

## Chapter 9

# Deposit Considerations

“No other arts are known, nor were any suggested, where words alone may be incapable of describing an invention sufficiently to enable one skilled in the art to make and use it in a reproducible manner.”

U.S. Patent and Trademark Office  
Proposed Rule, Deposit of Biological Materials for Patent Purposes

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## Deposit Considerations

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### INTRODUCTION

In 1949, the Patent and Trademark Office (PTO) began recommending to inventors that patent applications for an invention involving a micro-organism should include the deposit of the pertinent micro-organism with a culture collection. Although not a formal requirement, patent examiners advised applicants that in cases where words alone were not sufficient to describe the invention adequately, a deposit was advisable.

On July 8, 1949, Parke Davis Co. deposited a culture of *Streptomyces venezuelae* in the American Type Culture Collection (ATCC) which was assigned ATCC number 10712. It is listed in U.S. Patent 2,483,892 (process for the manufacture of chloramphenicol) which was issued October 4, 1949.

In August 1949, American Cyanamid Company deposited a culture of *Streptomyces aureofaciens* with the Agricultural Research Service Culture Collection, better known as the Northern Regional Research Laboratory (NRRL). It was assigned NRRL number 2209 and is listed in U.S. Patent 2,482,055 (for the production of aureomycin) which was issued September 13, 1949.

These two historic deposits for patent purposes were apparently the first in the world. They stand as forerunners to the current practice that patent applications for inventions involving micro-organisms, plasmids, vectors, cells, plant tissues, seeds, and other biological materials that are newly isolated, novel, manmade, or not generally available to the public on a long-term basis be supported by a deposit in a recognized patent depository.

Whether or not a deposit is necessary is a decision made on a case-by-case basis. The decision generally takes into account the reproducibility of the invention based upon a written description alone, the level of skill in the art, the teaching of the prior art, and the availability of starting materials. Although not automatically required, a deposit is employed in many cases to meet the requirement that a patent provide enablement or the best mode of practicing an invention (10).

### INDEPENDENT DEPOSITORIES

A culture depository accepts, maintains, and distributes cultures of micro-organisms, viruses, cells, or other genetic-type material. A depository may be public or private; nonprofit or for-profit. The main function of a public culture depository is the preservation and distribution of reference cultures that serve as standards for users in the scientific and educational communities.

A culture collection also improves the strains in the collection as much as possible. The depository, for example, insures that strains are named and classified correctly and uses the best methods to preserve the cultures in their original state (i.e., not mutated). In addition, public depositories communicate information learned about the cultures in their care through publications, workshops, and other means.

Among organizations accepting deposits in the United States, there are currently three depositories (table 9-1) recognized for patent purposes under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure (see ch. 10). One other depository existed until 1968.

#### *American Type Culture Collection*

*The American Type Culture Collection* (12301 Parklawn Drive, Rockville, MD 20852) is a private, nonprofit institution organized in 1925 for the purposes of acquiring, preserving, and distributing cultures of micro-organisms to scientists. Its Board of Directors is composed of scientists elected from 19 major scientific societies in the United States and 2 in Canada. Since 1949, ATCC has served as a depository for patent purposes (the first formal recognition of ATCC for patent deposit purposes was provided in a 1952 letter from PTO). In 1949, only bacteria and fungi were accepted for patent purposes.

ATCC, responding to the needs of the patent community, has grown to include many other types of biological material. It now holds an estimated 8,000 deposits for patent purposes, which include

**Table 9-1-Selected U.S. Depositories and Strains Accepted**

Depository	Kinds of cultures accepted	Number of cultures on hand	
American Type Culture Collection (ATCC)	Algae, animal viruses, bacteria, cell lines, fungi, hybridomas, oncogenes, plant viruses, plasmids, plant tissue, cultures, phages, protozoa, seeds, and yeasts.	1949-1985 estimated 1988-1987	500 7,500
Agricultural Research Culture Collection/ Northern Regional Research Collection (NRRL)	Nonpathogenic cultures of bacteria and fungi that can be preserved by freeze drying.	1949-1987 estimated	3,000
In Vitro international, Inc. (IVI)	Algae, animal viruses, bacteria (and with plasmids), bacteriophages, cell lines, fungi, plant viruses, protozoa, and seeds	1983-1987	100

SOURCE: B.A. BrandOn, "Deposit Requirements for Microorganisms, Plants, and Animals in U.S. Patent Claims," contract report prepared for the Office of Technology Assessment, U.S. Congress, December 1987.

algae, animal viruses, bacteria, cell lines, fungi, hybridomas, oncogenes, plant viruses, plasmids, plant tissue cultures, phages, protozoa, seeds, and yeasts. It was the first depository institution acquiring the status of International Depository Authority (IDA) in 1981 under the Budapest Treaty, which is administered by the World Intellectual Property Organization (WIPO).

At its inception, ATCC did not charge for deposit of a culture for patent purposes; but since 1952, a fee has been charged for the deposit and distribution of cultures deposited for patent purposes. In 1988, the fee was \$670 for 30 years of maintenance and viability testing.

### ***Northern Regional Research Laboratory***

*The* Northern Regional Research Laboratory, (1815 N. University Street, Peoria, IL 61604) was established in 1940 as part of the U.S. Department of Agriculture (USDA) for the study of micro-organisms of agricultural and industrial importance. Since 1949, it has also served as a patent depository for nonpathogenic micro-organisms that are not difficult to grow. There are approximately 3,000 cultures on deposit.

At its inception, NRRL charged no fee; but since 1983, a fee has been charged for the deposit and distribution of cultures deposited for patent purposes. In 1987, the fee was \$500 for 30 years of maintenance and viability testing. NRRL acquired the status of International Depository Authority in 1981.

### ***Institute of Microbiology, Rutgers University***

*The* Institute of Microbiology at Rutgers University (IMRU) accepted its first deposit for patent purposes in 1952, and served as a depository for bacterial cultures involved in patents until 1968. At that time, IMRU discontinued the acceptance of cultures for patent purposes. In 1978, all cultures on deposit at IMRU for patent purposes were transferred to ATCC, where they are maintained today.

### ***In Vitro International, Inc.***

In Vitro International, Inc., (IVI) (611 (P) Hammonds Ferry Road, Linthicum, MD 21090), was incorporated in 1983 as a for-profit company for the purpose of accepting cultures for patent purposes. It acquired the status of International Depository Authority in 1983. The 1987 fee for 30 years of maintenance and viability testing of a culture deposited for patent purposes was \$610. There are approximately 100 cultures on deposit.

IVI is the first for-profit repository for patent deposits. Generally, the necessity for many types of professional expertise to handle the various culture deposits makes it an unprofitable venture.

## **DEPOSIT ISSUES**

U.S. patents in microbiology had their beginning in 1873 when the first patent dealing with microbiology was granted to Louis Pasteur (U.S. 141,072). That patent included a claim to a biologically pure culture of a micro-organism. Since the granting of that historic patent to the Pasteur Institute, many

hundreds of patents have been issued on microbiological processes.

The practice of making deposits of micro-organisms began in 1949 with the first historic deposits at ATCC and NRRL and this practice was followed until 1970 when it was challenged in the U.S. Court of Customs and Patent Appeals (CCPA) (8). CCPA, in a landmark decision, approved, but did not require, this practice.

#### *Patent and Trademark Office Guidelines*

*The* first published guidelines by PTO on the deposit of micro-organisms for patent purposes

appeared in the Official Gazette in 1971 (17). In these, PTO adopted the procedure approved by CCPA in 1970 (8) as complying with (but not required by) the statutory requirements of 35 U.S.C. 112 for an adequate disclosure of the micro-organisms required to carry out the invention. PTO said:

- (1) the applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganisms in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted, under conditions which assure



Photo credit: American Type Culture Collection

Tanks for maintaining samples in liquid nitrogen.

- (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under Rule 14 of the Rules of Practice in Patent Cases and 35 U.S.C. 112 and
- (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;
- (2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and
- (3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1).

In 1975, an important decision was reached in *Feldman v. Aunstrup* (5) in which the court held that the use of a theretofore unknown strain in an old process was patentable due to the prior unavailability of the strain. *Feldman v. Aunstrup* also expanded the scope of the type of depository PTO would accept—that is, private, nongovernmental, non-U. S., or even for-profit type depositories.

In 1977, establishment of the Budapest Treaty required contracting states that allow or require the deposit of micro-organisms as part of their patent procedure to *recognize* the deposit of a micro-organism with any International Depository Authority. Any such institution must be approved by WIPO. To acquire the status of IDA, a depository institution must comply with the requirements of the Budapest Treaty. Acquisition of IDA status must be requested by the contracting state or territory in which the IDA is located. The procedure for the acquisition of IDA status is specified in the Treaty. No contracting state may require compliance with requirements different from or additional to those provided in the Treaty.

The Budapest Treaty was modified in 1980 and the United States became a contracting party in August 1980 when the Treaty became effective. As of January 1988, there were 22 countries party to the Treaty. There are 19 International Depository Authori-

ties under the Treaty, three of which are located in the United States (table 9-2). PTO has accepted the requirements of the Treaty as meeting deposit requirements.

In 1985, another landmark decision, *In re Lundak* (9), was handed down by the Court of Appeals for the Federal Circuit. PTO had refused to grant a patent to Lundak because the claimed cell line was not deposited with a recognized depository as of the filing date of the patent application. It had been on deposit in Lundak's laboratory. The Court concluded that the only requirement regarding enablement during the pendency of the patent application was that a specimen of the cell line be made available to PTO should the Office so request, as authorized by 35 U.S.C. 114. The Court held Lundak's deposit with ATCC, which was made a few days after filing but prior to issuance of his patent and which is referred to in his specification, met the statutory requirements for enablement.

Patent applicants may not be wholly safe in relying on the *Lundak* decision as a general proposition that deposits can always be made after the U.S. filing date. *Lundak* was exceptional in that there was only a 7-day gap between deposit and filing. Moreover, the *Lundak* specification was descriptively complete in regard to taxonomic description. There was little dispute as to the identity of the deposited material and the material described in the specification (3).

It is noteworthy that a deposit made under the *Lundak* doctrine does not satisfy deposit requirements abroad. U.S. applicants, therefore, as a rule, will lose the possibility to claim the Paris Convention's Priority Right (Article 4) (see ch. 10) if they deposit with independent depositories later than the U.S. filing date (13).

In 1988, PTO published a notice of proposed rule making for deposit of biological materials for patent purposes (see app. C) (15). These rules, if adopted formally by PTO, will assist the inventor and the depository in defining the position of PTO on deposits. A 1987 advance notice of the proposed rules (14) stimulated written comments from 20 sources to PTO. The majority of the comments were directed to the conditions of the release or availability of a culture once a patent is granted.

Table 9-2—institutions Having Acquired the Status of International Depository Authority

Name of depository	Address
Agricultural Research Culture Collection Northern Regional Research Laboratory (NRRL)	1815 N. University Street Peoria, IL 61604
American Type Culture Collection (ATCC)	12301 Parklawn Drive Rockville, MD 20852
Australian Government Analytical Laboratories (AGAL)	Commonwealth Department of Administrative Services New South Wales Regional Laboratory 1 Suakin Street Pymble, New South Wales Australia 2073
Centraalbureau voor Schimmelcultures (CBS)	Oosterstraat 1 Postbus 273 NL-3740 AG Baarn Netherlands
Collection Nationale de Cultures de Micro-organismes (CNCM)	Institut Pasteur 28, rue du Dr Roux 75724 Paris Cedex 15 France
Culture Collection of Algae and Protozoa (CCAP)	Freshwater Biological Association Windermere Laboratory The Ferrey House Far Sawrey Ambleside, Cumbria LA22 0LP United Kingdom  Scottish Marine Biological Association Dunstaffnage Marine Research Laboratory P.O. Box 3 Oban, Argyll PA344AD United Kingdom
Culture Collection of the CAB International Mycological Institute (CMI CC)	CAB International Mycological Institute Ferry Lane Kew, Surrey TW93AF United Kingdom
Deutsche Sammlung von Mikroorganismen (DSM)	Gesellschaft für Biotechnologische Forschung mbH Grisebachstr. 8 3400 Göttingen Federal Republic of Germany
European Collection of Animal Cell Cultures (ECACC)	Vaccine Research and Production Laboratory Public Health Laboratory Service Centre for Applied Microbiology and Research Porton Down Salisbury, Wiltshire SP4 0JG United Kingdom
Fermentation Research Institute (FRI)	Agency of Industrial Science and Technology Ministry of International Trade and Industry 1-3, Higashi 1-chome Yatabe-machi Tsukuba-gun, Ibaraki-ken 305 Japan
Institute of Microorganism Biochemistry and Physiology of the USSR Academy of Science (IBFM)	Pushchino-na-Oke USSR-142292 Moscow Region Soviet Union
In vitro International, Inc. (IVI)	611 (P) Hammonds Ferry Road Linthicum, MD 21090
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)	Block 2 125, Lenin Blvd. Sofia Bulgaria

Continued next page

**Table 9-2—Institutions Having Acquired the Status of International Depository Authority-Continued**

Name of depository	Address
National Collection of Agricultural and Industrial Microorganisms (NCAIM)	University of Horticulture Department of Microbiology Somloi ut 14-16 I-I 118 Budapest Hungary
National Collection of Industrial Bacteria (NCIB)	The National Collections of Industrial and Marine Bacteria Ltd. P.O. Box 31 135 Abbey Road Aberdeen AB98DG United Kingdom
National Collection of Type Cultures (NCTC)	Central Public Health Laboratory 61 Colindale Avenue London NW95HT United Kingdom
National Collection of Yeast Cultures (NCYC)	AFRC Institute of Food Research Norwich Laboratory Colney Lane Norwich NR47VA United Kingdom
USSR Research Institute for Antibiotics of the USSR Ministry of the Medical and Microbiological Industry (VNIIA)	Nagatinskaya Street 3-a USSR-1 13105 <i>Moscow</i> Soviet Union
USSR Research Institute for Genetics and Microorganism Breeding of the USSR Ministry of the Medical and Microbiological Industry (VNII Genetika)	Dorozhnaya Street No. 8 USSR-1 13545 <i>Moscow</i> Soviet Union

SOURCE: Adapted from *Industrial Property*, pp. 24-30 (January 1988).

The rules proposed in 1988 by PTO would continue and clarify both long-standing PTO practices and judicially developed principles of patent law. The proposed rules prescribe:

- conditions under which a deposit may be made;
- kinds of materials that may be deposited;
- the type of depository acceptable to PTO;
- the time for making the original deposit;
- procedures and obligations applicable to the making and maintaining of a deposit, and its possible replacement; and
- the term of a deposit.

The proposed rules make clear that the material, if the patent application enables it, must be publicly available. This can be accomplished by making a deposit of the material or making it otherwise publicly available. Commercial availability from the patent owner or another party would satisfy the requirement of public availability for U.S. patent purposes (7).

It is noteworthy that the deposit system is not intended to resolve substantive issues of patent law

or to anticipate matters that are more properly left to contentious patent office proceedings or court jurisdiction. The responsibility for performance of the deposited material rests on the shoulders of the applicant, who must face the consequences of an invalid patent in the event of failure of the deposit to perform (3).

### ***Role of the Independent Depository***

The role of the depository is to retain and be a convenient source of the inventor's deposit. It is an objective entity—independent of the patent applicant/patentee and PTO. It is not the role of the depository to provide legal advice or to know about the legal requirements of the patenting system. However, in order for a depository to facilitate the deposits of cultures, it has become necessary to know the legal requirements for deposit in the United States and internationally. In the United States, for example, it is possible to make a deposit up until the date a patent is granted, but if an applicant wishes to claim the U.S. filing date as his priority date when filing in other countries, it is necessary for the deposit to have



been made by the date of filing of the patent application in the United States.

In some cases, the patent culture depository is the first place inventors contact when they believe they have made a patentable invention. In other cases, depositories are asked to advise inventors on whether a deposit is necessary in order to disclose the best mode of carrying out the invention, as required in the United States, or to disclose how to make and how to use the invention (i.e., an enablement of the invention), as required in almost all countries. Inventors often do not understand the traditional function of the depository (1).

In order to assist biotechnology patenting, one depository has arranged an annual "Biotechnology Patent Conference" at which U.S. patent attorneys and agents, PTO examiners, patent attorneys from Japan and Europe, and patent depository staff acquaint inventors and attorneys practicing in this field with information on patent disclosure and



Photo credit: American Type Culture Collection

Glove box for handling special cultures.

claim requirements, as well as depository practices regarding patents (1).

Many depositories have had to expand the types of material accepted and to develop expertise in the maintenance and growing of materials never before anticipated. In 1982, for instance, no depository in the world accepted plant tissue cultures for patent purposes. In response to this need, ATCC developed the expertise to maintain a collection of plant tissue cultures, and in 1983 began accepting this material (and later on, seeds) for patent purposes.

None of the depositories at this date accepts animal life. ATCC has been asked by at least one inventor if it will accept an animal form, and is currently considering the consequences of doing so (1).

## HOW ARE DEPOSITS MADE AND MAINTAINED

Any depository approved by WIPO meets the requirements of the Budapest Treaty and is, therefore, acceptable for PTO purposes. In addition, patents have been granted based on deposits in institutions that do not meet the requirements of the Budapest Treaty, although PTO has no standard procedure for recognizing depositories other than those recognized under the Budapest Treaty (16).

In most cases, procuring cultures is easily accomplished by requesting the culture in question and paying the depository's fee. In a few cases, *procuring cultures is more complicated and time-consuming.* The patent depository in Japan, for example, requires a number of forms and a power of attorney. In a few instances, depositories in other countries have denied access to a culture even though it was cited in a U.S. Patent as on deposit, and probably legally available without restriction to the public (1).

The Department of Commerce requires an export license before export of many types of microorganisms (including most bacteria and viruses) outside the United States. The depository must apply for the license, which sometimes delays the request for 2-3 weeks. In some cases, USDA or the Department of Health and Human Services requires an import permit before allowing cultures into the

United States. This can also delay the receipt of cultures from outside the United States.

Generally, cultures involved in the patent process must be made available either when the patent is issued (as under the U.S. patent system) or when the patent application is published (as under the European patent system). If an issued patent cites and relies on the use of a culture deposited at a patent depository for the enablement of the claimed invention, the depository is obligated to make the culture available to the public upon request and payment of a fee. The European Patent Office (EPO) must certify one's right to a culture if the patent application has been published by its office, but the requestor must agree to use the culture for research purposes only and not to redistribute it to another party, unless this requirement has been waived by the depositor. Also, under the EPO system, an inventor may choose an option that requires the culture to be made available through an expert; experts are approved by the EPO President.

### ACCESS TO SAMPLES ON DEPOSIT

The availability of samples from U.S. depositories for cultures involved in the patenting process is straightforward. If the depository number and the U.S. Patent number are known, the culture may be requested, and it is routinely made available. Obtaining cultures from depositories outside the United States can be delayed and, since the depositories are not always knowledgeable of U.S. patent requirements, on occasion requests have been denied. There have been few reasons given for such denial. A collection in the Soviet Union, for example, implied that someday, perhaps, the requested culture would be made available. Several years later it still has not been made available. Another collection in the Netherlands simply stated a requested culture was not available, with no reason given. There is no record of a U.S. depository ever denying access to someone eligible to receive a culture (1).

Mere citation to a deposit in a U.S. Patent is not necessarily an indication of its unconditional accessibility once the patent is granted. The deposit is accessible only where it is required to make or use the claimed invention. In one case, for example, PTO determined that certain deposited material was



Photo: American Type Culture Collection

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not required for enablement even though cited in the patent, and a request for PTO to certify that the requestor was entitled to samples was denied (16).

Some patent owners contend that free access to a deposit is more revealing than the patent disclosure and therefore amounts to superdisclosure (12). Some owners of hybridoma patents, for example, object to making their deposits available to the general public at little or no cost. They contend that this practice amounts to giving away their invention plus all of the know-how they might have been able to sell separately. Their claim of loss, however, may be exaggerated. Knowledge of how to produce and maintain hybridoma cells in culture does not generally permit large-scale operation. The latter methods must either be reverse-engineered or the knowledge purchased separately (2).

The Budapest Treaty and PTO require a culture to be maintained for 30 years from date of deposit, or 5 years after the most recent request for a sample, whichever is longer. In addition, PTO requires the culture to be on deposit for at least the enforceable life of the U.S. Patent plus 6 years for statute of limitations on infringement.

The 30-year maintenance requirement, if deposit is made at the time of filing for a patent, assures in most cases that the culture is available for a period of time after a patent has expired. In most instances, therefore, the public has reasonable access after patent expiration, since the normal life of a U.S.

Patent is about 17 years. (An additional 6 years for statute of limitations on infringement is not considered part of the patent life.) Should deposit and issuing of the patent occur years apart and actually consume part or all of 30 years, periodic requests of the deposit will still ensure that it is maintained by the depository after patent expiration.

International Depository Authorities must post a bond to ensure that, in the event of the default of a depository, sufficient funds would be available to transfer patent cultures to another depository.

Inventors are required to agree to replace cultures if they are lost, or die, during the "30 years plus 5" deposit period. In cases where inventors or their heirs or assignees are unable to replace a culture, the patent may be invalidated. In most cases, a patent is assigned to a company or institution, and replacements are a corporate responsibility, not an individual one. In rare cases, the nonpayment of a maintenance fee to a depository could result in the return of the culture to the inventor, thereby placing the patent in jeopardy. In most cases the fee is paid in advance, thereby alleviating the problem. There appear to be adequate safeguards for the safekeeping of a patent culture during the required storage period.

Some U.S. companies have expressed concern about free access to a deposit once the patent issues. At present, nothing prevents a foreign competitor from obtaining the deposit and duplicating and selling the invention abroad. These American companies advocate that the U.S. adopt a law similar to that of West Germany, which requires that an individual obtaining a sample be contractually bound to use the deposit material only for experimental or research purposes. PTO does not currently have authority to place such conditions on deposits (6).

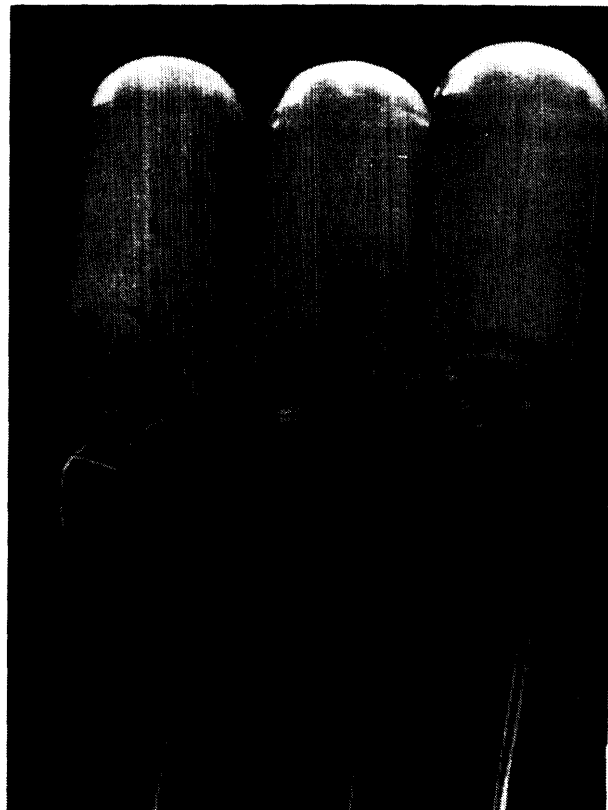
### **POSSIBLE METHODS OF DEPOSIT FOR PATENTED PLANTS AND ANIMALS**

Inventors are now depositing seeds and plant tissue cultures to support patent applications. The first plant tissue deposit at ATCC was in 1983 and the first seed deposit in 1985. Since that time approximately 40 plant tissue and seed deposits have been made. And, in administering the Plant Variety

Protection Act, USDA requires a deposit of 2,500 seeds for the grant of a Plant Variety Protection Certificate.

The deposit of seeds and plant tissue culture has become an established practice. Although there are few depositories worldwide which accept such deposits, there are two in the United States that do-American Type Culture Collection and In Vitro International, Inc. In addition, USDA maintains a vast seed depository at Ft. Collins, CO.

There is no requirement under the utility patent statute for the deposit of a plant or seed. A deposit of a plant or seed is only required where reproduction of the plant or seed cannot be reliably achieved from the disclosure in the patent application. In the usual case, an enabling disclosure can be made for genetically engineered plants and seeds. Accordingly, deposits of plants and seeds will usually not be required (4).



*Photo credit Diversity, Genetic Resources Communications Systems, Inc.*

Plant culture.

The new patentable status of animals raises the possibility that PTO will encourage or require the deposit of animal forms to support certain patent applications. Already ATCC has received a request from an inventor's attorney to consider accepting oyster larvae to support a patent application in PTO.

To date, no animal has been deposited with a depository. In the case of the first animal patent granted, U.S. Patent 4,736,866, the deposit requirement was satisfied, not by deposit of a mouse or other animal, but by deposit of the cancer-causing genes intended for transfer into an animal. DNA plasmids bearing those genes were deposited at ATCC. In the patent, the inventors describe detailed instructions for inserting those genes into mouse embryos to produce transgenic mice.

It is not practical to maintain or make available whole animals, but the maintenance of embryos in a frozen state may be possible. If culturing fertilized ova to the blastula stage as an indicator that growth of the animal would occur is feasible, and would be an acceptable test of viability, it may not be impractical to maintain and make available animal forms. What constitutes "viability" must be defined. This is also coupled with acceptability of statistical probability that the ovum/embryo would be capable of implantation and successful gestation.

### IMPACT OF PATENTED ANIMALS ON INDEPENDENT DEPOSITORIES

The patenting of animals could cause problems for a depository if deposit of the animal is required. Currently there is no depository willing to accept the deposit of animals for the following reasons:

- The cost of facilities and expertise that might be needed to maintain animals would be prohibitive.
- A depository maintaining animals for patent purposes might be subject to adverse publicity.
- If it were necessary to maintain the animal, a depository might need to grow another sample to prove the replication of the animal. After growth of the animal, disposal might not be acceptable, and, therefore, maintenance of progeny would be necessary.

- How would a depository make samples of the animal available? Grow more animals?
- Maintenance of many kinds of animals for the current required period of 30 years would not be practical or possible, as their life spans are shorter than 30 years.

The deposit of animal embryos may not present the same difficulties, as long as the embryos can be successfully frozen and recovered. To date, at least 13 species of animal embryos (cattle, mice, rats, rabbits, hamsters, sheep, goats, horses, cats, antelopes, and three species of nonhuman primates) have been successfully frozen and recovered, and many thousands of live young from frozen mice and cattle embryos have been produced (11). U.S. Patents 4,380,997 and 4,419,986 were issued in 1983 for the process of freezing animal embryos. If culturing thawed animal embryos to the blastula stage is a technically feasible and acceptable test for viability, patent depositories may be willing to accept animal embryos for deposit. If deposit of animal forms is desirable for patent purposes, PTO will need to develop specific guidelines for such deposits.

### SUMMARY

The practice of depositing micro-organisms to provide enablement or the best mode of practicing an

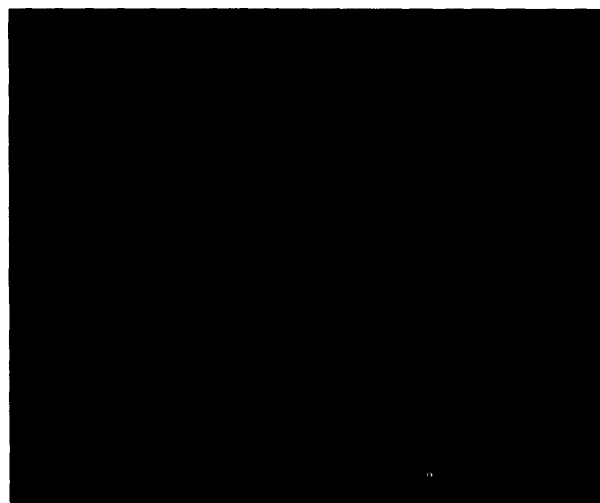


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invention has been in place since 1949, although a deposit is not always required. The ability to patent novel life forms created through biotechnology, as held in the *Chakrabarty* case, and the ability to protect plants with a utility patent as held in the *Hibberd* case, has resulted in increased patenting in these areas and thereby increased deposits of microorganisms, cells, and plants. The deposit of microorganisms, plants, and similar material in support of a patent application is a well-established practice, though not all problems associated with this practice have been resolved.

Depositories facilitate the deposit of cultures for patent purposes by providing current information on deposit requirements, and by developing the expertise necessary to maintain new types of material as needed. There are currently three institutions in the United States that have achieved the status of International Depositary Authority under the Budapest Treaty and are so recognized by the World Intellectual Property Organization. These and others may accept and maintain cultures to meet PTO requirements.

With PTO policy holding that nonnaturally occurring, nonhuman, multicellular living organisms, including nonhuman animals, are patentable, the first animal patent was issued in 1988. The enablement requirement of the first animal patent was satisfied by deposit of genes—but not live animals. Enablement by deposit of animal forms is not likely to be required to support many animal patent applications. Yet deposit of animals or embryos may be necessary for some inventions. There are problems associated with the deposit of animal life that need to be examined and guidelines concerning these deposits need to be developed.

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