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Public Order or Ordre Public of Patent Act 1983 in the Context of Biotechnology

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ABSTRACT

TRIPS and Article 27.2 permits country members to reject a perfectly patentable subject matter on morality and ordre public basis. Malaysia as a member to World Trade Organization (WTO) and subsequently Agreement on Trade Aspects of Intellectual Property Rights (TRIPS) has abided to the minimum standard requirements thereto. The existing Patent Act 1983 was amended for the said purpose in 1998. The ordre public requirement of Article 27.2 of TRIPS is embedded in section 31(1) of Patent Act 1983. Noticeably section 31 of the Act uses the term public order instead of ordre public. It is unknown whether the same is done intentionally, due to typo error or a case of oversight. The small fact is significant. Both terms carry totally different meaning, has differing scope of intention and consequently impacts on the direction and future technical advancement and developmental progression locally. Considering the Malaysian government has identified biotechnology as one of the key drivers in achieving its Vision 2020, it is only appropriate then for the nation to use the correct legal terminology.

Keywords: biotechnology, patentability, ordre public, Article 27.2 TRIPS, section 31 Patent Act 1983

ABSTRAK

TRIPS dan Artikel 27.2 membenarkan negara ahli untuk menolak permohonan mempatenkan rekacipta yang layak atas alasan moral dan "ordre public". Malaysia sebagai ahli kepada Pertubuhan Perdangan Dunia (WTO) dan seterusnya Perjanjian Mengenai Perdagangan berkaitan Hak Harta Intelek (TRIPS) telah memenuhi kehendak minimum TRIPS itu. Pada 1998 Akta Paten 1983 sedia ada dipinda untuk tujuan tersebut. Kehendak Artikel 27.2 TRIPS tentang "ordre public"ada tertera dalam seksyen 31(1)Akta Paten 1983. Diperhatikan bahwa seksyen 31 Akta Paten 1983 menggunakan perkataan ketenteraman awam dan bukannya polisi awam. Tidak diketahui samada ini sengaja dilakukan atau pun wujud kesilapan menaip atau terlepas pandang. Fakta kecil ini penting. Kedua-dua terma membawa maksud dan skop niat yang berbeza yang seterusnya boleh memberi kesan kepada hala tuju dan masa depan kemajuan dan pembangunan teknikal setempat. Memandangkan kerajaan Malaysia telah mengenalpasti bioteknologi sebagai salah satu pemacu untuk mencapai Wawasan 2020, adalah lebih baik sekiranya negara menggunakan terma perundangan yang tepat.

Kata kunci: bioteknologi, kebolehpatenan, ordre public, Artikel 27.2 TRIPS, seksyen 31 Akta Paten 1983

INTRODUCTION

The government of Malaysia has identified biotechnology[1] as one of the key drivers for its economic growth in achieving the goals of Vision 2020.[2] This is parallel with the nation's aspiration in becoming a biotechnology producer internationally.[3] Malaysia should not have any problems in moving towards that direction. She has the right ingredient in terms of rich biodiversity, strong governmental support, right commitment in Research & Development (R&D) and a sound financial system.[4] The future looks even brighter when the government put in place a viable legal infrastructure in support of the above aspiration in 1998. Malaysian is the first few members amongst developing countries to amend and strengthen its existing Patent Act 1983, just shortly after acceding to the World Trade Organization (WTO) and subsequently Trade Related Intellectual Properties Issues Agreement (TRIPS) memberships.[5] This is to ensure Malaysian intellectual property rights law is in line with the requirements of the TRIPS document.[6] It is hoped the move towards the local technological development and economic progression could be expedited. Moreover despite member countries' diverse backgrounds, TRIPS did pledged that both technology producer and user countries would under its purview mutually benefit from a better flow of technology transfer, promotion, dissemination and participation in trade and economic development.[7]

TRIPS introduces several new elements and margin of actions that are available to members when implementing them. TRIPS amongst other, standardizes and eliminate the problems of varying types of patent protection faced under the Paris Convention 1883 document[8] and succeeded. This is despite the fact patent

law always remain a national jurisdiction, independent and territorial in nature.[9] As far as patent is concerned, Article 27 must be abided at all time, except whenever there are exceptions or exemption. At the same time, Article 27.2 equally provides states especially those reluctant and uncomfortable with the demands, with discretionary power to refuse and reject a perfectly patentable invention with patent.[10] They can do so on the grounds of protecting their *ordre public* or morality.[11]

The above liberty is very useful and important for biotechnology invention and the future of biotechnology in Malaysia specifically. As a hybrid, biotechnological invention stands between product of nature and manmade invention, blurring the division of non-patentable and patentable.[12] As such it usually drags or triggers ensuing controversies in terms of social, moral, cultural, legal, economic, environment or religious values.[13] As a result, biotechnological invention stands a bigger chance of being rejected on morality or *ordre public* grounds as compared to inventions in other fields of technology. As far as patent law is concern, Malaysian Patent Act 1983[14] has been amended several times[15] either to adopt and replicate the provisions of TRIPS exactly or promulgate provisions using own words whilst staying as close as possible to the intention of the TRIPS' provisions and its minimum requirements.[16] In the local context the *ordre public* requirement of TRIPS is embedded in section 31(1) of the Act. The section uses the term public order rather than *ordre public* as used by TRIPS. This small fact is very important. Even though they may appear to be the same, realistically they are not. Both carry different meaning with one terminology has a bigger scope than the other. Naturally there shall be different criteria and indicators for patentability consideration. Consequently they shall impact the chances of patentability of a claim invention and the future of particular industry locally. The same also shall determine whether the intellectual property rights law of the host country is attractive and competitive or not in the international scene. In case of Malaysia specifically the use of right terminology has the determining factor in converting Malaysian economy from manufacturing based to knowledge and innovation based economy, boasts its economic resources sustainably and ultimately achieves the objective of current new economic plan and Vision 2020.

The article first provides some background facts of TRIPS[17] being the latest and so far the most powerful international trade agreements governing patent. It explains how TRIPS is applied to and in every member country. Part II briefly explains about the new provisions in patent law brought by TRIPS, Part III discusses about patent law and the patentability requirement particularly in relation to biotechnology invention. Part IV focuses on briefly on the peculiar characters biotechnological invention. Part V focuses on element on public order and *ordre public* requirements of both Patent Act 1983 and TRIPS respectively. Part VI relates on the legal and economic impacts of both terms on biotechnology industry. It is unknown whether the term public order as found in section 31(i) of Patent Act is by choice or otherwise. It is preferable if it is to be replaced with the *ordre public* as originally intended by TRIPS as the same might be hampering the local biotechnology industry from flourishing.

TRIPS

Under the banner of WTO and TRIPS documents Malaysia has legal obligation to discharge her international obligations and uphold the promised rights either towards her counterparts or TRIPS itself at all times. TRIPS came into picture to *inter alia resolve the loopholes and harmonize the varying types of patent protection problems of the Paris Convention (PC) 1883 document.*[18] The problems were successfully eliminated by introducing minimum standard requirement provisions,[19] where all members despite their diverse backgrounds, economic needs or technological capabilities are equally expected to meet those demands.[20] Members must grant patent right to "any inventions, whether product or process, in all filed of technology, provided they are new, involve an inventive step and capable of industrial application"[21] for a period of at least 20 years.[22] This is irrespective whether they benefit the country or otherwise. Malaysia must also treats all applications to patent an invention as equal regardless of the background of the country of origin, inventor, types of inventions or field of technology.[23] Positively TRIPS is ensuring state is not penalizing[24]a patent application solely because of the nature of the invention or place of invention.[25]Inventors regardless of their diverse backgrounds stand an equal chance in obtaining patent in every jurisdiction of TRIPS. The non-discriminatory clause of Article 1.3 of TRIPS[26]and second part of Article 27.1[27] are significant in helping Malaysia, who is at verge of development to soar further. Malaysians stand an equal chance of getting their inventions patented abroad once the patentability requirements are satisfied.

A member country could also introduce and apply a more stringent domestic patent policies and law respectively than what have been prescribed by TRIPS. However TRIPS forbids member country from diluting the minimum standard requirements. TRIPS is the first and currently the only international document willing to grant patent protection to biotechnological invention provided they satisfy the three basic patentability requirements. Realistically the general words of Article 27 are fashioned in such a way to cater the ever evolving technology advancement and to give support for budding industries with potentials to develop and blossom. As such other sunrise inventions of the future are eligible

too, regardless of the controversies they may trigger. Nonetheless TRIPS has ostensibly made the patenting any controversial invention such as biotechnology, presently or invented in the future on international basis far easier than in the past. Procedurally inventor only needs to satisfy two simple conditions under Article 29 before patent could be finally accorded. He is to disclose his invention[28] and make known to the granting patent office information concerning his corresponding foreign application or grants.[29]

Before the provisions of TRIPS could be applied locally the legislative body of each country member must enact and pass a new or amend the existing intellectual property law to be in line with TRIPS's requirements on individual basis. Malaysia has legally fulfilled her international legal obligations when Parliament amended the existing Patent Act 1983 (Act 291) in 1998. Currently the Ministry of Domestic Trade, Cooperation and Consumerism is in the process of amending the Act. This effort is highly timely and commendable as part of the bigger efforts to accommodate the ever evolving requirements of biotechnology industry. As a result, a few new provisions and terminologies shall be inserted therein to strengthen the Act so that it could be supportive towards the local biotechnology industry and in line with international legal requirements and trends.

NEW PROVISIONS

As the first international patent law document, the PC 1883 has loopholes and weakness rendering it almost ineffective. For example, the PC 1983 expects members to grant inventions with patent protection. Yet it fails to specifically define what an invention is and the criteria for statutory patentable or non-patentable subject matter. Such definition or criteria hold the first important key towards patenting. It determines what should be patented or otherwise. Such absence has led to variations in definitions or interpretations of requirements leading to differing actions amongst member countries. These tiny details have profound impact on a claim invention, industry and a country's industrial future. For the purpose of this writing, the PC 1883 is also silent on the right of a state member to reject or refuse a patentable subject matter or the grounds for so doing. It is unknown whether a member country could and have the legal right to refuse or reject a perfectly patentable subject matter. The loopholes and lack of clarity then allow member countries to purposely take advantage[30]of the system. Technically and hypothetically they can do so without actually committing any wrong doing. In all, the same is weakening the strength of the PC 1883 all over again.

TRIPS overcame the above problems by granting member countries the right to refuse an otherwise a perfectly patentable invention with patent on the grounds of protecting the national morality or *ordre public* as enumerated in Article 27.2 of TRIPS.[31] The grounds for such refusal have nothing to with pure legal considerations. In fact they lean more towards social science considerations. This is the first time an international patent law document[32] provides member countries with such right, adding another unique character to the TRIPS document. Before TRIPS, the same provisions could only be found in the European Patent Convention 1973[33] and European Directive 99/44/EC on Biotechnology Invention 1998.[34] As a matter of speaking, TRIPS later on absorbed the tenor of both provisions. The social and ethical consideration gives a succinct character to both TRIPS and European Directive documents.

Basically a claim invention may be patent eligible.[35] However state still has the last say in determining whether it should be protected with patent protection at all or rejected. Such refusal or rejection are only limited to these grounds. For example States as a matter of policy can denounce patent if the exploitation of an invention does not conform to its morality standard of conduct or *public ordre.*[36] The first limb of Article 27. 2 of TRIPS is very liberal. Perhaps this is to accommodate the needs and demands of member country[37] that does not associate their patent law or patentability of an invention with any social or ethical considerations.[38] Article 27 actually gives every member the equal opportunity to patenting and subsequently technologically progresses and develops any industry to capitalize on. Moreover in the extreme TRIPS is even willing to disregard any beliefs or ideologies per se that a member country may harbour at domestic level against the patenting of certain controversial invention such as biotechnology. In that sense TRIPS is correct. After all, patent law is supposedly to be neutral and should never about morality, ethics, religious or social issues.[39] It concerns more about protecting inventor's creativities, proprietary rights, promoting incentives for a continued innovation activities to fulfil the national development or economic requirements of a nation. Any issues regarding the unacceptability of any controversial invention and the patenting them on the grounds of moral, ethics, religious, social, or even environment grounds should be dealt with in that area of knowledge per se or other forums and not patent law. At the same time, just like the EPC and European Directive 99/44/EC documents, the second part of the Article 27 is conservative in nature. Thus it is not a legal err for the Malaysian patent office or courts to refuse a perfectly patentable invention on those grounds mentioned above. The same is in line with the general intention of TRIPS Article 7 and Article 8 of TRIPS encouraged members to adopt, promulgate and execute patent policies laws[40]in a manner that is conducive to their social[41] and economic welfare.[42] Practically it plays as a second filtering system[43] for patent. Generally it would ensure that the country is not awarding patent to "outrageous or bizarre" invention

presently or created in the future. For instance, maybe the techniques involved or the nature of the end product and the very practices of patenting such inventions are mostly unheard of or socially unacceptable therein.[44] Such notion is felt stronger when inventors use sacred, strong religious meaning or objects in developing an invention,[45]stirring further uneasiness, objections from society at large.[46] This is common sense considering they are in the best position and appropriate parties to do so.

Malaysia first amended her Patent Act 1983[47] in 1998[48] to adopt the above provision of Article 27. 2 of TRIPS, three years after patenting of modern biotechnology became a legal requirement and international trend.[49] Relatively even though modern biotechnology had begun in the 1970s[50] to modify plants and animals, the eligibility for patenting of such invention was still not possible then. When the Patent Bill 1983 was tabled in the Parliament, the idea of patenting biotechnological inventions was still new to most Malaysian. Furthermore the international developments in patenting modern biotechnology were also at a very early stage. Thus it is doubtful if there was much information on the scientific technologies of modern biotechnology made available to the Malaysian legislators when the Act was drafted. Otherwise, the parliamentary debates would have disclosed some of the scientific developments considered by the legislators. Upon a quick glance of the Hansard Report 1983, it seemingly indicates that the government is agreeable with the provision to reject patentability of inventions on grounds of public order without really addressing or deliberating the reason for the change of term of public order from the TRIPS's original term of *ordre public.*

The term public order is embedded in section 31(1) of the Act.[51] As at 1998, the Act only permits rejection of an eligible claim invention on the ground of public order only. Section 31(1) was further amended[52] in 2000 to include the term "or morality" therein. The effort to streamline the Malaysian Patent Act with the requirements of Article 27 of TRIPS then became almost complete. On the first basis, Malaysian too is adopting a liberal patent law policy as found and practiced in the USA or Japan. In addition it equally adopts a more "conservative" approach towards patenting like the European Union does. Positively the discretionary powers give Malaysia rooms to decide whether to grant or refuse patent. Malaysia could usefully utilize it in biotechnology or other controversial in nature inventions, especially the nation as a whole still feels reluctant and uncomfortable with the demands of granting patenting them.

Realistically, things are more complicated. The issues involved are beyond having one biotechnology policy in place or deciding whether to grant or refuse patent protection. Article 27. 2 of TRIPS is tricky for biotechnology as a scientific subject matter, invention and industry. When TRIPS accepts biotechnology as a patentable subject matter, it brought existing debates and controversies which were, formerly restricted to one jurisdiction to central international stage and along the way intensifies them. Secondly, it is difficult to clearly divide the issues between morality, religious, ethics, social acceptability and patent law in biotechnology. In fact they become more blurry because they are heavily laden, integrated and intertwined with each other. As a naturally murky subject matter, the individual compartmentalization or clear separation between biotechnology, patent law and those non-legal considerations could not truly happen. Whenever discussions involving biotechnology arise, they would naturally draw wide ranging issues or controversies amongst its diverse members. They would inadvertently include or revolve around those non-legal considerations. The said provisions may pose significant problems to biotechnologist in patenting his biotechnological invention. Additionally those issues may vary from country to country. They cause uncertainty amongst biotechnologists, unsure whether they would finally succeed in getting the patent in jurisdictions they seek or otherwise. For example liberal countries[53]with broad patent policy[54]and do not attach any moral or religious issues to patent law[55] may have no qualms in patenting biotechnological inventions.[56] In fact they would use it rather pragmatically[57] as an economic platform to attract investment.[58] Other hand, conservative countries may be due to differing cultural, social or legal views are uncomfortable with this latest invention. They thus may oppose and rejects patent application on morality or *ordre public*.[59]

MANY FACES OF BIOTECHNOLOGY

There are many facets of biotechnology. Understanding each of its characters is important. In context of Malaysia or other countries, they shall later on relate to if not forming social, cultural and morality barriers towards the patentability of biotechnological invention locally. Such lack of understanding too may have detrimental consequence on the bright future of biotechnology industry locally.

In the first instance, biotechnology is a basic science research or applied research or both.[60] It actually started in universities or research centres and laboratories particularly in the field of molecular biology and biochemistry,[61] where DNA and genes were first discovered and developed thereon by academicians who usually are mostly interested in establishing underlying scientific principles or theories for the sake of expanding knowledge and intellectual. Later on their scientists or biotechnologist counterparts in applied science based research develop and convert the basic science research into commercial applications.[62]As

discussed in greater details elsewhere,[63] biotechnology is a patentable process as well as product too. Both the biotechnological process and end product stand between a product of nature and man-made animate invention.

CONVENTIONAL BIOTECHNOLOGY

Biotechnology could be categorized as conventional and modern. Conventional biotechnology has been first employed by the ancient Egypt for mummification, fermentation of wine, cheese or baking bread. It was also used in agriculture, especially for horticultural and animal husbandry. The cross-breeding and hybrid techniques are capable of producing new selection of "man-made" self or cross pollinate plants, seeds, and later on animals for the purpose of increasing the quality and quantity of produce either for a longer and better food supply, future stocks, sellable commercial commodity.

MODERN BIOTECHNOLOGY

Modern biotechnology involves alteration and manipulation of DNA (deoxyribonucleic acid) and genes between transborder species, through genetic engineering. As a process the biotechnological invention produces animate living end product. As such biotechnology appears to stand between a product of nature and man-made invention.

PATENTABILITY REQUIREMENTS

Legally and procedurally biotechnologist has to satisfy the three standard patentability requirements generally acceptable internationally. They are namely novelty[64] inventive steps[65] and industrial application,[66] as found in sections 14, 15 and 16 of the Act respectively. Regardless of its unique nature or the fact that is alive and animate, the same is eligible for patent provided it satisfies the patentability requirements.[67]

THE FIRST FILTER

Once the three patentability requirements are satisfied, the patent office or courts have two choices to make. It could award the said invention with patent or otherwise.[68] This is patent law policy issue. If it is the policy of Malaysia to grant patent to biotechnological invention that satisfies the requirement of section 11 of the Act, then it is mandatory for them to do so. Usually such option is exercised when there is nothing peculiar or controversial about the claim invention. Once protected with patent, the biotechnologist could enjoy the quasi monopoly rights of patent for the next 20 years. On the opposite if it is also a policy of Malaysia not to immediately grant the claim invention with patent, the patent office and courts can now proceed to evaluate whether to still grant it with patent or refuse its patentability under section 31 of the Act. As far as Malaysia and biotechnology are concerned it is preferable for Malaysia to adopt the latter as her patent law policy. Although the patenting process would take a longer time than the first option but positively it would give all parties inclusive of the public to contribute and have a better understanding of the impact of the biotechnological invention in question for their well being.

SECOND FILTER FOR PATENT

Section 31 is a specific provision as an exception to section 11 of the Act. Therefore the exclusion of section 31(1) could neither be invoked arbitrarily to suit the Malaysian social, developmental or economic needs nor made merely because the exploitation is prohibited by law. Based on the intention and explanation as stated in the draft report of TRIPS 1998, it is clear that TRIPS intended member states to satisfy a few precautionary steps before enforcing the *ordre public* rejection. Firstly, the rejection is necessary to prevent the commercial exploitation of the invention within its territory. The wordings of the provision dictated that the risk must come from the commercial exploitation of the invention, not from the invention as such. Mere marketing restrictions cannot justify exclusions from patentability. There has to be a specific link between the commercial exploitation of the patent and the respective Member's *ordre public* or morality. In other words, Article 27.2 requires that the commercial exploitation of the invention would represent a particular danger to either *ordre public* or morality of the host country. For example, the technique of modern biotechnology in creating a hybrid vegetable between tomatoes and apple is harmless. Conversely if the inventor applies to patent the recombinant technique, there is a possibility that state might grant patent to protect the invention. Since the exception based on this Article 27(2) can only be applied when it is necessary to prevent the "commercial exploitation" of the invention, therefore the condition for the application of the exception would not be met if there is a need to prevent the non-commercial uses of the invention such as for scientific research purposes. Practically if the recombinant technique is not for sale or be commercialized through licensing, it is still eligible for patent protection. After all as exclusive patent right holder, the inventor has the total liberty and can by choice sits on his invention and not commercially exploiting it. On the other hand, if the recombinant technique uses a DNA from swine to transport the DNA of apple to be inserted into the tomatoes or vice versa and eventually

makes the hybrid vegetable inherently unsuitable for Muslim consumers in Malaysia, then the patent office should stop the commercialization of such technique on the ground of *ordre public*. Given the wording of Article 27.2, it would also seem, that the likely impact must be within the territory concerned, not that of another member countries.

It has been debated whether the exception can only be applied when there is an actual prohibition on the commercialization of the invention, or when there is need to prevent it. Logically an effective ban should be put in place in order to make the exception viable. It has been held,[69] however, that TRIPS does not require an actual ban of the commercialization as a condition for exclusions. Suffice when there is such a necessity of such a ban and the requirement of Article 27.2 is deemed satisfied. In order to justify exclusion under Article 27 (2) TRIPS, a Member state would therefore have to demonstrate that it is necessary to prevent, by whatever means the commercial exploitation of the invention. As such member country would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited. In all section 31(1) is applicable after taking into consideration the impact of the invention on the public order or morality of the Malaysian society. Logically the provision wants to ensure the commercial exploitation of the patent rights is not in any way going to cause any prejudice or harm to the *ordre public* or morality standard of conduct of the local society.

Notably the term commercial exploitation is absent from the provision of section 31(1). With due respect arguably the phase "...the performance of any act in respect of the claimed invention..." of section 31(1) is wide enough to include the commercial exploitation of the invention. This argument is line with the exclusive rights of the patent holder to exploit his patented invention. It is illogical for the patent office or courts to refuse or prohibit the patent award, yet allows the commercial exploitation of the invention. Moreover a patent only has economic value when it commercially exploited. Alternatively state equally cannot deny an inventor a patent on this basis and still let others exploited the invention freely.[70] Secondly, the patent office and courts must also satisfy that their decision to refuse a perfectly patentable invention was done for the purpose of protecting the Malaysian public order or morality.[71] Conversely the patent office can only exclude an invention in order to stop its commercial exploitation or if allowed, shall be an offence against the country public order or morality.

In this context, the public order and morality clause is giving the patent office or courts another chance to re-evaluate their initial findings and subsequently decide whether to finally grant the claim invention with patent or otherwise. Such measure is a precautionary step in protecting the local interests. For example they can ask the biotechnologist to submit certain reports. The patent office may on its own initiative or hire others to investigate the long impact of the claim invention on the society. At the end if the answer is affirmative then they can appropriately refuse the application to patent the invention and otherwise.

PUBLIC ORDER OR *ORDRE PUBLIC*

As mentioned, TRIPS only provides minimum standard requirements. By design TRIPS purposely does not provide definitions to terminologies used to avoid rigidity. Member countries can fill in the gaps provided they do not dilute the efficacy or strength of TRIPS provisions and documents. In light of the above spirit and by comparison, Article 27.2 of TRIPS uses *public ordre* terminology whereas section 31(1) uses public order terminology instead. At a glance they may appear to be similar, have the same meaning and refer to the same thing. Theoretically and realistically they are not. Both are different with one terminology has a bigger scope than the other. Naturally the criteria and indicators used in determining the patentability of a claim invention by both terminologies differ too. In bigger picture, one of the terminologies used therein shall permit patentability of any controversial, bizarre or outrageous invention easily than the other. As such depending on which term is used, the same shall consequently impact the chances of patentability of a claim invention and the future of particular industry in Malaysia. It also shall determine whether Malaysian intellectual property rights law is attractive and competitive or not in the international scene. Furthermore the use of the right terminology has the determining factor in converting Malaysian economy from manufacturing based to knowledge and innovation based economy, boasts its economic resources sustainably and ultimately achieves the objective of current new economic plan and Vision 2020.

It is not known whether the parties responsible in drafting and amending the current Patent Act 1983 in 1998 have specifically by choice choose and prefer to use the term public order rather than the original *ordre public*. Tentatively was it case of pure mistake or oversight due to innocent belief that the two words which sound almost the same, thus bears a similar meaning. Attempts to trace a complete legal history of the Patent Act 1983,[72] such as how this Act came about and the series of track record and documents used in the drafting or amendments process of the Act to specifically clarify matters reached dead end with open ended answers. This is quite unfortunate, because the complete legal history and track records of documentation would to great extent inject some sense of certainty in the current discussion on this provision. Inquiries, interviews and tracer study done on the legal history of section 31 revealed that most officers responsible in interpreting, drafting, applying

or enforcing section 31(1) specifically or the Act itself generally are familiar with the term *ordre public.* They believe both terms have the same meaning. Even though some of the legal officers, patent examiners and drafters are aware that the term *ordre public* is originally a French terminology, few know the real meaning of the said term. This is regardless of the peculiarity in spelling the term *ordre public.* Appearance wise many noted the fact the term *ordre public* of TRIPS appears in italic font. No party ever questioned in greater details for the specific reasons for so doing. They nonetheless believe and presume that both terms must have borne the same meaning. There are also quarters that believe it is harmless for section 31(1) not to replicate the exact term of *ordre public* as prescribed by Article 27.2 of TRIPS.

MEANING, DEFINITION AND THEIR IMPACTS

In absence of any definition either in TRIPS document, Patent Act 1983 or through usage elsewhere in international law[73] what is understood from both terms public order, *ordre public* and specifically the concepts of *ordre public* is subjected to further examination and interpretation. This action is only a prudent since Malaysia is generally new thus quite unfamiliar with biotechnology again an equally new field of knowledge with considerably underdeveloped biotechnology law. Considering the fact Malaysian Patent Office (MYIPO) has started receiving applications to patent biotechnological inventions it is unwise to have a vacuum in law as it could subsequently creating legal uncertainty. As at January 2010, MYIPO received 32 applications to patent biotechnological inventions. 13 of these applications involved claims to patent 'transgenic animals' which includes 'transgenic mice' and transgenic cattle' as product patent. Applications are from United States, United Kingdom, Sweden, Cuba, Thailand and Finland. Thus far, 9 claims have been refused. 2 of these claims were refused based on section 31(1) of the Patents Act.[74] 7 other claims were refused due to other administrative grounds such as the absence of a response from applicants and non-payment of required fees. To date none of the rejected applicants are opposing or appealing against the decision of MYIPO above. There is not a single case challenging a patent claim or invalidate a biotechnological patent either. MYIPO or the courts then have no real opportunities to judicially interpret the terminologies or provisions of the Patent Act 1983 in regards to biotechnology invention and *ordre public*. Such exercise usually would enrich and develop the local biotechnology law. The same also would contribute and determine the success and future of the biotechnological invention in question, the nation and biotechnologist in generating income from the said patent.

In view of the above, Malaysian patent office or courts could refer and seek guidance from the legal history and judicial precedents of the European Unions and United States of America patent laws in interpreting the Patent Act 1983. Courts in both jurisdictions have a long and extensive legal history thus plenty of opportunities in interpreting the patentability requirements and their applications in biotechnology locally. Such reference is necessary because behind the simple legal terms lay intricate and long legal jurisprudence concepts. Such insights are therefore useful and able to shade some lights for the Malaysian patent and legal fraternity. After all the provisions of the Act to large extent are replicating the same terms as found in TRIPS, European Unions and United States of America patent laws.

It is interesting to see how the courts are going to interpret the meaning of public order, defines its scope as well as apply section 31(1) in the context of biotechnological inventions locally. For instance, what action(s) might be constituted as against the public order or morality of Malaysians and Malaysia as a nation is still unknown and unclear. It is also unknown which and what yardstick should the courts use therein, if any. Since the patent office or courts are allowed to turn to the public order and morality principles applicable and recognized in the local context to supplement the standard legal examinations under patent law, inevitably that shall be variance and divergence in the interpretation and application.

Perhaps the courts could also utilize the opportunity created therein to legally decide on the suitability of the term public order in lieu of *ordre public* of TRIPS With due respect it is verily believe section 31 should use the original terms of *ordre public* of TRIPS than public order. This is because *ordre public* has a much wider scope of application and more realistic. As indicated above, it also has different criteria and indicators in determining the patentability of invention with different impacts on an industry in question. By the same accord the Patent Act 1983 would be streamlined with the TRIPS' provisions as well as with other member countries.

TRIPS uses the French term *ordre public,*[75] derived from French law.[76] By consensus[77] it is agreed that it is not possible to directly or literally translate the term *ordre public* into the English term of public order. Both carry different meanings. This explains why the original the original French term was maintained and used in TRIPS. Public order in English means maintaining the safety of the public.[78] It denotes public order of a society,[79] which is actually a question of fact. For example social harmony, public peace, orderly society and sense of security are basic elements of public order.[80] In terms of application, public order is a subset of public policy and not otherwise.

Generally *ordre public*[81] means public policy.[82] Public policy usually covers wider and stricter concepts than public order.[83] It usually covers matters which

benefit the population and nation at large, stretches from social to economic and political interests of the country. Being the case public order also falls under its umbrella but not otherwise. For example, as a matter of public policy, smoking inside a building is banned in Malaysia since research evidence shows secondary smoking is equally hazardous. In this illustration the ban has nothing to do with public order. As far as the government is concern an orderly society has nothing to do with the smoking habit of the population and vice versa. However the hazardous effect of smoking not only could jeopardize health, it also increases the financial cost as well medical expense of the population and nation. Therefore for the benefits and in the interests of the population and nation, the government can interfere with the population's social lifestyle. By using legal provision it can impose a restriction on such habit with intent of eliminating it forever.

The legal expression *ordre public* has a long tradition in the area of international private law.[84] Either at TRIPS's or domestic levels, many countries and jurisdictions had equally taken the o*rdre public* considerations into account before granting or rejecting patents. This is not withstanding the fact that both patent offices and courts in all jurisdictions might differ in defining and interpreting the term *ordre public* or usually view and value invention and technology as neutral. However this statement does not mean that the patented technology could not be used "for constructive or destructive purposes. For example, in the United States,[85] traditionally the concept of inventions contrary to *ordre public*, as applied by the courts, referred to an invention that was "frivolous or injurious to the well-being, good policy, or sound morals of a society". The European Law regards o*rdre public* as something that encompasses the protection of public security and the physical integrity of individuals as part of society. This concept includes also the protection of the environment. Therefore if an invention has a tendency of polluting the environment, then the invention would undoubtedly under Article 53(a) EPC, be against '*ordre public*' or morality of that country in particular. Before patent office or court could a reach a decision to reject the claim invention on the ground of contrary to *ordre public*,[86] they must be in the affirmative that the damage to the environment must be serious thus no patent may be granted in respect of an invention directed to such use.[87] Holistically *ordre public* refers to the basic and fundamental values of a domestic legal system. It expresses concerns and shields the country against matters that are threatening the social structures which tie a society together as such, either in terms of economy,[88] moral, ethical[89] or political.[90] Legally *ordre public* serves as a last resort when the application of foreign law leads to a result which would be wholly unacceptable for the national legal order. Again this strengthened the justification for the proponents and drafters of TRIPS to deliberately chose *ordre public* instead of 'public order'.[91]

Technically behind the *ordre public* terminology there are several other separate and distinct concepts[92]applicable in different circumstances.[93] The first is called *ordre public interne*[94] which incorporates judiciary and legislative powers.[95]In applying this concept[96] the public is statutory barred from contracting certain transactions[97] that are found to be offending the public order or policy and if any, a judge is given a limited statutory power to exercise his discretion in preventing that transaction from being enforced.[98] For example, two parties might have the legal right to enter into a contract that involves pornography. However a judge by virtue of the *ordre public interne* of that country and in the name of public policy could stop them. Their rights are not unlimited but governed by their public policy and order. The second part is termed as *ordre public externe,*[99] which is partially connected to *ordre public interne* at one end and private international law at the other half.[100] The *ordre public externe* comes into play when a country principally finds the application of foreign law, under which it is legally obliged to execute would sanction conducts that offends its domestic's fundamental norms[101] and endangering its institution or society locally. The said country can invoke its discretionary power in applying for an exception[102] or not applying it at all.[103] In this context and eventuality, the *ordre public externe* is applied to protect the country's fundamental norm that could not be derogated at all times.[104] This warrants careful considerations since these non-legal issues are not easy to assess. For instance the ethical perspective could not be clearly distinguished from the legal assessment.[105] Consequently they might to a large extend influence the Malaysian biotechnology law policies as well as the patent office and courts' decisions in granting or refusing patent protection to a claim invention. In the long term all of the above could either be detrimental to the invention, field of technology, industry or the country's future.

When section 31(1) continues to use the term of public order, it is quite hard for the relevant parties to relate the claim invention such as biotechnology with public order, safety and security issues that deserves rejection of patent application. For example the possibility of a public unrest arising out of public's protest against MYIPO's decision in patenting a genetically engineered hybrid vegetable (tomatoes and apple) which later on leads to public insecurity is quite unlikely. By the same accord the term naturally reduces their already limited scope of considerations in rejecting or refusing a claim invention as compared to public policy. Presently the patent office or courts for instance could only use section 31(1) to reject a claim invention involving a technology to produce a bioweapon of mass destruction and the bioweapon itself. This is because the commercial exploitation of the patented process or end product if allowable would have the tendency to hold the public safety at ransom. In other instances, there are tendencies

that the patent office or courts might have to grant patent to any claim biotechnological invention. This because the remoteness of associating a biotechnological invention and its impact on the public order or safety is may be too difficult to establish or none at all. Contrary to general belief, it is harder to relate a claim invention to the issues of public order, safety or security. Based on the developed nations' experience, they so far only rejected two types of invention based on public order. They are namely gambling machine kiosk and technology to create nuclear weapon. Furthermore it must be borne in mind that the above provision is applicable to all field of technology and not limited to biotechnology solely. If the practice continues soon the intention and objective of section 31(1) would become obsolete. Due to difficulties to associate biotechnological invention or invention from other field of technology with the public order of Malaysia or there is none at all, the patent office or court is forced to grant patent. This is despite the fact that the invention in question is outrageous in nature, has bizarre character, hazardous, unsuitable for the society or uses controversial raw material or technology. It is even more unfortunate when there is public outcry and the society in general is uncomfortable with the invention or thought of patenting it. It is foreseeable the patent office or courts y could rarely exercise the right to refuse or reject application.

On the other hand, the proposed term *ordre public* would make the patenting activities more orderly and regulated. It increases the patenting bar to a new height. Realistically and practically the issues of patenting biotechnological inventions usually confront a wide ranging public policy sphere. The relevant offices have wider rooms to manoeuvre either to award or refuse a patent. For example they could argue that it is necessary to protect the health, general welfare or religious requirement of the public. Hypothetically Malaysia may find it necessary to exclude a perfectly patentable pharmaceutical drug, a biotechnological product. This is to lower and control the price of drug and allow a wider access to quality pharmaceutical drugs so that the quality of the population would generally improve. Otherwise Malaysia in an attempt to counter the effects of patent may need to provide some sort of subsidies to its citizens to enable easier and cheaper access to those drugs. Yet such decision is straining the country's annual budget. Considering together the impacts of the monopoly price and tremendous disparity in wealth that exists between the society in rural and urban areas, it is possible that patenting the above would only allow the wealthiest citizens to gain access to beneficial products than those in need. As such it is for the country's best economic interest to exclude pharmaceutical products or process from patent under section 31(1) of the Act. This argument is strengthened by Article 7 and Article 8 of Doha Declaration 2001, which allow countries to introduce flexibilities in patent protection to guard their national health interests and public welfare.

Though European law may be an important source for the interpretation of *ordre public* concept, there is no generally accepted notion of "*ordre public*". This is a good opportunity for Malaysia, known for its rich diversity and multi-cultures Malaysia should seize the opportunity to identify and set basic criteria of matters which when introduce to the society or act upon would potentially be regarded as against the Malaysian *ordre public.* In greater details, what act or matters of such nature could be categorized according the each particular race, ethnics groups, culture or religious beliefs of the Malaysian society, thus enriching the local patent legal history and resources.

In the second context, the above statement also means that though preferable, there is no obligation and reason for Malaysia or other member countries of TRIPS to follow the European approach. Malaysia has a considerable flexibility to define which situations are covered, depending upon the local own conception of the protection of public values. In furtherance most patent examiners are not specifically trained in public policy issues, ethics or in risk assessment. This means that other bodies may have to shoulder the responsibility for the decisions of society whether certain technology can and should be put into practice.

In order to stay relevant and viable, all parties and countries must respect the *ordre public* requirement. As such, it is foreseeable that soon in the very near future all claim inventions must go through the *ordre public* assessment process notwithstanding the safe nature or which field of technology such invention belongs to. This is because the assessment corresponds in particular to safety, ethical or moral principles recognized locally. Likewise all patent officers, patent examiners or courts must ensure that such practice is duly and properly executed and enforced without fail, no matter how mundane or taxing the *ordre public* assessment process is going to be. This is despite the fact *ordre public* requirement shall only supplement the standard legal examination and assessment under patent law for patentability. Such necessity is due to the fact biotechnology is always closely intertwined with safety ethical or moral principle. Such consideration becomes more important and relevant in view of the potential scope of inventions and their relationships to living matter.

At the same time the requirements of *ordre public* of Section 31(1) as an exception must be narrowly construed because such exception intends to safe guard national interest. It cannot operate as a general blanket targeting a particular field of technology or invention. Since o*rdre public* or public policy is the body of fundamental principles underpinning the operation of legal systems in each country, it requires studies that address the social, moral and economic values that tie a society together. Unfortunately this is not an easy task as such values may vary in different cultures and change

over time. In that case it is only appropriate and just for any o*rdre public* decision to be assessed and decided on individual and on a case by case basis. In assisting the patent office or courts to arrive at a correct decision, patent examiners or courts could again follow the footsteps of EPO in employing methods to approach the problems. They are namely the balancing of interests at stake approach or simply based on the opinion of the vast majority of the public.[106]

The above also raises another issue that relates to the strengthening of TRIPS minimum standard requirements. The same is unfortunately done at the perils of Malaysia. Conversely section 31(1) is self–derogating. When TRIPS *ordre public* gives members bigger scope of actions, section 31(1)[107] adopted a smaller scope of considerations and actions. As said above, it automatically reduces the grounds and scope of decisions in refusing or rejecting a perfectly patentable subject matter. Most importantly, patenting would become very easy in Malaysia. For example, a controversial invention may be rejected in another jurisdiction due to the fact that it is prejudicial or harmful to the country's *ordre public*. Yet there is possibility that the same could be patented in Malaysia. Malaysia as a whole would suffer economic loss if this hypothetical becomes a reality. This is because the Malaysian public is firstly subjected to pay the licensing fees or royalty for access to the said invention. Through-out the patent lifespan, everybody then has the legal obligation not to infringe the invention. However once they gained access to protected technology it might not be suitable at all with the general well being of the society and nation. In that sense the public are being taxed twice over the same subject matter and making the technology transfer costlier than necessary. Inadvertently it would also hike up the price of a supposedly "unsuitable or useless" technology. In the long term, Malaysia would always play the catching up with technology game, probably slowing down the technological progression or development of a particular industry locally.

CONCLUSION

Whilst the current Act 1983 is due and is in the process of amendment, it is preferable for the relevant office to take the available opportunity to review the suitability of using the term *ordre public* rather than public order. The current provision is not exactly in line with the intention of TRIPS or international trends. It is foreseeable that section 31(1) will be used more frequently in the near future as compared to ten years ago considering biotechnology has now reached the shores of Malaysia. By then issues on the term public order, suitability of the term public order, should it be *ordre public* or what constitutes public order or *ordre public* of Malaysia shall be put to test rigorously.

Although the disparity of terminology in section 31(1) of the Act and *ordre public* in Article 27.2 of TRIPS is small, it has significant impact. The term public order has the effect of opening the patent gate wide open unguarded, making all inventions, biotechnology and all potentially patentable. Consequently the patent office or courts may not be able to exercise their discretionary powers appropriately as originally intended by the Act or TRIPS. Worst still it may defeat the intention of section 31(1) rendering it obsolete in the near future. The concept of *ordre public* is broad enough to include ethics, religious social or moral values under its umbrella. The said exception is useful in preparing the nation with influx of biotechnological applications as the same is often associated with wide ranging controversies. Malaysia could selectively refuse or reject a biotechnological invention when the same is against her public policy and not in the national interests. By so doing Malaysia could avoid the stringency of the Article 27(1) of TRIPS which makes it mandatory to grant patent once the claim invention satisfies the three patentability requirements.

Article 27 of TRIPS provides legal arenas, wide enough for Malaysia to refuse patent particularly if and when the nation is reluctant or uncomfortable with thought of patenting biotechnological invention. It is a known fact, granting patent means subjecting countries to prior consent, licensing fees, limited public access to genetic resources, technological information and increased selling price. Therefore it is humbly submitted should Malaysia is keen in protecting its citizens, domestic economy or merely uncomfortable with the patenting biotechnology, Malaysia could opt for the above option. The second limb of Article 27 equally functions as a grace period. Whilst the government continuously monitor and review the national biotechnology law policies, it could also encourage biotechnologist to invent value add technology that is for example, sustainable, environmentally safe or socially acceptable to the Malaysian scene. Positively such re-direction would ensure that patented technology in Malaysia is of economic, financial, social values to the nation.

NOTA

[1] As first announced. See Malaysian Biotechnology Report 2005.

[2] As announced by the current Prime Minister of Malaysia, "Plan Baru Ekonomi Malaysia". Utusan Malaysia. 23hb Feb. 2010, p 1.

[3] Malaysian Biotechnology Report 2005.

[4] As stated in the Malaysian Biotechnology Report 2010.

[5] History of WTO-TRIPS. www.wto.org/history/TRIPS/country (1st March 2003).

[6] D. Bhagirath-lal, *An introduction to the WTO agreement*, Third World Network, Penang, 1998, p 23.

[7] Article 1, Article 7 and Article 8 of TRIPS.

[8] Nor Ashikin Mohamed Yusof, Biotechnological patents in developing countries in the post–TRIPS era, PhD thesis, University of Nottingham, Nottingham, 2007, p 22.

[9] C. Correas, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, OUP, London, 2007, p 45.

[10] Article 27. 2 of TRIPS.

[11] Article 27. 2 of TRIPS.

[12] Nor Ashikin Mohamed Yusof, Biotechnological patents in developing countries in the post–TRIPS era.

[13] Nor Ashikin Mohamed Yusof, Biotechnological patents in developing countries in the post–TRIPS era.

[14] Hereinafter referred to as the Act.

[15] The responsible parties and ministries are still negotiating and in drafting process of amending Act 291. It is expected that the amendment would take effect at the end of this year latest.

[16] Article 1 of TRIPS.

[17] By focusing solely on section Five (5) of TRIPS which deals with patent rights.

[18] S. Bondure, & L.G. Farr, "Intellectual property rights abroad and at home: After GATT" (1998) 7 *South Carolina Lawyer* 20-27, at p 25.

[19] For example, Article 1-11, Article 27, Article 33.

[20] Article 1.3 of TRIPS and reading it together with Article 27 of TRIPS forbid member countries to give discriminatory treatment.

[21] Article 27 of TRIPS.

[22] Article 33 of TRIPS.

[23] See Article 1.3 and Art 27 of TRIPS.

[24] P. Champ, & A. Attaran, 'Patent rights and local working under the WTO TRIPS agreement: An analysis of US-Brazil patent dispute' (2002) 27 *Yale Journal of International Law* 365-398, p 366.

[25] This statement does not mean that developing countries simply exploited the weakness of the international system by taking advantage of foreign inventor.

[26] First sentence "members shall accord ...to national of other members."

[27] Stated no discrimination shall be made according to the field of technology, place of invention or whether it involves a local or foreign invention.

[28] Article 29.1 of TRIPS "...adequate disclosure and enabling". Also see S. Crespi "Enablement and written description- A trans-Atlantic view" (2005) 87 *Journal of the Patent and Trademark Office Society* 343-388, at p 343; S.J.R. Bostyn, "Written requirement and description after Enzo Biochem: Can the real requirement step forward please" (2003) 85 *Journal of the Patent and Trademark Office Society* 131-179, at p 131.

[29] Article 29.2 of TRIPS - conditions on patent applicants.

[30] There is no legal repercussion for not doing it.

[31] Article 27.2 of TRIPS.

[32] Both the European Convention 1973 and European Directive 99/44/EC on Biotechnology Invention 1998 are regional in nature.

[33] Article 53(a) of EPC 1973.

[34] Article 6 of European Directive 99/44/EC.

[35] The second sentence in Article 52.4 of EPC.

[36] H. Hans Morten, 'Human Rights and TRIPS Exclusion and Exception Provisions' (2009) *The Journal of World Intellectual Property* Vol. 11, nos. 5/6, pp 345–374.

[37] Japan and USA.

[38] E. Derclaye, 'Patent law's role in the protection of the environment - re-assessing patent law and its justifications in the 21st century' (2009) *International Review of Intellectual Property and Competition Law,* p 1-15.

[39] D. Burk, 'Biotechnology and patent law: Fitting innovation to the procrustean bed' (1991) *17 Rutgers Computer & Technology Law Journal* p 1-60, p 7; K. Boonf, 'Parallel imports in pharmaceuticals: increase access to HIV drugs' Unpublished proceedings from Thailand Law Forum, 1-3 June Bangkok 2009.

[40] Article 8 of TRIPS uses the word "..protection of intellectual property right…"

[41] It could be construed to include moral, ethics, cultural or religious values.

[42] See Article 7 and Article 8.1 and Article 8.2 of TRIPS.

[43] The first is the three patentability requirements.

[44] D. Long, 'The impact of foreign investment on indigenous culture: An intellectual property prospective' (2000) 23 *North Carolina Journal of International Law and Commercial Regulation* 229-256, p 236.

[45] E. Donavan, 'Beans, beeans, the patented fruit: The growing international conflict over ownership of life' (2002) 25 *Layola of Los Angeles International & Comparative Law Review* 117- 142, p 120.

[46] N. Seeratan, 'The negative impact of intellectual property rights on developing countries; An examination of the Indian pharmaceutical industry' (2001) 3 *SCHOLAR; St. Mary Law Review on Minority Issues* 339-397, p 346.

[47] Malaysian Hansard HR vol 1 cols 7767-7768 (25 July 1983).

[48] Act 291.

[49] *Diamond v Chakrabarty*. US S. Ct. 1980 447 U.S. 303, 100 S. Ct 2204 65 L.Ed. 2d, 206 USPQ 193.

[50] History of UPOV. www. wipo. org/ plant inventions. htl_02 (23. 7. 2010).

[51] History of UPOV. www. wipo. org/ plant inventions. htl_02 (23. 7. 2010).

[52] Act A 1088, Patents (Amendment) Act 2000 and is enforced commencing 1st August 2001.

[53] So far only USA, German and UK are willing to do so. R. Wosawki, "The evolution of patentable composition of matter: The United States Patent Office accepts genetically altered animals or patentable subject matter under") (1998) 35 U.S.C S.101. 2 *Administrative Law Journal* 309-367 at p 327.

[54] R. Wosawki, 'The evolution of patentable composition of matter: The United States Patent Office accepts genetically altered animals or patentable subject matter under'.

[55] R. Wosawki, 1998.

[56] R. Wosawki, p 329.

[57] S. Pepa, 'International trade and emerging genetic regulatory regimes' (1998) 29 *Law & Policy International Business* 415-444 at p 420.

[58] R. Skarstad, 'The European Union's self-defeating policy: Patent harmonization and the ban on human cloning' (1999) 20 *University of Pennyslavania Journal of International Economic Law* 353-378, at p 358.

[59] V. Di Cataldo, 'From the European patent to a community patent' (2002) 8 *Columbia Journal of European Law* 19-37, at p 22.

[60] Merges & Nelson, 'On the complex economics of patent scope' (2002) 90 *Columbia Law Review* 839, p 842.

[61] Merges & Nelson, 'On the complex economics of patent scope' (2002) 90 *Columbia Law Review* 839, p 842.

[62] Merges & Nelson, 2002, either in producing process or products.

[63] Nor Ashikin Mohamed Yusof, 'The third patentability requirement of patent; Still a constraint to Malaysia' (2009) *Jurnal Undang-Undang*, UKM, 2009, 52-75.

[64] Based on Chakrabarty's decision, p 2208 –2210, *Kuehmsted v Farbenfabriken of Elberfeld Co*, 179 F. 701 (7th Cir. 1910), cert. denied, 220 U.S. 622 (1911), *Funk v Kalo*, 333 U.S. 217, (1948), T19/90, Harvard/Onco-Mouse, [1990] E.P.O.R. 501, 503 (Technical Board Appeal, 1990), See S 102(a) of 35 U.S.C., See S 102(a) of 35 U.S.C.

[65] ICOS Corporation/Novel V28 seven transmembrane receptor. O.J.EPO 6/2002.

[66] Article 52 of EPC, S.101 of US patent law, See the footnote of Article 27 of TRIPS, Article 57 of EPC 1972, ICOS Corporation/Novel V28 seven transmembrane receptor. O.J.EPO 6/2002.

[67] As at January 2010, MYIPO received 32 applications to patent biotechnological inventions for 'transgenic animals' which includes 'transgenic mice' and transgenic cattle'. 13 of these applications involved claims to patent 'transgenic animals' as products. Applications are from United States, United Kingdom, Sweden, Cuba, Thailand and Finland. Thus far, 9 claims have been refused. 2 of the claims were refused based on section 31(1) of the Patents Act. 7 were refused due to other administrative grounds such as the absence of a response from applicants and non-payment of required fees.

[68] In the context of Malaysia, such option is made available by virtue of section 11 of Patent Act 1983 as postulated by Article 27 of TRIPS.

[69] T 356/93 EPO (Plant Genetic Systems).

[70] R. August, *International Business Law*, Prentice Hall, New Jersey, 1997, at p 323.

[71] T. Ackermann, 'Dis'orderly loopholes: TRIPS patent protection, GATT and the ECJ' (1997) 32 *Texas International Law Journal* 489-510 p 493.

[72] Malaysian Hansard, HR vol 1col 7916 (26 July 1983).

[73] K. Murphy, 'The traditional view of public policy and ordre public in private international law' (2002) 11 *Colorado International & Comparative Law* 591 -620, p 593.

[74] The claims were refused on the ground of morality and not ordre public.

[75] P. Morret, *A Concise Guide to Intellectual Property Rights-Patent*, Longman, London, 1996, p 36.

[76] K. Murphy, 'The traditional view of public policy and ordre public in private international law', p 593.

[77] At the drafting stage of TRIPS. See also Standing Committee on the Law of Patents, 13th Session, Geneva, March 23 to 27, 2009, on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights.

[78] Morret, *A Concise Guide to Intellectual Property Rights-Patent*, p 36 . See also *Concise Oxford Dictionary* (9th Ed), Oxford Press Ltd., London, 1998, p 1107.

[79] According to the *Concise Oxford Dictionary*, (9th Ed.), Oxford Press Ltd, London, 1998, p 1107.

[80] *Concise Oxford Dictionary,* (9th Ed.), Oxford Press Ltd. London, 1998, p 1107.

[81] According to French legal history. T. Ackermann, 'Dis'orderly loopholes: TRIPS patent protection, GATT and the ECJ', p 495.

[82] Murphy, 2002, p 593.

[83] D. Gervais, *TRIPS Agreements: Drafting History and Analysis*, Sweet & Maxwell, London, 1998, at p 149.

[84] R. Moufang, The Concept of "Ordre Public" and Morality in Patent Law, in Geertrui Van Overwalle (Ed.), *Patent Law*, *Ethics and Biotechnology*, Katholieke Universiteit Brussel, Bruxelles 1998, No.13, p 69.

[85] See S. A. Jameson, 'A Comparison of the Patentability and Patent Scope of Biotechnology. Biotechnological Inventions in the United States and the European Union' (2007) 35 *American Intellectual Property Law Annual Quarterly Journal* p 190- 230.

[86] Stem Cell Patents: European Patent Law and Ethics Report, p 23-24, www.nottingham.ac.uk/law/StemCell-Project/project.report.pdf, 20/12/06.

[87] Stem Cell Patents: European Patent Law and Ethics Report.

[88] Unpublished 1999 Report and working paper Report Q 150 on Patentability Requirements and Scope of Protection of Expressed Sequence Tags (EST's), single Nucleotide Polymorphisms (SNP's) and Entire Genomes by the Dutch Group to the Administrative Council of EPO.

[89] D. K. Miller, 'A patent on the conscious: a theoretical perspective of the law on patentable life' (2010) *Journal of Animal Law & Policy* p 145-164.

[90] United Nations High Commissioner for Human Rights, 2005, p 10.

[91] D. Gervais, *TRIPS Agreements*: *Drafting History and Analysis* p 222.

[92] K. Murphy, 2002, p 594.

[93] T. Ackermann, 1997, p 491.

[94] T. Ackermann, 1997, p 491 .

[95] T.Ackermann, p 491.

[96] By virtue of Articles 1131 of the French Civil Code. See Ackerman, p 493.

[97] French Civil Code. Article 6. Ackerman, p 494.

[98] French Civil Code. Article 1131, Ackerman, p 494.

[99] T.Ackerman, p 495.

[100] T. Ackerman, p 495 .

[101] T. Ackerman, p 495.

[102] T. Ackerman, p 495.

[103] T. Ackerman, p 495.

[104] K.Murphy, 2002, p 595.

[105] R. Gana, & M. Bagley, 'Patent first, ask questions later: Morality and biotechnology in patent law' (2001) 45 William and Mary Law Review 469-495, at p 471.

[106] V8/94 Relaxin, OJ EPO 6/1995. The opinion of the majority of the public was considered by the Opposition Division of the EPO in a decision of 8.12.94 in the case of "Relaxin". The patent related to a DNA fragment codifying for a human protein. The Office examined whether the invention would appear immoral for the vast majority of the public.

[107] As discussed above, either by choice, mistake or oversight.

REFERENCES

Ackermann, T. 1997. Dis'orderly loopholes: TRIPS patent protection, GATT and the ECJ. *Texas International Law Journal* 32: 489-510.

Anon. t.th. Stem Cell Patents: European Patent Law and Ethics Report, www.nottingham.ac.uk/law/StemCellProject/project.report.pdf.

August, R. 1997. *International Business Law.* New Jersey: Prentice Hall.

Bondure, S. & Farr, L.G. 1998. Intellectual property rights abroad and at home: After GATT. *South Carolina Lawyer* 7:20-27.

Boonf, K. Parallel imports in pharmaceuticals: increase access to HIV drugs, Unpublished proceedings from Thailand Law Forum, Bangkok, 1-3 June 2009.

Bostyn, S.J.R. 2003. Written requirement and description after Enzo Biochem: Can the real requirement step forward please. *Journal of the Patent and Trademark Office Society* 85:131-179.

Burk, D. 1991. Biotechnology and patent law: Fitting innovation to the procrustean bed. *Rutgers Computer & Technology Law Journal* 17: 1-60.

Champ, P. & Attaran, A. 2002. Patent rights and local working under the WTO TRIPS agreement: An analysis of US-Brazil patent dispute. *Yale Journal of International Law* 27: 365-398.

Correas, C. 2007. *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*. London: OUP.

Crespi, S. 2005. Enablement and written description-A trans-Atlantic view. *Journal of the Patent and Trademark Office Society* 87:343-388.

D. Bhagirath-lal. 1998. *An Introduction to the WTO Agreement.* Penang: Third World Network.

Derclaye, D. 2009. Patent law's role in the protection of the environment - re-assessing patent law and its justifications in the 21st century. *International Review of Intellectual Property and Competition Law*:1-15.

Di Cataldo, V. 2002. From the European patent to a community patent. *Columbia Journal of European Law* 8: 19-37.

Donavan, E. 2002. Beans, beeans, the patented fruit: The growing international conflict over ownership of life. *Layola of Los Angeles International & Comparative Law Review* 25:117-142.

Dutch Group to the Administrative Council of EPO. Unpublished Report Q 150 on Patentability Requirements and Scope of Protection of Expressed Sequence Tags (EST's), single Nucleotide Polymorphisms (SNP's) and Entire Genomes.

Gana, R. & Bagley, M. 2001. Patent first, ask questions later: Morality and biotechnology in patent law. *William and Mary Law Review* 45: 69-495.

Gervais, D. 1998. *TRIPS Agreements: Drafting History And Analysis.* London : Sweet & Maxwell.

Hans Morten, H. 2009. Human Rights and TRIPS Exclusion and Exception Provisionsection. *The Journal of World Intellectual Property* 11(5/6): 345–374.

History of WTO-TRIPS www.wto.org/history/TRIPS/country.

Jameson, S.A. 2007. A Comparison of the Patentability and Patent Scope of Biotechnology. Biotechnological Inventions in the United States and the European Union. *American Intellectual Property Law Annual Quarterly Journal* 35 (193): 202-238.

Long, D. 2003. The impact of foreign investment on indigenous culture: An intellectual property prospective. *North Carolina Journal of International Law and Commercial Regulation* 23: 229-256.

Malaysian Hansard HR. 1983. 1: 7767-7768 25 July.

Malaysia. 2005. *Biotechnology Report 2005*.

Malaysia. 2009. Plan Ekonomi Baru Malaysia 2009.

Malaysia. 2010. B*iotechnology Report 2010*.

Merges & Nelson. 2002. On the complex economics of patent scope. *Columbia Law Review* 90: 839.

Miller, D.K. 2010. A patent on the conscious: a theoretical perspective of the law on patentable life. *Journal of Animal Law & Policy*: 145-164.

Morret, P. 1996. *A Concise Guide To Intellectual Property Rights-Patent.* London: Longman.

Moufang, R. 1998. The Concept of "Ordre Public" and Morality in Patent Law. In Geertrui Van Overwalle (Ed.). *Patent Law, Ethics and Biotechnology*.

Bruxelles: Katholieke Universiteit Brussel.
Murphy, K. 2002. The traditional view of public policy and ordre public in private international law. *Colorado International & Comparative Law* 11: 591-620.
Nor Ashikin Mohamed Yusof. 2009. The third patentability requirement of patent; Still a constraint to Malaysia. *Journal Undang-Undang* 13: 52-75.
Nor Ashikin Mohamed Yusof. 2007. Biotechnological patents in developing countries in the post–TRIPS era. Ph.D thesis, University of Nottingham.
N. Seeratan. 2001. The negative impact of intellectual property rights on developing countries; An examination of the Indian pharmaceutical industry. (2001) *SCHOLAR; St. Mary law Review on Minority Issues* 3: 339-397.
Pepa, S. 1998. International trade and emerging genetic regulatory regimes. *Law & Policy International Business* 29: 415-444.
Skarstad, R. 1999. The European Union's self-defeating policy: Patent harmonization and the ban on human cloning. *University of Pennyslavania Journal of International Economic Law* 20: 353-378.
Standing Committee on the Law of Patents. 2009. *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*. Geneva: t.tp.
United Nations. 2005. United Nations High Commissioner for Human Rights Report 2005.
Wosawki, R. 1998. The evolution of patentable composition of matter: The United States Patent Office accepts genetically altered animals or patentable subject matter under 35 U.S C Section 101. *Administrative Law Journal* 2: 309-367.

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