Biotechnology Law Policy For Developing Countries: The Third Patentability Requirement Is Still A Constraint

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ABSTRACT

Biotechnology either as a subject matter or invention and the act of patenting are relatively new to many developing countries. Biotechnological invention has limitless potentials. It is particularly important to pharmaceutical, medicinal, drug, chemicals, foods and agricultural industries worldwide. Developing countries could take advantage of the mandatory obligations of TRIPS as they have abundance of genetic resources. By supplying raw ingredients for biotechnology they may occupy the position of biotechnology producers globally. . This looks even brighter due to the current trend in patenting the same where the bar for non-obvious has been lowered drastically. This note explores on how the above current intellectual property trend and policy particularly in context of biotechnology law purportedly benefiting developing countries are putting constraints upon many of them instead. Firstly some background facts of TRIPS, which governs patent and is binding upon every country member domestically are presented. It then briefly explains biotechnology invention, the basic patentability requirements and the new trend of judicial courts in developed nations in interpreting the non-obvious requirement and reasons for doing so. Finally, the study will examine the disabilities of developing countries in overcoming even the much lowered standard of non-obvious requirement. This paper also points out that there are still many major tasks undone at national level which are hampering them from producing their first biotechnological invention or becoming active biotechnological producers.

Keywords: *biotechnological invention; patentability of biotechnological invention; patent; TRIPS; Art. 27 of TRIPS; developing countries; non-obvious requirement.*

ABSTRAK

Bioteknologi sebagai satu perkara atau reka cipta dan tindakan mempatenkannya merupakan sesuatu yang baru kepada negara membangun. Reka cipta bioteknologi mempunyai potensi yang tidak terhad dan sangat penting kepada industri phamasutikal, perubatan, kimia, makanan dan pertanian di seluruh dunia. Negara membangun boleh mengambil kesempatan ke atas peruntukan mandatori TRIPS memandangkan mereka mempunyai sumber genetic yang banyak. Dengan membekalkan bahan mentah asas bioteknologi, negara-negara ini berupaya menjadi pengeluar bioteknologi di peringkat antarabangsa. Situasi ini nampaknya cerah memandangkan negara maju telah memulakan trend melonggarkan syarat ke-tiga untuk mendapatkan paten dengan drastiknya. Kajian ini mengkaji bagaimana trend semasa di atas yang sepatutnya membantu dan mendatangkan kebaikan kepada negara membangun mewujudkan keadaan yang sebaliknya. Fakta tentang TRIPS yang mengawal paten dan mengikat semua negara ahli di peringkat domestik akan dibentangkan sebagai latarbelakang. Ia kemudiannya

menerangkan tentang bioteknologi sebagai invensi, syarat asas mendapatkan paten dan trend baru di kalangan mahkamah di negara maju dalam mentafsirkan kehendak syarat ke-tiga mendapatkan paten serta alasan mereka berbuat demikian akan diterangkan. Akhir sekali, kajian ini akan membentangkan hujah-hujah ketidakupayaan negara membangun untuk mengatasi syarat ke-tiga yang telah dilonggarkan itu. Ada banyak lagi kerja serta tanggungjawab yang belum dilaksanakan di peringkat nasional yang menghalang mereka daripada mengeluarkan produk bioteknologi atau menjadi negara pengeluar bioteknologi yang aktif.

Katakunci: *rekacipta bioteknologi; kebolehpatenan reka cipta bioteknologi; paten; TRIPS; Art. 27 of TRIPS; negara membangun; syarat ' non obvious '.*

INTRODUCTION

The courts[1] of United State of America[2] have recently interpreted the non-obvious[3] requirement of patent law for biotechnological product leniently. This is possible typically because TRIPS does not specifically stipulate what test or standard to apply. Since patent law is always a matter of national jurisdiction members are free to set a low or high bar[4]of standard as preferred. Consequently it shall lead to a varying degree of non-obviousness standard amongst subscribing countries. Although the judicial precedents are applicable to domestic jurisdictions, they nonetheless have international impact. Depending on which lines of case or applicable standard for non-obviousness is adopted[5], inventive step could principally be found in one jurisdiction but not the other. Since the European Union[6] adopts a higher standard of non-obviousness as compared to US, the EU has the tendency of frequently rejecting patent application for lack of inventiveness. On the other hand, with the lowered standard for non-obviousness, the US patent law is becoming more competitive and appealing internationally. Such drastic move makes patenting biotechnological invention much easier than before or in any other jurisdictions thus opening the floodgates of patent rights.

Theoretically if developing countries adopt the same approach above they would have the equal opportunity of becoming key producers of biotechnological inventions internationally. This note explores on how the above current intellectual property trend and policy particularly in context of biotechnology law purportedly benefiting developing countries is putting constraint upon many of them instead. Attention is focused on biotechnology invention and industry since they are still new to many, especially those in developing countries generally. Logically developing countries should more actively

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[1] The US(as well as the European Union) cases and patent laws in particular are most frequently referred to and cited in most writings in interpreting the patentability requirements.

[2] Hereinafter referred as the US.

[3] The term non-obvious is interchangeably used with inventive steps. TRIPS documents permits this. See the footnote for Art. 27 of TRIPS.

[4] *In re Deuel*, 51 F.3d, 1552,(Fed. Cir. 1995) p. 34.

[5] These decisions become more relevant especially in countries where they are unfamiliar with biotechnology law, without judicial precedents or have no biotechnology law or policy in place.

[6] Hereinafter referred as the EU countries.

promote biotechnology[7] as a new industry thus economic source for its populations and consequently a better quality of life for the whole nation generally. As the guardian of tropical forests most of them are naturally endowed with biodiversity and genetic resources the main raw ingredients for biotechnological inventions in bountiful, in their backyards. This extra advantage gives them the head-jump over other countries, even amongst the more developed and biotechnological producers' nations that are usually poor in terms of biodiversity. They could potentially exploit these resources positively. Some of them are more developed than their other counterparts[8] and subsequently the ability to provide the skilled human resources and other physical infrastructures needed for such highly complicated and technical endeavour locally. The legal infrastructure for biotechnology industry is equally ready. As members of World Trade Organization[9]/TRIPS[10], many have amended their existing or pass new patent law to be in line with the mandatory provisions of Art. 27 of TRIPS. Prior to this discussion, it may be appropriate to note that the study intends to provide policy arguments rather than theoretical socio-legal analysis. It has to be pointed out that strict empirical considerations are not the yardstick for analysis. However, basic socio-economic, political and legal considerations provide the basis for discussion on cost and benefits of the biotechnological patents policy in developing countries generally.

The article first provides some background facts of TRIPS[11] being the latest and so far the most powerful international trade agreements governs patent. It explains how TRIPS is applied to and in every member country biotechnology's industry domestically. Part II briefly explains about biotechnology invention. Part III dwells on the basic requirements of the patentability test and patentability of biotechnological invention. Part IV shall focus on the new trend of judicial courts in developed nations in interpreting the non-obvious requirement and reasons for so doing. Due to the constreints of writing, this article shall focus solely on the impact of the lowered non-obvious requirement on biotechnological product patent in developing countries only. Part V shall argue the disabilities of developing countries in overcoming even the much lowered standard of non-obvious. There are still amny major tasks undone at national level which are hampering them from producing their first biotechnological invention or becoming active biotechnological producers.

I. TRIPS

All subscribing countries to WTO[12] are legally obliged to accept the TRIPS document, one of WTO's 13 annexure. TRIPS document is legally significant. It is the first international document that is willing to grant patent protection to biotechnological invention.[13] It is

[7] Refers and discusses about modern biotechnology as the traditional biotechnology process or product such as crossbred plants, seeds or animals are limited in capability and not protected by utility patent.

[8] G.H Brundtland, Report of the World Commission on Environment and Development entitled *"Our common future"*, London, Oxford Univ. Press, 1987, p.47, K. Hossein, *The right to development in international law*", Ed S.R. Chorudhurry et al, Martinius Nijhoft Pub, Doerdecht, 1995, p.34-54 .

[9] Hereinafter referred as WTO.

[10] Agreeement on Trade RelatedAspects of Intellectual Property Rights 1994.

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

[12] Hereinafter referred as the WTO.

[13] Triggered by the decision of *Diamomd v Chakrabarty*, discussed below, which prompted biotechnologists, lobbyists and governments supporting them to make biotechnology an acceptable patentable subject matter globally, and encourages others to follow. Their efforts were handsomely rewarded when TRIPS is born.

equally very powerful since it enjoys an intrusive jurisdiction. Members are firstly bound by agreements they signed under its banner and must uphold promised rights to other countries.[14] Secondly other countries could challenge another's actions as violating a specific WTO agreement or principle by bringing the issue before the Disputes Resolution Body (DRB).[15] If a country loses a dispute and does not cooperate and abide by the DRB's decision, the WTO then can authorize trade sanctions against the losing party.[16] It also gives rights to the aggrieved party to initiate a personal legal action against the infringer personally as well as his home country.[17] In regards to international patent law, TRIPS expects member countries to grant patent right to "any inventions, whether product or process, in all filed of technology[18], provided they are new, involve an inventive step and capable of industrial application"[19] for a period of at least 20 years.[20] All country members are obliged to comply with this minimum general requirement. However they are "free to determine the appropriate method of implementing the provisions of this Agreement with their own legal system and practice".[21] Practically the legislative body of each country member must enact and pass a new patent right law or amend the existing law to be in line with TRIPS's requirements on individual basis.[22] They are permitted to enact stronger patent laws policies and patent protection than what is specified in TRIPS. Major industrial players, primarily based in wealthy nations have historically lobbied for increased protection above and beyond the minimum standards outlined by TRIPS. For example many US based medicinal drugs and pharmaceutical industries that rely heavily on patent protection have consistently funded large campaigns in support of enacting and enforcing more stringent patent laws.[23] Increased level of patent protection is associated with higher profitability thus the willingness to invest in efforts towards that direction.

II. BIOTECHNOLOGY INVENTION

Modern biotechnology revolves around selective crossbreeding technique at molecular level called genetic engineering. It alters DNA (deoxyribonucleic acid) and genes, the genetic make-up of living organisms and manipulated them in any directed way.[24] This is because DNA contains complete instructions for bodies to produce what or which necessary proteins so that they can continue their existence in a recognizable form,[25] grow

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[14] Art. 60 of TRIPS.
[15] Art. 64 of TRIPS.
[16] Art. 68 of TRIPS.
[17] *Ibid.*
[18] The general words of Art. 27 of TRIPS ostensibly include biotechnology invention or any other sunrise invention created in the future, regardless of its nature or controversies it stirs. This is good news to biotechnologist, biotechnology as an invention or industry or any countries that are interested in joining the biotechnology industries communities.
[19] Art. 27 of TRIPS.
[20] Art. 31 of TRIPS.
[21] Art. 1 of TRIPS.
[22] Malaysia has legally fulfilled that legal obligation when the Legislative body amended the existing Patent Law Act 1993 in 1998.
[23] P. Kameri-Mbote, Patents and development. http://www.ielcr.org/content/a9401.pdf. (4.4.2003).
[24] Something impossible to do under conventional biotechnology due to its inability to cross specie borders.
[25] Courteney Millier. Patent law and human genomics. *26 Capital University Law Review 893*, p. 896.

and carry on their functions[26] on daily basis.[27] For example, biotechnologist can combine the genes responsible in making a firefly glows with genes strand of a maize to produce a glowing maize. Technological advancement in genetics has made it possible for human to alter and manipulate the genetic makeup between transborder species no matter how distance, such as plants, animals or any living organisms as desired. Biotechnologist only requires their DNA as the raw ingredient to create a new breed of viable offspring. These techniques could be applied in various fields.[28] By virtue of Art. 27 of TRIPS, both the DNA and genes used as the starting ingredients, process to produce the end products and the produced end product are eligible for patent protection. The biotechnologist then could enjoy a very wide scope of protection of his invention and in most probability would have almost a complete monopoly of the same. As the exclusive rights holder, he could exclude others from dealing with his patented invention in whatsoever manner unless by way of licensing fees and royalty.[29] Obviously businessmen and investors' communities are keen to get involve[30] with the final intention of converting such inventions into marketable products[31] so much so it triggers a new business interest and opportunities domestically or internationally.

Patentability of biotechnological invention

Biotechnology[32] as patentable subject matter is relatively a new phenomenon.[33] It started with the case of *Diamond v Chakrabarty*[34] before becoming an international mandatory requirement.[35] Chakrabarty wanted to protect his genetically engineered Pseudomas bacterium[36] with enhanced hydrocarbon degradative properties with both process[37] and product patent.[38] His application for product patent was rejected by the US Patent and Trademark Office (USPTO)[39], Patent and Trademark Office Board of Appeal[40](PTO Board of Appeal) and Courts of Customs and Patent Appeals(CCPA).[41] The Supreme Court however reversed those decisions.

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[26] *Ibid.*

[27] Despite their apparent differences in physical appearance, such structure is alike for every form of lives. By virtue of modern science, the same could now be easily transferable and extracted out from blood, semen or skin of a specimen. James Watson. *DNA The secret of life*, London: Arrow books, 2004, p. 42.

[28] D. Burk Biotechnology and patent law: Fitting innovation to the procrustean bed. 17 Rutgers Computer & Technology Law Journal 1-60, p. 8

[29] Art. 28 of TRIPS.

[30] K. Ives, The benefits of biotechnology, the intersections of GATT/WTO and other trade issues. 10 Michigan state University-DCL Journal of International Law 13-22 p. 18.

[31] Ibid.

[32] Despite existed for centuries patenting modern biotechnology only started in 1980.

[33] Though it is not the first case that ever attempted but it is the first application that succeeds.

[34] Diamond v Chakrabarty US S. Ct. 1980 447 U.S. 303, 100 S. Ct 2204 65 L.Ed. 2d, 206 USPQ 193. By virtue of the same it is now possible for inventor to apply for a patent for his invention involving biological material under US patent law .

[35] Art. 27.1 o TRIPS, by inference.

[36] In nature, the bacterium only has one plasmid, whereas here it has two.

[37] For the process of producing such bacterium.

[38] For the bacterium per se.

[39] US Patent and Trade Office.

[40] The PTO agrees with Chakrabarty that his bacterium is a non-natural occurring organism thus willing to grant patent but it is legally incapable of so doing. The Board concluded that S.101 does not intend to extend patent protection to living things.

[41] Courts of Customs and Patent Appeal.

Comparatively Chakrabarty's bacterium is very different from those of *Funk v Kalo*.[42] His bacterium has shown new trait, different in structure and character.[43] His inventiveness in using the natural occurring bacterium as raw ingredients to manufacture the new and useful bacterium[44] renders it eligible for patent protection. The court also accepted the bacterium as an invented process, manufacture or composition under the purview of S.101. The term "manufacture" in S.101[45] is read in accordance with the dictionary's definition[46] which is defined as "the production of articles for use from raw or prepared materials by giving these material new forms, qualities, properties or combinations, whether by hand or by machinery".[47]

Similarly, "composition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they are gases, fluids, powders or solids."[48] In both contexts, Chakrabarty fulfils the said definition and satisfied its requirement. He can patent the bacterium as product manufacture and composition of matters. He too could patent the process to produce the bacterium since it is clearly a manmade process.

III. PATENTABILITY REQUIREMENTS

In order to enjoy the patent protection, biotechnologist must prove that his biotechnological invention is novel, has industrial application and non-obvious[49].

(i) Novel

Biotechnological invention is considered new if it is different from others, never existed-invented, patented, sold, used, written, published or known to the public before[50].

(ii) Industrial application/ useful[51]

As applied technology[52], invention must be of practical use[53] too. The biotechnological

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[42] *Funk Bros. Seed Co v Kalo Inoculant Co.*, 333 U.S. 217, (1948). p.217 .

[43] In light of this the courts affirmed the decision of *Funk v Kalo*. They are discovery per se.

[44] *Diamond v Chakrabarty, Ibid.*

[45] There is no need to consider whether the invention is a machine or otherwise since it is obviously not. *Ibid*, at p. 2210.

[46] *Ibid.*

[47] *American Fruit Growers, Inc v Brogdex Co.*,283 U.S. 1, 11, 51 S. Ct. 328. (1931) p. 283.

[48] *Funk Bros. Seed Co v Kalo Inoculant Co.*,(1948), p. 217.

[49] As found in Art. 27 of TRIPS or domestic patent laws worldwide.

[50] *Funk v Kalo* 333 U.S. 217, (1948) at p. 129.

[51] Both terms are acceptable as Art 27 and footnote of Art. 27 of TRIPS use them interchangeably. If the country in question adopts "useful" as its second patentability term, then it is sufficient for biotechnologist to merely show that his biotechnological invention has certain practical function and benefits the public. In context of "industrial application" the biotechnologist has to go one step further and proves that his invention is capable of being produced on industrial scale. *ICOS Corporation/Novel V28 seven transmembrane receptor*. O.J.EPO 6/2002.

[52] Carlos Correas. Public health and patent legislation in developing countries. *3Tulane Journal of Technology and Intellectual Property 1*, p. 12 .

[53] *Graham v John Deere Co.* , 383 U.S. 1, 9 (1966) .

invention must be functional and is beneficial to the public. By the same accord, bio-technologist must show how to make and use the same.[54]

(iii) Inventive steps/Non-obvious

Invention must be non-obvious, unusual, innovative and of high quality technologically.[55] This is to eliminate patent application over a cosmetic changed invention, regardless how hefty the financial investment, laborious and lengthy those researches[56] are.

Non- obviousness assessment

Procedurally patent examiner must access the non-obviousness of the claimed invention from the ordinary skilled person in the art's point of view[57] and at the time the invention was created to avoid circumstances where he is dazzled by the complications of terms or technology. The ordinary skilled person of the art must be competent with his job and not someone of highly skilled or with very imaginative minds as he understands what is relatively considered as routine, obvious, unexpected or inventive in his field of technology.[58] What is not beyond or exceeding his ability or skill shall not be consideredinventive[59] and must be rejected.[60] As explained by *Gillette Safety Razor v Anglo American Trading*,[61] it is unjust to set a higher standard for such man for subsequent applications as the court is signaling a high quality of work performed and produced by mechanical genius. It would result to fewer patent rights being awarded. There is a high tendency he might regard everything as routine. It is equally unjust to the public if the standard is lowered. It gives the impression even a poor quality of work could survive the obvious attack.[62]

Test and standard

In conducting the non-obvious test, the patent office[63] or court[64] shall procedurally[65] rely

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[54] *ICOS Corporation/Novel V28 seven transmembrane receptor*. O.J.EPO 6/2002. General assertion the invention in question performs certain function or mere claim that it could be used or made in industry, or teaching via disclosure others how to make or use the invention is useless and no longer sufficient in proving utility as the court have concluded without disclosing the specific utility of the invention, the statement would tantamount to speculation.

[55] *In re Duel*, 51 F.3d, 1552,(Fed. Cir. 1995).

[56] Kristin Connarn. Section 103(b); obviously unnecessary. *5 Journal of High Technology*. 287, p. 287. Philippe Ducor. The Federal Circuit and In re Duelle: Does S. 103 apply to naturally occurring DNA? *77 Journal of Patent & Trademark Office Society. 871*, p. 874.

[57] Art. 56 of EPC, S.103 of US patent law.

[58] *Harvard* EPO T 60/89-OJ 1992, 268.

[59] *Ibid.*

[60] *Brugger v Medic Aid.* [1996] RPC 635, at p. 654.

[61] *Gillette Safety Razor v Anglo American Trading*. 30 RPC 465 at 481.

[62] Holyoaks & Torremans, *Intellectual property law*. 4th Ed. Oxford: University Press, 2005, p. 65.

[63] At the first instance.

[64] When legally challenged.

[65] Based on the patenting practice of EPC and US patent law.

on the same prior art, used for assessing novelty. In this context, the practice of countries subscribing to EPC[66] differs slightly from US. Their assessment is comparatively more subjective[67] where the assessment generally involves three steps;(i) closest prior art is determined, (ii) the technical problem is determined by comparing the results achieved in the invention with the closest prior art and (iii) the obviousness of the solution is assessed in light of other art and knowledge of the person having ordinary skill in the art.[68] Questions are asked whether an ordinary skilled person in the art, based on the information disclosed in the prior art would have made the claim invention[69]. Is he expected to modify, improve and succeed in his attempt when tried?[70] The applicable standard is a reasonable expectation. In reaching its decision, the patent office or court shall ask whether the solution reached by the invention is obvious to an ordinary skill person in the art.[71] They shall look for the use of technical steps, namely requiring a degree and complexity in producing an end product or in isolating-identifying the compound's function.[72] Again this generally has something to do with the problem-solution approach adopted by EPC[73] where they are more concerned more with what a reference teaches regarding a technical advance or a technical achievement.[74] Whereas under US patent law, the (i) scope and content of prior art and the claims at issue are determined, (ii) differences between claimed invention and prior art are ascertained and (iii) level of ordinary skilled person in the said art is established. It is against the background in which non-obviousness is determined.[75] Generally a claim invention is considered lack of inventive steps if the differences between the same and prior art[76] is plain to see to the ordinary skilled person[77] in the art at the time of invention.[78] The applicable test[79] is whether the information in the prior art teaches motivates or leads him to modify or make the invention[80] and whether he has a reasonable expectation to succeed if attempted.[81] Generally, regardless of their difference in approach, both systems basically considers an invention is routine[82]or lacks inventiveness if based on the prior art,[83] an ordinary skilled person in the art would have made[84] or tempted to make

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[66] European Patent Convention.
[67] *Mosanto/Milk* T249/88 .[1995] EPOR 1.
[68] *Ibid.*
[69] *Dainippon Pharm Co Ltd v Otsuka Pharm Co. Ltd.* Eur. Pat. Off., T 236/96 (1999).p. 69.
[70] *Mosanto/Milk* T249/88 [1995] EPOR 1.p.1.
[71] Art.56 of EPC.
[72] *Genetech Inc.'s Patent*, [1989] R.P.C. 147 (Eng.C.A.1988).
[73] J.Thompson, The grey penumbra of interpretation surrounding the nonobviosness test for biotech patent. *E.I.P.R. 1996, 18(2), 90-96* at p. 92.
[74] *Mosanto/Milk* T249/88, Supra.
[75] J.Koopman.. The patentability of transgenic animals in the United States of America, the European Union and Japan: A proposal for harmonization. *13 Fordham Intellectual Property Media & Entertainment Law Journal 103-150*, at p.107.
[76] The same prior at used in assessing novelty.
[77] *In re Vaeck* 947 F.2d 488, 20 USPQ 2d.(BNA) 1438 (Fed.Cir.1991), *Genetech Inc.'s Patent*, [1989] R.P.C. 147 (Eng.C.A.1988).
[78] *Graham v Deere Co.* 383.U.S. (1996).
[79] Based on the patenting practice of S.103 of US(patent law) *In re Dillion.*919 F.2d.823 (Fed.Cir. 1990).
[80] *In re Dillion*, 919 F.2d.823 (Fed.Cir. 1990) p. 695.
[81] *In re Durden* 763 F 2d. 1406, 226 USPQ 359 (Fed.Cir 1985).
[82] *Genetech Inc.'s Patent*, [1989] R.P.C. 147 (Eng.C.A.1988), Dillion LJ.
[83] That teaches the method of making the subject matter.
[84] *Dainippon Pharm Co Ltd v Otsuka Pharm Co. Ltd.* Eur.Pat. Off., T 236/96 (1999).

or modify[85] the claim invention, and reasonably confident of succeeding[86] if tried. To succeed the biotechnologist must show evidence his invention[87] is unique, different or he encounters an acceptable degree of difficulties[88] so much so he is still uncertain with the final outcome of his invention.[89]

Non-obvious challenges for biotechnological compound

Patentability of a biotechnological compound is at best challenging particularly when it involves a second generation invention.[90] Biotechnologist usually encounters an attack of obviousness, mainly when the public generally knows about the methods of producing the compound,[91] thus lack the required acceptable degree of difficulties. Secondly when some partial information about the compound's basic properties or structure[92] has been revealed to the public[93], either through earlier patent disclosure, other publication or oral discussions amongst the inventors' community or academicians.[94] Considering the fact it is allowable for the examiner to combine all existing prior art in order to evaluate non-obviousness, theoretically[95], an ordinary skilled biotechnologist who knows about the process to produce it could[96] then modify[97] the existing compound to produce another useful compound. Plausibly the newly invented compound is not significantly different from the naturally occurring compound. In terms of public confidence and commercial viability, it is extremely desirable if the former mirrors the same function and properties of its naturally occurring substances. Technically and legally the compound may be deemed old and obvious. It is feared the examiner, based on chemical–structurally similar rules[98] may find the claim compound similar, adequately close or identical structures with other known compound.[99] In that circumstances the same lacks the unexpected result[100] element in overcoming the obvious attack.[101] Apparently biotechnologist faces a higher bar of non-obviousness where it is easy to build a case of prima facie obvious[102] than rebutting it.

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[85] *Chiron Corp. v US Surgical Corp* European Patent Office. T 475/93 (1997).
[86] Court in *Unilever N.v Celltech Ltd.Chr. Hansens* Lab European Patent Office, T 386/94 (1996) uses this term.
[87] Either process or product invention.
[88] *Avensis Crop. Sci. v Agrigenetics LP Norvatis.* European Patent Office. T 1054/97 (2000).
[89] *Chiron Corp. v US Surgical Corp* European Patent Office. T 475/93 (1997).
[90] *In re Bell*, 26 USPQ2d 1210, 1215 (Fed.Cir.1995), In re Duele, 51 F.3d, 1552,(Fed. Cir. 1995).
[91] Especially when most of them are typically or basically produced based on earlier invention
[92] Genetech [1989] R.P.C. 147 (Eng.C.A.1988), and In re Durden, 763 F 2d. 1406, 226 USPQ 359 (Fed.Cir 1985)
[93] *In re Bell, 26 USPQ2d 1210, 1215 (Fed.Cir.1995).*
[94] *These information serving some sort of explicit speculation about the future research or the necessary suggestion to ordinary skill person in the art in producing the new invented compound, then could be used against patenting any newly created compound in the future, making the same vulnerable for obviousness attack. I. Conley Toward a clear standard of obviousness for biotechnology patents. 79 Cornell University Law Review 735-761, p. 741.*
[95] When there is partial disclosure of the compound's structure, based on the compound's some basic properties.
[96] In re Bell above, p. 1215.
[97] *By substituting or combining it with other.*
[98] Discuss below.
[99] In re Bell, , 26 USPQ2d 1210, 1215 (Fed.Cir.1995. In re Dillion, 919 F.2d.823 (Fed.Cir. 1990).
[100] *Ibid.*
[101] *Ibid.*
[102] *Thus fails the third patentability requirement.*

Approach

In conducting non-obvious inquiry for biotechnological compound, member countries of TRIPS could follow either the EU or US's footsteps.[103] In determining whether the prior art technology teaches others in producing the claim compound, the EU focuses on the method of producing the end product rather than the end product itself.[104] This is done based on the theory that the production of isolated, purified gene and other biochemical compounds by way of genetic engineering process requires significant mental steps[105] which adds new technological information to the existing pool of knowledge.[106] Questions are asked whether the applicant encounters an acceptable degree of difficulties[107] in the said process.[108] Inventive step is established when the biotechnologist does not have a reasonable expectation to succeed.[109] If an ordinary skilled biotechnologist based on a standard knowledge and prior art[110] which taught and "suggest"[111] to him to undertake a routine and predictable task of isolating a genetic compound, so that he without any difficulties[112] or confident enough would successfully arrived at the endresult[113], the invention is declared obvious. They however are willing to reverse the finding if the biotechnological compound exhibited improved[114] or unexpected properties[115] not found in prior art, even when the process of isolating or producing the same is routine.

Structurally similar thus obvious

The courts[116] in the US focus on the compound per se[117] and use different test, known as structural similarity.[118] Since biotechnology is considered as part of the evolution of judicial precedents for chemical[119], its judicial precedents is equally applicable to

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103 Genetech, [1989] R.P.C. 147 (Eng.C.A.1988).

104 *Based on Art. 56 of EPC and as decided in Genetch case above.*

105 See EU Commission, Legal protection of biotechnical inventions: Frequently asked questions on scope and objectives of the EU Directive. (98/44) July 3, 2000. , at http://europa.eu.int/comm/internal_market/en/intprop/indprop/2k-39.htm.

106 *Ibid.*

107 *In re Farber* Eur.Pat Off T 111/00 (2002), p.2, 4.

108 *Genetech Inc's* patent [1989] R.P.C. 147 (Eng C.A. 1988), p. 243.

109 *Ibid. Genetech Inc. v Celtix Pharm, Inc.* Eur.pat.Off. T637/97 available at http// legal.epo.org/dg3/biblio/t97063 eu.1htm. (7th Aug 2004) ,p 6-7 " lack of linking information in prior art so much so applicant would not have a good starting point" in embarking on the job-thus inventive step., p. 9.

110 *Unilever N. V. v Celltech Ltd Chr.Hansens* Lab A/S Eur.Pat.Off. T 386/94 (1996), p.193-94.

111 *Chiron Corp. v US Surgical Corp.* Eur.Pat.Off T 475/93 (1997) , p.441.

112 *Avensis Crop Sci v Agrigenetics LP Novartis AG* ,Eur.Pat.Off, T 1054/97 (2000) http//legal epo.org/dg3/biblio/t97063 eu.1htm. (7th Aug 2004).

113 *Genetech Inc's* patent, p.243 *Genetech Inc. v Celtix Pharm,Inc.* Eur.pat.Off. T637/97 available at http// legal.epo.org/dg3/biblio/t97063 eu.1htm. (7th Aug 2004), p. 8-9.

114 T 301/87 *Biogen/recombinant DNA* [1990] E.P.O.R 190 (Eur.pat.Off.-technical board) 1989.p.210-211.

115 *Avensis Crop Sci v Agrigenetics LP Novartis AG* ,Eur.Pat.Off, T 1054/97 (2000) http//legal epo.org/dg3/biblio/t97063 eu.1htm. (7th Aug 2004).

116 *Amgen*, 927 F.2d 1200 (Fed. Cir.1991), *In re Bell*, 26 USPQ2d 1210, 1215 (Fed.Cir.1995) *In re Dillion*, 919 F.2d.823 (Fed.Cir. 1990).

117 *In re Bell* and *In re Dillion* above.

118 *In re Hass*. 141 F.2d 127,127-28 (C.C.P.A 1944). In re Henze, 181 F. 2d. 196 (C.C.P.A 1950).

119 P. Ducor, above at p.371. The Hass-Henze "structurally similar" doctrine, where a chemist could expect or predict that the new claimed compound-invention would have the same properties as in the prior art.

biotechnology.[120] The courts[121] then willingly extend and adopt the said doctrine and prima facie obviousness developed therein[122] in finding non-obviousness of biotechnological compound.[123] The doctrine of structural similarity assumes[124] if two chemical compounds have the same structure, they are obvious because they produce an identical, similar or closely similar[125] properties, characteristics and functions.[126] Such assumption is intimately linked to the traditional method for finding new chemical compounds. Briefly, by nature a chemical compound or molecule is usually structurally built[127] which determines the properties, characteristics or function[128] of the compound.[129] Chemist uses the built in structures as starting basis[130] in making a new useful and patentable chemical compound,[131] by adding new or removing existing chemical compound in that structure.[132] When the structure is changed, the function of the compound also changes.[133] However if the change is relatively very minor, it is deemed unworthy of patent protection. It does not fundamentally add anything to the existing pool of public knowledge.[134]

A higher bar of non-obviousness for biotechnoligy

When the structural similarity of a biotechnological determines the patentability and non-obviousness of the same, it poses a higher standard of non-obviousness for biotechnology as an invention and industry to overcome. DNA is such a complex molecule. Despite sharing the same structure with a known compound, it may have a totally different properties thus functions. If the rule is applied strictly[135] many biotechnological compound

[120] *Amgen v. Chugai.* 927 F.2d 1200 (Fed. Cir.1991).
[121] For chemical inventions.
[122] *In re Dillion*, 919 F.2d.823 (Fed.Cir. 1990).
[123] *Amgen v Chungai.* 927. F.2d 1200.
[124] *In re Dillion above, p.692.*
[125] *Ibid.*
[126] *Ibid.*
[127] Bruce Greehaus. Patentability of compounds which are structurally similar, what is new. *3 Hofstra Property Law Journal 211-236*, at p. 217.
[128] *Ibid.*
[129] These facts are usual in the field of chemistry. Bruce Greenhaus describes it as rules of chemistry. *Ibid.*
[130] Given the compound's relationship with its structure, the disclosed information of its structure may provide an ordinary skilled chemist the requisite motivation to modify known compounds or he has a reasonable expectation to succeed in obtaining a new compound as predicted by prior art. *In re Lalu.* 747 F. 2d 703 (Fed. Cir. 1984), *In re Dillion.* 919 F2d 688 at 701, 16 USPQ 2d, (BNA) 1897, 1908 (Fed. Cir. 1990).
[131] B.Cannon. Toward a clear standard of obviousness for biotechnology patents. *79 Cornell University Law Review 735-761* at p. 745.
[132] *Ibid.*
[133] Hypothetically on the same basis, by correctly changing the numbers and proportion of molecules in the structure of carbon and oxygen, two known compounds, the inventor potentially can produce two types of new compound, namely carbon monoxide and carbon dioxide. The alteration in forms of numbers, proportion or potency of molecules is now changing the structure of the compound, enough to consequently trigger different chemical properties leading to changes in the compound's function or characteristics entirely.
[134] P. Ducor New technology and patent. *27 Rutgers Computer & Technology Law Journal 369-402* at p. 373.
[135] As in chemical inventions.

may be rejected. For example, once the biotechnological compound is structurally similar, without taking any due consideration the examiner could safely presume the newly invented compound[136] is prima facie obvious[137] unless there is rebuttal evidence.[138]

Rebutting the presumption

In rebutting the structural similarity thus obvious presumption, the US courts so far are willing to consider few rebuttal grounds. The compound must has unknown,[139] different,[140] and unexpectedness properties[141] such as having a new use or with unusual potency or having a superior quality.[142] Principally the non-obviousness of a compound may principally lay in its "unknown and unexpected benefits."[143] Tentatively biotechnologist could also prove that his compound is something not taught by[144] or found in prior art.[145] The compound is non-obvious if an ordinary skilled biotechnologist has no reasonable expectation to succeed.[146]

Proving the above elements are easier said than done. Biotechnologists operate differently from traditional chemists.[147] As part of the process of constructing and producing recombinant compound, biotechnologists usually studied the prior art to know and understand the genetic code so that they could precisely predict and produce the expected coded protein.[148] Therefore it is questionable if they could claim the produced product as the "unexpected" results.[149] As knowledge about biotechnology matures, it increases the techniques, knowledge and understanding in the relationship between the structure of the compound and its function[150] thus fewer unexpected properties in a genetically engineered compound. Therefore it becomes difficult to apply or satisfy the demand for the "surprise effect," which is used to distinguish a recombinant protein from its natural counterpart to biotechnology.[151] This is a lost to the biotechnologist's business and industry as the law fails to provide them the promised economic incentive, despite of its bright future.[152]

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[136] *In re Lalu* above, p. 703.
[137] *In re Dillion* above, p.692.
[138] *In re Deuel*, 34 USPQ2d. 1210 (Fed. Cir. 1995).
[139] *In re Papesh*.315 F.2d 381, 391 (C.C.P.A 1961)
[140] *In re Lamboy* 300 F.2d 950,954 (C.C.P.A. 1962)
[141] *In re Papecsh* above, p. 391
[142] *Ibid*
[143] *In re Dillion* above, at p. 701.
[144] *Ex Parte Gray*. 919 F.2d. at 619-92, 16 USPQ 2d. 1922 at 1901.
[145] *In re Papecsh* above, p. 392
[146] Even if there is a prior art teaching the public about the invention. *Ibid*
[147] *In re Dillion*, (Newman J. Dissenting) at p. 701. "Structure similarity alone without consideration of the applicant's newly discovered properties is an incomplete focus for consideration of these factors"
[148] P. Ducor, above p. 375
[149] *Ibid*
[150] *In re Eli Lily & Co*. 902 F. 2d 943, 948, 14 USPQ2d. 1741, 1744-45 (Fed. Cir. 1990).
[151] *Ibid*.
[152] A. McAndrews. Removing the burden of Durden through legislation. *72 Journal of Patent & Trademark Office Society 1188-1215* at p. 1193.

Non-obvious due to degeneracy of codon

To circumvent the high standard above, the US courts[153] have conveniently lowered the non-obvious bar thus diluted its stringency. In conducting the said test, it is allowable for the examiner to ignore or assume certain things. For example, if the inventor is seeking product patent, the examiner[154] must consider the prior art for methods to isolate, purify sequence or produce the compound as irrelevant[155] and focus on the claim compound[156] itself instead. It is because they do not necessarily yield the targeted or desired compound.[157] Despite the similarity in structure between the newly invented compound with other known compounds in prior art or the compound's structure or properties are partially disclosed to public, the former could still be non-obvious.[158] Accordingly, the relationships between invented and known compounds either in the sense of structural similarity or properties is not so straightforward, to the effect a ***prima facie*** case of obviousness cannot be made between two biotechnological molecules specifically.[159] This is possible due to the degeneracy of genetic code[160] which inevitably causes lost of some genetic information in the genetic code during the translation process.[161] Admittedly degeneracy of codon is fairly predictable.[162] However these lost could and would naturally and biologically cause slightest change in some of the genetic sequences, biochemical structures thus the coding activity[163] with or without affecting its function.[164] It would be twice harder then for the skilled biotechnologist, armed with information in the prior art to predict with certainty whether the produced molecule would have the same sequences, properties, utility or characteristics as other known compound.[165] Considering there are a vast numbers of possibilities of genetic codes, without any actual or accurate suggestion from the prior art[166] the biotechnologist must

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[153] *Amgen v Chungai, In re Bell, In re Duel* (citations omitted).
[154] In determining non-obviousness of the compound.
[155] *In re Deuel*, 51 F.3d, 1552, (Fed. Cir. 1995), p. 1569-1570.
[156] *Ibid.*
[157] *In re Duele* above, 1569.
[158] *Ibid.*
[159] *In re Deuel* above, p.1570.
[160] To translate the genetic code for as many as twenty different amino acids, the four different bases of DNA and RNA have to be combined into coded words of at least three adjacent nucleotides letters, known as codon hypothetically TAG, GAT, TGA, ATG, GCA, ACG, CAG, GAC and so on. The matter complicates further as the numbers of possible codons which can be formed with four letters alphabet are 64, exceeding the number of natural amino acids (20). As a result several different DNA molecules each having a different sequence of bases can code for the same protein, where two or more codons are possibly codes for most amino acids. The relative loss of information from DNA to protein is generally referred to as the degeneracy of codon or redundancy of genetic code. They are sometimes regarded as junk DNA since they do not contain any code for genes at all. Due to degeneracy of codon, there is no one to one correspondence between codons and amino acids. In short the DNA sequence of a protein cannot directly be deduced from its amino acid sequence.
[161] *Ibid.*
[162] *In re Deuel, Ibid. In re Bell.* 26 USPQ2d 1210, 1215 (Fed.Cir.1995), p. 785.
[163] *In re Bell., Ibid.*
[164] *In re Bell*, p.783 (citing In re Vaeck 947 F2d. 488,493 (Fed.Cir 1991).
[165] *In re Bell* above, p. 783.
[166] *Ibid.*

make a correct decision in selecting which of those possibilities he thinks are the corresponding genetic sequences[167] responsible and would eventually lead him to the desired compound specifically. Conversely the degeneracy of codon is denying the inventor from having the necessary details in predicting suggesting or arriving at specific sequences of compound as desired with certainty[168]. Likewise the knowledge provided by the prior art or structural similarity are not enabling enough for skilled biotechnologist to produce the desired compound[169] as they do not guarantee him anything. Although he has such knowledge, he is still uncertain which of the possible sequences is likely to be of the desired compound, until the actual discovery or production of particular compound.[170] A compound is obvious if and only when the prior art particularly lead to the particular compound, its sequences in details and indicates how it could be prepared, produced or used. This is regardless of the fact whether an ordinary skilled biotechnologist would consider it is routine to obtain such molecule using familiar prior art methods. The degeneracy of codon could not lead the biotechnologist successfully to the subsequently produced molecule as desired, thus makes the compound of same structure non-obvious. Seemingly, the predictability of structure becomes the key to patentability for biotechnological product. If we can predict the sequences of the biotechnological compound with certainty from the prior art[171], it then would be obvious.

Low bar of non-obviousness

By right the real sense of inventive skills or ingenuity of minds should lie in the difficulties of producing a compound and if the process has become routine then, in isolating, purifying or determining the compound's genetic code hence function. However by demanding detail prior art information and relying on degeneracy of codon, a natural phenomenon that occurs within the genetic code instead, the US courts have lowered and diluted the stringency of non-obviousness requirement. Given the general unpredictability of biotech invention, complexities of DNA molecules, lack of understanding of DNA, and their functions as well as the fact such invention when it does occur often results from shifting through a great variety of unlikely possibilities,[172] the above move by the courts would render virtually any new biotechnological compound as unpredictable thus By demanding for detailed description and increasing that level of motivation to certainty standard, the courts therein have relatively and effectively shield the biotechnologists from failing in their applications. Only explicit prior art description of biotechnological compounds would render the same obvious. Non-obviousness requirement becomes

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[167] N.Lissy, Patentability of chemical and biotechnology inventions: A discrepancy in standards. *81 Washington University Law Quarterly 1069-1095* at p. 1073.

[168] *In re Bell* above, p.784. See also D. Burk. Biotechnology in the Federal Circuit: A clockwork lemon. *46 Arizona Law Review 441-455* at p. 441.

[169] *In re Deuel* above, p. 1554-1558.

[170] *In re Deuel*, (citation omitted), p. 1554.

[171] In terms of disclosing or accurately predict the compound's structural sequences, formula, chemical name, function or physical properties in great details.

[172] In re Farrell. 853 f 2d 894, 903 (fed. Cir. 1983).

something easy to satisfy and less demanding after all. Such policy is of course very rewarding to the biotechnology industry. Apparently the courts are assuming the ordinary skilled biotechnologist not a very bright person at all. This is based on the courts' comment that "a mere description of the compound's function or partial information about its structure may not be able to directly lead the skilled biotechnologist to the desired compound immediately, thus is insufficient in attacking obviousness".[173] The assumption could be against what actually happened.[174] As seen from the cases above, it is routine for ordinary skilled biotechnologist[175] to invent new compound of similar structure with other known compounds, either based solely on the structural similarity, partial disclosure about it in prior art or by using familiar prior art methods.[176] Yet the courts chose to believe otherwise. The above argument is strengthened when the courts' expressly relegated the argument over the process of producing the compound as irrelevant[177] to the question of non-obviousness of biotechnological compound. The courts simply ignoring the knowledge of the ordinary skilled biotechnologist as legally intended originally. For example, the court in *In re Bell* finds the 1036 numbers of possibilities that the biotechnologist has to chose from the genetic codes as compelling thus readily accepts the subject matter as non-obvious. Realistically this may not be the case. In most cases the selection is far easier, since lesser numbers of possibilities are involved than originally taught.[178] This is done by not selecting the non-redundant region but the least redundant region only.[179] As proteins are coded by more than one codon, the above approach reduces the number of possibilities of genetic codes for selection to a much lower numbers[180] making it plausible for the ordinary skilled biotechnologist to arrive at the desired sequences eventually. Even if some quarters are to regard that number of possibilities still large, the technology has advanced so much after the invention of Bell and Duele. It is then possible to produce such biotechnological compound at a greater speed.[181] After all, the suggestion and motivation required could be provided by other means than the structural similarity. There is a wealth of information published either in forms of genomics library containing DNA database, molecular strategies or computer algorithms.[182] These are sold on a commercial basis providing any interested biotechnologist with the necessary tools to enable them to routinely handle such large numbers of sequences[183] and produce a biotechnological compound.

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[173] *In re Bell*, 26 USPQ2d 1210, 1215 (Fed.Cir.1995).
[174] Or what ordinary skill biotechnologist had said. *Ibid.*
[175] Due to the advancement of technology.
[176] *Ibid.*
[177] *In Re Deuel*, above, p.1559.
[178] Varma & Abraham, DNA is different: Legal obviousness and the balance between biotech inventors and the market. *9 Harvard Journal of law & Technology 53-82* at p. 64.
[179] *Ibid.*
[180] 36 numbers. *Ibid.*
[181] P. Ducor Recombinant products and nonobviousness: A typology. *13 Santa Clara Computer & High Technology Law Journal 1-67*p. 45.
[182] S.Dastgheib-Vinarov. A higher nonobviousness standard for gene patents: Protecting biomedical research from the big chill. *4 Marquete Intellectual Property Law Review 143-174* at p. 149.
[183] *Ibid.*

Comparison

The differing standards of non-obviousness between jurisdictions have led to two different results of great legal, economic and developmental impacts. The EU is (still) applying a higher standard of non-obviousness than the US.[184] Relatively the EU has the tendency of finding an invention obvious much more frequently than courts in the US . Such approach may be chosen solely for policy reason due to pressures from the biotechnology industry and its lobbyists that protecting those compounds and molecules are necessary. If biotechnology invention is unprotected, it will never be developed. Eventually it could seriously damage the industry before it even begins. Being the case, such choice of policy is chosen due to the varying capabilities and needs of different countries, for example, to protect the country's industry and economic interests. The lowered the non-obviousness bar protects biotechnology as an invention so that it could overcome the usually stringent patentability requirements. This move will offer many patent to first generation inventions to wider society and encourages R&D so that inventors will continue innovating second and third generation of inventions. By so doing the country in question could fully extract the full benefits of Art. 27 of TRIPS.

IV. DEVELOPING COUNTRIES AND NON-OBVIOUS REQUIREMENT POLICY- A BIG CHALLENGE

Any developing countries that are interested in becoming biotechnological producers domestically or internationally should take advantage of both the TRIPS's leniency and the trend of lowering the non-obviousness bar as the US has done. In this context it is only prudent for them to imitate the US's footsteps and adopt a low bar for non-obviousness. As seen in the US such move has opened the patent floodgates for biotechnology inventions and subsequently helps local biotechnologists to venture into biotechnology as an industry. Furthermore most of them are naturally endowed with rich biological resources and biodiversity[185], the basic "raw ingredients" used in biotechnology invention and industry, ranging from agricultural to pharmaceutical.[186] Regardless of their current inadequacies and internal weaknesses, TRIPS has impliedly challenged them to positively exploit their natural resources above and use it as an extra advantage over their more developed but lack or poor in biological resources counter-parts of TRIPS in increasing their chances to join the biotechnology producers community. This is based on TRIPS's pledges guaranteeing economic and developmental progression for all members irrespective of their backgrounds and inadequacies in return for their agreement in strengthening their patent laws at domestic levels and ostensibly accepting biotechnology as patentable subject matter.[187]

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[184] *Supra*, note no. 105.

[185] Either in the form of plants, plants or microbes. Glowka et al, *A guide to the Convention On Biological Diversity*, The Burlington Press, Cambridge, 1994 at p.16.

[186] C. Lawson. Patenting genetic materials: Old rules may be restricting the exploitation of a new technology. *6 Journal of Law & Medicinal 373-399*. at p. 381.

[187] Preamble of TRIPS.

With a lowered bar for non-obvious, theoretically they would not encounter any serious problems in satisfying the third patentability barrier. Consequently the same would directly encourage inventors and research communities to continuously conduct research and innovate. Unfortunately the above statement is only half true for developing countries. Despite the lowered standard, the above requirement still poses many big challenges to many developing countries[188] in many forms. When developed nations consider certain standard of inventive steps as low enough, that acceptable standard is still a (too) high standard for the developing countries.[189] Underneath the term of non-obvious, lays a requirement for qualitative technological contribution capable of making the technological jump. It is the very asset most developing countries with the exception of a few handfuls are lacking on a wide-ranging basis.[190] Despite being the host country of genetic materials, they in other sense are so ill-equipped. They are mostly technology users rather than producers. Even though they may have achieved certain standard of development and wealth, they are comparatively still poor, under developed and lagging far behind in terms of physical development, basic education, skilled human resources, highly qualified researchers, poor in R&D programs and high technology infrastructure.[191] For example, their productivity level is low,[192] with their per capita incomes mostly less than US$1,000 per annum.[193] Consequently it may affect their abilities to gather sufficient financial funds to finance the necessary basic facilities as steps towards rich R&D programs locally.

As technology users they are forced to totally rely on protected data or information from abroad to gain to basic knowledge or latest technology[194] in preparation for enriching their R&D programs or innovative activities as spring board to new innovations or improvements.[195] Usually access is only possible[196] via licensing fees and royalty. At the same time it is usual for patent holders with quasi monopoly rights to charge a hefty fee for both payments.

Again there are doubts on their abilities to pay the same. Without the above, they may not have the capabilities to compete with the established foreign competitors locally and internationally or may take a very long time to establish and produce an independent biotechnological invention. As written elsewhere,[197] the patent protection, licensing fees, illegality of reverse engineering, infringement suits and varying or overlapping levels of intellectual property rights protections,[198] have the effect of delaying and stalling technology transfer from happening locally. For example, when the local biotechnologist

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[188] Not only in satisfying the same but equally towards their quest for biotechnology industry.

[189] Typically when they glaringly do not possess the right technological capability or brain to start with.

[190] G.H.Brundtland, Report of the World Commission on Environment and Development entitled "*Our common future*", London, Oxford Univ. Press, 1987 at p.47.

[191] R. Nwebueze, What can genomics and health biotechnology do for developing countries? *15 Albany Law Journal of Science & Technology 369-430* p. 375.

[192] *Ibid.*

[193] *Ibid.*

[194] T. Kawolski International patent rights and biotechnology Should the United States promote technology transfer to developing countries? *25 Loyola of Los Angeles International & Comparative Law Review 41-74* at p. 47.

[195] T.Kowalski , p. 50.

[196] When Art. 27 of TRIPS ban reverse engineering when it demands countries to grant process and product patent to eligible invention.

[197] G. Zekos *Patenting biotechnology. 4 Journal of Information, Law & Technology 155-198* p. 167.

[198] A condition that comes into being as a result of Art. 27 of TRIPS or tentatively TRIPS biotechnology policy.

lacks the capital funds for licensing fees, they are barred from learning thus the disability to create new innovations. The process of catching up technologically then takes a longer time, harder and more expensive to happen. They will be isolated from new technologies, reducing their bargaining power in negotiating for licensing rights further. When the existing technological gap widens, their overall programs for technological and economic development would be likely affected.

When the advancement of technology in biotechnology is advancing at a neck breaking speed, the bar of non-obviousness shall move at equal speed too[199] constantly raising the bar to a new level on a regular basis. This pushes biotechnologist to competitively create new inventions, which are more unusual, radical, difficult and less predictable than the last. Whilst many biotechnologists in developed nations are facing difficulties in chasing and keeping up with the technological advancement[200] it is highly likely local biotechnologists in developing countries are struggling too, in many folds. In order to be competitive, developing countries generally need the "brain" to invent. These human resources must be equipped with the necessary skills, qualifications, understanding and insight of the subject matter. This is relevant in relation to their ability to fulfill the written and enabling requirements of patent law.[201] As seen from litigated cases above, researchers in biotechnology companies typically have advanced degrees, often with Ph.D. in chemistry, genetics, biology or other related disciplines with several years' of lab experiences in the academic community or private biotechnology companies. Unfortunately such asset is glaringly absent in many developing countries. Across the board developing countries commonly lack expertise such as highly trained biotechnologists, scientists, engineers and human resources of different skills and capabilities.[202] If they are, there are only a few handfuls of them. For example, when India is often cited for her viable R&D capabilities amongst developing countries, the ratio of researcher available therein are 3.12 researchers to 10 thousand people,[203] a sparse figure compared to those available in advanced nations.[204]

Furthermore there is a clear absence of technical and institutional capacity involvement in research and innovative activities in many developing countries with exception of Cuba, Singapore, Taiwan and India.[205] This problem is deeply inter-twined with the exodus of skilled manpower from these countries abroad, looking for greener pasture and better prospective.[206] Quoting Remigus[207], there are 30 thousands African PhD holders working outside their home countries. Those who stayed behind are either of

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[199] Since non-obviousness is examined at the date of invention.
[200] G. Zekos, above p. 167.
[201] At. 29 of TRIPS.
[202] T. Kowalski above, p. 51.
[203] *Ibid.*
[204] In developed nations (US and EU countries), the ratio is 1 researcher to 376 persons. *Ibid.*
[205] R. Nwebueze, *Supra* note no. 191, p. 379.
[206] *Ibid.*
[207] Q. Remigus Intellectual property rights in biotechnology: Addressing new technology. *34 Wake Forest Law Review 827-845*, p. 834.

same qualification but in much lower figure or with no qualification.[208] Likewise every year, there are 100 thousands Indian professionals in technology related fields awaiting the Green card from US government.[209] Without them technology transfer or advancement,[210] could not materialized as it diminishes the countries' abilities and chances to build the critical mass necessary for technical growth. Seriously developing countries need to revamp and make overall developmental programs inclusive of patent polices at national levels as their first initial steps towards biotechnology industry. They could start investing in education, the underlining and fundamental requirements for any R&D undertaking and being the "factory manufacturing and supplying the nation with future qualified human resources" in such a scale. Furthermore such education system must emphasize on research cultures.

As a complex, highly technical and research based invention, biotechnology requires high initial investments to conduct various overlapping experiments or research before an end product is successfully produced. So far only wealthy corporations[211] or advanced countries can afford the necessary investment,[212] gathering capitals[213] from stock market, private or public funds.[214] These corporations usually allocate a huge budget, drawn from selling their shares to the public or money generated from licensing fees, royalties or profits of selling invention(s) for their R&D programs.[215] They could afford to employ the best experts in the related field to work provide the best facilities and have enough sustaining willpower or financial resources to endure the lengthy time needed between the conception of ideas until obtaining patent for the invention or carry out further improvements or developments.[216] They could conduct many parallel researches on the same or different inventions of different level simultaneously too, to investigate its function and the commercial viability or safety of the same.[217] Their in-house advertising and marketing departments helps as part of their commercial strategy in promoting their product to wider markets.[218] They have enough financial resources, practical, legal experiences and working force to do the patent application in multiple jurisdictions simultaneously.[219] However the pattern is totally different for developing countries. Inventors in the developing countries are mostly private, individuals, relatively new to the industry and of small scales.[220] Their financial resources are usually limited coming out of

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[208] *Ibid.*

[209] *Ibid.*

[210] In this case in the field .of biotechnology

[211] having many subsidiaries all over the place. J. Barton. et al.(2004). at p. 806-807.

[212] As seen in developed nations, the sector is mainly dominated by private enterprises that are actively involved in conducting researches and producing end products. G. Zekos, *Supra* note no. 196, p. 167. D. Burk Biotechnology and patent law: Fitting innovation to the procrustean bed. *17 Rutgers Computer & Technology Law Journal 1-60* at p. 7-8.

[213] For developing or furthering research.

[214] D. Burk , above p. 9.

[215] *Ibid.*

[216] *Ibid.*

[217] Barton International challenges for the pharmaceutical /biotech industries in the 21st century. *24 Loyola of Los Angeles Entertainment Law Review 1-49* at p. 15.

[218] *Ibid.*

[219] *Ibid.*

[220] Balat & Loutfi. The TRIPS agreement and developing countries: A legal analysis of the impact of the new intellectual property rights on the pharmaceutical industry in Egypt. 2 WEB JCLI online http://webjcli.ncl.ac.uk/2004/issue2/balat2.hmtl (31 Dec.2004).

their own pockets or if lucky,[221] some sort of grant awarded to them or subsidies from their governments. Although very enthusiastic about the project and the thought of obtaining patent, especially if the invention is their first or only product,[222] their efforts could be hampered and delayed by the patentability requirements. For example, they might not be able to provide the same kind of better facilities provided by the larger richer corporations in conducting further researches and thus less competitively. Because of the same they might not be able to maintain the existing work force let alone draw the "brains" to work with them. Due to the complexity of biotechnology, it is questionable whether they have the necessary expertise and technological infrastructure required for establishing even a low standard of non-obviousness. Even if they do have the much needed budget, the amount allocated or invested is considerably small compared to the budget allocated by developed nations. For example in 2002 the Indian government pledged a sum of US$2.5 million for biotechnology R&D,[223] a pittance in amount and insufficient to bring even a new GM crop or pharmaceutical products to the market.[224]

CONCLUSION

Depending on the locality and technological capability, inventive steps requirement could either make the technological progression happens or otherwise. When the basic and necessary foundation necessary for the technological advancement is not available, the task of overcoming the non-obvious requirement, even at a lower standard would become a major obstacle for the developing countries, with ensuing significant impacts. In terms of knowledge, expertise, high technology and industry, most of the developing countries, are still lagging far behind the more developed nations. Their technological infrastructure and industrial level are almost non- existing or at best, very basic resulting in a huge developmental and technological gap between themselves and developed countries, the technology producers. Despite the current trend of lowering the non-obvious bar or standard for biotechnology as favoured and adopted by the US patent law, most developing countries may not be able to draw benefits there from. In fact, many would encounter hardship and eventually fail in meeting the above standard. Looking at their common predicaments in relation to the non-obvious requirement, developing countries are practically not in the same league or race in chasing this moving target or maintain thepace. They are still lacking of so many necessary foundation subject matters for any research and innovative program in various fields of technology generally or biotechnology specifically and the same are hampering them. Additionally the very complicated natures of biotechnology either as field of science and invention seem not to

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[221] S. Aziz. Linking intellectual property rights in developing countries with research and development, technology transfer and foreign direct investment policy: A case study of Egypt's pharmaceutical industry. *10 ILSA Journal of International & Comparative Law 1-* , at p. 12.

[222] As their tickets to a better prospect and future.

[223] T. Kowalski *Supra* note no. 194, p. 49.

[224] *Ibid.*

help their course either. The abundant raw genetic materials found in their backyard would be left unexploited and totally useless if they do not even have the necessary facilities and know how to start with. They are most likely going to stay on the edge for quite some time or pushed further in the background if they are not careful. They need to take proactive actions in improving their abilities ranging from financial capabilities, human resources, basic physical and high technology infrastructures and so on to achieve their goals in becoming active biotechnology producers.

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