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BACKGROUND

In patent law biotechnology is a fashion. There is currently an on going discussion as to whether DNA and resulting proteins as well as genes of living species, including human beings, can be patentable subject matter. The developed world has taken the lead in granting the first patents in the field of biotechnology; and Mexico has followed that initial steps. The purpose of this article is to provide an insight to the readers of how Mexico has dealt with the patentability of gene technology, with a special focus on the human genome.

FOREIGN INFLUENCE

UNITED STATES

In the US the question of gene protection – nucleic acid and amino acid sequences – has been responded by applying the Chakravarty rule[1], which means that biotech products and processes shall be patentable if they meet the statutory criteria: utility, novelty and non-obviousness. Originally, the USPTO rejected patent applications for DNA sequences, finding that the claimed inventions did not satisfy the novelty and/or non-obviousness requirements. In addition, the question arose whether genes should be protected as they are a part of nature, existing in living beings. Can a gene or any DNA sequence be an novel invention and not merely a discovery, if it relates to something already existing in nature?
All the initial objections were changed afterwards. US Courts granted the first

DNA patents during the 1980's. The basic argument was that genes are a chemical substance which can be patentable if extracted by artificial means, and perform a useful function. Patentable subject matter became thus open for isolated and purified DNA molecules, RNA molecules or amino acids molecules; as well as for full-length genetic sequences, gene fragments or ESTs, SNPs and amino acid sequences.

The USPTO has set a rather high standard for utility though as gene, expressed in a sequence for example, must be "isolated and purified from its natural environment[2]" "and they are getting quite specific about it[3]". Some commentators state that in practical terms, the DNA gene sequence for which patent protection is being sought "will need to be some actual, credible, specific utility described for that gene[4]". Homology comparisons with known genes may be just not enough, and rather the PTO "will need some credible scientific data presented that addresses the actual utility[5]". Also, the utility requirement will normally not be fulfilled in cases in which isolating a DNA is made to obtain a protein of which the function is unknown[6].

As to the notion of non-obviousness, the case law has developed criteria by which, a DNA invention would not be rendered obvious if "there is an enormous number of corresponding base sequences", and unless "a structurally very similar DNA (in which only a minimum part of the base sequence is different) is known[7]".

EUROPE

Europeans have a similar view, although made under the principles of industrial application and inventiveness or inventive step.

There is no difference between patenting chemicals and all the other chemicals and pharmaceuticals that have been patented for hundred of years, and patenting genes, so long as genes are isolated and a specific utility is disclosed by the patentee for the gene based products[8].

In Europe gene patents will meet the utility (industrial application) standard if, as it is the case of the USA, the function of the protein can be known and when the use for the diagnosis of a specific disease was adequately demonstrated[9].

Similarly, the inventive step requirement is generally fulfilled by applying the 'problem and solution approach'. The test may sometimes not be extendable to

for example ESTs as it will be possible to conclude from the discussion hereunder.

ESTS, SNPS AND SEQUENCE IN GENERAL

The case of ESTs (Expressed Sequence Tags), SNPs (Single Nucleotide Polymorphisms and genetic sequences) shows many particularities as it was the first real step taken for the testing of whether human genes could be the subject matter of protection. During the nineties the USPTO refused patent applications filed by entities such as the National Institute of Health (NIH), for a number of ESTs obtained from a DNA library of genes from the human brain, on the grounds that they indicated "general uses of the ESTs as diagnostic probe or for chromosome identification, chromosome mapping, gene therapy, identification of individuals, etc[10]". "The ESTs of these applications were so-called gene fragments, "and the function of the fragments was described merely by comparing the similarity with known sequences[11]". "All NIH's applications were found not to comply with novelty and non-obviousness standards and were thus refused in the end.

The in *re Deuel[12]* decision superseded the original argument of the PTO. There the Court rejected the position of the PTO by holding

that the cDNA sequence coding for the proteins termed heparin binding growth factors (HBCF), isolated by standard gene cloning techniques are not obvious and that these cDNA sequences constitute patentable subject matter[13].

A determination of non-obviousness was made based on the argument that methods used for isolating cDNA are irrelevant regardless how general they are and how they are used to obtain the specific molecules.

As a result of in *re Deuel*, an announcement of February 1997 given by the Deputy Commissioner of USPTO and the opinion of May 1998 of Mr. John Doll, Examiner-in-Chief of the USPTO, this authority started to grant patents for ESTs and not only for probes, but for DNA fragments, similar as those of the NIH applications. The utility standard would be met in anyway.

COMPARATIVE STUDIES

The comparative studies[14] discussed at the trilateral meeting of June 2000, have served the purpose of harmonizing, as much as possible, the practice of the US, European and Japanese offices regarding patentability of DNA fragments, from various points of view. As a matter of fact, the outcome of the study was that the three offices would adopt certain general principles applicable to this type of inventions[15]. However, said principles come back to the same basic idea: DNA inventions have to show a function or specific utility, and have to fulfill, in general, all principles of patent law.

THE SITUATION IN MEXICO

BACKGROUND

On a general basis, all patent applications for DNA technologies originally filed in the USA, Japan or Europe, have then been filed in Mexico. There is simply no doubt that Mexico has become an important market for national and international investors. Biotech industries have found in Mexico a good place where to do business[16]. Due to the foregoing, and to the fact that its patent system has reached a fair level of development – among others Mexico is a member of the major patent treaties as PCT – Mexico has taken a more important role internationally, certainly, as a leader in the Latin American region.

The Mexican Institute of Industrial Property (herein after referred as to “IMPI”) has followed the trends taken by the European and US offices. Likewise, it has been consistent with the standards of the “Law on Industrial Property” (herein after referred as to “LIP”), which state that the scope of patent protection can be extended to virtually every field of technology, as dictated by NAFTA and TRIPS. These treaties have set, among others, rules for restricting patentability to only very few fields, living organisms being one of them.

RESTRICTION FIELDS

In line with the foregoing, the Law on Industrial Property, excludes the following from patent protection:

I. Processes that are essentially biological for the production, reproduction and propagation of plants and animals;

II. Biological and genetic material as found in nature;

III. Animal breeds;

IV. The human body and the living parts that compose it; and

V. Plant varieties[17]

As in other jurisdictions, a question under the LIP has been whether DNA technologies, including DNA sequences, genes of living species and ESTs, would fall into the statutory prohibition. A simple answer would be yes they are excluded, but that would be a very superficial approach and finally wrong. Fortunately, IMPI has not shared this point of view and as mentioned above, it has been granting patent protection on a continuous basis, for biotech products and processes, and for DNA structures and genes specially, not per se, but when having a particular function, in a similar way as US and Europe are doing obviously if statutory requirements are met.

PATENT PROTECTION FOR DNA TECHNOLOGIES

The LIP regards as an invention

every human creation which allows for the transformation of matter or energy existing in nature, for its utilization by man and to satisfy man's specific needs18.

In biotechnology, isolation and characterization of genes in any form by which it can be read (ie: by sequencing and presenting the resulting information as a sequence listing), and the ulterior production of something new as a useful protein, would be regarded an invention as 'matter' existing in the nature is 'transformed' for the 'needs of man'. However, the LIP would anyway require that statutory requirements of novelty, inventive activity and industrial application are satisfied. Accordingly, 'matter' would be 'transformed' not only if a DNA sequence listing has been obtained and a gene found, but that a useful, tangible and practical result is obtained.

The patentability factors of the LIP do not have the exact same meaning as the

corresponding concepts in the Canadian and US laws. However, they are considered by NAFTA as implying equivalency19.Perhaps, the notion of inventive activity would have a broader scope and industrial application a stricter approach. But they all three can perfectly deal with the question of patentability of DNA sequences and gene-based technologies, same as they have been capable to cope with the issues and queries triggered by all other technologies.

In line with the above, the question whether ESTs are patentable subject matter under the LIP goes very much in the same direction as in countries as Canada, US and Europe. In Mexico, however the specific question would not be, again, if the fragments have a known or unknown 'utility', but if they have an 'industrial application'. Could the narrower scope of this latter concept mean that said forms of biotechnology are not patentable in Mexico? The LIP understands for industrial application

the possibility that an invention may be produced or utilized in any branch of economic activity.[20]

And as DNA fragments are chemical compounds or in other words, physical substances subject to be 'used' in connection with any 'economic activity', then they should be regarded as patentable subject matter.[21]

IMPI believes that once human genome is completely known lots of different patents for related genes could potentially be granted. And as mentioned above, patentability will depend on how much function is shown in the specification and claims of the patent application. Currently, IMPI has been conducting examination of applications going back to the year of 1998; the turn is now for transgenic plants and animals and for other related cloning technologies. For example, Dolly and Polly are being subject to examination at present. The younger generation of biotechnologies as ESTs is awaiting their own turn, which will definitively be made in the near future. For the moment, it can be stated that a substantial number of applications have been filed and that some of them will be published soon. Then it will be possible to determine, precisely, how the industrial application and inventive step principles will be address. Whether IMPI will take *re Deuel* type approach, characterized by a liberal interpretation of said principles or a less flexible view by requiring that the ESTs technologies indicate a specific function, is something that still remain to be seen.

BIOETHICS THE MEXICAN WAY

Worldwide there has been a big debate as to whether life generated from the

manipulation of genes should be controlled and restricted. That debates turns more challenging when human genes come into play. Various groups, specially in developing countries, strongly believe that plants, animals and human beings should not be patented22. On the other hand, experts in biotechnology claim that people are not getting the right message as to what biotechnology patents are all about. Accordingly, a consensus has been reached by everyone in the biotech industry, whether in the public or private sectors, that the public need to be educated. One commentator has stated that

a number of the concerns that are expressed are actually based on a complete misapprehension of the patent system-what a patent allows a patentee to do and what it doesn't23.

In part, the fact that the Human Gene Project has been publishing through the Internet all genes that has been discovering, aiming thus preventing that patents being granted for them, will definitively not stop people from doing other type of research and seeking patents in new areas or as to different applications of the DNA technologies24. So, patents on gene-related inventions will continue to be sought and granted by patent offices in many countries as long as there is a patent system in support of them.

In Mexico there has not been a truly important debate on bioethics. The reason may be twofold, as it on the one hand, the issue is completely new, looking as a kind of science fiction not pertaining to reality or at least not involving Mexico at all. However, the reasons could also be that the Mexican society has been growing up and has understood that the granting of patents for biotech inventions in general, and of human beings in particular, will assist people-particularly poor people-to get the right tools to fight against starvation and disease25.

CONCLUSION

Mexico, the NAFTA partner, is having a positive reaction towards patentability of human gene inventions as it has been having for all other forms of biotechnology. IMPI's position that DNA fragments are to be regarded as chemical compounds, found and developed by 'man', will certainly facilitate their protection, as long as they meet the statutory requirements. Currently, transgenic animal applications are in the process of examination and of course,

the forecast is positive for them maturing into patents. Finally, as to bioethics Mexico appears not to be part of the group of countries which are not against patentability of DNA and gene related inventions. At least the authors has not become aware of any voices being opposed to the trend so far, at least openly. Therefore, the future looks good and that environment will contribute for the industry to continue growing, supported by a local and foreign infrastructure of research and development.

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[1] Diamond v. Chakravarty, 447U.S. 303 (1980). There bacteria obtained from genetically engineering was considered patentable under the rule “anything under the sun that is made by man” shall be patentable.

[2] See cases as Amgen Inc. v US Int’l Trade Commission, 902 F. 2d 1532, 14 USPQ 2d 1734 (Fed. Cir. 1991; Asgrow Seed Co. v. Winterboer, 982, F. 2d 486, 25 USPQ 2d 1202 (Fed. Cir. 1992). Rev’d 513 US 179 (1995). Kristi Rupert in her conference at the Forum entitled “Le Propriété Intellectuelle et les Nouvelles Technologies”, jointly organized by IPIC, AIPPI and FICPI in Quebec Canada, February 15, 2001, at slide number 3, explained that 6,000 US patents have been issued to genetic issues, including full length genetic sequences from human, animal, plant, bacteria and viruses, and of that number 1,000 pertain to human genetic sequences and 20,000 applications to human sequences are still pending.

[3] Cuck Ludham at the Gene Patents Round Table of the Managing Intellectual Property Magazine, Euromoney Institutional Investor Plc, England, September 2000, Issue 102, page 16.

[4] Sean Johnston, id. p. 18. The USPTO has issued guidelines of February 5, 2001. The foregoing standards as well as the case law develop the standards of substantial and specific utility, among others. As Kristi Rupert explains these refer to utility that is specific to the particular subject matter disclosed and substantial utility, which refers to the real world use.

[5]Id. P. 18.

[6] Kiyoshi Kuzuwa, Developments in Human Genome Analysis and Possibilities of Patent Protection; text of conference delivered at APAA Annual Meeting, Cebu Philippines, November 2000. See also “Comparative Study on Biotechnology Patent Practice” of June 1999.

[7] Simon Cohen, Round Table MIP, opus cit. p. 16. See also, In Re Bell, 991 F.2d. 781 (Fed. Cir. 1993) and In re Deuel, 94-1202, slip op. (Fed. Cir. Mar 28, 1995).

[8] Simon Cohen, Round Table MIP. Id. p. 16.

[9] Comparative Study of June 1999.

[10] Kiyoshi Kuzuwa, opus cit. P. 4.

[11] Id p. 4.

[12] 94-1202, slip. Op. (Fed. Cir. Mar 28, 1995).

[13] Mentioned above in footnote 7.

[14] Kiyoshi Kuzuma, opus cit. p. 6.

[15] “All nucleic acid molecule-related inventions (gene-related inventions including full-length cDNAs and SNPs), of which function or specific, substantial and credible utility is not disclosed, do not fulfill industrial applicability, enablement or written requirements. Isolated and purified nucleic acid molecule-related inventions (gene-related inventions including full-length cDNAs and SNPs), of which function or specific, substantial and credible utility is disclosed, which fulfill industrial applicability, enablement and written description requirements are patentable as long as there is no prior art (i.e., as long as there is novelty and inventive step/non-obviousness) or other reason for rejection (e.g., best mode [US] or ethical grounds [EPC/JP])”.

[16] Hedwig Lindner and Miguel Angel García; Condiciones de Patentabilidad y Alcance de Protección de las Secuencias (EST) de los Polimorfismos Singulares

de Nucleótidos (SNP) y de los Genomas Completos (Enteros); Report of Mexican Group AIPPI to Q150, Sorrento Italy, 2000.

17 Article 16, LIP.

18 Article 15, LIP.

19 Article 1709 (I) of NAFTA states that expressions “inventive activity” and “industrial application” shall be regarded equal to “non-obvious” and “utility”.

20 Article 12 (IV) LIP.

21 In a Canadian case the Federal Court declared to be patentable subject matter as a "physical substance" the transgenic higher life from comprising an oncogene.

22 Alex Wijeratna: MIP Roundatable: opus cit. p. 19.

23 Catriona Hammer; MIP Roundtable: opus cit. p. 20

24 Id. p. 24

25 While doing research for this paper, the autor came accross an article of a science magazine entitled “Cómo ves”, under “El Proyecto del Genoma Humano”, page 10, this is basically focused at explaining the phenomenon. The article makes specific reference about the discussion on patentability of human gene, by describing the problem and the race between the Human Genome Project and Celera. It also refers to the sensitive issues on the patent protection on this field. Besides that it does not adopt-or even explains- any position against that issue from a “Mexican” standpoint.