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Patenting of Living-Matter: An Entry too odd to be Allowed a Place within Patentable Subject Matter?

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ABSTRACT

Patents in the field of biotechnology have always remained a hot-spot for conflicting views on the grant of patents and a call for more stringent standards so as to negate the possibilities of ache on the part of the society as opposed to the benefit granted to the inventor. However, the debate gets even more sensitive when the question of grant of patents relates to claim of patents over life-forms. In this paper, the author makes an attempt to briefly analyze, taking into consideration relevant patent philosophy, scientific reasoning, the patent law in India and international prescriptions, whether or not the patenting of life-forms be allowed to find a place within the patent subject matter.

Keywords: Patent, Stem Cell, Living Matter, Subject Matter.

I. INTRODUCTION

Although the concept of patentable subject matter as it exists today was not so well framed until a few decades back, a solid enactment dealing with the system of granting patents can be traced back to the late 1400s, i.e. the Venetian Patent Act of 1474. However, it never dealt with what was patentable and what was not patentable². The concept of patentable subject matter came into consideration much later, and today one can find this to be enshrined within the TRIPs Agreement itself under Article 27 (3) of the Agreement. It ought to be noted that, this provision uses the word “may” and not “should”, as in it suggests that Members may exclude from patentability certain inventions listed under the provision. This in fact implies that there is absolutely no compulsion on any Member country to necessarily exclude the matter from patentable subject matter. Rather, TRIPs simply provides for a scope for nations to flexibly decide for themselves whether or not they deem it appropriate to exclude those matters falling under the “27 (3) exceptions” from the patentable subject matter within their municipal patent law. The relevant parts of 27(3) in extracted below: *Members may also exclude from*

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² The Venetian Patent Law, 1474, available at http://www.copyrighthistory.org/cam/tools/request/showRepresentation?id=representation_i_1474 (accessed on 2nd September, 2019)

*patentability: ... plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...*³ This freedom itself has resulted in a diverging practice in various countries throughout the world, and one of the most diverging differences in practice can be seen when one compares the practice in US with that of the U.K. Post TRIPs, India, upon amending its municipal patent laws to bring it into conformity with TRIPs, brought several changes to the previous enactment, and the present law clearly lays down the patentable subject matter in India under Section 3 of the Indian Patent Act. The relevant parts of Section 3 under the context discussed under this paper are as follows: *the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature*⁴; *plants and animals in whole or any part thereof other than micro organisms....*⁵

The former lays down that the discovery of any “living thing” occurring in nature is not patentable in nature, while the latter lays down that patents are not to be granted over plants and animals in whole or any part thereof, other than micro-organisms. To be noted here, is that these are provisions which deal with a merger between the field of science and the field of law. An argument raised by the author, and an argument which often finds much prominence within the relevant literature in this regard, is that matters of science (as in scientific truths) should be stated and laid down by science itself, and not by a mere piece of legislation. The most substantive justification for taking such a view is that it is evident based on logic as well as common sense that questions relating to a matter that falls under a particular branch of study is always best answered by that branch of study rather than by a different one. This is especially true in the field of science and biotechnology because the field is ever expanding and too complicated, and more over, it is too related to the human life that it makes absolutely no sense to expect framers of law to be best fitted to decide or answer questions arising in the field of science. As one can rightly see, these are areas where there comes into picture an interlinking between science and the law itself. If the law is to declare something related to science, the law ought to primarily and pre-dominantly consider the relevant and accepted principles under science in that particular context which the law is attempting to deal with, and only upon giving due consideration to the same, should the law be framed.

With the above argument in picture, it can be asserted that Section 3(j) of the Indian Patent Act

³ Article 27 (3) (b) of TRIPs

⁴ Section 3 (c) of Patent Act, 1970

⁵ Section 3 (j) of Patent Act, 1970

which excludes plants and animals in whole or in part, except for micro-organisms, from patentable subject matter, excludes human being and parts of human beings also from patentable subject matter. Human beings belong to the animalia kingdom⁶, and therefore patents over human beings and parts of human being too should be considered to be excluded under Section 3(j). This would imply that the patents granted over DNA, and product of the human body, would be excluded from patentable subject matter. It is to be noted that neither DNA, nor any part of the human body is considered to be a micro-organism by science. Rather, they are simply a part of the human body. Thus, if patents over animals and plants in part or in whole are to be excluded from patentable subject matter, the same exclusion is valid and should apply in the case of human beings as well. And, so far as Section 3(c) which lays down that discovery of living or non living substances occurring in nature are excluded from patentable subject matter, is concerned, there is a very relevant argument existing in literature which argues that human DNA, even upon isolation, and regardless of how so many scientific procedures or “n” number of advanced techniques were put into use to extract a human DNA, if the patent claim relates to a claim over the DNA, or a property or a use arising in the so called “invention” arising merely due to the property of the DNA⁷, then it has to be accepted that any claim which relates to DNA would have to be denied as it ought to be excluded from patentable subject matter.

The Indian Courts, whenever the question of patents over life forms came into picture, at least in the initial stages, were in the trend of relying on American jurisprudence and decisions on this regard to answer the same. Perhaps, it can be stated that there was also much pressure on India (and across the globe) to consider the practice in the US and bring it laws into conformity with that of the practice in theirs. Thus, it would be relevant to discuss the US position in this regards. The following part will make an attempt to briefly cover the US view and practice in this context.

So far the US case laws are concerned, the most significant and primary case laws which dealt with patents over life forms was the case of *Diamond v. Chakraborty*⁸. To sum up the facts in brief, a bacterium was developed artificially, which had the potential of breaking down crude oil, a potential which not naturally seen in any bacteria. A patent application was filed, and along with claims over the process / method of creating the genetically modified bacteria and over the inoculums, there was also a claim over the living bacteria itself. Issue arose when the patent examiner refused to grant the third, but accepted the former two claims. The third claim,

⁶ Virginia C. Maiorana Leigh M. Van Valen, Animal, Encyclopaedia Britannica, March 25, 2020 <https://www.britannica.com/animal/animal>

⁷ Section 3 (j), when read together with Section 3 (d), 3(e).

⁸ *Diamond v. Chakraborty*, 447 U.S. 303 (1980)

that is, the claim over the living bacteria was rejected on the ground that it was excluded and not patentable under the exclusions to subject matter under the patent law in the U.S. laid down under the US Patent Code⁹. The initial appellate body too agreed with the decision by the patent office, but upon appeal to the Court of Customs and Patent Appeals, it was held that it was not the concern of patent law as to whether the micro-organism was living or not. Thereafter the Apex Court upheld the same, and went to hold that anything under the sun made by man was patentable. The impact of the Court's decision was such that even living matter that was produced by science and biotechnology could be patentable under the US law. This was the landmark decision that paved way for the almost "n" number of biotechnology patent claims that were witnessed in the US. It is also this view by the US in general that led to the exclusion of micro-organisms from the exclusion of plants and animals from patentable subject matter. However, with this, the desire to seek patents (and the trend of granting patents) over higher life forms came into practice.

The patent granted to Harvard University for the Onco-mouse¹⁰ was a next step taken in this direction and after this patent claims over higher life forms started to come into the picture. This made space for patent claims over parts of the human body as well. The initial claim over human parts related to one over the human cell line¹¹. The grant of patent over human genetic material in this case paved way for several patent claims being made over various human genetic material and the US Courts were in the habit of deciding in favour of grant of such patents whenever the matter came before the Court.

Also relevant here would be the practice that is followed in the UK. It should be noted that the UK has an overall framework set by the European Patent Convention (called as the EPC). When a patent claim was made in the UK with regard to the Onco-mouse, the Court considered the relevant provisions under the EPC¹² and the Rules¹³ set forth there-under. Although the claims were accepted, a difference witnessed in the UK was that the opposition to the grant of patents in this regard was raised also relying on moral grounds, and this was not witnessed in US. However, although the Court did not completely overlook the moral aspects of this, it was held by the Court that the moral objections should not be allowed to out-weigh the benefits that would accrue to the human race. Next in the line of patent claims was (obviously and quite similar to the trend seen in US) a patent claims over human genetic material, starting with a

⁹ Section 101, U.S. Patent Code.

¹⁰ Bioethics and Patent Law: The Case of the Oncomouse, WIPO Magazine, WIPO (June 2006), available at https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html

¹¹ John Moore v. The Regents of the University of California, 51 Cal. 3d 120

¹² Article 53(a), Article 53(b) of the EPC

¹³ Rule 23(b), Rule 23(d), Rule 23(e) of the EPC

claim over a hormone found in women¹⁴. The same was opposed based on moral as well as other grounds, but the Court deemed it fit to grant patent in this regard.

It should be noted that as argued in the previous parts of this paper, these were instances where patents were granted, in fact, for the discovery of naturally occurring substances in the nature. The application over human cell line in the US, as well the application over the human hormone in the UK, both were patent claims arising out of discovery and perhaps a successful isolation of the discovered naturally occurring substance. This therefore ought to not have been granted in the first place as the same should have been rightly identified to fall under the exclusions to patentable subject matter all the more because they are essentially a claim over the human body in part, which ought to not be accepted, and should have therefore been properly rejected by the Court.

Now, coming back to the Indian scenario, as stated previously, the Indian legislature had no option but to bring its municipal laws in conformity to TRIPs, but the Indian Courts, due to no such compulsion, yet seems to have chosen to often rely on the American practice in deciding cases, IP as well as non-IP. Although there exists not many relevant cases relating to patenting to life forms in India, it is clear that patents are granted, and have been granted for substances such as DNA.

Notable decision in the context of grant of patent over life forms is the decision in *Dimminaco A.G. v. Controller of Patents and Designs*.¹⁵ The case related to a patent application claiming patent over a process for preparation of a vaccine which had application in protecting poultry from a particular infection. Issue however was with regard to the fact that the patent claim encompassed within itself a living virus as well as a product of process for which the patent was claimed. To be exact, the core issue herein was whether a claim over a process of manufacture can be accepted if the end product contains a living organism. The Court here applied the vendibility test and granted the patent although the process did involve a living organism. The result of this decision was that the position is such that there exists no bar to accept a manner of manufacture as patentable merely because the end product contains a living organism. It is to be noted that the claim was not, in essence, over the virus (that is the living substance), but rather over the process for making the vaccine (which is regarded as the manner of manufacture).

Now with all that said, the underlying reason for the grant of patents under the philosophy of

¹⁴ Bioethics and Patent Law: The Relaxin Case, WIPO Magazine, WIPO (April 2006), available at https://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html

¹⁵ (2002) I.P.L.R. 255 (Cal)

patent itself is that it is granted as a reward to the patentee for the contribution the patentee makes to the society in adding to the existing state of art a contribution from his or her knowledge in the form a new art or manufacture. Now, there are various theories suggesting why the said reward (i.e. monopoly) should be granted, but all of these can be said to agree upon the fact that this reward would serve as a tool to promote further innovation, and aid the inventor in recovering the costs involved in the said innovation and to make reasonable profits out of the same. So far as biotech inventions are concerned the “reward” is often touted to be all the more necessary as these inventions often involve a lot of investment into research and development. Advancement in the field of science and technology takes place only when one ventures into research and further development, and if such research and development is of such a kind that it requires a major investment of money, then it becomes obvious that such an investment would be made only when there is a likeliness of being profited from it. But, does this imply that anything that amounts to a new art or manufacture ought to be protected?

Consider US for instance, although it is often perceived that the US does not take into consideration elements of morality while framing laws on IP, particularly IP, but are more concerned about the economics, it should not be forgotten that the US did take into consideration morality and elements thereof when the US framed laws that excluded patents from being granted on nuclear technology. The same can be seen in the age old decision by the US Court in *Lowell v. Lewis*¹⁶, wherein the Court did give ample prominence to morality considerations in holding that the law does not allow for grant of rewards if the invention is of a mischievous or injurious tendency. These in fact, are moral considerations. Although how far these principles are adhered to by the US today are worthy of another discussion, the point that morality was never an element completely ousted from patent law is quite clear. It is only the result of a false propaganda, often successfully furthered by extreme liberalism and extreme utilitarianism that the concepts of morality doesn't find place within the patent system. History certainly proves it to be incorrect.

Thus, coming back to the question of whether that anything that amounts to a new art or manufacture ought to be protected, it can be rightly answered that it isn't so. This is especially true when it comes to a matter as important as one which involves life and living matter, more especially human life. Why? Because, life and living substances are quite different from any other field under which innovations, investments and R&D takes place. This is essentially so because the innovation, research and the development in this field has close link to life and life

¹⁶ *Lowell v. Lewis*, 15 F. Cas. 1018, 1817 U.S. App. LEXIS 169 (C.C.D. Mass. May 1, 1817)

forms itself. When considering human life, this becomes even more important. When parts of the human body or a human life itself (in case of stem cells, cloning etc.) there arises a number a questions relating to the rights of ownership over the products involved and the data relating to it. It is not as simple as answering who should own the patent over a newly developed engine or a newly developed chipset, because while the former two relate to non-living subjects, the situation is drastically different when it comes to life and life forms and parts thereof.

Questions that relate to the exceptional and predominant nature of human life itself, and their dignity and worth ought to not be turn blind eyed to. If the same are protected under the realm of human rights and fundamental rights, the same ought to be considered when a conflict arises when the same is touted against economic interests of inventors. The former should certainly be understood and accepted to outweigh the latter, because certainly it does. Considering the patent philosophy itself, which says that rewarding the inventor is with the intention of promoting the further development of art, it should not be forgotten than very often the patents granted over life and life forms only result in stifling of further development in this field. Take the US for instance, as early as 2005, reports suggested that about twenty percent of the human genes were intellectual property owned by US corporations. For instance, about fifty percent of the genes which are believed to be connected to cancer are also patented. This has drastic impact on access to treatment by people. Now is this surprising? Not at all, because the subject herein is essentially linked to human life, and it would only be logical to have expected such detrimental effects to follow the grant of patents over such matter. These are instances where the elements of morality cannot and should not be overlooked, instances where element of morality (in so far as it relates to life and dignity of human life) becomes or should be allowed to outweigh any other man-made interests.
