider range of diseases.[60] The " pros" the term used in the title of the paper or the benefits of life form patenting from a pure technological stand point is so obvious that it need not be discussed further.

The dilemma from the ethical standpoint gets further aggravated by the use of inherently vague biological concepts, such as human and lower and higher life forms which make it difficult to determine in a non-arbitrary, consistent, and predictable way whether a life form patent claim deserves to be granted.[61] For instance, even in the face of intense opposition in Canada, the United States, and Europe, isolated human elements, including nucleotide sequences, are generally eligible for patenting, while at the same time, however, one cannot patent a human being in any of these

jurisdictions.[62] This dichotomy leads to an uncertainty in intermediary
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cases, such as determining the amount of human DNA that is required to make a part-human organ grown un-patentable.[63]

Another issue which arises in this context, are the consequences of countries and their trading partners making an unilateral moral choice to not patent certain life forms; because then given the large volume of trade that has come to characterise the world today such restrictions would not only allow free riding but also operate as a strong disincentive for inventions across the borders in a different jurisdiction all together.[64] However, having said that, it is also important to note, that morality by its very nature is unlikely to be uniform across the globe and in the near future atleast such dichotomy will continue to subsist owing to a lack of consensus.

Conclusion

As regards life form patenting thus, the consensus even if somewhat forces lies on an utilitarian balancing of the benefits to society with the moral ethical concerns while at the same time ensuring that even this balancing exercise stays within the realms of an accepted notion of morality as well as the patentable criteria of the life forms being synthetically produced, non-naturally occurring and as regards human genetic materials being completely isolated etc. It is said to be constrained within the accepted notion of morality because notwithstanding all justifications and benefits supporting it, human cloning is still not patentable in any the world's major jurisdictions indicating that there are certain non derogable fundamental societal precepts which cannot be compromised upon no matter what the benefits from doing so.

So life patenting as of the present lies on an evolving if somewhat hazy dichotomous consensus among growing tolerance for the intrusions of science. While there is growing convergence on issues relating to patentability, there is still an occasional difference in opinions of different patent offices which renders the law unpredictable.