Legal Policy Implication in Industrial Application Terminology as Second Patentability Requirement on Biotechnological Inventions

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Abstract

To establish the utility of biotechnology, a hybrid of basic science research and applied science invention, is not an easy task. The conviction becomes twice as hard in the case patent offices or courts traditionally acknowledge that only applied technology inventions are a patentable subject matter. This paper investigates the impacts of employing 'industrial applicability" and "useful" terminologies as choice terms for second patentability requirement. Countries can choose their terms of second patentability requirement. Malaysia has chosen industrial applicability. The concept, definition and standard of industrial applicability are comparatively higher compared to "useful" jurisdiction. The actual choice of terms is important, and more complicated, than mere preference of terms. The small details can potentially influence the future of an industry, and the rate of local technological progression. In the context of biotechnology, it determines the survival of the local players, as well as the budding local biotechnology industry. Ironically, it is neither the fault of policy makers, nor of law drafters. A part of the fault is attributed to the nature of biotechnology as an invention, and to the lack of technological capabilities of the key players in local biotechnology.

Keywords: patentability requirement, industrial applicability, biotechnological inventions, TRIPS

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Introduction

Patent laws are meant for doers, and not for dreamers. An invention must be different from a basic research, hence, the imposition of the second patentability requirement. An invention must have practical and specific use that is beneficial to the society as a whole (Torremans, 2012). This is the reason the law of nature, physical phenomena or abstract ideas are not patentable. The second patentability requirement demands inventors to prove and explain the practical use and benefits of their inventions, specifically so others could independently re-create them without the need to consult the original inventors, or to conduct further research (In Re Fiers, 1967). Legally and procedurally, inventors must demonstrate that their inventions are comparatively novel from prior art, and that they perform different functions from existing, readily-available inventions.

Universally, there are two terms associated with the second patentability requirement. Section 101 of the US Patent law apply the term “useful”, whereas the EU and the rest of the world apply the term “industrial applicability”. Both terms are acceptable under Article 27 of Trade-Related Aspects of Intellectual Property Rights (TRIPS). In fact, the footnote of Article 27(1) instructs member countries to deem both terms as synonymous. TRIPS is among World Trade Organization (WTO) agreements. It sets down minimum standards for many forms of intellectual property (IP) regulations for nationals of WTO members, including Malaysia. Most importantly, TRIPS is the first international document that grants patent protection to biotechnological inventions. Despite the instruction, TRIPS does not define the meanings of the term “industrial applicability” or “useful”. In the absence of any definitions, it has become a

legal norm for countries and courts to refer to legal provisions and judicial precedents of the US and EU for assistance and guidelines. These two jurisdictions have defined the terms considerably. Their experiences are useful for Malaysia and other developing countries of TRIPS, especially for those without patent law systems, and those that lack judicial precedents interpretations.

Based on the experiences and judicial precedents of both jurisdictions, the two terminologies may not necessarily be the same. Each reflects a different meaning. The "useful" concept is literally broader than "industrial applicability." They have different tests or standards in establishing utility. The choice of terminology would thus directly influence the decision of the patentability of the invention, as well as determining the scope of patents in both jurisdictions. Generally, certain inventions are patentable in one jurisdiction, but not in the other.

The second patentability requirement is applicable to all fields of technology, including biotechnology. Biotechnologists must initially satisfy the first patentability requirement (i.e., novelty). In this sense, their biotechnological inventions must be novel, and must have never existed in prior art, before proceeding to prove the utility of their biotechnological inventions. In proving the utility, it is important for biotechnologists to ensure that their inventions perform different functions than their readily-available counterparts. For example, biotechnologists must prove their genetically modified DNA functions differently from naturally occurring DNA.

This is where things get complicated for biotechnological inventions. Legally, if a process invention is only capable of producing a compound of no apparent use (In Re Kirk, 1967), both the process and the product are ineligible for patent per se (Brenner v Manson, 1966). Such a problem is more common in biotechnology than in other fields of technology. Biotechnologists are not always able to successfully identify the real functions and benefits of

their inventions. There are instances in which the invention, either as a process or a product, or both, are replicates the very same function performed by naturally occurring DNA or genes. Although biotechnologists manage to satisfy the second patentability requirement, they may, in this case, be trapped by the novelty requirement of the patent law instead.

This study focuses on modern biotechnology, since conventional biotechnology is not eligible for patent protection. It shall use the term biotechnology SMEs, since they are key players in the local biotechnology industry. It is to differentiate them from SMEs in other industries. Biotechnology SMEs refer to small and medium enterprises that use biological organisms, through various biotechnological techniques, for the development of products for the betterment humans and animals. Biotechnological processes or products can be used in biomedical, agriculture veterinary, food, environmental and industrial, and other biotechnology business activities (BIOTEK, 2001; National Pharmaceutical Control Bureau [NPCB], 2005).

The structure of this paper is as follows. Part I explains the policy behind the second patentability requirement. Part II discusses briefly the characters of biotechnology. Part III and IV discuss the second patentability requirement, and the two concepts of utility, respectively. Part V dwells on the application of the second patentability requirement in biotechnological inventions. Part VI focuses on judicial precedents from developed nations in interpreting the second patentability requirement, as well as the reasons for this. Part VII focuses solely on the impact of the choice terms for utility requirement on patenting biotechnological inventions in the context of Malaysia.

Methodology

This study adopts a qualitative approach, using both primary and secondary data. The data were collected from interviews, surveys, a comprehensive literature review, and government documents and statutes. The study samples comprise players in the biotechnology industry. The respondents are biotechnology SMEs accorded with Bionexus status. Bionexus status is accorded by the Malaysian BiotechCorp to target SMEs that have successfully satisfied stringent tests in proving their capacity and capabilities as biotechnology producers. As of January 2015, there existed 321 Bionexus SMEs in Malaysia. Survey instruments were distributed to all of them, of which a total of 290 responded. The data was analysed using SPSS version 2.0. The information obtained from the survey was used to build an overview of the Malaysian biotechnology industry, as stated in part VII of the study. Interviews were conducted with policy makers, and the Ministry of Domestic Trade, Consumers and Corporation and Attorney General Chambers, as the main governmental arms in charge of the execution of Patent Act. Results of the interviews were used to support and analyse the findings of this study.

Formal Definition

Utility is defined as usefulness (Concise Oxford, 1998), or the ability to satisfy the desire of society in general (Chambers, 1998), not for decoration, ornamentation or other aesthetic purposes (Webster, 2012). A Patent is awarded to inventions with practical use to the society (Newman v Quigg, 1989). The suggestion to use seawater as rocket fuel for space travel is a brilliant alternative solution to using fossil fuel. Yet, the same is illegible for patent protection. It is a bare idea per se, abstract in form. There is a lack of physical evidence to prove such idea is workable and doable. Furthermore, inventors need to build the rocket's prototype in order to separate between a working idea and a working invention. Even when someone manages to

create an operative multi-arms machine, there is no guarantee the same is patentable. Although inventors may have reduced their ideas into physical and tangible prototypes, they must show the use, function and benefits of the machine. In the current stage, the machines could be best regarded as incomplete working inventions, lacking practical function that is beneficial to the public.

Two Concepts of Utility

Globally, there are two different terms of the second patentability requirement. The US and the Philippines are the only two jurisdictions that use the terminology "useful". Malaysia, along with European countries and rest of the world, use the term "industrial applicability". Countries are free to choose their preferable term for the second patentability requirement. There is no legal reason behind such choice; it is rather attributable to historical factors. The Philippines was once under the rule of the US. Her patent law was based on the law of the former. Likewise, Malaysia was colonized by the British. Many of the Malaysian domestic laws are either based on, or adopted from, British laws. After independence, Malaysia continues using the same laws as found in the British laws. Therefore, when the British Patent Act 1944 uses the term "industrial applicability" as its second patentability requirement, it is no surprise to find almost identical provision and terminology in the Malaysian Patent Act 1983 (Parlimentary Hansard Report, 1983).

Section 16 of Patent Act 1983 adopts the same meaning of Article 57 of the European Patent Convention 1998 (EPC) in defining the term "industrial applicability". Ostensibly, Section 16 uses the same standard of industrial application as applied by the EU. This statement is made in view that the Malaysian courts are yet to have a real opportunity to deliberate on the appropriate standard of proof in proving the industrial application for biotechnological

inventions. To date, there remains no local case challenging or invalidating the patent awarded to biotechnological inventions on the ground of industrial application. The exercise of determining the definition, standard and proof is important. It shall define whether the applicable standard for industrial applicability should be low, to purposely fit and cater the needs of local biotechnologists; or high, so that the protected invention is of technical quality, hence, survives any potential legal challenge in the future. The information would further aid policy and law makers to determine whether to standardize the said standard for all fields of technology. This is regardless of the special requirements of biotechnology, or of the inability or disability of the locals in satisfying the said standard. These considerations shall later determine the success and future of both the biotechnological invention in question, the local biotechnology industry and the biotechnologists in generating income from the said patent. Until this occurs, it is most likely Malaysia patent offices or courts will adopt the same standard of industrial applicability of the EU, as a standardized standard to all fields of technology, biotechnology inclusive.

Biotechnological Invention

Modern biotechnology has many facets. It is important to appreciate them in order to understand the difficulties in identifying and establishing the utility of a biotechnological invention, as compared to inventions from other fields of technology. Biotechnological inventions revolve around the alteration and manipulation of deoxyribonucleic acid (DNA) and genes between transborder species (Miler, 1997). The DNA could be cut, re-joined or inserted with another string of DNA of same or different species, through genetic engineering. The technique could be applied and duplicated in various fields (Burk, 1991). This makes biotechnology a highly technical and technologically sophisticated field (Nor Ashikin, 2007). Those fantastically tiny DNA and genes are invisible to the naked eye, and could be found at a

molecular level. They are mixed with both wanted and unwanted genetic materials (Burk, 2002). Enormous initial investments and resources are required for numerous overlapping experiments and research to discover and extract the desired molecules, making biotechnology a research and material intensive field of technology (Burk, 2004). Once extracted, biotechnologists must use highly sensitive tools in a series of sophisticated procedures to ascertain, characterize and manipulate the molecules, with hope of identifying their use and functionality (Burk, 2003).

Complex and Unpredictable

Such an effort is often hampered by the nature of DNA, genes, gene sequences and molecular systems that are inherently complex, unpredictable and not clearly understood. There are many influencing factors for such predicaments. Humans are still unable to fully comprehend the manner in which the DNA and human body functions. Many of the genetic cells or their properties are still poorly characterized, understood or completely unknown (Yahya, 2001). Degeneracy of codons, a natural biological process is partly responsible for making biotechnology wholly unpredictable, and prone to produce radical results (Lin, 2011). It makes some genetic information for manufacturing protein at a molecular level disappear (Watson, 2004). This genetic information acts in a way that is similar to a recipe book. It contains coded information for the body to manufacture proteins, and subsequently determine and construct the building blocks of necessary amino acids in a linear arrangement. The arrangement of amino acids is vital, since it determines the function of each protein the body requires. It is, however possible to have more than one genetic code for the same proteins or amino acids. Thus, a removal or insertion of one amino acid in the protein linear structure may or may not radically affect the molecule's structure, properties or functionality. To certain extent, managing the

complexity of the cellular systems and unpredictability of the results is indeed a challenge of its own kind in the field of biotechnology.

Young Field of Studies

Modern biotechnology is less than 50 years old; a relatively young industry. Modern biotechnology was first patented in 1980. For this reason, there are plenty of unexplained scientific principles and expectations in the field (Cantor, 2000). It forces biotechnologists to adopt a trial-and-error approach pick at random methodologies in their R&D to confirm any ideas or results (Burk, 1994). Each input from their empirical research helps biotechnologists to form a better understanding of biotechnology as a science, and subsequently make it more predictable. The predictability is beneficial in predicting the use or parameters of the technology (Hunter, 1995). Until that happens, biotechnologists may have to carefully select potential successful cases and design the experiments surrounding it. For example, in order to insert a piece of DNA into one particular cell, thousands of cells must first be transfected. This is done with the knowledge that only a small percentage of the cells will take up the foreign DNA. If the biotechnologist is lucky, only a few cells would become stably integrated, and perform exactly as the new genetically engineered DNA instructs. This is why biotechnologists usually have low expectations for success at the beginning of their research project, unsure of its outcome or utility, and consequently the difficulties in meeting the mentioned requirements. The above demonstrates why R&D is becoming the pre-requisite requirement and backbone in every step of real progress.

Industrial Applicability as Utility

Before TRIPS, the EPC was the most widely known and discussed legal document using the term "industrial applicability" as its second patentability requirement (Recital 20, Recital 21, Article 1(3) of EPC). The meaning of industrial applicability is defined in Article 57 of EPC. An invention is deemed to have industrial applicability when it can be made or used in any kind of industry, including agriculture. The applicable test herein is whether the invention can be used and made on an industrial basis rather than what the invention can make or which industry could use that invention (ICOS Corporation, 2002, Singer & Saunders, 2003). This is because the term "industrial application" denotes that the invention could be carried out continuously (Chambers Dictionary, 1972) on a large-scale, independently (Chambers Dictionary, 1972), for the purpose of generating profit (Prime, 2000).

Biotechnological Invention and Industrial Applicability

In proving the industrial applicability of their biotechnological inventions, biotechnologists must initially prove that their creation has a function that benefits the public. Next they must prove how to make and use this biotechnological invention (ICOS Corporation, 2002). For example, in claiming patent protection for their genetically modified DNA or gene sequence, biotechnologists must state the function of the gene sequence, and then show how the DNA or gene sequence functions before explaining how to make the DNA or gene sequence, and use it. It is not sufficient for them to make bare claims that the compound in question is a genetically modified DNA or gene sequence, and it could produce certain encoded protein that is required for the human body. Such is a classic example of bare assertions. Instead, they must show that their DNA or gene sequence could produce amino acids required for the human body (e.g., to produce insulin to maintain and balance sugar level).

Biotechnologists must also prove that their DNA or gene sequence are indeed capable of being used and made on an industrial scale (ICOS Corporation, 2002). Otherwise, their claim would be construed as speculative and bare of any technical information (T870/04, Max-Planck, 2006). They could provide specific, substantial and credible evidence to assure the patent examiner that their claim is beyond mere speculation (Recital 23 of EPC). The supporting evidence could come in various forms, including direct clinical experiments, laboratory tests and experiments, reports, or human clinical data (Recital 23 OF EPC). For example, it is insufficient if biotechnologists merely state that their DNA or gene sequence is capable of producing protein on an industrial basis (Recitals 24 of EPC). They must also disclose the specific protein of the DNA or gene sequence, the "function" of that protein, the "profitable use" of that protein, and whether it could be produced or used on an industrial scale (Recital 24 of EPC). These are the types of technical and technological information which patent as a quid for quo system, wish to elicit from every patent claim (Gitter, 2001, Aerts, 2004).

Useful as Utility

US patent law is often cited as an example of a jurisdiction that uses the term and concept "useful" as its utility requirement. The requirement could be found in Section 101 of the US Patent Law.

Easier Old Standard

Before 1966, US courts have defined and interpreted the term "useful" rather broadly (Bedford v Hunt, 1817). It is defined as capable of being of use per se. The requirement is considered satisfied as long as the intended use is non-injurious to the general public. The interpretation sets a rather low standard that is easy and achievable. Generally, it is based on the idea that inventions would benefit the society at large, provided they are harmless to public

welfare. Such ideology could be traced directly to the US Constitution, Article 1, Section 8, Clause 8, which intends to promote "useful arts". Under those circumstances, the courts mainly focus on the "usefulness" of the invention by looking at the functions and capabilities of the invention (Graham v Deere, 1966). The use does not need to be better than state-of-the-art. Suffice if it is different (Bedford v Hunt, 1817). This approach is totally different from that of their European counterparts. Generally, even if the invention cannot be used or made in any industry, it is still eligible for patent protection. In satisfying the burden of proof of usefulness, it is acceptably sufficient when inventors merely insert and state the use and function of the invention. By today's standards, regardless of the field of technology, the Judge Story's doctrine is regarded as a very low standard of utility, and poses no real difficulties for the inventor to satisfy.

Higher New Standard

Brenner v Manson (1966) changed the above standard. This case is particularly relevant to biotechnology. Firstly, the facts of the case deal with chemical inventions, where its ruling and interpretation is equally applicable to biotechnology cases (Amgen v Chugai, 1991). Secondly, the court has raised the existing utility standard to a new level, directly affecting biotechnology. Lastly, it has defined and issued guidelines for proving and satisfying the utility requirement for biotechnological invention.

According to the facts, Brenner successfully produced a chemical compound of no immediate use. The compound could only be used as a research tool in furthering further scientific research. Brenner applied to patent both process and product inventions. He described that the process "is useful in producing a chemical compound in furthering other scientific research". He claimed the product compound is "useful" because the structure of his invented

compound is chemically similar to an existing compound of a known utility. Brenner therefore claims that his product invention would automatically have the same function as the existing compound. His argument is based on a similar chemical compound theory (Kubinyi, 1998). According to the theory, compounds of a similar linear structure would have similar properties, hence, similar functions (Johnson et al., 2013; Martin, Kofron, & Traphagen, 2002). Brenner believes his claim is sufficient enough to satisfy the utility requirement. In arriving at the decision, the trial judges took into consideration the intent of US patent law in promoting progression of arts and science through research culture. Bearing in mind that patent is capable of "blocking off the whole areas of scientific development", the court took a restrictive view in interpreting the utility provision. The court wanted Brenner to identify the invention's capabilities, its boundaries and proof of utility. The court is concerned if Brenner is allowed to enjoy the patent without specifically disclosing the real functions of his creation; he might from thereon exclude others from using the claimed invention, even in areas that are not legitimate use or exclusive to him. He then is barring others from developing the technology further, and thus generally restricting science and arts from being developed to their fullest capabilities. This is clearly against patent policy. It impedes further research, and ultimately, is detrimental to society. In view of the above, the court rejected both claims of patent protection. Despite Brenner's analogy in associating and applying the chemical structural similarity test, the court still disagrees, and is unwilling to do so. Acknowledging the unpredictability of the chemical compound, the court thinks that a mere similarity in chemical structure or properties does not necessarily lead to similarity in biological activity or function.

Functional When…

The court issued the following guidelines in proving and satisfying utility requirements. Three key elements must be present. The invention must in its current form and: (i) have practical utility; (ii) must be able to solve a specific problem; and (iii) must not be frivolous or injurious, but of real world value, and beneficial to the public. The mentioned are tentatively described as general, substantial specific and morality-safety utility requirements.

Proving Utility for Biotechnology Invention

When the above guidelines are applied to biotechnological invention, biotechnologists must generally demonstrate that their process invention has specific techniques, or is capable of producing a compound of certain capabilities (Diamond v Chakrabathy, 1980). If a process invention is capable of producing a compound, but the use of that compound is unknown, then the court has no option but to refuse patent protection on the grounds of lack of real-world utility.

The end product of the process too must have a definitive use (Diamond v Chakrabathy, 1980). In case of Brenner's, the compound could be used as a research tool intermediate. Though research tool might be useful in satisfying scientific curiosity or for academic and intellectual expansion, it is legally insufficient for patentability (In Re Kirk, 1967). Likewise, a mere claim that the invented compound has "biological activity", without clarifying the actual biological activity, is still vague, and too broad (In re Fiers, 1993). The specific function and the benefits of the process (Genetech Inc.'s Patent, 1989) and product (Parke-Davis v E. K. Mulford Co., 1912) invention must be stipulated in a clear and credible manner (Genetech Inc.'s Patent, 1989; Warren-Jones, 2003; Kunin, 2012). For example, if a biotechnologist claims his gene sequence is useful as a probe, he must disclose the targeted DNA specifically. Similarly, if he claims the gene is useful for diagnostic purposes, he must disclose the targeted disease or

conditions. He cannot leave the courts, patent examiners or other parties to speculate the function or benefits of the invention. Therefore, before applying for patent, biotechnologists need to know if their invention is of: (i) known, (ii) new, or (iii) unknown, utility. If the invented compound has a similar utility that of a known, existing or patented compound, it lacks novelty. Then perhaps only the process is patentable (Amgen v Chungai,, 1991). As rightly decided by Amgen v Chungai (1991), both new process and product of the process are eligible for patent protection, under the condition that the product has specific practical use. This is based on the same principle that a product is useful if it is capable of performing certain specific function(s). If the end product compound such as a genetically engineered cell, gene, gene sequence or DNA shows no immediate or unknown utility, the application to patent both the process and product compound of the process must be rejected (Brenner v Manson. 1966). The use of such a process is no other than producing a product of unknown use. So far a mere claim that a process is capable of producing a biotechnological compound in the form of DNA, molecules or gene sequence that is inherently capable of doing something inside living organisms, as originally intended by nature, is unacceptable; it is too general under the industrial applicability or useful rulings.

Furthermore, the product of nature doctrine also forbids patent offices from accepting it (Funk v Kalo, 1948). Nature has designed DNA, and the likes to be become operative and useful in replicating and synthesizing the necessary encoded protein. In the real world, biotechnologists must inform and prove the public the function and the use of their genetically invented or modified process, once they have inserted the DNA into a host cell (ICOS Corporation/Novel V28, 2002). Without specifying its ultimate function, an rDNA plasmid, for example, is none other than a strand of circular DNA (Amgen v Chungai,, 1991). This explains the reason courts

in both the USA and the EU remain reluctant to grant process invention with a patent solely based on its capability of producing a product of unknown function (Amgen v Chungai,, 1991, EPO Eli Lily, 2001). It still lacks immediate or "real-world value", as demanded by patent law.

Analysis: Impacts of Legal Policy

Apart from assisting biotechnologists to satisfy the written, disclosure and enablement clause of patent law, the second patentability requirement helps patent examiners to determine the mete and bounds of the claim invention, so that an appropriate scope of protection would be accorded (Newman v Quigg, 1989). The same shall consequently determine the technological outflow to technology users. However, when the same requirement is applied to biotechnology, it leaves some unexpected impacts on patenting generally, and biotechnology specifically, as well as the future of the local biotechnology industry. As a country which adopts an "industrial applicability" approach, Malaysia is not excluded from facing the same problems. Under certain circumstances, the situation might be worst for the country.

1. On Patenting.

Although the standard and burden of proof under both systems are streamlined with each other, under careful inspection, the term "industrial applicability" is comparatively a narrower scope and concept of utility compared to the term "useful". As long as the claim invention has certain practical use that is of benefit to the public, it is eligible for patent protection in "useful" jurisdictions. However, the same is not so acceptable in "industrial applicability" jurisdictions. In order to succeed, the claimant must go one extra mile in proving that his invention is capable of being used on an industrial basis.

Strictly based on EPC's experiences, it shall exclude certain inventions from patent protection. For instance, computer programs or methods of doing business are not eligible for

patent protection under EPC. Often, the European Patent Office (EPO) rejects such applications for lack of technical characters, and in turn industrial applicability. It merely carries extracts stores data (Muir, Brandi-Dohern, & Grubber, 2002). EPO is more comfortable to categorize them as discoveries. Comparatively, the same is patentable in the US due to their capability of carrying out some useful function. In that sense, patenting may become relatively easier in one jurisdiction, but not in another.

In terms patenting biotechnology invention, it is likely that the same term shall naturally exclude certain biotechnological process inventions used in surgery, diagnostics or therapeutics as methods for treating human or animal bodies for medicinal purposes, from patent. Though legally patentable under "useful" patent systems, European countries are historically and generally (Meshbesher, 2001) not keen to regard them as susceptible to industrial application (John Wyeth & Brother Ltd's Application, 1985). They are more comfortable in treating them as methods of treatment (Vaver, 2003). For example, gene therapy, a biotechnology invention and ground breaking medicinal treatment would be inadvertently excluded. Gene therapy is a treatment for patients who suffer certain genetic disorders or chronic disease. It replaces their gene(s). The use and ability to replace damaged or mutated gene(s) is considerably good and acceptable, and is thus patentable in "useful" jurisdictions instead. Morally, the invoked policy of keeping the activity in the field of human and veterinary medicine from patent is to protect the practice of medicine (Chambers, 2012).

A Patent could be disruptive with expensive results. Otherwise, medical professions must embark on lengthy negotiations on expensive licensing fees or royalty before being able to lay their hands on any valuable and lifesaving technology. Failure to do so would lead to a litigation threat. Both could affect the quality of the medical services provided to public. There is also a

possibility that the Patent would restrict the said professions from making available the best possible medical treatments (Mulcare, 1992). Due to licensing fees and royalty, only the rich could have access to the best medical services. Furthermore, the medical profession does not need Patent as an economic incentive to motivate them (Mulcare, 1992). Doctors do not need Patent to monopolize the market or protect their skills. They are highly sought after by clients, hence, enjoy certain an 'extra edge' in the market. They do not require any further financial inducement in providing the best medical services. They are duty bound by their professional codes of conduct and ethics. Additionally, the skills acquired by an individual through his or her career are exercised in the interests of a particular patient. The profession cannot forbid others from following or adopting their specific method of treatment, or demand the imitators, followers or students to pay them. As professionals, doctors are to share their knowledge, skills, and expertise for the benefits of the public in the widest possible areas.

2. On Biotechnology.

Considering the unique character of biotechnology, the task of satisfying and proving the real, practical utility or industrial applicability requirement is always easier said than done. Perhaps a non-issue in other fields of technology, currently, the standard bars in proving utility for biotechnological invention are too high for biotechnologists to satisfy. It is not a secret, due to the unpredictable and complex nature of DNA, genes, gene sequences or molecular cells, the main raw ingredients used in developing biotechnological inventions, biotechnologists at large could not prove the specific utility of their inventions in every case (Cantor, 2002).

The problems in identifying the utility of biotechnological compounds or molecules are heightened by the frequent use of host cells to express cultured foreign biological materials (T870/04 Max-Planck, 2006). When injected with a foreign genetic material, the host organism

may have problems in identifying or distinguishing the molecules within their bodies (T870/04 Max-Planck, 2006, Miler, 1997). Nature has programmed organisms in such a way that it can only recognize its own cells, and rejects other alien elements (Yahya, 2001). Once a foreign agent is detected, the host organism would send signals to the DNA to build necessary antibodies. Under normal circumstances, the antibodies are designed to act as a defence mechanism against defective native proteins or foreign aggression (Yahya, 2001). The natural enzymes produced therein may attack and destroy the unfamiliar cell injected by biotechnologists, and in turn makes the cultured cell toxic.

The whole process shall consequently affect the process of extracting and identifying the function of the cultured protein. The toxicity would pollute the cultured cell, making the process of identifying its function and use trickier (Burk, 2002). When it is hard for the biotechnologists to specifically predict the usefulness or actual function of their invention, it shall be twice as hard to contemplate its industrial applicability. The patent office is unlikely to see the logic of awarding Patent rights when the use of the invention is still unknown, or whether it would indeed be made or used in any kind of industry. Without really knowing its true capabilities, there are tendencies that some of the information revealed through empirical research is speculative. It is unknown whether the Patent offices or courts, when faced with the question on the acceptable degree of speculative information, are willing to legally accept it as utility.

3. On Future of Local Biotechnology Industry

Regardless of their choice term for utility, the standard under both terms is still a high barrier for local biotechnologists to meet. When biotechnologists from developed nations are constantly complaining of the burden of finding and ascertaining the utility of their inventions under both concepts, local experts would face the same problems, but in many folds. Malaysia's

biotechnology industry is dominated by biotechnology SMEs. They were formerly technology users. All are young players in this industry, with a small annual budget allocated for R&D activities, licensing fees and royalty.

In furtherance, many do not have their in-house R&D departments, but work together with universities or research institutes to conduct R&D. This is due to lack of expertise, technological facilities and financial resources. Almost all biotechnology SMEs have no more than two biotechnologists working for them on a permanent basis. Their financial resources are usually limited, coming out of their own pockets, or if lucky, grants or subsidies from the Government. Only a handful of the biotechnology SMEs interviewed are capable of providing between US$ 1 million to US$ 1.5 million for R&D. Such a sum is meagre. It becomes questionable whether the sum is sufficient or otherwise, since the initial investment for biotechnology spent on multiple parallel and repetitious R&D activities is usually high. They rely heavily upon imported and protected technology, which they have to purchase. All of these factors cumulatively make them less competitive in conducting further research. They might take a longer period of time than necessary. Once the true utility is discovered, their rivals from developed countries might have already obtained the Patent first.

The second patentability requirement places biotechnology SMEs in a fix. Undeniably, biotechnology SMEs need Patent protection to remain competitive. The 20-year protection supposedly acts as an economic incentive in helping them to recoup the initial investments, and fund further undertakings to sustain the business in the long run. However, they have shortcomings in satisfying the said requirement. As a chain reaction, these factors would determine the technological outflow and abilities to invent and innovate on a wide spread basis.

Any delay would eventually hamper the Government's short- or long-term plans to generate the local economy. Overall, it would affect the national plans for industrialization.

Conclusion

The small detail of having the "right" terminology of patentability requirement is crucial, and more complicated, than a mere preference of terms. It could influence the future of an industry, as well as the rate of local technological progression. In the context of biotechnology, it determines the survival of the local key players, and of the local biotechnology industry. Such a finding may be dampening to new players like Malaysia, in joining the biotechnology bandwagon.

Apparently, the term "useful" is more protective towards local inventors, encouraging them to indulge in research activity and reap rewards for their creativities. Eventually, it helps to satisfy Patent law's economic incentive, as reflected in US patent law history. Seemingly, Patent law with "industrial applicability" as a choice term is not able to cope with the challenges in providing sufficient economic incentive for biotechnologists to continue inventing. Ironically, it contradicts the very purpose of the Patent system. It potentially causes a decrease in research funds, and consequently, in the quality of service provided to the public (e.g., in medicinal treatment). It seems that countries with industrial application terms are losing out the Patent race to their counterparts with useful jurisdictions. It may leave inventors, the granting countries and the local biotechnology industry, in a state of patenting uncertainty.

It is almost unlikely for the government to discard the term "industrial application", and replace it with the term "useful", or other terms of the same effect. It is beyond imagination that the government is willing to do so simply because it wants to render the fullest support to the budding biotechnology industry. The motivation and reason d'etre is too weak and impractical. It

would also mean the government would in the future constantly modify the terms or requirements for patentability in order to cater the specific needs of any sunrise inventions or industry. It is always preferable for the government to maintain the industrial application as second patentability requirement. Although the standard of proof is high, the same could protect inventors from abusing the system on a wide spread basis, by claiming Patent for frivolous inventions. In the same context, biotechnology SMEs must from now onwards strengthen their technological capabilities and competitiveness in creating new inventions. They need to continuously improve and increase all efforts towards R&D. Only by so doing would they increase their chances in satisfying the high standards of the industrial application of second patentability requirement.

References

Aerts, R. J. (2004). *The industrial applicability and utility requirements for the patenting of genomic inventions: a comparison between European and US law*.

Amgen v. Chugai. (1989). 706 Supp. 94, 9 U.S.P.Q 2d. (BNA) 1833 (D. Mass) 94, 927 F.2d 1200 (Fed. Cir.1991).

Article 1(3) of European Patent Convention. (1998).

Article 57 of European Patent Convention. (1998).

Article 27 of TRIPS.

Article 29 of TRIPS.

Article 1, Section 8, Clause 8 of USA Constitution.

Bedford v Hunt 3 F. Cas. 37 (No.1217) (C.C.Mass.Ct.1033 1817).

Brenner v Manson 383 U.S.519, 534. (1966).

BIOTEK, 2001; National Pharmaceutical Control Bureau [NPCB]. (2005).

Burk, D. (2004). Biotechnology in the Federal Circuit: A clockwork lemon. 46 *Arizona Law Review* 441-455.

Burk, D. (2003). Tailoring patent policy to specific industries. *7 Marquette Intellectual Property Law Review.*

Burk, D. (2002). Is patent law technology specific? *17 Berkeley Technology Law Journal 1155-1192*.

Burk, D. (1994). Misappropriation of trade secrets in biotechnology licensing. 4 *Albany law Journal of Science and Technology*.

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

Cantor, A. E. (2000). Using the Written Description and Enablement Requirements to Limit Biotechnology Patents. *Harv. JL & Tech.*, *14*, 267.

Chambers, J. (2002). Patent Eligibility of Biotechnical Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy. *Geo. Wash. Int'l L. Rev.*, *34*, 223.

Chambers Dictionary. (1972), 4th Edition, Toronto; Wiley Pub., 1972.

Concise Oxford. (1998), 8th Edition, London; Oxford Publication, 1998.

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

EPO T24/95-OJ 2001, 103- Eli Lily.

Funk Bros. Seed Co v Kalo Inoculant Co., 333 U.S. 217, (1948).

Genetech Inc.'s Patent. (1989). R.P.C. 147 (Eng.C.A.1988).

Gitter, D. (2001). International conflicts over patenting human DNA sequences in the USA and the European Union: An argument for compulsory licensing and fair use exemption. 76 *New York University Law Review* 1623-1676.

Graham v Deere. (1966). 383 U.S 148 USPQ 459.

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

Hutter, J. (1995). A Definite and Permanent Idea-Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law, 28 J. Marshall L. Rev. 687 (1995). *The John Marshall Law Review*,*28*(3), 9.

In re Fiers 984 F. 2d 1164 (Fed. Cir 1993).

In re Kirk. 376 F 2d. 936 (C.C.P.A 1967).

John Wyeth & Brother Ltd's Application, Schering Application. (1985). RPC 545.

Johnson, M., Vogt, S. & Bajorath. (2013). Concepts and Applications of Molecular Similarity. *New York: John Willey & Sons*.

Karczewski, L. (2000). Biotechnological gene patent applications: The implications of the USPTO written description requirement guidelines on the biotechnology industry. *31 McGeorge Law Review 1043-1088*

Kubinyi, H. (1998). Similarity and dissimilarity: a medicinal chemist's view. Perspectives in Drug Discovery and Design, 9, 225-252.

Kunin, S. G. (2000). Written Description Guidelines and Utility Guidelines. J. Pat. & Trademark Off. Soc'y, 82, 77.

Lin, Q. (1999). Proposed Test for Applying the Doctrine of Equivalents to Biotechnology Inventions: the Nonobviousness Test, A. *Wash. L. Rev.*, *74*, 885.

Martin, Y. C., Kofron, J. L., & Traphagen, L. M. (2002). Do structurally similar molecules have similar biological activity?. Journal of medicinal chemistry, 45(19), 4350-4358.

Miler, C. (1997). Patent law and human genomics. 26 *Capital University Law Review* 893-917.

Miller, T. R. (1993). Motivation and Set-Size: In Re Bell Provides a Link Between Chemical and Biochemical Patent Claims. *U. Balt. Intell. Prop. LJ*, *2*, 89.

Muir, I., Brandi-Dohrn, M., & Gruber, S. (2002). *European patent law: Law and procedure under the EPC and PCT*. OXFORD university press.

Mulcare, M. F. (1991). International Patent Protection: A First Step Towards Curing AIDS. *Suffolk Transnat'l LJ*, *15*, 648.

Meshbesher, T. (2001). The role of history in comparative patent law. *1 Patent & Trademark Office Society 594-653.*

Newman v Quigg. (1989). 877 F.2d. 1575, 1581, 11 USPQ 2d. 1340, 1345, modified, 886 F.2d. (Fed. Cir. 1989).

Yusof, N.A., (2007). Biotechnological patents for developing countries in post TRIPS era. PhD thesis. University of Nottingham, UK.

Parke-Davis & Co. v. H.K. Mulford & Co. 196 F. 496 (2d. Cir. 1912).

Parliamentary (Malaysia) Hansard HR vol 1 (25 July 1983).

Prime, T. (2000). European Intellectual Property Law. Ashgate: Dartmouth Publishing, 2000.

Recital 20 of European Patent Convention. (1998).

Recital 21 of European Patent Convention. (1998).

Recital 23 of European Patent Convention. (1998).

Recital 24 of European Patent Convention. (1998).

Section 16 of Patent Act. (1983).

Section 101 of U.S Patent law.

Singer/Stauder. (2003). The European Patent Convention. A commentary. 3rd Ed. Vol. 1 Preamble to Art. 89. *London; Sweet & Maxwell*. 2003.

T870/04, Max-Planck. (2006). E.P.O R. at [18]-[20].

Torremans, P. (2012). *Intellectual property law.* 11th Ed. Oxford: University Press, 2012.

Vaver, D. (2003). Invention in patent law: A review and modest proposal. *11 International Journal of Law & Information Technology* 286-306.

Watson, J. (2004). DNA The secret of life, London: Arrow books.

Warren-Jones, A. (2003). Patenting DNA: A lot of controversy over a little intangibility. 12 *Medical Law Review* 97-125.

Webster Dictionary. (2012). 15th Edition, New York*; Tristar Publication*, 2012.

Yahya, H. (2001a). The Evolution Deceit. 6th Ed. *Kultur Publishing*, *Istanbul*, 2001.

Yahya, H. (2001b). For men of understanding. 2nd ed. *Ta-Ha Publishers Ltd*, London, 2001.