



Industrial Application As Utility Requirement and the Future of Malaysian Biotechnology Industry

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INTRODUCTION

Patent law only protects practical works of arts and not ideas or concept. This has always been the basis of the second patentability requirement. Philosophically it is to separate basic research science from applied science, avoids protecting premature, unwarranted, frivolous or injurious invention. Procedurally inventor must demonstrate the specific function, practical benefits and how to use the invention. Otherwise he must conduct further research to perfect the invention until the real utility, capabilities and parameters of the same are known finally.

CHARACTERS OF BIOTECHNOLOGICAL INVENTION

Biotechnological invention has many facets with specific characters. Some might be unique to biotechnology alone. It is important to appreciate them in order to understand the required capabilities in satisfying the second patentability requirement. Biotechnology is a highly technical and technologically sophisticated invention since it revolves around alteration and manipulation of deoxyribonucleic acid (DNA) and genes between same or transborder species through genetic engineering techniques. The transgenic nature of biotechnology inherently makes it controversial on morality, ethics, social acceptance, safety, environmental and health grounds. Lots of genetic materials are used in R&D to discover and extract the desired molecules and subsequently ascertain, characterize and manipulate the molecules with hope of identifying their true use and function in series of technologically sophisticated procedures. Such undertaking may take a longer time and costly. The effort could be hampered by the inherently complex, not fully understood or unpredictable character of DNA, genes and cellular system. A hybrid between science based research and applied science, biotechnology blurs the demarcation line, making it hard to clearly identify biotechnology's utilities beyond the academic realms. At times biotechnology tends to lean more towards research and expansion of knowledge. It might be hard to convince patent office that such invention has practical utility, since the same has traditionally interpreted patentable subject matter is only for applied technology inventions.

CHARACTERS AND CAPABILITIES OF LOCAL BIOTECHNOLOGY PLAYERS

Majority of Malaysian biotechnology players are private small or medium size family business enterprises with small working capital and consequently annual budget. Most were previously technology users, new to the industry, had little or no experience as technology producers and rely on protected foreign technology. Access to latest technology is largely through licensing. Some are keen in employing family members with no technological background in biotechnology to head the R & D department or senior posts in the company. Only 6 % of biotechnology companies have the desired state of art R&D facilities but they lack qualified employees to fully utilize them. 45% of biotechnology companies do not have any R&D facilities at all. They partnered with public research institutes or universities in conducting the R&D instead. Shortages of experienced-knowledge workers like intellec-

tual property experts, researchers, biotechnologist, genetic engineers, or computer programmer are common problems. The academic qualification of experienced-knowledge is not so-highly qualified as those found in developed nations. This affects their confidence in understanding and mastering the technological skill to conduct R&D to potentially produce new products.

UTILITY REQUIREMENT

Article 27 of Agreement on Trade Related Issues of Intellectual Property Rights (TRIPS) accepts industrial applicability and useful as second patentability requirement. Members can choose the preferred term. TRIPS deems them as synonymous. Malaysia chose industrial applicability. The choice of term is important and far more complicated than mere preference of terms. The two may not necessarily be the same. Each reflects a different meaning and standard. TRIPS phrased the utility requirement as the same as patent laws of developed nations. TRIPS impliedly expects members to use the same standard as developed nations in interpreting and applying the same. Certain inventions are patentable in one jurisdictions but not the other. It could influent the future of an industry and rate of technological progression locally. In furtherance Article 27. 2 of TRIPS permit patent office to reject a perfectly patentable invention from patent protection on ethics, safety, morality or environmental grounds.

USEFUL

Only the United States of America and the Philippines are using useful as their utility requirement. Legally they have defined the term broadly. The invention must be capable of use per se, thus easier to satisfy. It focuses on the "usefulness" of the invention, by looking at the practical function and capabilities of the claim invention. The intended use of invention must not injure or harm the general public. Three key elements must be present in proving utility for biotechnological invention. The invention must in its current form (i) has practical use, (ii) able to solve specific problem (iii) with real world value, beneficial to the society, not frivolous or injurious. For example if biotechnologist claims gene probe as the utility of his DNA sequence, he must disclose the targeted DNA specifically.

INDUSTRIAL APPLICABILITY

By definition, an invention is of "industrial applicability" when it can be made or used in any kind of industry including agriculture. The test is whether the invention can be used and made on industrial basis rather than what can the invention make or which industry could use it. In satisfying the utility requirement, biotechnologist must disclose the specific, credible and beyond speculation the use and function of his invention through evidences. For example, it is insufficient for biotechnologist to claim his DNA sequence produces protein on industrial basis. He must show the specific function and benefits of the protein on potentially profitable basis. Otherwise his assertion remains speculative, not containing any technical information thus non-patentable.

NARROWER CONCEPT

Generally both systems have the same the standard and burden of prove in satisfying the utility requirement. Both expect biotechnological invention to have specific function, with practical real world use that benefits the public. Claims like a process is capable of (i) producing a biotechnological compound or a product in the form of DNA and gene sequence or (ii) inherently capable of doing something inside living organisms as originally intended by nature are too general and unacceptable in both systems. Without specifying the ultimate function, a rDNA plasmid for example is none other than a strand of circular DNA. It is not until the molecule is inserted into a host cell that the DNA becomes operative and useful in replication and synthesizing the encoded protein.

At closer look, the term industrial applicability comparatively has narrower concept and scope than useful. It is still insufficient to prove the biotechnological invention has specific function, practical use in real world and non injurious. Biotechnologist must go one extra step in proving his invention has potential in generating profits commercially.

Learning from the experiences of United States of America and European Union, the choice term shall render certain biotechnological inventions ineligible for patent protection. It naturally excludes biotechnological invention used for medicinal purposes in surgery, diagnostic, or therapeutic treatment. Undoubtedly these methods of treatment are useful thus patentable under "useful" jurisdictions but not industrial applicability jurisdictions. Understandingly such policy is to protect the medical professions and encourage them to offer the best medical treatment to all. Otherwise hospitals or doctors have to pay licensing fees before laying their hands on the technology or liable for legal suit.

TOO HIGH FOR LOCAL BIOTECHNOLOGY PLAYERS

Currently the standard bar of industrial application is too high for invention from any field of technology to meet. The bar has been heightened further for biotechnology. On top of that, there are the safety and morality barriers to overcome. Due to biotechnological invention's unique characteristics and weakness of local biotechnology players, the task of satisfying the utility and safety requirements is easier said than done. The local players lack the necessary expertise, capacity or technological capabilities and infrastructure. Even biotechnologists from developed nations largely complained of their disabilities in proving the specific utility of invention in every case. Often the biotechnological inventions are without known immediate use or useful for research only. Without indentifying the invention's true capabilities, some of the empirical research based information might be speculative. Patent office is unlikely to see the logic of awarding such invention with patent protection. Likewise when it is hard for

the biotechnologist to specifically predict the usefulness or actual function of his invention, it shall be twice harder contemplating its industrial applicability.

SAFETY OR MORALITY REQUIREMENT

Positively the safety and morality requirements protect the public from any hidden risks probably caused by biotechnological inventions or treated as guinea pigs in a vast biotechnology experiment by unscrupulous few. Biotechnologist shall continue to face insurmountable battle against patent office, courts and public in proving the morality or safety of his invention. Whether the benefits out-weigh the risks so much so our morality accedes to patenting it would always be questioned. This is where the uncertainty starts. The concept or degree of safety, morality and immorality has no fix answers. It changes with time, people and places, even within a single country at a single time. People naturally have a second thought. The adopted standards adopted may differ from one society to the next. As such the patentability of biotechnology invention would always dependable upon "sense of righteous" of the granting country leading to divergence of thoughts and results amongst worldwide communities.

SLOW DOWN OF TECHNOLOGICAL PROGRESSION

Patent law system demands certainty about the practical function, benefits and use- industrial application as well as the safety of biotechnological invention before patent protection is awarded. Biotechnologist may have to delay and continue conducting further research. If rich and large biotechnology companies in developed nations constantly complaining of the financial burden of finding and ascertaining them, the local biotechnology players would likely face the same problems twice harder. Their willpower, capabilities and resources would be stretch to the limit in pursuing the safety requirement too due to lack of technological capacity, capability and infrastructure. They have to consider and include the safety and morality analysis, which comprise of complete scientific data and information analyzing the impacts of invention to society when planning their future or applying for patent. Again it mandated research activities and investigations.

The high standard of utility requirements would delay local players from applying for patent protection and consequently hamper the dissemination of protected information to technology users. Most local players are heavily dependent on protected foreign technology, accessible provided they could afford the high price. As such the technology transfer would decrease and Malaysia as a whole would face a more acute problem of technological flow and adoption of technology than before. The biotechnology industry would take longer time to fully blossom.

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