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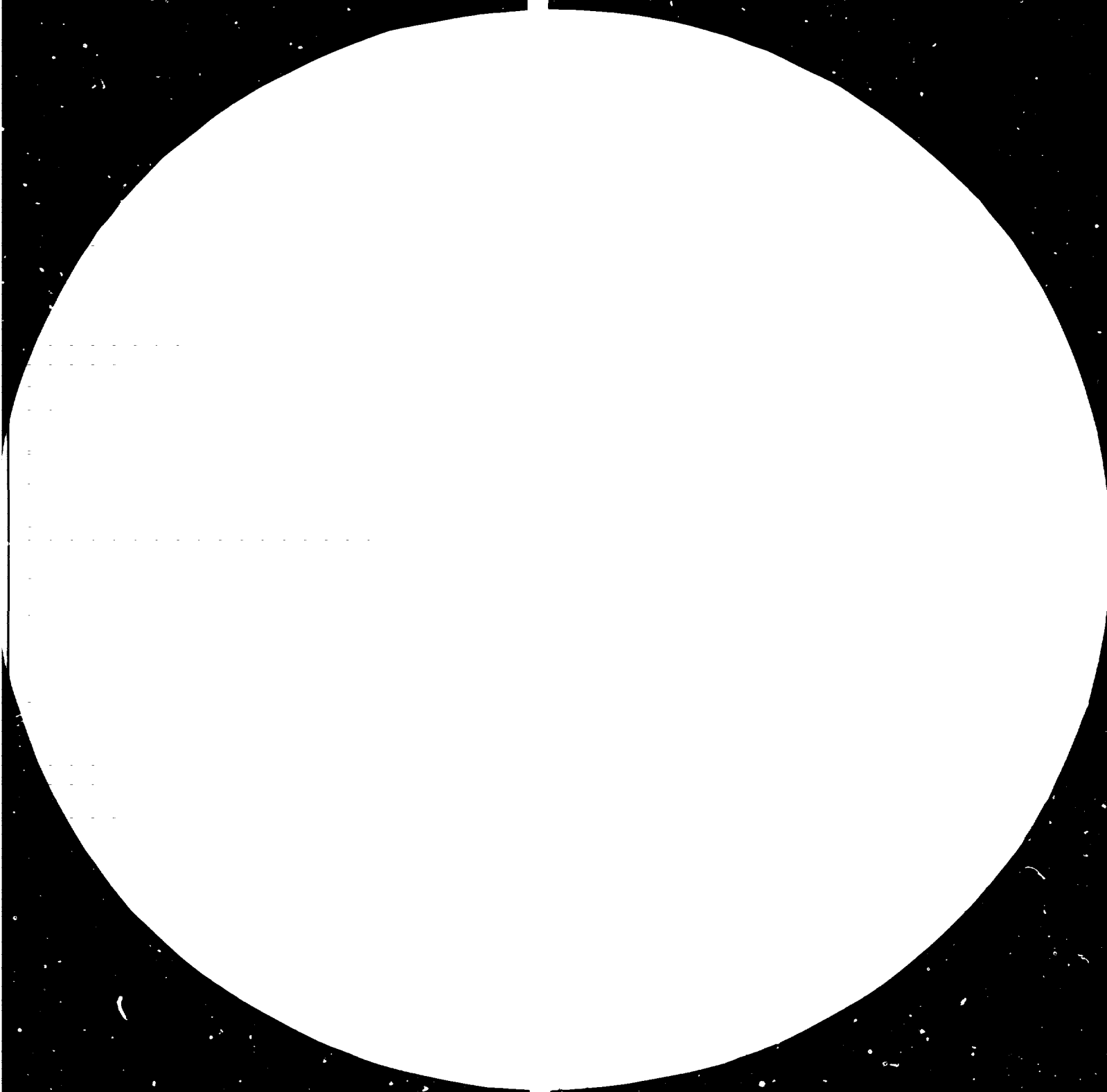
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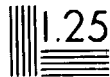
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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

VIENNA INTERNATIONAL CENTRE

P.O. BOX 300, A-1400 VIENNA, AUSTRIA

TELEPHONE: 26 310 TELEGRAPHIC ADDRESS: UNIDO VIENNA TELEX: 135612

REFERENCE: 453/23

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**CONSULTATIONS ON THE IMPLICATIONS OF ADVANCES IN
GENETIC ENGINEERING FOR DEVELOPING COUNTRIES**

Vienna, 4-6 February 1981

PATENTABILITY OF THE MICRO-ORGANISMS
AND IMPLICATIONS IN THE
DEVELOPING COUNTRIES.

A preliminary note
prepared by the Technology Programme of UNIDO

INTRODUCTION

The oil spills treated with hay dosed with man-made, oil-eating micro-organisms have produced the patent controversy of the century.

After prolonged discussions the Supreme Court of Justice in the United States reversed, by a narrow margin of 5 to 4, earlier decisions by the Patent and Trademark Office of the United States and accepted patentability of "life human made micro-organism".

The case of patent application filed by General Electric in the name of scientist Ananda Chakrabarty thus went into the history of patents. The patent application was filed in 1972 and revolved around a type of pseudomonas bacterium that had been modified artificially by man.

The issue soon became extremely important to many parties interested in the growing recombinant DNA industry, some of which filed briefs with the Supreme Court warning that genetic research is dangerous. The court, however, rejected such considerations.

At present, it is difficult, if not impossible, to predict how the court decision of June 1980 will affect efforts to turn recombinant DNA technology into commercial use. It is estimated that there are probably hundreds of patent applications pending all over the world.

The future of several such applications is deemed to be crucial to the future of the genetic engineering and will in no doubt affect the cost of products to users of the technology and customers.

For example researchers from Stanford University and University of California, Berkeley, applied for patents for very fundamental processes necessary for gene-splicing.^{1/} The Genetech based in California also made broad patent claims for some of its early work in producing peptide hormones in bacteria.

^{1/} Chemical and Engineering News, June 25, 1980.

Should these applications follow the two cases of Bergy ^{2/} and Chakrabarty et.al., royalties charged for licensing of such patents, even if nominal, would bring a very substantial sum of money to the patent holders.

Potential fields of industrial application of so-called genetic engineering of micro-organisms are manifold. For the purpose of the present paper, let us follow the few enumerated by Dr. Herbert W. Boyer. ^{3/} Micro-organisms can be used to amplify an enzyme or set of enzymes which can direct the synthesis of organic compounds (such as ethanol, acetone, antibiotics or naturally occurring drugs). Further one can generalize that genetic engineering techniques provide the basis for designing specialized bacteria or other organisms such as viruses, fungi, or tissue culture cures which will produce useful gene products. Associated applications will utilize cloned genes or gene fragments as diagnostics in medical genetics.

A more futuristic application is one that has been described as "gene therapy". This possibility shows that individuals afflicted with severe genetic defects might have a sufficient number of malfunctioning cells corrected by the incorporation of an artificially deprived gene or set of genes into their chromosomes.

The response of neuropeptide hormones and transmitters to stress, drugs, disease and aging will be a major area of research in the next few years.

The historic United States Supreme Court decision caused a lot of movement and feverish activity in and around recombinant DNA industry with large investments being made or increased among major and minor corporations involved in genetic engineering.

^{2/} M. Bergy et.al. - here scientists developed a purified culture of a micro-organism capable of highly increased production of anti-biotic.

^{3/} Herbert W. Boyer "The Age of Molecular Biology" in American Patent Lawyers Association Journal Nos. 3 and 4, Vol. 7 - 1979.

Such companies as Eli Lilly, Revlon, Brunswick, Johnson and Johnson, Schering, Abbott Laboratories, Standard Oil, Sumitomo and others are stepping up research in bio-technology. In addition a number of privately-owned small companies like Genetech, Biogen, Life Instruments etc. received substantive financial inputs (partially by way of going public) which proves the great future of this industry.

Current Practice of Patenting Man-Made Micro-Organisms in Selected Countries

The Federal Republic of Germany

In the Federal Republic of Germany both the micro-organism invention, that is, the micro-organisms as such as well as the process of using the micro-organism can be patented, however, it is necessary that the micro-organism be deposited at the culture collection at the time of filing the application. Furthermore, the product claims for the micro-organism per se are also patentable; the pre-condition for granting a patent for such per se micro-organism is that the inventor should disclose a repeatable method for the production.

European Patent Convention

According to this convention, an invention can be granted a patent concerning the micro-biology process where a product of the invention covers the use of micro-organism which is not available to the public. As in German Law such micro-organisms are to be deposited and should be in certain cases reproducible.

Japan

According to the Japanese Patent Law the micro-organism per se can be patentable provided that they can be reproduced. There is a special description regarding specifications which should be filed for the invention of the micro-organism.

The United Kingdom of Great Britain and Northern Ireland

According to the United Kingdom Patent Law, patents claiming micro-organisms per se have been granted for many years.

Finally, it should be noted that in August 1978 a convention has been signed in Budapest providing for the establishment of international depository of micro-organisms for patenting purposes.

In the light of the above, it seems that from now on, no major obstacle exists prohibiting application of similar rights to patenting man-made micro-organisms, as those enjoyed in other types of patents world-wide.

Implication of Patenting of Micro-Organisms in Developing Countries

At the outset it seems that in principle in all so-called developing countries man-made micro-organisms can be (and were in the past) patented, using predominantly similar formulas concerning their reproducibility.

The above situation is based on the fact that in a great number of these countries the patent system is based either on British or French patent laws, both enabling grants of patents on living micro-organisms.

In the introductory part of the present paper a sketchy attempt was made to picture the great potential effect that genetic engineering may have on the industry and society in the immediate future.

Participants to this consultative meeting of UNIDO are undoubtedly the best equipped people to judge much better the likely effects of genetic engineering industries in the next 5 to 10 years, both in the highly industrialized, as well, as developing countries.

With these probable effects and implications in mind, the Secretariat of UNIDO is putting forward for consideration the issue, whether Governments of developing countries, within the framework of existing national patent laws should take a decision at this time or postpone their decision until they could examine their own work in this area, including the strategy of development of their works relating to micro-organisms. Alternatively, they could also examine whether there is a need for a special type of patent for this subject.

It should be stressed in this context that it is the prerogative of the Government and its institutions (like their Patent Offices, for example) to decide on the patentability of certain types of products. Such practice is generally applied in the area of military inventions and technology (due to the so-called national interest) as well as other fields (for example, in the field of pharmaceuticals, access to which may have a profound effect on the health of human beings etc.).

The implications and effects of genetic engineering are far more important than those in the above outlined spheres and therefore careful consideration should be given to the issue raised.

The discussion has far-reaching consequences for developing countries, that is more than two-thirds of the human race, may lose access to the current new technological revolution.

What is even more important, as centres of research are concentrated in only a few countries, and basic research is already covered by patent application, the possibility of carrying parallel further development in this field in and by developing countries, seems remote and difficult, and may ultimately lead to further increasing the technological gap between the rich north and the poor south.

The establishment of an international research facility to which free access would be provided would benefit all countries and in particular the scientists and technologists from developing countries. Such research would be extremely useful if unrestricted by existing patent law.



