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Chapter 14

IP and The Budapest Treaty—Depositing Biological Material for Patent Purposes

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INTELLECTUAL PROPERTY RIGHTS—WHY TO DEPOSIT BIOLOGICAL MATERIAL

Many discoveries in science fall in the category of "inventions" with commercial value and might result in patent applications. The invention of a product or a process is an intellectual property owned by the inventor. The term "intellectual property" refers to "creations of the human mind." According to the *Convention Establishing the World Intellectual Property Organization* (http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=283854) (WIPO, 1967) matters like literary, artistic and scientific works, performances of performing artists, phonograms, and broadcasts, inventions in all fields of human endeavor, scientific discoveries, industrial designs, trademarks, service marks, commercial names and designations, protection against unfair competition, and "all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields" are protected by intellectual property rights.

Intellectual property rights are divided into two main categories, (1) the copyright and related rights and (2) industrial property rights.

- *Copyright and related rights* include rights of authors of books, paintings and computer programs, of actors, musicians etc. and grant protection for a period of at least 50 years after the death of the copyright owner. Thus authors, artists, singers etc. are encouraged and rewarded for their creative work.
- *Industrial property* comprises two main areas: trademarks and geographical indications (with the aim to stimulate and ensure fair competition and to protect consumers) on the one hand and industrial property on the

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other hand which is supposed to stimulate innovation, design, and the creation of technology. The second one includes patent protection for inventions, industrial designs, and trade secrets. The protection serves as incentive for the necessary investments. The period of protection for patents is shorter than for a copyright and ceases after 20 years. Patent protection will guarantee the inventor some degree of exclusivity on the invention to assure a reasonable profit and to justify the risks of development. In return, the inventor discloses the invention by giving an exact written description of the process. The knowledge will be available to the public and others may build upon this knowledge. The disclosure gives the public the possibility to rework the invention for experimental purposes and, *after* expiration of the period of patent protection, for commercial purposes. The best-known examples are generic drugs which often are based on the patents that are expired. They are, for example, available for pain relief (Voltaren), antibiotics (Amoxil, Ampicillin), and Combivir (HIV treatment).

Most biological processes use live organisms, such as microorganisms, plant, or animal cells. This biological material could be naturally occurring, isolated from the environment or modified in the laboratory either by introducing mutations (improved strains) or genetically modified (recombinant strains). An example of former are antibiotic producing organisms like *Streptomyces venezuelae* which was cited as in the patent for the production of chloramphenicol. A well-known example of the later is the production of human insulin (humulin) using *Escherichia coli* as host. In such cases, even a detailed description of generating such cells may not ensure reproducibility of the process and this will necessitate deposition of such material at an independent place. Such material then becomes a "strain deposited for patent purposes" but is collicially known as a "patent strain." As patent offices do not have the facilities for the storage of microorganisms, independent and scientifically recognized culture collections have been entrusted with the handling of the biological material to be deposited. *The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* (WIPO, 1989) regulates the process of patent deposits in an international framework. The most important feature of the treaty is that a patent deposit which has been made with one International Depositary Authority (IDA) (http://www.wipo.int/treaties/en/registration/budapest/) is sufficient and recognized by all member states of the Budapest Treaty (http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=7). Nonmember countries may also accept deposits according to the Budapest Treaty as per the norms of the country. To date (January 2017), 80 states worldwide and three intergovernmental industrial property organizations are party to the Treaty.

IDAs are impartial, objective, and available to any depositor on the same terms, and they comply with the requirements of secrecy. Information on sample deposited with an IDA is never disclosed to anyone, except to parties entitled to obtain a sample of the said organism. IDA tests the viability of the biological material promptly after receipt and stores the organisms for the minimum period of 30 years as specified by the treaty (Sharma and Shouche, 2014). The treaty also stipulates further storage of 5 years after the most recent request for the furnishing of a sample of the strain (Note 1). Samples of the deposited material are furnished for testing and verification to the entitled parties. At present (January 2017), 45 culture collections across the world have been given the status of IDA (Table 14.1).

TABLE 14.1 List of International Depositary Authorities (as of October 2016)

Institution	Country	Date status acquired
Advanced Biotechnology Center (ABC)	Italy	February 29, 1996
Agricultural Research Service Culture Collection (NRRL)	United States of America	January 31, 1981
American Type Culture Collection (ATCC)	United States of America	January 31, 1981
Banco Español de Algas (BEA)	Spain	October 28, 2005
Belgian Coordinated Collections of Microorganisms (BCCMTM)	Belgium	March 1, 1992
CABI Bioscience, UK Centre (IMI)	United Kingdom	March 31, 1983
Centraalbureau voor Schimmelcultures (CBS)	Netherlands	October 1, 1981
China Center for Type Culture Collection (CCTCC)	China	July 1, 1995
China General Microbiological Culture Collection Center (CGMCC)	China	July 1, 1995
Colección Chilena de Recursos Genéticos Microbianos (CChRGM)	Chile	March 26, 2012

(*Continued*)

TABLE 14.1 List of International Depositary Authorities (as of October 2016) (*cont.*)

Institution	Country	Date status acquired
Colección de Microorganismos del Centro Nacional de Recursos Genéticos (CM-CNRG)	Mexico	August 25, 2015
Colección Española de Cultivos Tipo (CECT)	Spain	May 31, 1992
Collection nationale de cultures de micro-organismes (CNCM)	France	August 31, 1984
Collection of Industrial Yeasts DBVPG	Italy	January 31, 1997
Culture Collection of Algae and Protozoa (CCAP)	United Kingdom	September 30, 1982
Culture Collection of Yeasts (CCY)	Slovakia	August 31, 1992
Czech Collection of Microorganisms (CCM)	Czech Republic	August 31, 1992
European Collection of Cell Cultures (ECACC)	United Kingdom	September 30, 1984
Guangdong Microbial Culture Collection Center (GDMCC)	China	January 1, 2016
IAFB Collection of Industrial Microorganisms	Poland	December 31, 2000
International Depositary Authority of Canada (IDAC)	Canada	November 30, 1998
International Patent Organism Depositary (IPOD), National Institute of Technology and Evaluation (NITE)	Japan	May 1, 1981
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna «Bruno Ubertini» (IZSLER)	Italy	February 9, 2015
Korean Agricultural Culture Collection (KACC)	Republic of Korea	May 1, 2015
Korean Cell Line Research Foundation (KCLRF)	Republic of Korea	August 31, 1993
Korean Collection for Type Cultures (KCTC)	Republic of Korea	June 30, 1990
Korean Culture Center of Microorganisms (KCCM)	Republic of Korea	June 30, 1990
Lady Mary Fairfax Cellbank Australia (CBA)	Australia	February 22, 2010

TABLE 14.1 List of International Depositary Authorities (as of October 2016) (*cont.*)

Institution	Country	Date status acquired
Leibniz-Institut DSMZ–Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)	Germany	October 1, 1981
Microbial Culture Collection (MCC)	India	April 9, 2011
Microbial Strain Collection of Latvia (MSCL)	Latvia	May 31, 1997
Microbial Type Culture Collection and Gene Bank (MTCC)	India	October 4, 2002
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)	Bulgaria	October 31, 1987
National Collection of Agricultural and Industrial Microorganisms (NCAIM)	Hungary	June 1, 1986
National Collection of Type Cultures (NCTC)	United Kingdom	August 31, 1982
National Collection of Yeast Cultures (NCYC)	United Kingdom	January 31, 1982
National Collections of Industrial, Food and Marine Bacteria (NCIMB)	United Kingdom	March 31, 1982
National Institute for Biological Standards and Control (NIBSC)	United Kingdom	December 16, 2004
National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD)	Japan	April 1, 2004
National Measurement Institute (NMI)	Australia	September 30, 1988
Polish Collection of Microorganisms (PCM)	Poland	December 31, 2000
Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)	United States of America	April 26, 2013
Russian Collection of Microorganisms (VKM)	Russian Federation	August 31, 1987
Russian National Collection of Industrial Microorganisms (VKPM)	Russian Federation	August 31, 1987
VTT Culture Collection (VTTCC)	Finland	August 25, 2010

HOW TO DEPOSIT BIOLOGICAL MATERIAL—THE PRACTICAL PROCEDURE OF A PATENT DEPOSIT

Before filing a patent application, it is desirable to verify from a patent expert whether a patent deposit is necessary to ensure the reproducibility of the invention (Note 2). If the properties of the organism can be described in sufficient details in writing, for example, DNA sequence information etc., then a deposit may not be required. If, however, a sufficient written description is not possible, the material should be deposited. To be on the safer side, it might be advisable to deposit the biological material even in former case. If the biological material is already deposited, then it has to be ensured whether this deposit is deposited according to patent regulations. If the organism has already been deposited by the patent applicant according to the Budapest Treaty, the application can be filed immediately (Fig. 14.1).

A deposit which is not in accordance with the Budapest Treaty (a patent deposit performed before the collection was given the IDA status; a safe deposit) should be converted into a patent deposit as per Rule 6.4 (d) of the Treaty. The original accession date may—but not necessarily—remain valid but it may be easier to deposit the organism again according to the Treaty. If the organism has been deposited by a party different from the patent applicant it has to be checked whether the patent applicant is authorized to refer to the biological material in their application (Fig. 14.2). Deposits in the open part of a collection should not and type strains cannot be converted into deposits, according to the Budapest Treaty.

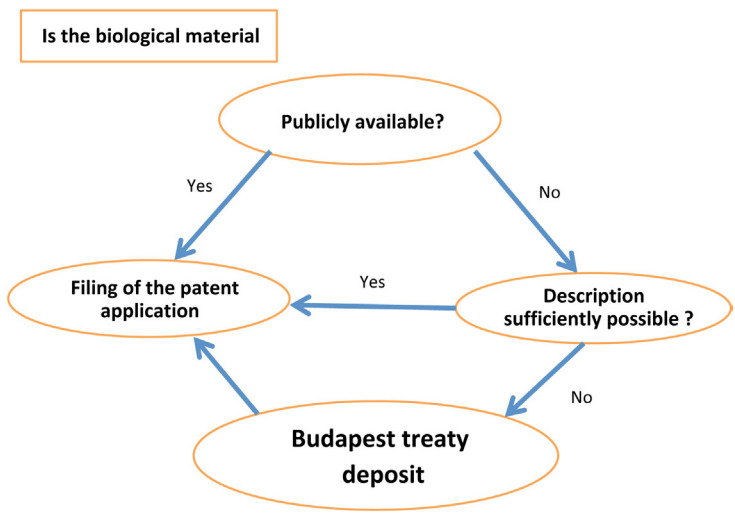


FIGURE 14.1 **Assistance key for decision making whether biological material has to be deposited or not.**

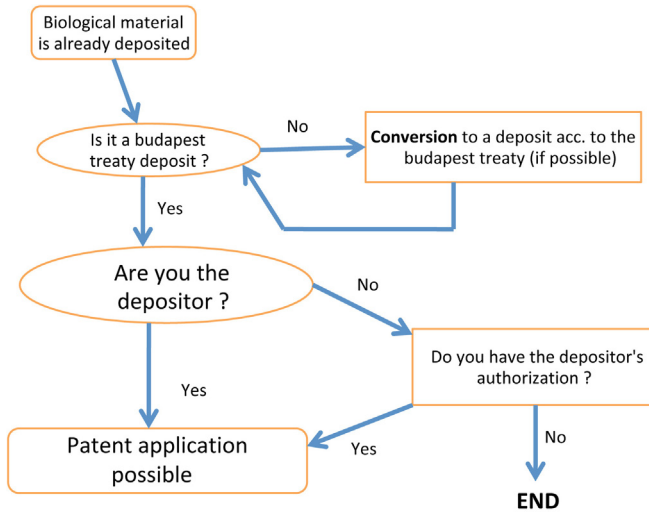


FIGURE 14.2 **Assistance key for decision making whether the correct kind of deposit has been chosen.**

Where to Deposit—Choice of an IDA

Once it is ensured that a patent deposit is advisable or necessary, the future depositor should first look for the suitable IDA as each IDA accepts different kinds of biological material. The Budapest Treaty does not offer a specific definition of the term "microorganism." It is interpreted in a broad sense: isolated DNA and cell cultures are regarded as microorganisms as well as bacteria or bacteriophages. The actual definition suitable for all kinds of biological material accepted as deposit for patent purposes states that the biological material must contain genetic information and must be self-replicating (e.g., bacteria, fungi) or of being reproduced in a biological system (e.g., plasmids, viruses) (European Parliament, 1998a). Considering the diverse nature of biological materials, the type of material accepted differs between the individual IDAs. There are some which accept only one or two kinds of organisms, whereas others accept a broader range of different kinds of biological material (Table 14.2).

Furthermore, an IDA decides about the Risk Group of the biological material it accepts. Biological material beyond these Risk Groups have to be refused and may not be accepted by the IDA. Therefore, material should at least be characterized to a certain minimal taxonomic level to enable its risk classification before it is sent to an IDA. Within the European Community, compliance to the Council Directive 2000/54/EEC (http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32000L0054&from=EN) on the protection of workers from risks related to exposure to biological agents at work is mandatory

TABLE 14.2 Kinds of Biological Material Accepted by 12 out of 45 IDAs

IDAs	Kind of biological material accepted	Risk group
ABC	Animal and human cell lines	2
ATCC	Algae, bacteria, fungi, embryos, human, animal and plant cell cultures, bacteriophages, animal and plant viruses, seeds, DNA, RNA, Protozoa	4
BCCM	Bacteria, fungi, yeasts, plasmid DNA, RNA, animal and human cell lines	2
BNA	Microalgae, cyanobacteria and macroalgae	1
CBS	Bacteria, fungi, yeasts, bacteriophages, plasmid DNA	3, 2 for GEMs
CCAP	Algae, free-living protozoa, microorganisms	1
DSMZ	Bacteria, fungi, yeasts, bacteriophages, plasmid DNA, plant viruses, plant cell cultures, animal and human cell cultures	2
CABI Bioscience, UK Centre (IMI)	Fungi, bacteria, nematodes	2
MCC	Bacteria, fungi, yeasts, plasmid DNA	2
KCLRF	Animal, human and plant cell cultures	1
KCTC	Algae, animal and plant viruses, animal, human and plant cell cultures, bacteria, fungi, yeasts, bacteriophages, embryos, protozoa, seeds	1
VKM	Bacteria, fungi, yeast	1

(European Parliament, 2000). In the case of genetically modified organisms these must be classified accordingly (http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009L0041&from=EN) (European Parliament, 1998b).

As a result, the potential depositor and/or patent applicant first needs to classify the biological material that they wish to deposit before identifying the suitable IDA. The information about which kinds of biological material are accepted by an individual IDA can be obtained directly from the IDA (in most cases by consulting their respective websites) (Table 14.1) or by consulting the Guide to the Deposit of Microorganisms under the Budapest Treaty (http://www.wipo.int/treaties/en/registration/budapest/guide/index.html) (WIPO, 2016). The choice of the depositary should be made taking into account, inter alia: (1) the kind of biological material involved in the patent application; (2) the language(s) spoken and accepted by the IDA (to facilitate correspondence); and (3) the availability of the IDA considering possible import and export restrictions.

When to Deposit—Date of Patent Deposit

As the patent deposit can be interpreted as an essential part of a patent application it is extremely important that both, patent application and strain deposit, are performed before publication of any results (lecture, poster, publication). Otherwise, patent protection would not be grantable anymore as the invention would lack novelty. As it is desirable to file the patent application *including* the deposition statements, the deposit ideally should be performed in good time before the prospective filing date. Generally speaking, and depending on the respective patent legislation, the last date for depositing the biological material is the date of the filing of the patent application.

The Deposition Procedure Itself

While depositing a patent culture it should be accompanied by a deposit form which has been duly filled in and signed by an authorized official of the depositing organization. The depositor can obtain this form directly from the depositary. It is the deposition contract between the depositor and the IDA. The form should contain all information necessary for the IDA to handle the biological material and will allow the allocation of the material to the responsible IDA representative upon receipt at the culture collection. To allow the immediate processing of a deposit it is advisable to inform the IDA beforehand of an intended deposit and to specify which kind of biological material will be involved.

The culture should be supplied to the IDA in the amount and form requested by the culture collection in order to guarantee a smooth deposition procedure. The relevant information might be obtained directly from the IDA or the WIPO Guide to Deposit of Microorganisms under the Budapest Treaty (www.wipo.int/treaties/en/registration/budapest/guide). On the WIPO website, all necessary information is available. Depending on the IDA selected, different amounts of biological material might be requested:

The DSMZ (Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures) (https://www.dsmz.de/deposit/patent-deposit/biological-material-accepted-as-patent-deposit.html) as an example requests the following forms and amounts of biological material:

1. *Bacteria and fungi*—strains without plasmids or plasmid bearing strains—should, where possible, be deposited in the form of actively growing cultures (two separate preparations, preferably in the form of screw-capped test tubes). Freeze-dried and cryocultures are accepted as well.
2. *Plasmids* as isolated DNA preparations should be deposited in a minimum quantity of 2×20 µg (2 vials containing 20 µg each).
3. *Bacteriophages* should be deposited in minimum quantities of 2×5 mL (2 vials containing 5 mL each) having a minimal titer of 1×10^9 pfu/mL.

4. *Plant viruses* should be deposited in the form of dried or frozen plant material along with the host's seeds, unless the host is generally available. 100 µL of serum suitable for immunoelectron microscopy should be deposited in addition for the purity and identity test. When hybridomas for antibody testing of plants are deposited, the antigen (not pathogenic) necessary for the specificity test should be deposited at the same time.
5. *Plant cell cultures* should be deposited as active cultures in the form of a callus (4 Petri dishes), suspension (4 culture vessels) or—preferably—as frozen cultures in a dry shipper (25 ampoules).
6. *Human and animal cell cultures* should be deposited frozen in dry ice in a quantity of 12 cryoampoules containing 5×10^6 cells per ampoule, all prepared from the same batch of the culture.

The technical and administrative procedure of a deposition is as follows (see "checklist for depositors" in Fig. 14.3):

1. The depositor prepares the culture in the form and amount requested by the IDA.
2. The accession form is filled in and signed.

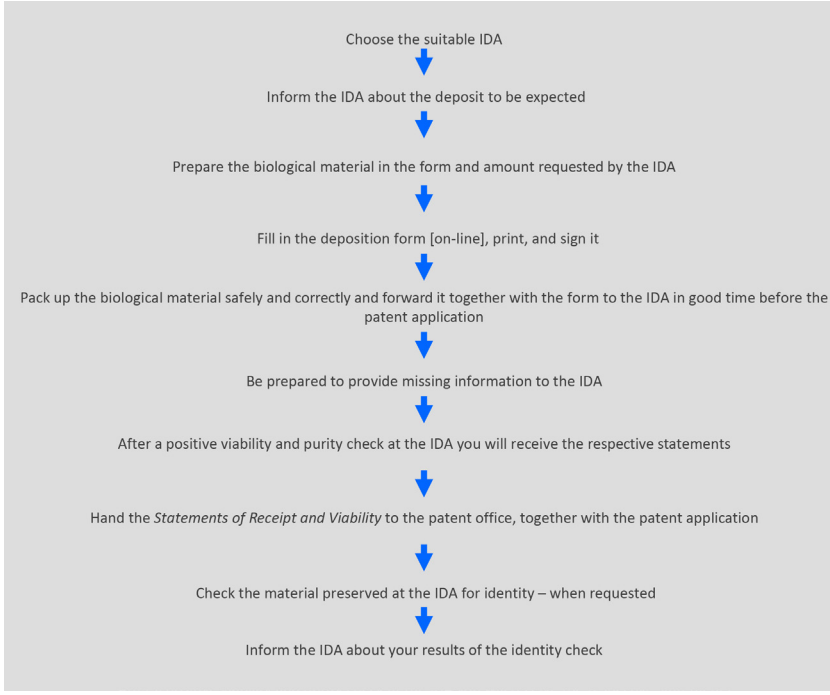


FIGURE 14.3 **Procedure and checklist for a patent deposit.**

3. The IDA is informed about the deposit to be expected (by phone, e-mail, fax, or letter).
4. The culture is packaged in a manner it will reach the IDA in a good condition. The relevant regulations for the shipping of biological material have to be taken into consideration (Rohde and Smith, 2013; Universal Postal Union, 2013; WHO, 1994).
5. Documents are checked for completeness at the IDA. If necessary, missing data will be requested from the depositor by the IDA.
6. After viability and purity of the culture is been checked at the IDA, the accession number will be assigned to the culture. Some collections assign provisional accession numbers when the culture reaches the IDA.
7. The depositor receives a statement of receipt and a statement of viability. These statements are important for the patenting procedure and should be submitted to the patent office involved when filing the application.
8. The biological material will be preserved and stored at the IDA.
9. After preservation at the IDA, the depositor will receive samples for identity checking (depending on the biological material deposited and the IDA chosen).
10. After checking the identity of the material, the depositor informs the IDA about the results of the check (material preserved at the IDA is identical/not identical).

According to established practice, an IDA will perform a viability test before assigning an accession number to the culture. Therefore, it must be in the interest of the depositor to send the cultures to the IDA as early as possible to provide sufficient time for the cultivation of the organism before the date of the filing of the patent application. This applies to all kinds of biological material. In general, the testing for viability and purity of bacterial and fungal cultures takes from one to several days. In the case of human and animal cell cultures viability testing, including the essential testing for contaminations with mycoplasmas, about 2 weeks might be required; the cultivation of plant cell cultures needs approximately 4 weeks. The individual time needed not only depends on the kind of biological material but may also vary considerably according to the species of organisms handled and often is even strain specific. A culture deposited for patent purposes cannot be claimed back after it has been deposited. Patent strains will be preserved by sufficient safety measures to minimize the risk of losing deposits. If, however, a strain deposited under the Budapest Treaty should die or be destroyed during the period of storage, it is the responsibility of the depositor to replace it by a viable culture of the same organism. Thus the patent can be kept alive. Therefore, it is advisable that the depositor also maintains the culture for the same period of time: in case the culture is for any reason no longer available from the Depositary Authority the stock may be replenished by the depositor.

HOW TO REQUEST THE FURNISHING OF SAMPLES OF PATENT ORGANISMS

As pointed out earlier the main reason for the deposit of biological material which is of relevance for a patent application is to render it available to entitled parties for verification, thus allowing the reproducibility of a protected invention. The accessibility to a deposited organism depends on the status of a patent. According to the Budapest Treaty, samples might be furnished either to interested industrial property offices (Rule 11.1), to the depositor and third parties who obtained the authorization of the depositor (Rule 11.2) or to parties legally entitled (Rule 11.3).

A request for the furnishing of a patent culture by a third party can be sent either to the IDA harboring the strain or, in certain cases, directly to the respective patent office involved. The IDA checks its files for information whether or under which conditions the culture is to be furnished. In most cases there is no information available whether the IDA is authorized to release a sample of the strain. The requestor will be asked to submit to the IDA a copy of the first page of the patent document in question and a copy of the page where the accession number of the collection of the strain in question is cited. After receipt of the requested documents the IDA can provide the relevant official forms (request for the release of a patent strain). In case of a national or a European patent the form must be filled in and sent to the relevant patent office for confirmation. The European Patent Office offers the necessary form 1140/1141 online (http://www.epo.org/applying/forms-fees/forms.html). If a US-Patent had been granted the strain is available without further examination by the patent office.

After receiving a pertinent confirmation from a patent office, the IDA will ship the sample taking into consideration of other national and international relevant regulations, for example, postal regulations (Universal Postal Union, 2013) or biological weapons conventions like the EU dual use directive (European Parliament, 1994) (Fig. 14.4) (Note 2). Please consult also (Rohde and Smith, 2013) and (WHO, 1994).

COMPLICATIONS ARISING DURING THE DEPOSITION PROCEDURE

There are a number of pitfalls in the course of a patent deposit which might cause serious problems to the patent applicant and therefore should be considered before the patent deposit:

Refusal of the IDA to Accept a Culture

An IDA may refuse to accept a culture for the following reasons:

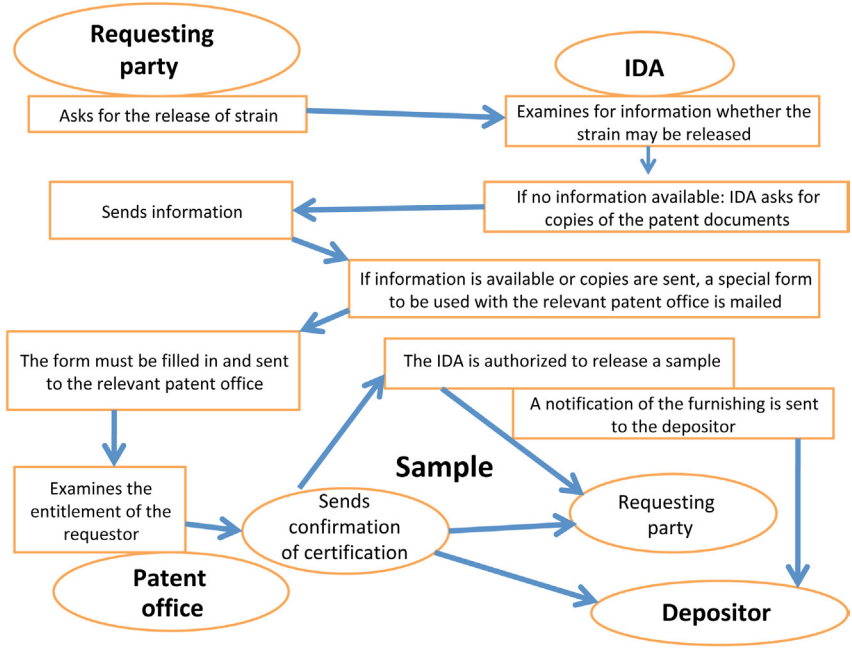


FIGURE 14.4 **Procedure for the furnishing of samples according to Rule 11.3 of the Budapest Treaty.**

- Where the biological material is not a kind of biological material that the IDA accepts (Rule 6.4 (a) i) (see section "Where to Deposit—Choice of an IDA").
- Where the conditions for cultivation are so exceptional that the IDA is technically not in a position to handle the organism. Here the depositary has the right to refuse an organism though it might belong to the kinds of organisms it gave assurances for (Rule 6.4 (a) ii).
- Where the organism is received by the IDA in a condition that clearly indicates that it is impossible to handle it properly (e.g. broken vials) (Rule 6.4 (a) iii).
- The most relevant reason to refuse a deposit, however, is if the organism proves to be nonviable at the first viability check. (Rule 10.2 (b)).

The Need of a New Deposit—the Reasons For

The viability of a deposited patent culture is tested from time to time at reasonable intervals. If an organism is no longer viable when tested at a later date the depositor within 3 months has the right to furnish the IDA with viable material of the organism originally deposited (Article 4(1)(a) i). The depositor has to confirm that the newly sent material is the same as the culture previously

deposited (Article 4(1)(c)). In case the sending or receipt of samples of deposited organisms abroad is prevented by export or import restrictions the depositor has the right to make a new deposit of the organism with another IDA without losing the original deposit date (Article 4(1) (a) ii).

Transfer of a Deposited Organism

If an IDA temporarily, permanently, or partly ceases to carry out its functions as an IDA (e.g., restricts the kinds of biological material accepted) a transfer of the cultures in question to another IDA shall be done. (Article 4(1) (b) (i) (http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=283784#P74_5277).

Conversion of Deposits Made Outside the Budapest Treaty

If a patent deposit has been done before an IDA acquired the status of an IDA such a non-Budapest deposit might be converted into a deposit according to the Budapest Treaty since the patent depositary has been recognized as an IDA (Rule 6.4 (d)). A non-Budapest, nonpatent deposit with a recognized IDA might be converted into a valid Budapest Treaty deposit by the original depositor. This will depend on the culture collection's policy. The original deposition date might remain valid. The decision about the effective deposition date is up to national patent legislation. The date of receipt of the request for conversion is considered as conversion date. This date ideally should be before the date of the filing of the patent application, especially in the case of safe deposits (which have to be considered as not being available to the public at all). Thus the accessibility of the biological material in time can be assured.

Problems Which Can be Prevented

As patent deposits have to be regarded as part of the written manifestation, the date of deposit has to be before or latest the date of filing the patent application. It is advisable that deposits are made well in advance to avoid the following problems:

- The depositor might have to cope with unexpected delays due to the transport (e.g., postal strikes, accidents) or customs problems.
- If a package is damaged or the biological material is not in the form requested by the IDA or the culture is proven to be nonviable there would be no time left to send a replacement culture to the depositary.
- If a culture is not of the kind of organisms accepted by the IDA time would be required to find a suitable alternative IDA.

Therefore, proper communication between patent attorney, depositor, and IDA is required to ensure smooth deposition of culture well in advance before filing patent.

Type Strains as Patent Strains

A conflict might arise from the interest of a researcher to obtain both: patent protection and scientific merit. This conflict is based on the demand for the free availability of taxonomic reference strains which is in contrast to the patent practice of restricting the distribution of samples of patent deposits to entitled parties only. Many of the patented microorganisms isolated from unusual habitats are not only of industrial interest but are also new to systematists. Thus, the scientists might also be interested in describing a novel taxon and also having the name validly published. The strain *Paracoccus marcusii* MH1, for example, produces carotenoids as described in a US patent (Hirschberg and Harker, 1999), on the other hand being the type strain of the species (Hirschberg and Harker, 1999). Here, as a result, the situation arose where the type strain for this new taxon, DSM 11574 is under patent protection. From a scientific point of view, however, type strains should be readily accessible for the user and no additional restrictions should lengthen the request procedure. The problem can be solved by keeping both activities separate and depositing a parallel subculture of the patent strain under a different accession number in the public part of a collection. The deposit of type strains is governed by the International Code of Nomenclature of Prokaryotes (Parker et al., 2015). Rule 30 3 (b) is explicit in requiring:

"As of 1 January 2001, the description of a new species, or new combinations previously represented by viable cultures must include the designation of a type strain (see Rule 18a), and a viable culture of that strain must be deposited in at least two publicly accessible culture collections in different countries from which subcultures must be available. The designations allotted to the strain by the culture collections should be quoted in the published description. Evidence must be presented that the cultures are present, viable, and available at the time of publication."

While Rule 30 4 specifically forbids:

"Organisms deposited in such a fashion that access is restricted, such as safe deposits or strains deposited solely for current patent purposes, may not serve as type strains."

Other unacceptable practices include changing the status of a type strain following publication of the collection number restricting access as either a safe deposit or imposing restrictions required when a strain is deposited solely for patent purposes (Tindall and Garrity, 2008)

NOTES

1. Material deposited for patent purposes according to the Budapest Treaty is stored at the IDA for at least 30 years (plus additional 5 years after the most recent release). What will happen to the deposited patent organisms after the prescribed period of storage? Are they to be transferred into the

public section of the collection to guarantee the state of the art? Are they to be destroyed as they might represent a whole "factory" which is available so easily? Should they be handed back to the depositor who is the original owner of the material? As there is no jurisdiction concerning the fate of the organisms, some IDAs offer the possibility that the depositor himself decides what will happen to the organisms after 30 years (+ 5 years). The depositor's declaration will be valid until relevant jurisdiction comes in place.

2. Patent applicants might fear that third parties will abuse the biological material deposited, especially in case a patent has been withdrawn. To allay these fears the IDA promptly notifies the depositor in writing of each furnishing of a sample of the deposited organism. In addition, in Europe Rule 32 of the European Patent Convention (EPC) (European Patent Office, 2000) offers the option to choose the "expert solution" in connection with patent deposits. Following this rule, after publication until the date of granting the patent, samples of the deposited organism will only be provided to a recognized expert. Experts in the field of research are scientists nominated by the European Patent Office. Alternatively, a scientist might be recommended as expert by the requesting party. Here it would be up to the depositor to accept this person as independent expert. If a patent is withdrawn the expert solution is applicable for 20 years.
3. IDAs typically are service culture collections. It is recommended to follow the *OECD Best Practise Guidelines for Biological Resource Centres* (OECD, 2007). These culture collections are now referred to as Biological Resource Centres (BRC). The Organization for Economic Co-operation and Development (OECD) recognized the needs to harmonize the quality of collection management to better serve bioindustry. "Biological Resource Centre (BRC)" stands for user-driven public culture collections with an improved quality management system. Issues of public interest, such as biorisk, intellectual property rights and material transfer agreement are additional tasks required of BRCs. They are compliant with appropriate national law, regulations, and policies and fulfil many crucial roles, including the preservation and supply of biological resources for scientific, industrial, agricultural, environmental, and medical R&D and biotechnological processes, the performance of R&D on these biological resources, the conservation of biodiversity, and to serve as depositary of biological resources for protection of intellectual property.

CONCLUSIONS

International Depositary Authorities serve as permanent facilities for the preservation and storage of biological material under confidentiality for the purposes of patenting. They are recognized according to the Budapest Treaty. IDAs make these "patent strains" available to third party for research and reworkability.

The number of IDAs is constantly increasing. In 1981 five IDAs started their function, to-date 45 IDAs are in existence. The IDA network is not evenly distributed over the world. In the developing countries biotechnology starts budding and the establishment of IDAs in Africa and South America certainly will follow according to the needs in these areas.

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