

THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

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Biotechnological inventions are concerned with processes occurring in living matter including animals, plants or microorganisms, the products so obtained and their industrial application. The field of their application is broad and covers, for example, the use of fungi in the bakery, wine and antibiotic industries, bacteria for the manufacture of vaccines, plant extracts and the like. Classical biotechnology was concerned with natural occurring biological processes and products and their improvement. This situation posed serious problems concerning patentability:

- Patentability of living matter that reproduces itself, that is, patentability of plants, animals and microorganisms.
- Patentability of chemical substances produced by living matter.
- Patentability of microorganisms extracted from natural sources.

With the advent of gene technology there arose new problems concerning patentability. The basic techniques for gene manipulation were discovered in the late 1970s and since then national and international research companies and institutions as well as universities are working in this field. Living matter reproduces itself according to the command of its genetic code. All characteristics of living matter whether they are physical, chemical or functional, are the result of specific genes. Gene technology succeeded in manipulating specific genes producing on an industrial scale important products such as therapeutic substances which exist in living matter in trace amounts. The products obtained, although identical in composition with the natural product, often differ in therapeutic activity because of their spatial configuration. Differences in spatial configuration might be caused by the method in producing it, or the work-up conditions used. It has been realised that, here also, new problems in patentability have arisen:

- A. Does the identification and separation by conventional methods of genes which code for well known compounds represent a discovery or an invention? A classical example in this area is insulin, a protein which has been known for some time and is produced by a specific gene in the animal body. The structure of this gene was not known until recently.
- B. Are claims directed to genetically-engineered known compounds acceptable? For example, should a claim directed to "genetically engineered insulin" be allowed, notwithstanding that the inventor discovered only one of the many gene manipulation methods, or should the claim be limited to a product by process?
- C. Are functional claims often so broadly worded that they may prevent further research in a specific field for fear of infringement suits, acceptable or should the claims be limited to the actual description in the specification.
- D. Last but not least, one must address oneself to the ethical problem. Should patents for gene manipulation with improved milk or meat production be produced by genetic engineering. On the international plane patent laws enacted after 1950 refer partially to the problems of chemical biotechnology but since genetic engineering appeared only in the late 70s new legal problems in this field have not found their way into the patent laws. Patent offices, therefore, have to rely mainly on patent office practice or court decisions.

The Israel patents law of 1967 does not distinguish between biotechnological or non-biotechnological inventions with the exception of section 7 (2) of the patents law which excludes from patentability new varieties of plants or animals, except microorganisms not derived from nature. According to Israel patent office practice natural chemical substances are not considered discoveries. The criteria for patentability for such substances are novelty, inventive step, sufficient description and industrial application. Microorganisms obtained from natural sources are not patentable according to the patents law and the patent office refuses claims directed to pure cultures obtained by selection of natural microorganisms. On this particular issue a decision of the commissioner of patents is pending.

Modified microorganisms obtained by mutation or by gene technology are patentable if they comply with sections 3, 4, 5 and 12 of the Israel patents law. The main problem for these type of inventions is insufficient disclosure, reproductibility and industrial application.

Israel has not yet ratified the Budapest convention, nor does the Israel patents law demand the deposition of microorganisms. The reproduction of specific microorganisms according to a complete description in the specification is very difficult and, therefore, the only real disclosure to the public is the deposit of the claimed species. It is of utmost importance for Israel to be a signatory to and to ratify the Budapest convention thus enabling the demand for the deposition of microorganisms.

In the field of genetic engineering the Israel patent office considers that identification and reproduction of gene (DNA fragments) coding for known natural occurring proteins does not justify claims directed to the gene per se. Likewise, claims directed to known compounds genetically produced should be limited to the specific process disclosed. Very broad claims, which express novelty by functional terms are not acceptable. Ethical problems have not occurred by reason of the exclusion from patentability of animals by the Israel patents law.

Plant varieties are not patentable according to the provision of the Israel law but processes for the production of plants are acceptable. In the United States patent office it was standing practice, until not so long ago, that animals and microorganisms were not patentable according to the U.S. patent office practice. That practice was changed by recent court decisions and the U.S. patent office now grants patents for microorganisms and transgenic animals except humans.

The EPO Excludes plant or animal varieties or essentially biological processes for the production of plant or animals as patentable subject matter [article 53 (b)]. Microbiological processes and their products, however, are patentable by the EPO. In general, the EPO practice, with few exceptions, is similar to that of the Israel patent office practice and there is a requirement there that new microorganisms must be deposited before the patent application is filed. Pure cultures of natural microorganisms are now patentable in the EPO court decision), as are inventions for improved plants with the exception of specific plant varieties.

Mayer Gabay, Esq., is Commissioner of the Civil Service of the Government of Israel and Chairman of the Patent and Copyright Law Revision Committee. He holds a Master's degree in Comparative Law from Columbia University, New York. Mr. Gabay was Director General of the Ministry of Justice for 11 years, President of the UN Association of Israel, a member of the council of the Israeli Bar Association and a lecturer at the Universities of Jerusalem and Tel Aviv. He has been involved in negotiations with Egypt under the Camp David Accords, has been designated as member of the World Bank pool of arbitrators, and was engaged in negotiating the Free Trade Agreement between the United States and Israel.