

Patenting Life the American, European and Indian Way

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The patent regime heralds an expansion of its protective umbrella to the emerging sphere of biotechnology, full repercussions of it are only just coming to fore. With revolutionary and rapid growth of industry, new legal and ethical questions have burgeoned which require a meticulous and concerned deliberation. This article discusses evolution of patenting life in the United States, Europe, and India. Additionally, implications of each country's impact on international patent regime in the light of TRIPS Agreement are also studied. The article also explores feasibility of offering similar statutory protection to living organisms manufactured with significant human intervention in India, which thus far has only witnessed a minimal onslaught of patent applications for 'utility patents'.

Keywords: Bio-patents (life patents), TRIPS, product of nature, natural process, EPC, Biotechnology Directive

Generally, a patent is a negative right which affords the opportunity of exclusive commercial exploitation to the patentee. However, a patent does not actually include permission to use or market the invention, marketing approvals are granted separately.¹ A patent hence furnishes a monopoly for a stipulated period of time² and is a legal means of limiting competition. The limitation period for the monopoly is designed to provide incentive to the inventor while adequately balancing the rights of the individual against those of the society.³ Though it is imperative to be mindful of the fact that patents⁴ are contested as a method of creating incentive for innovation and securing necessary investment in production, marketing and R&D. In spite of such opposition, patent laws being a part of the traditional IPR regime have strong national roots and are subject to other domestic legislation.

Novelty and industrial application form the basic criteria for determining patentability of subject matter. Novelty marks the distinction between a discovery and an invention. For decades this distinction has manifested itself in the form of 'product of nature doctrine' in the US and other similar rhetoric elsewhere. It has contributed heavily to the exclusion of living matter from patentability.

Patents granted on living matter (i.e. micro-organisms), genetically modified plant and animal species, genes, cell lines, etc., are commonly referred to as 'bio-patents.' Living matter is patentable to

varying extent in different countries. However, because traditional standards of non-obviousness and novelty apply to patenting of living matter as well, patenting of new life is based on the differences of new life with the characters and uses of known substances. Whether or not mere isolation of a microorganism or gene from its natural surroundings is sufficient to obtain a patent also differs from country to country. For instance, in the United States, 'isolated and purified' compounds are considered patentable subject matter when the application meets the statutory criteria for patentability. Yet a patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. However, in the European Union 'biological material, which is isolated from its natural environment or produced by means of a technical process, may be the subject of an invention even if it previously occurred in nature.'⁵ However, despite specific country's standard for granting a patent on living matter, it clearly is a delicate, and often controversial, issue.

In addition to the legal debate, several practical public health concerns have also been raised concerning whether patents should be granted on bio-medical research. Many commentators point out that the patents on human gene sequences will compromise medical treatments and medical research⁶ as well as overburden the courts.

To address growing concerns over consequences of patenting of human genes, in September 1999, the then British Prime Minister, Tony Blair, entered into

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an Anglo-American agreement with the then US President, Bill Clinton, to protect the 100,000 genes of the human genome through the Human Genome Project, which is an international, collaborative, research program aimed to completely map and understand all human gene, together referred to as the 'human genome.' It offered some relief to many who feared monopolization of the human genetic information, patenting of human genes, cell lines and tissues, for the substances deposited in the depositories would not be eligible for patents on account of having already been in public knowledge.

In spite of such efforts, concerns over patentability of living matter have acquired an increasingly global dimension with full compliance by the developing countries to WTO's TRIPS Agreement.

The article is divided into three parts. Part I discusses the American and European patent regimes. Part II discusses widely accepted fundamental legal and moral challenges to this new form of patent regime. Part III provides an insight into the Indian history with the TRIPS Agreement and numerous amendments made to the patent laws, before and after signing of the same. It also brings forth the authors' paradigm to India's position with respect to bio-patents.

The American and European Patent Regimes and Patentability of Bio-Patents

The American Jurisprudence on Life Patents

The Constitution of the United States empowers Congress to 'secure for limited times to authors and inventors exclusive rights to their writings and inventions'⁷ for the promotion of innovation. The United States Patent and Trademark Office (USPTO), was established as a federal administrative unit to implement and regulate the US patent system.⁸ Under US legislation,⁹ there are four requirements for granting a patent : the invention must be novel, must not statutorily be barred from acquiring patent rights, must have utility, and must be non-obviousness. There is no imposition of any statutory bar on the patentability of the subject matter, other than these aforementioned four prerequisites.

The American law regarding patentability of 'life patents' is 'all inclusive'. Traditionally the system of patents has been used for mechanical instruments, and the like. With the inclusion of biological material to patentable subject matter disputes over their

'inventive' status and private ownership or monopoly over life, *per se* emerged. There exists a debate over whether new advances in technology mandate a new patent regime. In many ways, the arguments in favour of an entirely new system resemble those voiced 30 to 40 years ago when polymer chemistry was an emerging technology.¹⁰ The debate goes beyond whether existing patent regime should extend to living matter or not. As Chief Justice Burger explained, the issue was 'not between living and inanimate things, but between products of nature—whether living or not—and human-made inventions.'¹¹ The ethical concerns are continually voiced even today but are far less vociferous. With bio-technology fast emerging as a profitable sector its influence in biomedical and bio-pharmacological sectors cannot be underestimated. An increase in the number of bio-patents can safely be predicted. It is hence imperative that a conclusion to the debate be found sooner than later.

Even though patents on living organisms were not expressly excluded from the purview of patentable matter, such a paradigm gained endorsement from the US Supreme Court in the epoch marking decision in *Diamond v Chakrabarty*.¹² In this case, the US Supreme Court held in a majority decision of 5:4, that Congress, while drafting the enactment in question (i.e. The US Patent Act) intended to 'include anything made by man under the sun.' In reaching its decision, the Supreme Court provided the requisite legal protection to living organisms as long as they fulfilled patentability criteria under 35 U.S.C. § 101.

In *Chakrabarty*, the appellant (a microbiologist) challenged the USPTO's decision refusing to grant a patent on his mutated bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids. This human-engineered organism could help breakdown oil particles and control oil spills; a novel attribute on which the appellant based his arguments for the formation of a process for generating organism and for some unique characteristics of the bacterium *per se*. The USPTO conceded that extraordinary characteristics exhibited made the organism non natural and hence could not be ousted as a 'product of nature'. The USPTO though agreeing to the plea of the applicant that such organism was not naturally occurring in nature and could not be barred patent rights as a 'product of nature'.¹³ The sole ground for dismissing the patent application was that the subject matter concerned was a 'living organism'.¹⁴

The Supreme Court of the United States, while examining these different arguments, agreed that an engineered organism constituted a novel invention and was not a 'product of nature'.¹⁵ It also stated that the Congress could have plausibly foreseen the rapid expansion of science and technology and stated that the patent umbrella can be expanded to any and every thing that 'man had made under the sun.'¹⁶ The Supreme Court agreed that a challenge posed on two previous legislations which regulated certain forms of plants from being patented should not prevent the appellant from successfully patenting his novel organism.¹⁵

The Supreme Court, while expanding the functional framework of § 101, held that if a product were novel and portrayed characteristics which were hitherto unknown to mankind,¹⁷ it would suffice the clause's requirement. The Supreme Court did not concur with the then prevailing imperative nature of the 'product of nature' doctrine. This doctrine had been propounded by the Supreme Court in the case of *Funk Bros Seed Co v Kalo Inoculant Co*¹⁸ and was relied upon by the USPTO to deny patent protection and inventor's rights to a majority of patent applications, filed in respect with living organisms. However, post this landmark judgment the Supreme Court has, in a series of decisions, averted from the age old doctrine and declared that life form constitutes patentable matter until the time it is significantly altered via human intervention.¹⁹

To summarize, the legal position in the US on life patents has undergone a transitional phase. Currently, the interpretation of statutory and regulatory principles on life patents has a liberal implication. For utility patents, it is necessary to disclose with the patent application the proposed or unique function of the novel invention. Without disclosure, patent application stands to be rejected and the application process terminated. However, the disclosure is necessary only with respect to one particular usage technique and not all plausible manners for securing a patent protection.

The European Jurisprudence on Life Patents

The European patent system displays a disciplined yet inclusive regime of according patent rights to biotechnology and its numerous progenies. The guideline prescriptions for the European nations regarding municipal patent laws are incorporated in two primary documents—the European Patent Convention²⁰ (EPC) and the Biotechnology Directive of 1998²¹ (the Directive).

Four criteria are highlighted in the EPC for determining patentability of any subject matter. The EPC directs that for successful patent protection, the matter concerned should be patentable; should display novelty and include an inventive step; and must prove industrial usage. These four criteria were reaffirmed in the Directive of 1998. In fact, for the purposes of ensuring compatibility between the EPC and biopatents, the Directive categorically under Article 3.2 specifies that biological material, after considerable human processing and intervention, cannot be precluded from the ambit of patent protection simply because its initial existence was inherent in nature.²²

A novel feature of the EPC is incorporation of a 'public order and morality' clause under Section 53(a). The said provision bars according of patent protection to any invention which is against public order and morality. This position is in contradistinction to the American patent law which is bereft of any such 'morality' clause. The complementary provision to this clause under Section 53(b) bars patent rights for any variety of plants or animals or natural processes.

The decision in *Harvard/Onco mouse*²³ represents adoption of these attributes by the European Patent Office (EPO). In this case, inventor successfully patented the Onco mouse, a transgenic organism, which was mutated and altered by sufficient human and technical intervention to improvise it into a novel organism. The Onco mouse was receptive to breast cancer and therefore, could successfully facilitate an early diagnosis. The EPO deliberated over Harvard's application for securing a patent for the 'Onco mouse'. However, this was dismissed by the EPO as it considered the subject matter 'a variety of animals' and thus barred from patent protection under Section 53(a). On appeal, numerous parties enjoined briefs to the motion before the appellate body which did not uphold EPO's decision of declaring Onco mouse as an animal variety. It did however, recommend the patent office to consider the briefs of the enjoined parties and determine if the invention in question was in violation of public order or morality. The EPO ultimately, in 1994, ruled in favour of applicants granting them the disputed patent. Du Pont, the main sponsor of the research and creation of the organism, was also granted the patent rights.

The *Harvard/Onco mouse* case clearly displays willingness in Europe to grant patents to adequately humanly engineered biological products. Again in

1995, the Court granted a patent for a DNA sequence encoding a human protein, produced by pregnant women, which assisted with the pregnancy.²⁴ It was held that the subject matter in question was more than a mere discovery as it 'had to be isolated from its surroundings and a process had to be developed to obtain it.' This case restricted the applicability of the 'products of nature' doctrine.

All this said, it is not to be misconstrued that the patent regime in Europe is 'all inclusive' like the American regime. The European regimes clearly bars inventions of varieties of plants and animals, naturally occurring processes, those opposed to public order and morality and certain other subject matters highlighted under Section 52(2) of the EPC. The European disposition, as far as bio-patents are concerned, has been liberal and derives a lot from the TRIPS Agreement. Under Article 27.1 of TRIPS, it is a prerequisite that the subject matter of the patent application be defined as an invention and not a mere discovery; following this the invention further has to sufficiently be 'new, innovative and capable of industrial application.'²⁵ However, in spite of this liberal inclination among the common European patent instruments, namely the EPC and the Directive, the national IP laws of a majority of the European nations are still in aberration and pursue a more rigorous and stringent approach to the grant of life patents. This is primarily because of the subservience of both the aforesaid documents to municipal laws.

Bio-Patents: The Ethical and Moral Dilemmas

The issue of patenting life or animate organisms and living cells, tissues *et al*, is more challenging than the simple task of enacting legislation and statutes. The issue has, at its heart, a conflict of interests, ideas, notions and paradigms. The challenges ensuing from it evolve into more of a debate of scruples rather than anything else.²⁶ A discussion of the moral and legal debates follow, which are considered as critical moot points under the bio-patent regimes.

The 'Invention versus Discovery' debate

A major argument has consistently irked anti-bio patent advocates; whether an organism or a living end product manufactured by essentially using a naturally occurring product can be contended to be more than a mere discovery, and go on to be granted patent protection as a 'novel invention'. The question is a fundamentally vital issue to be determined as a mere

discovery in all patent law regimes, has never been protected under the patent umbrella.

The only point which can be definitively concluded in such a debate is whether sufficient human intervention has occurred to create an organism distinct and independent in existence from the one previously occurring. Under almost all patent regimes, affiliated directly or indirectly to the TRIPS Agreement or deriving substance of their municipal law from it, bio-patents are permissible. The argument of the subject matter being 'products of nature' has been dismissed as archaic and obsolete and therefore, untenable.²⁷ However, circumspection needs to be exercised while traversing this realm of patent laws. An excessive award of 'utility patents' to living organisms and allied structures can often spark off ethical qualms.

The Issue of Informed Consent

'Every human being of adult years and sound mind has the right to determine what shall be done with his body.....'

Cardozo J., (1914)²⁸

The current argument examines the legal basis of informed consent doctrine as means to respect patents and persons who act as research subjects and it considers the extent to which consent to patenting does, and should play a role in contemporary patent law.

The idea of informed consent stems from the fundamental ethical principle of autonomy, which gives the patient right to knowledge of his own medical condition, and requires the physician to respect any decision made by the patient in regard to his own health care. In consistence with the autonomy principle, the goal of informed consent is to fully educate the patient on his condition, thereby enabling him to make the best decision for himself.

However, encumbering onus of obtaining an 'informed consent' of a research subject requires a meticulous disclosure of the intentions of the researcher, especially those of commercial nature.²⁹ A landmark judgment which expounds on the vitality of informed consent is the John Moore case²³, delivered by the Californian Supreme Court. The case involved removal of spleen from the appellant on the premise of an imminent medical procedure. The spleen was later used to manufacture an immortal spleen line which was subsequently patented. The Supreme Court, admonishing the defrauding action of the respondents, stated that the necessary information was not disclosed to the appellant thereby making his

consent redundant. A vital matter that was conspicuously absent in the court's deliberation was the validity of the patent granted to the respondents.

It is also not 'redundant' to incorporate a regulatory clause in the patent laws in addition to other regulatory mechanism. The aforementioned problem regarding the status of the patent in Moore's case can justify this stipulation. An eminent jurist³¹ has also suggested incorporation of a clause which necessitates procurement of the consent of the research subject before filing of the application. Such a provision is not supplanting or transgressing into the territory of the regulatory mechanism. It actually complements the same through its concomitant functioning rather than being contradictory to it.³²

The 'Environmental Ethics'²⁶ Question

The term environmental ethic has been defined as relationship between man and his surroundings which establishes a cardinal sense of respect for the land and not merely determines it as an exploitative resource. It also aspires to forge a more compatible existence of men and their fellow beings with the latter not only facing the brunt of an exploitation rage.

The 'Lockean' derivative in the 'fruits for labour' argument³³ is *prima facie* antithetical to the very principles of environmental ethics. While the former endeavors to accord adequate benefits to any man who creates a product, the latter is the flip side; it stems from the proposition that since the end product derives a valuable input from the originally innately occurring organism, hence, interests of this organism are paramount concern, ethically.

The authors at this point, wish to take strong note of the discrepancy and fallacy in this argument. As even in the stand taken by the US Supreme Court in *Diamond v Chakarabarty*, human intervention leads to the creation of a novel organism, something hitherto not unknown to mankind but one that was not there before. Even in Indian jurisprudence emphasis has been given to the crucial nature of inventive steps which alter the original substance into something considerably variable from its previous state.³⁴ It is the authors' firm belief that a presumption of ownership in favour of the subject of research, or the person from whom the research material is extracted, over the end product which uses human ingenuity, is fallacious even if the material is essentially his.

A second disagreement stems from an alleged neglect of the subject's welfare. Such an argument is untenable at least for the purposes of human life

patents. If the above stated 'subject's welfare' argument is forwarded with respect to human patents, the same can be contended on the presumption of a competent consent. Therefore, insofar private individuals are concerned the argument fails as adequate amount of care and interest protection is guaranteed while informing the subject of the nature of commercial interests that the researcher intends to pursue, thereby leaving the discretion of continuing with the research with the subject.³⁵

The Questions of *Ordre` Public* and Morality

The TRIPS Agreement under Article 27(2) maintains that member nations can exclude inventions from patentability for enforcing *ordre public* or morality. Similar provisions can be located under the Biotech Directive and European Patent Convention. The complexity arises as none of the text unequivocally stipulates what is the essence of such a provision. The TRIPS provision, for example, prohibits only commercial exploitation of the invention on grounds of public order or morality. This is a huge lacuna given the fact that the exception is handicapped in situations where certain unethical inventions are not put to commercial usage.

It is argued whether the provisions suggest a bar on research in those areas or limiting the grant of patents in the same. Thus there emerges a conflict providing patent law a transcendental role infringing into the territory of regulatory law. However, it is undesirable that patent law defends something when the very seminal research is considered unethical.

It is critical to scrutinize these arguments and try to diagnose their ramifications for the successful yet, ethical implementation of any IPR regime. The questions aforementioned are not unnecessary academic averments but indeed, stipulate certain legitimate apprehensions of an expanding patent regime. Simultaneously an overly cautious tone to any regulatory machinery will inevitably invite numerous unwanted but licit challenges to the same. Therefore, a quintessential system, especially ones in nascent patent regimes like India, needs to derive a balance between the two with the provision of enough room to insert situational exceptions.

Life Patents: The Indian Perspective

The Indian Patents Act, 1970 governs patent protection in India. It has been gradually amended over 1999-2005 to suit India's international obligations under TRIPS. The TRIPS seeks to remove

perceived barriers to 'free-trade' by establishing minimum IPR standards across the world. It directs member countries to provide for product patents to all technologies and on microorganisms. It also makes non-compliance with the statutes of the WTO liable to prosecution and severe punitive action including sanctions or fines. In spite of safeguards and other flexibilities provided in the form of preferential treatment to the developing and least developed countries, scope of patentability as outlined under TRIPS is considered far too wide by most developing members.³⁶ They argue that overly strong IPR with extended scope and duration of protection are proving to be detrimental to the very object and purpose of TRIPS Agreement.³⁷ India has always maintained that '...patent rights should be exercised coherently with the objectives of mutual advantage of patent-holders and users of patented medicines, in a manner conducive to social and economic welfare and to the balance of rights and obligations.'³⁸

When India became a party to the WTO in 1995, in spite of strong civil society opposition,³⁹ TRIPS was an indispensable part of the deal. The then national policy makers hoped that the overall gains made from greater links with the global trading community would more than upset any possible dangers of accepting a stricter IP regime.

Having contested to fully utilize its ten year transition period India has introduced three major amendments to the Patents Act, 1970. The first among these was the 1999 amendment which introduced exclusive marketing rights (EMRs)⁴⁰ and established mailbox applications for patents for pharmaceuticals and agrochemicals from 1 January 1995. The next amendment came in 2002 which allowed for patents on microorganisms.⁴¹ Even prior to this amendment, the judiciary had interpreted the patent regime under the unamended Patent Act to cover a patent on a living organism much to the displeasure of the Indian Patent Office. The Hon'ble High Court of Calcutta, in the matter of *Dimminaco A G v Controller of Patent Designs & Ors* (2002 IPLR 255 Cal. H.C.),⁴² was approached by a Swiss company which had been refused a process patent for preparation of a live vaccine for Bursitis. The Patent Office had denied to grant a patent on the grounds that the so-called invention, containing a living organism, was not patentable as under §2(1)(j). The Patent Office contended that the process of making a vaccine with a living organism is neither a process resulting in an

article, substance, nor is it manner of manufacture. It had claimed that since the vaccine involved processing of certain microorganism it was only a natural process. Even though there was no express or implied bar in the Indian Patent Act 1970, patents were traditionally granted only to non-living inventions that fulfilled the patentability criteria. The appellant contended that there had been a violation of rule of law as preference was given to discretionary administrative policy over the statutory definition of what an invention entailed, which did not bar the barring of a patent on the process of manufacturing a vaccine, containing a live virus.⁴³

The Court observed that the term 'manufacture' had not been defined in the Act and consulted a variety of dictionary meanings to conclude that the process for manufacturing such a vaccine is new process and such new process was patentable under §5⁴⁴ read with §2(I)(i)⁴⁵ of the Patent Act. The Hon'ble Court relied on the vendibility test⁴⁶ to determine the question of patentability of a process. It concluded that since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture. Reference was also made to *M/s Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries station* (AIR 1982 SC 1444) to clarify the other patentability requirements of newness and usefulness.

The Court adopted a careful stance though many considered it a bold step, legalizing patentability of living matter in India even before a legislative amendment expressly provided for the same. It is important to note that the case was for a process patent over the process of manufacture, as was repeatedly stressed by the appellant. It only allowed for patenting of a process resulting in a product with living matter not over the living matter itself. The case was also fundamentally different from that of gene patenting, which would have had other concerns of impediments to research *et al*, the case was about a process patent over a vaccine. Issues about all future mutations of a gene being covered by one patent and availability for further competitive research become more prominent in case of a product patent regime.

Moreover, even though the case was decided in favour of the Appellant, the Court reserved its right to decide such cases on a factual basis. It held that whether a claim for the grant of patent was an invention or not, had to be decided only after detailed scrutiny of the facts of each case.

This decision of the Calcutta High Court is also seen as concurrent with the position in US and most EU countries which allow patentability of biotech inventions.

Subsequent to the decision, the Act has been amended by the Patents Amendment Act 2002. The amendment has changed the definition of 'invention'. The earlier requirements under Section 2(j) which added to the primary requirement of newness and usefulness like those of an invention being art, product or process, method or manner of manufacture; machine, apparatus or other article; substance produced by manufacture, including any useful improvements on the said has been omitted. The definition has been simplified and the only requirements of patentability now are that a product of process must be new, non-obvious and useful.⁴⁷ The relevance of the decision subsequently, though debatable does highlight the relative unwillingness of the judiciary to refuse the patent merely on ethical grounds. However in the new scheme of things it is uncertain whether addition of §3(j),⁴⁸ which excludes from patentability essentially biological processes for production of plants and animals, or plants and animals in whole or in part other than microorganisms, would derail the benefits for future applicant, if the subject of patent application was adjudged to not be a microorganism by the virtue of being a non-microscopic organism.⁴⁹ It is therefore necessary to have a clear working definition for 'microorganism' either as a legislative explanatory amendment or judicial pronouncement. A review of the draft manual of patent, practice and procedure by the national working group on patent laws⁵⁰ also reveals that there is a need to define the term microorganism. Moreover, the draft manual on page 72, paragraph 4.10.1 of the draft manual indicates that any microorganism discovered from nature is not patentable while according to §3(j) of the amended act by implication all 'microorganisms' are patentable. If such discrepancies are not ironed out the judiciary may strike down the guidelines in the draft manual as administrative instructions which cannot overrule the statute.

Further, with the deletion of §5 of the Act, pursuant to the 2005 amendment, which provided for only process patents on chemical processes, including biochemical, biotechnological and microbiological processes as well as substances intended for or capable of being used as food or medicine, it appears,

if the Hon'ble High Court's intention is read right, that the doors have been opened for patenting products with living microorganisms with both legislative as well as judicial sanction.

The 2005 amendment substituted new §3(d) for the existing section which limited the scope of patentability by excluding 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance'.⁵¹ The constitutional validity of §3(d) was subsequently unsuccessfully challenged by global pharmaceutical giant, Novartis in the Hon'ble High Court of Madras.

The overall expansion of patentability criteria has resulted in an increased number of patent applications and, consequently, an increase in the number of patents granted in the field of biotechnology. An assessment of the annual reports of the Indian patent office (2007 Annual Report)⁵² reveals that from 2000-01, where four applications were submitted and no patents were granted, the number of applications has been steadily increasing. In 2003-04, 23 patent applications had been filed, though no patents were granted. During 2004-2005, there was a phenomenal increase in the number of applications; 73 biotechnology patents were granted in that year alone. The tally for 2007-08 (the last available report) stands at 1950 applications and 314 grants.

Judging from India's insistence upon substantial review of Article 27.3, support for the African group's proposal⁵³ on review of Article 27.3⁵⁴ presented in 1999 (which suggests that 'patents on life should be prohibited, including those on microbiological processes'). Indian polity does not seem too keen on allowing patents on life forms. In July 1999, India highlighted the need to focus on two complementary dimensions, one of which was fundamentally political question of whether patenting life is acceptable in terms of ethics.⁵⁵ India has also adopted a more conservative European approach on patents by opting to utilize the morality clause in TRIPS. It is in stark opposition to the US approach,⁵⁶ which argues that patenting of life forms has tremendous advantages.

There is no time frame stipulated in the TRIPS provisions for conclusion of the review process. Accordingly it has been delayed by the developed block effectively, little progress being made since the review process started in December 1998.⁵⁷

With all the increased application numbers, the Indian polity still robustly implements a more rigorous patent regime for protection of living organisms than its American counterpart. There are still options open to India and other developing countries reluctant to extend patentability provisions to living matter. Article 27.1 of TRIPS guards against discrimination but differentiation is still permitted.⁵⁸ The non-discriminatory provision does not prevent member countries from fixing the threshold of patentability criteria which are applicable to all fields of technology and hence not discriminatory. TRIPS leaves it to member countries to determine appropriate method of implementing its provisions and define certain key provisions that determine the scope of patentability. Carlos Correa argues that there is no obligation under the TRIPS Agreement to adopt an expansive concept of 'invention', as is currently done by many developed countries. In particular, nothing in the Agreement obliges Members to consider that substances existing in nature, biological or not, are patentable, even if isolated and claimed in purified form.⁵⁹

It is interesting to note that in *Novartis AG, represented by its Power of Attorney Ms Ritushka Negi and Anr v Adarsh Pharma and Anr* (2004(3)CTC95)⁶⁰, one of the contentions raised was how §3(d) was contradictory to Article 27 of TRIPS, which obligates WTO member states to provide patent protection to all fields of technology without discrimination, and therefore violates the obligations under the TRIPS Agreement. But the court sought jurisdiction issue and did not deal with the matter. The Hon'ble Court's suggestion to approach the WTO dispute settlement mechanism was also not followed. But the Court did reaffirm the provisions constitutional validity with Article 14. Further stipulation under Article 8 accords adequate discretion to TRIPS signatories to deny patents in observing and up keeping interests in '*ordre public* and morality'. And India has forever stressed, in a stance complimented by Paragraph 4 of the Doha Declaration, that any interpretation of the provisions of the agreement should be consistent with Article 8.

Another safeguard in place is the presence of a global depository of genetic data as mandated under Budapest Treaty and the Convention for Bio-Diversity. Microbial Type Culture Collection and Gene Bank (MTCC) at the Institute of Microbial Technology (IMTECH), Chandigarh ensures that all

micro-biological data is deposited, and the region of its availability disclosed and kept open to research and other such uses after the publication of patent application. The depositories under the human genome process perform a similar function, for once some information is disclosed or made public it is no longer new and cannot be patented.

To assess whether after the 2005 amendment India had indeed become TRIPS compliant and if the measures taken to ensure TRIPS compliance were in national interest the Mashelkar Committee was set up in April 2005. One of the issues the Committee dealt with was whether it would be consistent with TRIPS to exclude microorganisms from patenting. The Mashelkar committee submitted a report in December 2006 which it later withdrew citing technical inaccuracy and plagiarism as reasons.⁶¹ The revised version of the report was submitted in March 2009 which has only recently been released to the public. The revised version of the report restates to a large extent the Committee's previous findings, which had been criticized for not taking into account public health goals. The committee concluded that it shall be in violation of TRIPS to exclude microorganisms completely from patentability and that 'microorganisms involving human intervention and utility are patentable subject matter under the TRIPS Agreement, provided they meet the prescribed patentability criteria.'⁶² The Committee has also been criticized for not having taken a policy perspective on the issue. It furthers patents on bio-tech inventions on three grounds. The first one being increased prospects of FDI and contract R&D by attracting foreign collaboration to the ever growing and increasingly profitable bio-tech industry in a bio-diverse country like India.

The authors would like to point out that India would have an advantage in attracting FDI and other such projected benefits only so long as other nations do not provide similar relaxations. It is relevant to note that most countries with advanced bio-tech fields like, USA, Republic of Korea, Japan, China and European Countries already provide far wider patent protection on living matter than India.

The second reason cited by the committee was concern over biological matter of Indian origin being patented by foreign players. This is a faulty argument as well. India is already a signatory to the Convention on Bio-diversity (CBD), according to Article 15 of the CBD when a material is taken from a country prior

informed consent and material transfer agreements are required to be initiated to acknowledge the country of origin. It must be India's prerogative to uphold the CBD to prevent bio-piracy instead of looking for alternatives which require India to adopt a system least suited to its needs. The committee finally seeks to justify its suggestions by citing obligations under TRIPS. It refuses to realize that there are flexibilities available within TRIPS like non-definition of three criteria of patentability (novelty, non-obviousness, usefulness) which make it possible for India to define restrictively the scope of patentable subject matter.

Conclusion

There has been a systemic lobbying and subsequent successful shift towards greater IP protection for biotech inventions, including protection of living organisms. The process has quickened in the past decade with the developing countries becoming fully TRIPS compliant. However, even with such compliance the question of providing protection akin to that available in the developed world hangs in the balance with concerns over potential trade and FDI benefits and ethical political positions etc. weighing on either side. It is in view of this conflicting position that the authors would posit here the need to balance out; the commercial interests of individuals' *vis-à-vis* the interests of the rabble. It is the authors' belief that the direct and most effective implementation of TRIPS still leaves potential scope for introducing flexibilities considering the indigenous conditions prevalent in the Indian IP regime. Sensitivity towards interests of public by heeding adequately to the numerous ethical and public health issues raised is vital. However, any exhibition of unfounded paranoia must be diametrically denounced and abstained from; so as to promote scientific knowledge and temperament, as is also a constitutional (fundamental) duty to which every citizen is bound.

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- 1 For commercially exploiting a patented drug one needs to apply for marketing approval to various national regulatory authorities. These marketing approvals are granted upon satisfaction of a variety of criteria and effectively be used to negate monopolization of markets.
- 2 <http://www.worldtradelaw.net/uragreements/tripsagreement.pdf> (31 July 2009).
- 3 Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R (2000).
- 4 Patents are often viewed as instrument of economic policy aimed at rewarding the inventor, Straus Joseph, *Biotechnology and Patents*, 54 CHIMIA 293 (2000).

- 5 EU: Directive 98/44/EC, Art. 3.2.
- 6 <http://www.greenpeace.org/international/campaigns/genetic-engineering/feeding-the-world-facts-vers/risks>, August 1, 2009 (*Patenting allows industry to take control of and exploit organisms and genetic material as exclusive private property that can be sold to or withheld from farmers, breeders, scientists and doctors; See Interview of Dr Tewolde Egziabher, Head, Ethiopian environmental protection authority and the non-profit Institute for Sustainable Development by Michael Friedrich (Greenpeace) (20 June 2002).
- 7 U.S. Constitution. Art. I, § 8, Cl. 8.
- 8 35 U.S.C. § 1.
- 9 <http://www.bitlaw.com/source/35usc/index.html>. August 16, 2008 (*U.S. Patent Act (35 U.S.C.). The US Patent Act is found in Title 35 of the US Code and contains the federal statutes governing patent law in the United States).
- 10 Doll John J, *The patenting of DNA*, *Science*, 280 (5364) (1998) 689 - 690.
- 11 DeMott John S & Thomas Evan, *Test-Tube Life: Reg. US Pat. Off.*, 30 June 1980, <http://www.time.com/time/magazine/article/0,9171,924274,00.html> (1 August 2009).
- 12 447 US 303 (1980).
- 13 A product of nature, under both US and European laws is unpatentable as it fails to satisfy the preliminary criterion of a novel invention. The European paradigm as is reflected in the Biotechnology Directive and the European Patent Convention (EPC) is discussed in the subsequent pages.
- 14 The USPTO expressing its inhibitions of liberally construing the expression 'new matters of composition', stipulated that such proactive action would 'open the flood gates to patentability for all newly produced microorganisms as well as for all newly developed multi-cellular animals such as chickens and cattle.'
- 15 *Diamond v Chakrabarty*, 447 U.S. 303, 310-318.
- 16 The Court emphasized on the broader implementation that was envisioned under the Patent Act of 1793, authored by Thomas Jefferson. It also cited the Congress Committee's reports [Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)], on the re-codified Patent statute which imported the same broad essence of Jefferson's seminal statute.
- 17 *Funk Bros* case (333 US 127) ('Product of Nature' doctrine).
- 18 In *Funk Bros*, plaintiff Kalo Inoculant Company brought a patent infringement action against the Funk Brothers Seed Company. The Supreme Court applied the 'products of nature' doctrine to reject Kalo's patent. Justice Douglas declared that patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria are manifestations of laws of nature, free to all men and reserved exclusively to none.
- 19 *Ex Parte Allen*, 2 U.S.P.Q. 2d 1425, 1426-27 (1987); The *Amgen* case [927 F.2d 1200, 1206 (Fed. Cir. 1991)] (Patentability of Human Deoxyribonucleic Acid (DNA) sequences).
- 20 The EPC was signed in Munich as the Convention on the Grant of European Patents, 5 October 1973. Signatories to the EPC included the then fifteen EU member states, Switzerland, Liechtenstein, Monaco, and Cyprus. The term used is suggestive of an absolute coverage of the said convention in all of Europe. However, two points to be considered are, firstly, the convention does not grant an all-European patent and any patent accorded is to be

- corroborated under national patent laws. Secondly, the convention though ratified and signed by numerous EU members, is an independent entity. For an elaborate discussion on the provisions of the EPC, see Gitter Donna M, International conflicts over patenting human DNA sequences in the United States and the European Union: An argument for compulsory licensing and fair-use exemption, *N.Y.U. Law Review*, 76, 2001.
- 21 The European Biotechnology Directive; directive 98/44/EC of the European Parliament and the Council on the legal protection of biotechnological inventions. The directive was a consequence of the decision to uniformly structure the patent laws of various nations. The Directive was incorporated in the EPC in 1999.
 - 22 This particular provision of the Directive seeks to derive its endeavored goals from Recital 18 in the text of the Biotech Directive; the same exposing the inadequacy of European municipal legislations for protecting and encouraging biotechnological development. The provision under Article 3.2 is reinforced by the stipulation under Article 1.1 which cajoles European nations to amend their domestic enactments in conformity with the Directive. For example, UK amended the national legislation (the Patents Act, 1977) in 2000. The subsequent adoption of S-76A inculcates the Directive's objective with respect to Biotechnology.
 - 23 Harvard/Onco mouse, 1992 O.J. E.P.O. 588 (Examining Div.), reprinted in 1991 Eur. Pat. Off. Rep. 525, 525-27.
 - 24 *Hormone Relaxin*, 1995 O.J. E.P.O. 388 (Opp. Div.)
 - 25 Article 27.1 provides, 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are *new, involve an inventive step and are capable of industrial application.*'
 - 26 Hettinger N, Patenting life: Biotechnology, intellectual property and environmental ethics, *Boston College Environmental Law Review*, 22, 1994-1995, 267.
 - 27 The position of the American, European and Australian courts is articulated through a chain of case laws. These have already been alluded to in the Part I. the case law and legislative inclination strongly denounces the denial of patent protection on grounds of the object being 'a product of nature' or naturally occurring. As stipulated in the *Chakrabarty* case, a genetically altered organism is distinctively variant from its original form and therefore, novel and ingenious in nature.
 - 28 *Schloendorff v Society of New York Hospital*, (1914) 105 N.E. 92, 93 (NY).
 - 29 In fact one of the proposed amendments in the process of drafting of the European Biotechnology Directive was to incorporate a clause making it imperative for the researcher to purport his commercial interests, if any, to the research subject so as to provide the latter ample opportunity to exercise his will over his physical autonomy.
 - 30 *Moore v Regents of the University of California*, 271 Cal. Rptr. 146 (Cal 1990).
 - 31 Graeme Laurie, Patents, Patients and Consent: Exploring the Interface between Regulation and Innovation Regimes, in *The Regulatory Challenge of Biotechnology*, 214 (Hans Somsen ed., 2007).
 - 32 The aim of such a provision would be to 'achieve congruence' with the regulatory mechanism. Where the regulatory mechanism has already mandated consent and the patent regime follows suit, congruence would suggest that it re-enforces the system. Where a research process progresses infructuous to the right to self determine, such process culminating into a patent protected object would be offensive. Therefore, a mandatory check in the patent law only complements the delimitations of the regulatory mechanism.
 - 33 The argument derives its bedrock ingredients from the Lockean argument which concurs with the right to ownership of a man over any product crafted by him. The argument boils down from the 'I made it and it would not have existed without my intervention' paradigm. For a summary on the Lockean theory of labor argument of property see Lawrence Becker, *Property Rights*, Chapter 4, (1997) in Hettinger N, Patenting Life: Biotechnology, Intellectual property and Environmental Ethics, *Boston College. C. Environmental Affairs Law Review*, 22, 1994-1995, 267.
 - 34 *Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries*, AIR 1982 SC 1444.
 - 35 Such a disclosure is necessary as was also held in Californian Supreme Court's holding in *Moore* wherein they stated the imperative obligation of the researcher to disclose all of their commercial interests, if any.
 - 36 'When the Uruguay Round was launched, several developing countries resisted the entry of Intellectual Property Rights (IPRs) into the agenda. But under pressure from the U.S. (and its S.301 threats) they yielded, resulting in the agreement on Trade- Related Intellectual Property Rights (TRIPS) as part of the WTO agreements.' The industrialized countries (and the industries of the North that were the driving force behind TRIPS) succeeded in setting rules that were viewed by several economic experts of developing countries as having the potential to cause most damage to development prospects', *Failure of TRIPS: A time for review*, The Hindu, 21 April 2001.
 - 37 The objective of TRIPS, mentioned in Article 7, states: 'The protection and enforcement of intellectual property rights should contribute... to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare...'
 - 38 http://www.centad.org/focus_33.asp, 1 August 2009 (Gopakumar K M, *Mashelkar Committee Report: A Critique*).
 - 39 V R Krishna Iyer, O Chinnappa Reddy, D A Desai & Rajinder Sachar, *Peoples' Commission on GATT*, Centre for Study of Global Trade System and Development (1996).
 - 40 India's domestic patent law describes the EMR as the exclusive right to sell and distribute the substance or article concerned. TRIPS mandates a five-year EMR in the interim in exchange for letting the corresponding product patent application lie in the mailbox to be opened only after 1 January 2005 and until it is thereafter decided. MR should be allowed on satisfaction of two conditions: product patent and marketing approval in a foreign country, and marketing approval and product patent application in India.
 - 41 Patents (Amendment) Act § 4(e) (25 June 2002).
 - 42 The Indian Patent Office rejected the patent application of the appellants on grounds similar to those contended in *Diamond v Chakrabarty* (US Supreme Court). The Patent Office argued that the patent regime intended and had conventionally protected the rights of inventors of inanimate

- objects and living organisms were *per se* ineligible for the same protection. The Hon'ble Calcutta High Court overturned this order of the Patent Office.
- 43 The defendant argued that process for the preparation of the said vaccine, which had a living entity in it, would not be covered under the definition of manufacture. The controller of patents contended that the final product had the micro-organism in a dormant lyophilized state, hence not dead. Lyophilization is the technique of removing water from a frozen biomaterial via application of a vacuum.
- 44 Patent Act, 1970, § 5 says a product intended for use, or capable of being used, as food or medicine or drug, or which is created by a chemical process is not patented.
- 45 Defined invention under the un-amended Patent Act, 1970.
- 46 The vendibility test is a test to check if the process results in the production of some vendible item, i.e. an item which can be transferred upon sale and purchase. The Court ultimately held that the process for creating a vaccine leads to a vendible product, even if the end product contains live material.
- 47 Subbaram N R, Protection of biotech inventions, *The Hindu*, 29 December 2003.
- 48 Patents (Amendment) Act § 4(e) (June 25, 2002); § 3 (j) was developed along the lines of Article 27(3) (b) it states that plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not patentable.
- 49 The Patents (Amendment) Act, 2005, §3.
- 50 Microorganisms are generally described as microscopic organisms.
- 51 http://www.patentoffice.nic.in/ipr/patent/Patent_Manual_Feedback/NATIONAL_WORKING_GROUP_ON_PATENT_LAWS_NEW_DELHI.pdf, 1 August 2009.
- 52 The Patents (Amendment) Act, 2005, www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.
- 53 http://ipindia.gov.in/cgpdtn/AnnualReport_English_2007-2008.pdf, 1 August 2009 (Indian Patent Office, Annual Report 2007-08).
- 54 WT/GC/W/302; The African Group's comprehensive proposals have received much support from other developing countries in the WTO, civil society groups, and NGOs.
- 55 The developing countries which had little or no say in drafting most TRIPS provisions viewed the review process scheduled every 4 years as a means to make their demands heard. *See*, Review of Article 27.3(b), Paper IP/C/W/369/Rev.1.
- 56 http://www.iprsonline.org/ictsd/docs/IPR_collection.pdf (1 August 2009).
- 57 Article 27.3(b): Views of the United States of America, paper presented at the TRIPS Council, WTO, Geneva, 20 October 1999, p. 7.
- 58 For a detailed chronological account of developments in the long review process *see Grain*, for a full review of TRIPS 27.3(b), 15 March 2000, http://www.grain.org/briefings_files/tripsfeb00.pdf (1 August 2009); Cecilia Oh, *Available options Article 27.3(b) of the TRIPS Agreement: Review options for the South*, <http://www.twinside.org.sg/title/oh1-cn.htm> (1 August 2009).
- 59 Panel Report, *European Communities and their Member States*, WT/DS 114/R (17 March 2000).
- 60 Carlos Correa, Intellectual property rights, the WTO and developing countries: The TRIPS Agreement and policy options, Third World Network, London / Penang 2000.
- 61 Dr Raju K D, The debacle of Novartis patent case in India: Strict interpretation of patentability criteria under Article 27 of the TRIPS Agreement, *Indian Journal of Intellectual Property Law*, 1 (1) (2008).
- 62 Sharma Ravi and Hiddleston Sara, Mashelkar committee on Patent Law withdraws report; seeks more time, *The Hindu*, 22 February 2007, <http://www.thehindu.com/2007/02/22/stories/2007022206751200.htm>.
- 63 *Report of the Technical Expert Group on Patent Law Issues*, revised March 2009.