RISING ISSUES RELATING TO BALANCING PUBLIC ACCESS WITH PATENTABILITY IN THE FIELD OF HUMAN EMBRYONIC STEM CELL RESEARCH IN INDIA

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Abstract: New technology brings with it new openings and avenues for development and progress. Thus, providing the human race a step forward towards leading a life better than before. Not just socially, technology is also used by the Nations to establish their economic relations globally. Stem cell research being one such advancement in the biomedical field, that brings within its scope the social sciences involved in establishing the research; along with a need towards maintaining a political balance and leading towards global economic development. Human Embryonic Stem Cell research has become the new domain of research and development in biomedical science. But with the new technology and advancement comes its own issues and problems, that require to be dealt with and a path needs to be paved for better tomorrow.

Human Embryonic Stem Cells are characterized by great potential and flexibility to renew and regenerate into new cells. These cells can renew and regenerate into new specialized cells, while maintaining their original undifferentiated state. The research holds great promise for better cure and treatment of several diseases that are yet incurable; diseases such as cancer, Parkinson's and Alzheimer. But due to the derivation of these cells from an embryo of 5-7 days, it gives rise to several ethical and moral issues. This in turn creates challenges for regulatory bodies, policy makers and scientists as they try to establish their way through a tangled web of regulations.

In the middle of the ongoing debate relating to legality of the Human Embryonic Stem Cell Research emerges the question of patentability expected to arise in the near future. Once, the research has been proved and established the question as to who will own this medical breakthrough is expected to rise. The paper tries to establish the patentability trend expected to rise in the future in India, relating to Stem Cell Research based on the present laws and the recent Novartis AG v. Union of India Judgment[1].

Patentability gives rise to question relating to funding of the research. Funding being the source of investment for research and development majorly affects the right of patentability. The paper tries to evaluate the pros and cons of the State owned and private funding, and how it affects the patent rights.

At present there are no codified laws relating to stem cell research and development in India. With only draft guidelines introduced by the Indian Council of Medical Research, a non-bindery regulatory framework; the question of patentability still remains unanswered. The aim of the paper shall lie in establishing a test that shall balance the present laws of patentability and issues expected to rise in the future relating to patentability of Stem Cell Research as against social stability and accessibility, at the same time raising a question with regard to

[1] Civil Appeal No. 2706-2716 of 2013

availability of this technique and it's importance towards public health and benefit.

Keywords: Funding, Novartis AG v Union of India, Patentability, Public accessibility, Stem Cell Research.

INTRODUCTION

Stem research therapy has emerged as a ray of hope for patients suffering from several incurable diseases. The therapy has the potential to cure diseases such as cancer, Parkinson's disease and Alzheimer's. With the advent of new technology and medical advancement; scientists are exploring the scope of gene pool and finding new and effective means of cure and treatment. Stem cell research therapy provides scientists with new insights and possibilities for improved and effective therapies to cure diseases and provide better health conditions. Along with opening new avenues in the world of medical sciences; at the same time Stem Cell therapy opens large avenue for debates and discussions on an international platform relating to use of Human Embryo for effective use of the therapy and legality attached to it.

Whereas on one hand Stem Cell Research has lead medical sciences towards saving life of human beings; on the other hand it is rebutted on ethical and moral grounds as killing a life form and in the middle of the war between its legality and accessibility rises the question of its patentability safeguarding economic growth and development of a nation. From a scientific viewpoint the research is taking a step forward towards changing the face of the human medical sciences and taking it to the next level by forming an alternate and effective cure for any disease or organ failure. New technology brings with it not just a promise of prospective benefits expected to arise in future but also the difficulties and problems that the present generation might be expected to face due to the use of the new technology.

With the invention of the microscope way back in 1800, scientists have been intrigued by the cell structure and its potential. Hence one can roughly trace back the history of Stem Cell Research with the invention of microscope and then making its way through discovery of cells that were regarded as the building blocks of life carrying with them the potential to produce other cells. It was only in the 1900 that the first line of stem cells was discovered.

What are Human Embryonic Stem Cells one might ask? With the research in the biomedical field bringing in a huge change to human developmental biology led by research of human stem cells and from it bringing in the discovery of embryonic stem cells. These cells are considered to be the wonder cell with the characteristics of regeneration and multiplication. These cells carry with them the characteristics of differentiation and transforming from a single cell into multiple cells forming an organ in itself. These are primitive (undifferentiated) cells extracted from human embryo, characterised as the population of undifferentiated cells having the potential of self-renewal and to differentiate into specialised cell types (differentiation being the process whereby unspecialised cells acquire specialised characteristic e.g. heart, liver etc.). These cells can transform into more than two hundred varying tissues types making them a potential life saver. They are found in the early mammalian embryo after 5-7 days of fertilisation. When fertilised under favourable conditions these cells have the ability to give rise into specialised cells types forming a whole organism. There is evidence that few non-embryonic stem cells under appropriate conditions can also differentiate into special cell types but the degree of their developmental potential in not clear as of now. Stem cell researchers hope that it might be possible to use stem cells, or specialised cell types differentiated from them, to repair organs and tissues damaged by injury or by degenerative or autoimmune diseases including Parkinson's disease, multiple sclerosis and type 1 diabetes.

The process involves obtaining the cells from an early embryo that results in destroying the embryo, which brings us to the basis of the ongoing international debate of establishing the legality of the Human Embryonic Stem Cell Therapy. The use of embryo for the therapeutic purposes is often questioned and targeted by moralistic and ethical beliefs as being used as a means to maximise profitability with the grant of patentability. Economist might support the patentability and use of the therapy considering its sustainability factor as it brings in income by means of increase in profitability margin leading towards economic development and growth, but one might not overlook that at the same time it also provides cure for diseases being suffered by the present generation. The moral inhibition relating to killing of the embryo and the ethical issues attached to the use embryo for profitability raise a question on the legality of the use of an embryo for Stem Cell Research Therapy.

The science of Stem Cell Therapy carries with it not only moral and ethical beliefs but issues relating to patentability of the therapy opens the sphere for global market to enter the State boundaries and work towards economic growth and development.

Globalisation and Economic Development

Internationally, globalization can be solely regulated by the market forces but when it enters the Sate boundaries affecting the people within the

boundaries, there is need for the government of the State to take steps to regulate these markets. With the recent Judgment of Novartis AG v. Union of India and others [1], rejecting Novartis patent for Gleevec drug resulting in the firm's claim to withdraw its R&D investment in India, there have been several speculations regarding the implication of the judgment on India's foreign direct investment. In the light of the above case, there is a need to establish a test as to how the market forces influence globalization or rather is it globalization that influences market forces within the State boundaries? Moving along the same line; there is a need to determine how essential is the role of the State Government in balancing economic and social domestic factors with that of the global market. The author makes an attempt to evaluate and determine whether globalization is best formulated on principles of liberalism or neo-liberalism. In country like India where about 29.8% of the population is still Below Poverty Line, whether by bringing down its protectionist walls by granting patent for life saving drugs in an attempt for co-operation and participation in the International market to strive towards a better globalized network can actually be said to be in the interest of a developing country?

Globalization has become quite a dominant factor in shaping world economies. It encompasses the interdependence of two or more States for economic integration. With the advent of globalization it has brought in a promise for several new opportunities for developing countries relating to economic upliftment, new improved technological advancement and better interactive opportunities with other developed nations. In India during the nineteenth century trade and financial liberalisation flourished, welcoming a shift lowering the barriers of trade and moving towards progressive international standards. Globalization was the catalyst required for developing nations at a time when there was a long history of derailed economic growth. The concept of globalization emerged as an outcome of the need for interdependence between States post World War II; for economic growth and integration on an International level. It was at this time States opened-up to bring down their protective walls and come out of their isolated shells, to participate in free flow of trade globally by erasing the geographical boundaries. During the initial years of the post-World War II period; liberalism prevailed working towards an idea of global economy keeping in mind the social acceptability and moving towards an idea of public good. However, the idea of public good and community benefit seems to be diminishing over the past 25 years or so. The followers of neo-liberalism school of thought propose minimising government restrictions and encourage trade through freedom of capital, goods and services to be regulated by the market forces. In effect, neo-liberalism proposes privatisation and taking individual responsibility as the best means for free trade and global openness. In other words, it proposes eliminating social influence by abolishing government intervention and encourages maximization of profitability in the global market through means of "free market economy."

In the world of capitalisation and commercialisation; a borderless global economy might become a burden on the developing nations. It was only after World War II that a combined and concentrated effort was made towards globalization. Before that there was no effort towards development of developing countries or under-developed countries. As according to Dr. C. Rangarajan (Chairman, Economic Advisory Council to the Prime Minister) "International trade leads to allocation of resources that is consistent with comparative advantage. This results in specialization which enhances productivity… Emerging economies will reap the benefits of international trade only if they reach the full potential of their resource availability. This will probably require time."[2]. Due to an early start in development of technology; developed nations are undoubtedly technologically advanced than the developing nations. This in turn, provides an edge to the developed nations in the global market with better goods and services. And as it is a known fact that with technology in hand influencing the market goods it acts as a catalyst to stir the market forces in the favourable direction. It creates pressure on the domestic market and industries of the lesser developed nation, attempting to match up to the level of developed nations. Till the time developing and under-developed nations do not reach the level of technological advancement as that of developed nation, domestic economy and public would suffer due to open and free flow of trade under the garb of globalization. Hence, in the world of global economy and capitalisation, it would not be true or rather be incorrect to state that there exist no boundaries.

Where one talks about capitalisation it automatically leads towards the idea of profitability or greater economic benefit. In the era of globalization where the participating States claim globalization to be the process of unification of States into one big borderless society, it cannot be denied that it is not devoid of the essence of self-interest and self-promotion of individual States. It is an obvious observation that any State would enter the cycle of globalization for economic prosperity of its own nation. Globalization not just influences the international market but also impacts the social and economic structure within the boundaries of the participating States. For example, as per neo-liberalism tradition of globalization, it is considered

to be best connected with the concept of privatisation wherein the competition in the international arena for maximization of profitability and economic growth is not between the States but between the Capitalists in the international economy, that in turn is most beneficial to the private companies and it's investors, leading towards consequential widening of the gap between the rich and the poor.

It might be said that the States need to give up a part of their sovereignty in order for market forces to accelerate and shape the global economy. But as much as one might put it down theoretically supporting the concept of borderless State; it is quite not possible to create a world minus the role of the State. Dr. C. Rangarajan describes the term globalization as 'integration of economies and societies through cross country flows of information, ideas, technologies, goods, services, capital, finance and people. Cross border integration can have several dimensions – cultural, social, political and economic.'[3] In other words, an integration that gathers all sciences relating to economics and societies within its scope. Just like the currency ex-change rate of one nation affecting the other nations, similarly an impact on one sector of the society through democratic or global means affects the social stability of the whole society.

So what regulates the process of globalization internationally? Can it be said it is a majorly influenced by the market forces or is it the government that regulates the process of globalization? If we consider the factor that globalization is solely influenced by the market forces, then can it also be determined vice-versa; stating that globalization in turn influences market forces and consequential of affecting the society. If the latter case is to be considered then in turn it affects the domestic economic and political balance of the nation. Then, will such a situation not influence the government of a socialist state to take such measure on global front to bring stability within the boundaries of it's own nation.

When one talks about globalization it cannot be kept isolated from development. Globalization and development go hand-in-hand rather globalization can be said to be a consequential process towards achieving economic development. Globalization is often restricted to economic development on a global platform but development cannot be restrictive. As according to economic survey published in 2012, India emerged out to be fourth largest economy globally but it is still the poorest amongst the G-20 nation formed in 1999; with per capita income of $ 1,527 in 2011[4] that only increased to $ 1,591 in the year 2012 [5]. It is a clear indication that economic development on the global front is not consequently proportional to development of a nation. Therefore, the process of development gathers within its meaning all the sectors and spheres of the society. Hence, development is not just for the upliftment of a particular section of the society but development is for the progress and betterment towards common good of the society. Globalization flows through the economic channels and enters the boundaries of the State and plays a major role in economic stratification. When an element enters within the boundaries of the State, the politics of the State cannot be kept alienated from it and politics is never restricted only to economics. It involves several sciences clubbed together working towards a progressive nation, with a major attempt towards economic stability amongst different classes. Hence, globalization and development cannot be considered as two separate entities and be said to be restricted to only a specific class of society i.e. the capitalist but as a consequence globalization shall strive to incorporate social and political development of States.

Issues relating to Patentability

With the rise of new techniques and increase in the number of intricacies involved in technology and research process it is very difficult restrict the scope accessibility relating to patentability of generic projects. As scientist use high-throughput tools of study the properties of many genes, the burden on the investigator to obtain rights to gain intellectual property rights become difficult. The major reason for such difficulty arises due discovery of new technology everyday and due to the vastness of medical field, research and rapid new developments leading to lack of expertise and knowledge required for patentability. In the medical field smallest discovery or research of smallest particle as that like a new DNA strand can also entitle the researcher to its patentability rights. But Indian Patent Laws (Indian Patent Act, 1970) are very restrictive in granting patents in the medical field. The Novartis judgment has been well accepted keeping in view the consumer affordability in a country with huge economic disparity. In a country like India where 30% of the people live below poverty line barely being able to make the ends meet, patenting of drugs and medical breakthroughs would mean encouraging increase in the profitability of the investors; in turn resulting in high priced medicines, drugs and other related medical process. Hence, in such a situation in order to balance out the need to maintain social stability the policy makers restrict the scope of patentability, giving public health an edge above the profitability returns of investors.

Patent being a monopoly right given to its owner for a limited period in respect to his invention and his

research restricts any other person from using his research commercially. The benefit of reward in terms of money and recognition is what encourages a researcher to invest and utilise his skills and knowledge into a new hypothesis leading to research and discovery. Whereas, on the other hand commercial exploitation means better, improved and competitively priced products with increased circulation of the same. Patent being provided by the State has territorial applicability i.e. patent rights can only be exercised within the boundaries of the State providing patent rights to its owner; there is no law that guarantees global patent rights. In other words only the people within the boundaries of the State get affected by the patenting rights. If the patents are too liberal it in turns affects the consumer/public benefit. When the concern of patentability is made to balance out with public health and protection in terms of medical intervention; the State is required to be restrictive in its approach towards patentability of several medical inventions.

In the 1980s biotechnological developments started to take off, and there was a boom in new types of patent. These were patents on human genes and living organisms, originally found in nature and not created by an inventor [6]. The nature of biological inquiry and the norms of behaviour have changed in the wake of genomic inventions and projects since then. There is an expectation of potential patenting storm in future discoveries relating to genomics that would benefit the public health and well-being with increasing complexities in Intellectual Property Rights. The inputs of the biomedical research in the field of patenting are becoming complicated in the areas of gene expressions that could considerably become more complex with the advent of new technologies and inventions. With the increase in the awareness in the area of stem cell research institutions would become more concerned about their potential patent infringement liability with no protection from legal norms, in turn leading research institutions into taking more active steps to regulate their behaviour or revise their protocols in order to avoid intellectual property issues.

The moral and ethical controversy revolves around acceptability of patenting human genes and stem cells and partly due to the reason that such a research holds therapeutic value, the value that it holds in diagnosing, treating illness and disease. Companies see it as a means to recoup the money invested in R&D that leads us to the questioning the ethical question attached to the use of the embryo for commercial exploitation. To which the believers of the contrary raise that genetic information from human beings are entitled to special protection and no one can be granted sole ownership right to exploit them commercially.

As a general rule ownership rights rest with those who own and controls the resultant product. But the central premise is that the pitch of the ownership battle will rise proportionally to the success rate of the research. Thus, the more we achieve the vaunted promises of stem cell research, the more a crisis will be precipitated over the ownership of its results.

Funding leading to ownership rights

With the advent of science and technology in the field of Human Embryonic Stem Cell research there is expected to be a exponential growth in the literature on science involved in and behind stem cell research and potential growth of Human Embryonic Stem Cells as drivers of regenerative medicines. Extensive research is required for standardization of methods for the isolation of embryonic and adult stem cells from various sources like generation of therapeutic grade cell lines; identification of human embryonic stem cells growth factors; controlled differentiation, i.e. generation of specific cell population; study of fundamental changes in cell cycle control that occurs during embryonic stem cells differentiation; maintenance of stem cell in undifferentiated stage; regulation of differentiation of Embryonic Stem Cells; pluripotency and differentiation of established cell lines; standardization of animal free defined culture conditions; developmental potential of human versus mouse Embryonic Stem Cells; standardization in use of specific stem cells to specific organ systems, etc. [7]. Realizing the potential health benefits of stem cell technology will require a large and sustained investment in research. The hypothetical question that constantly pops up in this world of commercialisation and capitalisation; is who would exactly be credited for this medical breakthrough, if any, that might arise in the future considering the plausibility of the success rate of the on-going research. Followers of capitalist ideology might regard investors and companies as the rightful owners, whereas followers of socialist ideology would regard State as being the appropriate holder and regulatory body of the patent market specifically aimed at drugs and medicinal therapies. The world of demand and supply faces the dilemma of the end goal beneficiary, whether it is the private funding bodies/investors or non-profit funding bodies, State owned and controlled funding trusts or an admixture of them. When a company invests huge amount of money in a research it does the same with the presumption of reaping monetary benefits on establishing the results. The very term investment denotes using one's resources and funds in the present with a presumption to reap the exponential benefits expected rise in the future. Furthermore, if it is the investor, will it be rightful to hold him as the owner of the Patent or will it be the researcher, whose

knowledge, skill and years of experimentation and hard work is the reason for the behind the successful discovery of the new invention. There seems to be no dearth of raising questions as to the very core of granting a patent either to investor or the State holding the rights over it, considering the capitalist marketing approach in a welfare society.

Though private funding leading ownership rights might raise several doubts relating to commercial exploitation of the Human Embryonic Stem Cells but if one looks at the other side, it might be found to be most promising means of research due to the use human embryo for research; constraining the involvement of public sector due to public pull on ethical and moral grounds. The major challenge that might arise in the field of Human Embryonic Stem Cell research would be getting approval of the public for schemes relating to research funding and promotion of Human Embryonic Stem Cells. In case of State owned funding trusts, the research would keep getting delayed due to opposition on moral grounds. As before utilising of public funds and trusts public review and approval would be required, that would in turn require the State to device such means and modes of regulatory mechanism that would balance public interest along with encouraging scientific researches and investments. In other words it would create numerous delays and administrative obstacles in carrying out an extensive research that can result in boon for mankind. The same problem might arise in case of collaborative funding along with challenges relating to part patentability rights that might lead to non-disclosure of patentable material. But still collaborative funding optimizes the use of resources with a constant sharing of ideas and in case where the State fails to fund the research based on political reasons, it could be compensated through private funding and the research need not come to a halt. But in the ultimate analysis, regardless of the source of funding, it shall always be the public benefit that would be put ahead of individual right or claim. It is the public access, affordability and social requirement that would determine the claim over the patenting laws and rights attached to it.

It is in-fact too soon to determine or even try, considering the present Indian scenario and law relating to patentability of stem cell research under Indian Patent Laws. In the near future it seems as a very bleak possibility that the private profit funding bodies could gain rights over patentability of the Human Embryonic Stem Cell research. At present Indian Council of Medical Research (ICMR) is funding organisations carrying out the Stem Cell Research, subject to monitoring by a regulatory body to detect its unethical application and liable for punishment including imprisonment [8]. A 'CMC-DBT Centre for stem cell research' has been supported at CMC, Vellore. SCR facilities are also being created at the Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh. The training centre for embryonic and adult stem cells has been supported jointly at the National Centre for Biological Sciences (NCBS) and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCSAR), Bangalore. Clean room facilities for SCR are being established at SGPGIMS, Lucknow; KEM Hospital, Mumbai; and LVPEI, Hyderabad. Dedicated short and long-term overseas fellowship programmes have been initiated by the Government of India for providing training to twenty five fellows every year in niche areas including stem cells. It has been decided to support both clinical and basic research on stem cells simultaneously. To consider the clinical trial proposals, four separate committees have been constituted: (i) Human Studies Committee for Stem Cell Research in India: Emerging Scenario and Policy Concerns 49 evaluation and guidance for clinical research particularly for the development of clinical research protocols; (ii) Ethical Committee for Stem Cell Research to ascertain rigid ethical guidelines being followed while conducting research on human beings; (iii) Task Force to evaluate basic research and also recommend the funding for clinical research based on the evaluation of the above committees; and (iv) Programme Advisory Committee to consider the proposals received for the Centre of Excellence [9].

Impact of Novartis Judgment

The importance of the combined effort of the role of a Sovereign State and that of economic regulatory mechanism in the global market supported by the neo-liberal view can be explained by referring to the recent Supreme Court Judgment of Novartis AG v. Union of India and others wherein, the Supreme Court of India rejected the Swiss firm Novartis patent for cancer drug 'Gleevec.' Though the landmark decision pronounced rejecting the patent application was based on the test of inventive step laid down in Section 3 (d) of The Indian Patent Act, 1970 but on analysing the judgment as against the present Indian scenario it can be said that the judgment is directly linked in reference to the problem of ever-greening of the patents. Patent being monopoly right for commercial exploitation; given to its owner for a limited period of time in respect to his invention and his research; restricts any other person from using his research commercially. It is a right that is incorporated for profitability and benefit of an individual without any concern to common good, it allows the individual to maximise his profit through means of monopoly production and sale of a consumer good, as well provides him with the power to determine the price of the good and regulate its

supply in the market. At present there is no law supporting global patent hence, patent is exclusively a subject-matter of the State government and restrictive within the boundaries of the State; but it's impact and benefit being directly proportional to the income inflow into the State leading in the form of foreign direct investment makes it a part of the process of global integration.

In a country like India where 29.8% of the population is below poverty line, political openness in global market can be resultant of dire consequences on the democratic, political and social balance of the nation. Novartis Judgment sets a benchmark for socialist economies; highlighting the protectionist nature of a welfare State in the era of globalization and capitalism. The Judgment rejecting Novartis patent has been criticised by US-India Business Council (USIBC) on the ground that it would impact innovation and investment in the country in turn having a resultant effect on the nation's FDI [10]. In other words, stating that the judgment would in fact discourage foreign investors from investing in India. The critics of the judgment demand India to extend more protection to patent drugs developed in west. Roger Bate, a global health expert at Washington-based think tank American Enterprise Institute, stated that as a result of the Supreme Court order, Indians will receive lower-quality copies of Gleevec and other drugs, and are less likely to receive cutting-edge products in the future. "The quality and consistency of India's drugs could be enhanced by foreign investment through infrastructure funding, technology transfers and changes in management culture. Yet nothing halts foreign investment faster than uncertain rules over intellectual property," he said [11]. Taking cue from the statement as that of Roger Bate it could be deduced that the concept of 'borderless society' or 'unification of States' comes crumbling down the moment it raises a question upon the interest of one's own economic development. The statement in itself is quite evident that globalization minus State interference can be critiqued upon two factors; first, the dominant factor that the market forces play in globalization solely driven by individual profitability. One can say that market forces working on the principle of demand and supply often device such means of manipulating these two factors that is resultant of creating an inflation of prices in the market which is insensitive towards the social needs of the people. Like in case of patents the monopoly right holder has the power to regulate supply of such essential life saving drugs that in turn gives him superiority in deciding the prices of these drugs, and medicines and drugs being such goods that an individual has no alternative but to buy them at whatever price it might be marked. Often, economist critique that when one enters the pharmaceutical market the laws of demand and supply and market forces do not work in the same way as that of any other consumer market. But we must not forget that in the above illustrated case of a patent drug; we are ruling out an essentially considerable factor as that of competitiveness in the market, which plays a major role in regulating market forces.

Secondly, that economic factors works only towards the aim of maximisation of profit, without giving any special consideration towards the lesser developed nations who are technologically lacking behind in the race of commercialisation and capitalisation. There is a need to devise special laws and policies to help the developing States to rise up to the level of technologically advanced nations before they are expected to contribute to globalization by relaxing stringent laws. With Novartis holding the patent for the drug in about 40 countries including US, China and Russia [12] the economist might negate the judgment as being against the global economic policy of participation and inter-dependence, as it discourages foreign investors in making future investments in R&D as not being sure of their Intellectual Property Rights in future. With Novartis threatening to withdraw R&D investment in India [13], one may argue, that a socialist approach in situation like that Novartis Judgment as illustrated above might not be considered favourable for globalization and integration of States, discouraging investors to invest in India resultant of affecting State's economic development and growth. But before we get to the conclusion we must not overlook that Novartis holds 219 patents in India from 2005-06 and 2009-2010 [14] which is not in any way discouraging global initiative but again ascertaining the protectionist nature of the State Government as per the domestic stratification of the society. But it is also true that 'the verdict comes at a time when overseas drug makers are keen on gaining a bigger share of India's pharmaceutical market, which is seen growing to `5 trillion from `1 trillion by 2020, according to India's department of pharmaceuticals (DoP).' [15].

But more importantly, the judgment has been widely acclaimed due to the sociological perspective attached to it. As according to Data Portal of Government of India the total population of India for the year 2010 was 1190.52 million [16] out of which 354.68 million people lived below poverty line [17] with the per capita income of only $1369.54/- [18]. As according to 66th round of National Sample Survey (NSS) carried out between July 2009 and June 2010, all India average monthly per capita consumer expenditure (MPCE) in rural areas was Rs. 1,054. It was also pointed out that 10% of the population at the lowest rung in rural areas lives on a

meagre wage of Rs. 15 a day. With such huge social stratification as that of India it is the duty of the State to protect not just the rich but the also the poor. And in case of drugs and medicines that save an individual's life or affect in order relieve one from pain and suffering; keeping in mind the consumer affordability in a country with such huge economic disparity; the State needs to take measures and intervene to regulate laws on the global front for public good. This brings us to the question whether it is actually feasible in the wake of global initiative for developing nations like India to patent and sell a drug priced at Rs. 1 lakh per month [19] where there is huge difference in the income distribution and the per capita income for millions of people might not even be Rs. 1369.54/- and an estimate of 28 lakh patients suffering from cancer in India [20]. Whereas, on the other hand, we have Indian companies manufacturing generic drugs selling cheaper drugs for cancer priced at Rs. 8000/- for a month (Ibid). In such a situation the State Government cannot allow market forces to solely regulate the consumer market by allowing patent encouraging increase in profitability margin leading to high prices. In times of globalization MNCs are investing huge amount of money in R&D to provide better drugs and medicines that eventually entitle them to Intellectual property rights leading to higher prices of the monopoly drugs and medicines. In such a situation rather than the demand it is the price that plays an influential factor in the society and somewhere the demand of these drugs is also consequential of the purchasing power of these drugs. Economics and State Governance have conflicting interests as laws of economics works with the modus operand of profitability that is not quite patient oriented keeping in mind the huge economic disparity amongst different classes in developing countries like India.

Indian Perspective

Propelled by the utility, scope, importance, scientific and economic promise of the research in the coming years, in order to make the treatment affordable, the developing countries target innovation as a step forward in the economic development globally. Emerging economies like India are bringing in steps and guidelines to promote as well as keep a check on the development of stem cell research. At present several agencies in the government are promoting Stem Cell research. Various means like discussion on research specific disease and various programmes have been conducted to bring about the awareness in this field of biomedics. In addition to the studies that have been supported to explore the potential application of adult stem cells. There is a need to harness the potential of Stem cell treatments of various diseases. Yet, large amount of funding and investment is required to carry out good quality research in this field.

The Indian Council of Medical Research (ICMR) propose Draft guidelines for Stem Cell Research and Therapy, 2012 however, their recommendations are non-bindery at the point. The Guidelines propose a system of review and monitoring for Stem Cell Research and therapy an establishing Institutional Committees at Institutional level. Guideline 14.0 states as below:

***"14.0 Commercialization and Patent Issues**: Research on stem cells/ lines and their applications may have considerable commercial value. Appropriate IPR protection may be considered on merits of each case. If the IPR is commercially exploited, a proportion of benefits shall be ploughed in to the community, which has directly or indirectly contributed to the IPR. Community includes all potential beneficiaries such as patient groups, research groups etc."*

In principle ICMR's ethical guidelines for biomedical research shall be followed, a 2005 survey by ICMR showed that in the absence of any powers of enforcement only a minority choose to do so i.e. 40 (22%) of India's 179 institutional ethics committees followed the principles laid down [21]. Due to the lack of legal backing and being non-binding in nature there is hardly any check on the inventions or discoveries in the field of stem cell research. As Stem cell research being a recent study with no established or published reports of it's success, there are not many investors in the market for Human Embryonic Stem Cell research, in turn monopoly of the few leading players/clinics in this field who claim to be running successful tests and treatments in their clinics. Hence in terms of question related to patentability of Human Embryonic Stem Cell research it still hasn't come into light as of now.

Patenting in India is governed by Indian Patent Act, 1970. The history of Patent Law started in the year 1911 in Indian with the invention of Indian Patents and Designs Act, 1911. The present Patents Act, 1970 came into force in 1972. The Patent Act was again amended by the Patents (Amendment) Act, 2005, wherein product patents was extended to all fields of technology including food, drugs, medicines, micro organisms etc. Section 3 of the Act provides a long list of inventions that are not patentable under the Indian Law along with biotechnological inventions. Section 3(d) and 3(i) of the Act could be seen as being restrictive when it comes to patentability of Human Embryonic Stem Cells. Under the said sub-sections patentability of new substance and any process for medicinal, surgical or other treatment of human beings to render them free of disease are restricted respectively. But

there can be observed a conflict in the suggestion put forth and established law i.e. between ICMR guidelines and the present patent laws in India respectively. On one hand Guideline 14.0 of the ICMR is allowing commercialization and patentability of the research, on the other hand present Indian laws evidently oppose the proposal.

Novartis AG v. Union of India and others provides a benchmark for patentability of future investments relating to medicinal purpose and drugs. It can be interpreted that one of the major basis of the judgment was to balance out consumer affordability with the rights of patent. In India where 70% of the population living in rural areas and 30 % people living below poverty line, where they are barely able to make the ends meet, this judgment has been widely approved keeping in view the social and political aspect. But on the other hand the same judgment has been rebuked by investors due to lack of objectivity identifying the standard on which drug research should be based. If one is to look at the broader perspective of the judgment passed it could be well said that when it comes to medical inventions and research, the patentability laws need to be restricted keeping in view the sociological aspect, giving an edge to public health and benefit over individual rights of patentability and profitability. Such a judgment is seen as discouraging investors into investing in India with the Ranjit Shahani, vice-chairman and managing director of Novartis India Ltd announcing that the company would no longer invest in innovative drugs in India [22]. Based on the above scenario one could deduce that similar issues would be raised on question of patentability of Human Embryonic Stem cells in future. At present many companies are shifting their base from India due to lack in regulatory framework that would be binding for the purpose of stem cell research. Nitin Deshmukh, chief executive of Kotak Private Equity and an executive member of the biotech industry body, ABLE (Association of Biotechnology Led Enterprises) council: “Many of our companies are shifting their research and development and IP registration to Malaysia and Singapore. They even want to license outside India.” Visibly angry and disappointed, he says he has stopped investing in life sciences companies as they have no future in India [23].

Another major issue that is expected to rise in future relating to patentability of the Human Embryonic Stem cells in a culturally diversified nation as that of India relates to ethical and moral issues that might arise in future. With research in the biomedical field bringing in a huge change to human developmental biology that led to research of human stem cells and from it bringing in the discovery of embryonic stem cells. These cells that are considered to be the wonder cell with the characteristics of regeneration and multiplication are derived from early human embryos. Despite the potential benefit of using Human Embryonic Stem cells in the treatment of disease, their use remains controversial because of their derivation from an early embryo of 5-7 days. And patenting the technique used in deriving the treatment with the help of these cells would indirectly be granting a legal status to the process of extraction of stem cells from human embryo. This is presumed to raise several ethical and moral issues in a secular nation as that of India, where under several religions; killing an early embryo is equivalent to killing a foetus. Due to use and fertilisation of human embryos involved there is an additional facet added to it of manipulation and modification of embryos. If on one hand it makes treatment more affordable and provides certainty to it, on the other hand there is a chance of misuse of the same for commercial purpose.

Under several religions it is unethical to use an embryo for any purpose other than for pregnancy, yet there are several other religions that regard ‘human development’ as an essential part of an individual’s existence. At present the status of embryo is not established under law. With Article 21 of the Constitution of India protecting right to life and foetus killing being a crime under the present laws, it is questioned whether there would be exceptional cases incorporated under Indian Laws to promote Stem Cell Therapy wherein aborting embryo for medicinal and therapeutic purpose would be sanctioned. Keeping in mind the moral and ethical inhibitions instead of killing the embryo for commercial purpose, an unwanted embryo can be donated after proper background check establishing legality under laws of medical termination of pregnancy. Subsequently research can be carried out towards developing subsequent embryo lines from the donated embryos. All these questions and inhibitions lack answers in the present regulatory framework. Under the present guidelines by ICMR the Human Embryonic Stem Research is to be carried out on surplus embryos or specifically generated embryos for research or therapy purpose. These embryos can only be sufficient for research purpose but once the research has been established and published with definite results providing legality to it, the embryo bank would not be sufficient in proportion to its need in treatment.

CONCLUSION

The issue of patentability connected with that of commercial use or industrial use of the Human Embryonic Stem Cell needs to be evaluated as against economic development and growth of the country globally along with maintaining social

stability and accessibility within the boundaries promoting public interest and well being of the people of the State. As stated by Dr. C. Rangarajan "concern relates to the loss of autonomy in the pursuit of economic policies. In a highly integrated world economy, it is true that one country cannot pursue policies which are not in consonance with the worldwide trends. Capital and technology are fluid and they will move where the benefits are greater. As the nations come together whether it be in the political, social or economic arena, some sacrifice of sovereignty is inevitable. The constraints of a globalized economic system on the pursuit of domestic policies have to be recognised. However, it need not result in the abdication of domestic objectives." [24]

Therefore in the light of the above discussion, in order to ensure free and fair flow of trade for the purpose of medicinal and therapeutic use along with maintaining social stability, State Government need to regulate such policies that not only promote economic integration and participation globally but at the same time, there protects its people from getting affected by the impact of globalization within the domestic boundaries. The State needs to understand the benefits and ill-effects of political openness and try to strike a balance towards promoting global interest within it protectionist framework. There is a need to strike a balance between social stability and accessibility with that of economic growth and development of the nation. States need to marginalize global participation and interference keeping in mind the social and domestic politics existing within the State. Developing nations might be getting benefited from globalization of trade but there is a need to strive for global development. Global development can only be achieved if the global economic benefits trickle down to all levels of socially stratified domestic economy, moving towards the path sustained social and economic growth.

To obtain a patent an applicant must claim an invention that falls within patent-eligible subject matter. The invention must be new, useful, and non obvious in the light of the prior art. The patent application must satisfy certain disclosure requirements. Academic researchers and scientists commonly assume that their research is protected under the laws relating to Intellectual property but with the changing scenario one might have to reconsider the same in the wake of public accessibility and affordability to usage of the patentable material for commercial purpose. The implication of Novartis decision are not yet clear although it does appear that the researchers and institutions researching upon medicines, drugs or medical process involving public benefit might have to pay a little closer attention to the patentability related issues involved in their present and future work as against its commercial considerations. The current scenario is indicative of the fact that many aspects of law governing intellectual property rights to patents are yet not settled. The Government requires working on laws balancing between public accessibility and patentability rights. The issue of accessibility could be balanced by having access with streamlined licensing conditions under supervision from government bodies; regulating the internal framework with pre-approved patent contracts. Exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of technology as possible. And with the pre-approved patent contracts investors will get commercial benefits approved and accepted under the contract along with maintaining commercial affordability due to intervention of the public sector. Wherein, the government and private institutions together contribute to research funding. This way neither the State nor private investors will be burdened with arranging funds for research purpose.

In case of balancing the need for investment from foreign direct investment and patent policies in case of drugs and medicines, it can be regulated by means of pre-patented contracts. Wherein, the State shall provide patents on pre-contractual basis. As per the contract price fixed for sale and margin of profitability shall be fixed based on the amount of R&D investment (depending upon whether investment was made in that particular State where patent is being filed or any other State), present market and supply of the drug globally and market forces regulating domestic economy. Government can also enter into contracts to device means to provide essential life saving drugs on subsidised rates to the poor who cannot afford the patented drugs and medicines. Globalization should not be solely aimed towards economic prosperity but should be structure towards development of all the sections of the society within a State on the global front. Special laws and policies shall be framed keeping in mind the technological and economical scenario of the lesser developed nation and by giving special attention and support to under-developed nations.

Essentially it would be the combined effort of the State and private investors that would be a plausible model for social stability and progress. Like any society doesn't exist without social stratification, similarly the world is also economically and resourcefully stratified. So in order to work towards global prosperity with an intent of sustained global economic development and growth, there needs to be checked Government intervention by the State in shaping the globalization of world economy keeping in mind that it shall not disrupt the free flow of trade

but when need shall emerge built walls around it for protection of its people.

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