"Biotechnology & Patenting - Should Sri Lanka seek guidance from U.S. or E.U.?"

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INTRODUCTION

'Biotechnology' can be described as the utilization of any technique which encompasses living organisms to modify or manufacture products in order to enhance the desired characteristics of an animal or plants or to change the micro-organisms of the same. It is the utilization of biological processes for industrial, medical, agricultural or environmental purposes.

At present, biotechnology refers to a wide range of technologies ranging from industrial fermentation to animal breeding to genetic. These groundbreaking methods and the prospects offered by it have not been unanimously welcomed by everyone. Although some consider it to be a positive advance as it provides many benefits including the hope of curing or avoiding genetic disorders, nutritional enhancement of food, and opens doors to the possibility of many breakthroughs that will enable people to live longer, healthier lives and tackle environmental challenges, others are averse to genetic engineering and are apprehensive of such technology being the commercial property of a few companies in addition to being concerned on moral issues.[1]

Although Sri Lanka does not possess a significant presence of biotechnology and genetically modified crops or food at present, local scientists have not ruled out the existence of the same in the future. In fact, the common belief shared among scientists is that changing climatic and economic conditions could make genetically modified crops desirable in the domestic market, and the future lies with biotechnology and genetic engineering. In fact, a National Bio-safety

[1] K. Lee Lerner, *The Gale Encyclopedia of Science*, 5th ed., (Gale, 2014). pp.603-605

Framework Project was launched by the Ministry of Mahaweli Development and Environment in 2018, in an attempt to ensure the safe introduction of genetically modified organisms in Sri Lanka.[2]

When laws pertaining to patents are being enacted in a State, the moral standards of the community of that State are a prime factor that affects the content of those laws pertaining to patents. Correspondingly, morality usually seeps into the process of interpretation encompassed in judicial decision making on patent law.

In Sri Lanka, *inter alia*, plants, animals micro-organisms other than transgenic micro-organisms, essentially biological process for the production of plants and animals (other than non-biological and microbiological processes) and any invention, the prevention within Sri Lanka of the commercial exploitation of which is necessary to protect the *public order, morality* including the protection of human, animal or plant life or health or the avoidance of serious prejudice to the environment, are considered to be non-patentable.[3]

There exist many ambiguous aspects; in particular, the absence of a clear-cut standard of morality or approach to ascertain whether issuance of a patent to an invention should be denied on moral grounds as well as an explicit benchmark on what constitutes an immoral invention.

APPROACH ADOPTED BY THE UNITED STATES ("U.S.")

The U.S. courts have not been restricted by specific statutory exclusions on patentability. A broad approach to patenting of biotechnological inventions has been adopted and there is no explicit statutory proscription in opposition to the patenting of subject matter which could be deemed 'immoral' per se. There, however, exists non-patent legislation which may restrict patentability on the footing of national security.

[2] 'A future for GMOs in Sri Lanka' Daily News (Colombo, 13 April 2018)

[3] Intellectual Property Act No 36 of 2003, s 62 (3)

Thus, matters pertaining to the issuance of patents in the biotechnology field are determined in the U.S. under the same standards of patentability observed in all patent law systems; utilization, novelty, and non-obviousness.[4] [5]

For many years, a "moral utility" doctrine established by the judiciary, permitted both the United States Patent and Trademark Office ("USPTO") and courts to deny issuance of patents on subject matters which are deemed morally controversial on the premise that that the inventions cannot be deemed to be "useful".[6]

Justice Story instructed the jury in **Lowell v. Lewis**[7] that what is required by the law is for the invention to not be frivolous or harmful to the good policy, sound morals or the well-being of the society and that the term "useful" is "incorporated into the Act in contradistinction to mischievous or immoral."

Justice Story's direction set in motion the aforementioned "moral utility" doctrine where, for an invention to be deemed "useful" in terms of the patent statute and thereby qualify for patent protection, it had to satisfy the standards of morality identified by the judiciary.[8]

Courts later diverted from the aforementioned doctrine and, in lieu of an invention not being qualified for patent protection if it was deemed to be a morally controversial subject matter or could be used unlawfully, courts was of the view that an invention would satisfy the "moral utility" requirement if it possessed a single moral, legal purpose in the least.[9]

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[4] Title 35 of the United States Code, ss. 101-103

[5] Andrea D. Brashear, "Evolving Biotechnology Patent Laws in the United States and Europe: Are They Inhibiting Disease Research" (12 Ind. Int'l & Comp. L. Rev. 183, 2001) pp. 193-197

[6] Margo A. Bagley, "Patent first, ask questions later: morality and biotechnology in patent law" in *William and Mary Law Review.45.2* (2003) pp.1-2

[7] *Lowell v. Lewis* (C.C.D. Mass. 1817) (No. 8,568) 15 F. Cas. 1018

[8] Bagley, op.cit., p.4

[9] *Fuller v. Berger*, (7th Cir. 1903) 120 F. 274, 275

According to the USPTO Board of Patent Appeals and Interferences,

"*everything is useful within the meaning of the law, if it is used (or designed and adapted to be used) to accomplish a good result, though in fact it is oftener used (or is as well or even better adapted to be used) to accomplish a bad one*"[10]

Subsequently, U.S. Courts adopted a "patent first, ask questions later" approach with regard to patents as a result of judicial decisions which interpreted the extent of the standards of statutory utility and subject matter under the Patent Act of 1952 in a manner which does not enable the imposition of the "moral utility" doctrine.

In **Diamond v. Chakrabarty**[11], the U.S. Supreme Court held that the U.S. Congress "intended statutory subject matter to include anything under the sun that is made by man" and held that courts are not competent to rule on ethical issues as it was for the political divisions of the government to confront such issues in lieu of the courts. Hence, by declaring itself to be sans of competence to deliberate high policy contentions involving morality, the court broadly restricted its propensity and capacity to impose any moral limits on the eligibility of the subject matter for patent protection.

The phrase "anything under the sun that is made by man" was used to expand the scope of patentable subject matter to interminable bounds and was repeated by the court in the case of **Diamond v. Diehr**[12]. This case involved the use of the Arrhenius equation in a manufacturing process and the phrase "anything under the sun" was adopted to extend patentability to software.

U.S. Courts have consistently held that U.S. Congress intended the definition of subject matter qualified for patent protection under the Patent Act of 1952 to include any matter, as long as it is

[10] *Ex parte Murphy* (Bd. App. 1977) 200 U.S.P.Q. (BNA) 801, 802

[11] *Diamond v. Chakrabarty* [1980] 447 U.S. 303

[12] *Diamond v. Diehr* [1981] 450 U.S. 175

"made by man." These judgments, along with the judiciary's deference to U.S. Congress in intellectual property clause matters[13], manifest that no clear basis exists to deny the issuance of patents to morally controversial subject matters which would otherwise be deemed patentable.

In the case of **J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.**, the court once again quoted the aforementioned phrase in support of its holding that utility patents may be issued for sexually and asexually reproducible plants.[14] [15]

Having interpreted the Patent Act of 1952 to incorporate any invention "made by man", the court is sans competence to exclude morally controversial inventions from patent eligibility and makes way for morally controversial biotechnological inventions presented to the USPTO to be considered patentable. Hence, the interpretation adopted by U.S. courts as to patent eligibility does not impede the patenting of morally controversial biotechnological subject matter. Consequently, morality seldom seems to have played a role in the issuing of patents to biotechnological subject matter in the U.S.

Thus, the U.S. law pertaining to patents does not encompass any statutory basis for the courts or the USPTO to deny patent protection to a biotechnological invention which could be deemed to be a morally controversial subject matter. As per the Patent Act of 1952, a person is entitled to patent protection if their invention meets the statutory patentability requirements specified in the Act.[16]

The issue of moral standards with regard to biotechnological patenting arose again in the case of **Juicy Whip, Inc. v. Orange Bang, Inc.**[17] In the said case, the court attempted to render obsolete the "moral utility" requirement and

[13] *Eldred v. Ashcroft* [2003] 537 U.S. 186

[14] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* [2001] 534 U.S. 124

[15] Christopher J. Asakiewicz, "Separation of church and state while promoting the progress of biotechnology and modern science: does morality have its place in United States patents?" in *Journal of International Commercial Law and Technology. 7.2* (2012). p.2

[16] Patent Act 1952, ss. 101-102

[17] *Juicy Whip, Inc. v. Orange Bang, Inc.* (Fed. Cir. 1999) 185 F.3d 1364

pronounced that the threshold of utility is low and an invention is deemed to be "useful" in terms of Section 101 if it is able to dispense some identifiable benefit.

There has been a tendency of both federal courts and the USPTO to not impose the "moral utility" doctrine with regard to patentability, subsequent to the aforementioned judgment in *Juicy Whip*.[18] [19]

In **Geneva Pharms. Inc v. GlaxoSmithKline, PLC**, it was held that a patent will possess utility "if it will operate to perform the functions and secure the results intended, and its use is not contrary to law, moral principles, or public policy."[20]

Thus, it could be deduced that *Juicy Whip* judgment did not fully dispel considerations as to morality from the advancement of science. In the year 2009, the District Court for the Southern District of New York held in the judgment of **Association for Molecular Pathology v. U.S. Patent & Trademark Office**[21] that patents should not be issued to genes as they should be construed as "discoveries".

As the U. S. Patent Act lacks statutory morality inquiry, it could be said that there is no uniform and consistency guidance in relation to the patent "morality" conditions with regard to biotechnological inventions. Although, both the U.S. Court and the USPTO have disregarded the "moral utility" requirement in respect of the patentability of biotechnological inventions in most of the instances, contrary views have also been adopted by the same from time to time.

APPROACH ADOPTED BY THE EUROPEAN UNION ("EU") AND MEMBER STATES

[18] *Chiron Corp. v. Genentech, Inc.* (E.D.Cal. 2002) 268 F.Supp.2d 1148

[19] *Diamond Heads, LLC v. Everingham* [2009] WL *1046067* (M.D.Fla. 2009)

[20] *Geneva Pharms. Inc v. GlaxoSmithKline, PLC* (E.D. Va. 2002) 213 F. Supp. 2d 597

[21] *Association for Molecular Pathology v. U.S. Patent & Trademark Office* (S.D.N.Y. 2009) 669 F. Supp. 2d. 365

The substantive requirements under the European Patent Convention of 2000 ("EPC") are industrial application, inventive step and novelty. There exist certain exceptions to patentability under the EPC and the legal consideration with respect of morality of biotechnological patents in Europe pivot on an interpretation of Article 53 (a) of the "EPC" as it stipulates an exception for inventions which could be deemed to violate public policy or morality and is of paramount importance to the field of biotechnology.

Accordingly, the said Article stipulates that "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to '*ordre public* ' or morality;

"*such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States*."

This has permitted the expansion of the scope of interpretation of "morality", causing it to be interpreted vaguely and with immense uncertainty, thus, rendering the morality provision controversial.[22]

Case law pertaining to Article 53 is contradictory and has perhaps portended the need for European patent reform to respond to an increasingly technological world[23].

In the **Harvard/Onco-mouse** case[24], which involved the patentability of genetically modified mice used for cancer research, a utilitarian balancing test was adopted which assessed the potential benefits of a claimed invention against adverse aspects of it. Thus, the "unacceptability" standard was developed, which balanced the "acceptable suffering" and "unacceptable suffering." and the eventual decision weighed in favor of patentability of the invention by reason of the invention's massive benefits.

[22] Yan Min, "Morality - an equivocal area in the patent system."

[23] Brashear, op.cit., p.205

[24] *Harvard/Onco-Mouse* (1990) EPOR 501

The utilitarian approach to the morality issue was once again adopted in the **Upjohn case (Hairless Mouse case)**, in which it was deemed that the invention was contrary to morality and not patentable as the harm caused to the mouse outweighed the benefits derived from it.[25]

In **Plant Genetic Systems v. Greenpeace**[26], a case concerning transgenic plants, the Opposition Division initially refused to utilize the balancing test adopted in the **Harvard/Onco-mouse** case and stated that the "unacceptability" standard is not the sole method of assessing patentability. The "abhorrence" standard was adopted in lieu of the "unacceptability" balancing test and it was held that patents should not be issued for inventions that are universally deemed to be outrageous.

In **Howard Florey/Relaxin**[27] which concerned the issuance of a patent on the hormone Relaxin, it was held that the invention cannot be deemed to be contrary to morality as the general public would not view the invention as too "abhorrent" for a patent to be granted.

The aforementioned cases evince that two competing standards, "unacceptability" and "abhorrence" may be adopted sans any clear direction and guidance as to which approach is suitable and appropriate to be followed in any particular case. The "abhorrence" standard demands the invention to be "so abhorrent that the issuance of patent rights would be inconceivable", and seems to be a more austere criterion than the "unacceptability" standard which simply necessitates the immoral aspect to outweigh the moral aspect.

As evinced by Justice Neuberger's statement in **Kirin-Amgen Inc. v. Roche Diagnostics GmbH**[28], although EPO verdicts do not possess any precedent value on the courts of the EPC contracting states, the case law is highly

[25] Bently and Sherman, *Intellectual Property Law,* 3rd ed., (OUP Oxford, 2009), pp.455-456.

[26] *Plant Genetic Systems v. Greenpeace* (1995) EPOR 357

[27] *Howard Florey/Relaxin* (1995) EPOR 541

[28] *Kirin-Amgen Inc. v. Roche Diagnostics GmbH* (2002) RPC 1

influential on national judges and is taken into consideration when defining the practice of issuing a patent in EU member states. In the above case, Justice Neuberger held

"I am reluctant not to follow the approach of the Board, particularly in light of the sheer number of consistent decisions on this point. However, I am not bound by decisions of the Board."

In the case of **Wisconsin Alumni Research Foundation/Stem cells (WARF)**[29], which involved a method for culturing primate-embryonic stem cells, the Enlarged Board of Appeal hinged on direction as to morality provided in r 28(c) of the EPC Regulation and held that it debarred the patenting of claims directed to products which, at the filing date, could be formulated solely by a method which necessitated the eradication of the human embryos from which those products were derived and were in violation of the EPC morality prohibitions.

Thus, it is apparent that two different moral standards have been adopted in the E.U. and its member states sans a unitary opinion being formed. Although the "unacceptability" standard was adopted in the **Harvard/Onco-Mouse** and **Upjohn** cases, the "abhorrence" standard was applied as the criterion in **Howard Florey/Relaxin**, and **WARF** cases and as such, there seems to be a dearth of sound reasons in applying different standards in different cases.

CONCLUSION

Although the author is mindful of the fact that morality is an immensely complex and arduous standard to implement as one of the criteria of patentability, it is apparent there exists a dearth of global consensus on the patentability of biotechnological inventions which could be deemed immoral.

[29] *Wisconsin Alumni Research Foundation/Stem cells (G 2/06)* (2008) OJ EPO 2009

As in the U.S., the Sri Lankan Intellectual Property Act No 36 of 2003 lacks statutory morality inquiry, with no explicit, uniform and consistent guidance in relation to the patent "morality" conditions with regard to biotechnological inventions. Adopting the approach followed in the U.S. could be problematic as there is a dearth in explicit statutory provisions with respect to morality inquiry in the U.S., causing the application of the morality criterion by the U.S. Court and USPTO to be subjective.

In the E.U., there is no single, explicit and widely accepted morality standard. Case law has established contrasting and inconsistent standards and at present, there are two principal standards; the "unacceptability" standard and the "abhorrence" standard, sans any clear guidance as to which standard should be adopted in a particular instance.

The Author is of the opinion that explicit provisions should be inserted in the Sri Lankan Intellectual Property Act No 36 of 2003 as to the morality doctrine, citing a **single** morality standard to be adopted; the "unacceptability" standard **OR** the more austere "abhorrence" standard adopted by E.U and its member states.

As Sri Lanka gears towards the use of biotechnology and genetically modified organisms, the non-existence of consistent guidance in relation to the patent morality condition could lead to uncertainty; similar to what has transpired in the U.S., curtailing the ability of Courts to successfully impede the patenting of morally controversial biotechnological and other subject matter.