

The Agricultural Research Service Patent Culture Collection

Stephen W. Peterson

Microbial Properties Research, National Center for Agricultural Utilization Research, Agricultural Research Service, US Department of Agriculture, Peoria, IL 61604, USA

(Received 19 October 1993; accepted 4 January 1994)

INTRODUCTION

Patenting is the process of opening or disclosing previously secret information concerning new machines, devices or processes. In return for full disclosure of the patent subject material, the inventor is granted exclusive rights to the invention for a fixed period of time. Thereby, society gains new and useful information that may aid the development of additional inventions, and the inventor gains the chance to make a profit from the products of the research performed. In general, patents are granted for inventions that are novel and have utility [3,5]. Most countries hold that medical methods for the direct treatment of human patients are not patentable, but indirect treatments or tests may be patentable. In order for the patent to be granted the invention must be disclosed sufficiently for a skilled practitioner in the same field of work to duplicate the invention.

Patent culture collections are a recent phenomenon [3,4,5] whose need resulted from the discovery since the end of World War II, of a wealth of antibiotics and other useful metabolites of microbial origin. The first deposit of a microbial strain for patent disclosure in the US occurred in 1949. At that time, American Cyanamid Company applied for patent protection of a microbially mediated process for aureomycin production. Patent applications prior to this time concerned non-biological devices and process inventions that could be fully disclosed by providing descriptions, diagrams, formulae or models. Because a critical part of American Cyanamid's invention was mediated by a particular microbial strain, patent examiners ruled that the strain producing the aureomycin must be made available, in order to fulfill full disclosure requirements. The US Patent Office asked the Agricultural Research Service Culture Collection to act as a patent strain depository, and with acceptance of *Streptomyces aureofasciens* NRRL 2209, the first deposit of a microbial strain for patent purposes was accomplished. The other major US culture collection, the American Type Culture Collection, also began accepting cultures for patent

applications shortly thereafter. In accepting a patent deposit, the ARS Culture Collection agreed to maintain the culture for at least the lifetime of the patent.

PATENT CULTURE DEPOSITS

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure [1], signed on April 28, 1977, was a major step forward regarding patent strain deposits, and depositors should consider depositing strains under the rules of the Budapest Treaty. This treaty provides that the deposit of a microorganism at a single approved location will satisfy the culture deposit requirements of all of the signatory nations. The advantage of depositing cultures under this treaty is that one patent deposit will satisfy the disclosure requirements of all the countries chosen in a multi-country filing rather than requiring the inventor to deposit a microorganism in each country where a patent is sought. It is sometimes difficult and time consuming to transport certain types of microbial cultures across national borders. Deposit in the inventors' country of origin usually avoids the difficulties involved in transporting potentially harmful or hazardous microorganisms across national borders to patent culture collections in those countries. Also, deposit under the Budapest Treaty provides a single, uniform set of rules regarding patent deposits. Signatory nations under the Budapest Treaty may not require compliance with regulations in addition to, or in place of, those covered in the Treaty. Full information concerning the Budapest Treaty may be obtained from the World Intellectual Property Organization (WIPO), 32 chemin des Colombettes, 1211 Geneva 20, Switzerland.

The Agricultural Research Service Culture Collection, and the American Type Culture Collection are the two IDAs (International Depository Authorities) for the Budapest Treaty in the United States. Complete listings of the IDAs may be obtained from WIPO, and recent listings are available [2]. Each IDA culture collection formulates rules concerning what types of materials they will accept for patent deposit. At the ARS Patent Culture Collection acceptable materials generally include yeasts, bacteria, fungi, and actinomycetes [4]. The ARS Patent Culture Collection does not accept cell lines, hybridomas, algae or mixed

species cultures. Acceptable species must not be virulent plant, animal or human pathogens (maximum containment level P-1). Also, acceptable cultures must not require exotic media or growth conditions. For example, the ARS Patent Culture Collection does not accept strictly anaerobic organisms because of the special media, equipment and expertise needed to successfully work with these organisms. Other culture collections formulate their own rules concerning the types of organisms or biological materials that are acceptable.

Deposit of a culture in an IDA does not remove the depositor's responsibility for maintenance of the patented strain. Patent laws generally require that the depositor of the strain also maintain a viable culture, so that the patented organisms can be replaced in the event of loss at the IDA.

When depositing a strain under the Budapest Treaty, the depositor must inform the IDA in the letter of deposit, that the isolate is being deposited under the terms of the Treaty. The depositor must complete specific deposition forms, that include the identity of the organism and pay a service charge. Starting with cultures deposited after November 1, 1983, the ARS Patent Culture Collection charges a one-time fee of US \$500, in connection with a patent deposit. This fee covers the cost of maintenance of the strain under the terms of the Budapest Treaty (generally 30 years, and five additional years after the most recent request for the culture), viability checks and necessary correspondence. The culture collection must perform viability checks of the organism at regular intervals. Once completed, the culture collection certifies viability and returns a statement of viability, an accession number, and a sample of the deposited material to the depositor. The depositor verifies that the returned material is the same as that deposited. Upon receipt of an accession number, a patent application may be filed. The culture may be made freely available at the time of

deposit, or the depositor may delay release of the organism under Rule 11 of the Treaty, where the specific regulations concerning distribution of cultures are detailed. The depositor may receive a subculture of the deposit at any time, and may authorize release of a subculture to a third party. Also, any intellectual property (patent) office covered under the Treaty may receive the strain at any time if necessary for the patent evaluation process. Under the Budapest Treaty, the depositor will be notified of any strain distributions, once the strain is released.

The ARS Patent Culture Collection charges a fee of US \$20 for the distribution of strains deposited after November 1, 1983. Further, more detailed, information on patent deposits may be obtained from the Curator, (ARS Patent Culture Collection, National Center for Agricultural Utilization Research, Peoria, IL 61604) who maintains current information regarding deposits and requirements in conjunction with deposits.

REFERENCES

- 1 Anonymous. 1977. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. World Intellectual Properties Office, Geneva, Switzerland.
- 2 Bousfield, I.J. 1988. Patent protection for biotechnological inventions. In: *Living Resources for Biotechnology: Filamentous Fungi* (Hawksworth, D.L. and B.E. Kirsop, eds), pp. 115-161, Cambridge University Press, New York.
- 3 Cooper, I.P. 1982. *Biotechnology and the Law*. Clark Boardman, New York.
- 4 Kurtzman, C.P. 1986. The ARS Culture Collection: present status and new directions. *Enzyme Microb. Technol.* 8: 328-333.
- 5 Saliwanchik, R. *Legal Protection for Microbiological and Genetic Engineering Inventions*. Addison-Wesley, Reading, MA.