ASSOCIATION INTERNATIONALE POUR LA PROTECTION DE LA PROPRIÉTÉ INTELLECTUELLE
INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY
INTERNATIONALE VEREINIGUNG FÜR DEN SCHUTZ DES GEISTIGEN EIGENTUMS
AIPPI

Standing Committee on Pharma and Biotechnology

Position Paper

Harmonisation of Practice under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure

In this Position Paper, the AIPPI, through its Standing Committee on Pharma and Biotechnology, urges that a harmonised International environment for the recognition of the deposit of micoorganisms for the purpose of patent procedure be established by (1) encouragement of current non-contracting states to join the Budapest Treaty and (2) by virtue of adaptation of national and regional law, provide common restrictions to be applied to third party requesters of a sample of the deposited microorganism as to the activities they may carry out with the sample and the undertakings they must supply and harmonise the rights of the patent applicant or patent owner with respect to the sample.

About AIPPI

The International Association for the Protection of Intellectual Property, generally known under its French name abbreviation AIPPI, is the world's leading international organization dedicated to the development and improvement of legal regimes for the protection of intellectual property (***IP***).

AIPPI is a politically neutral, non-profit organization, domiciled in Switzerland, which currently has over 9000 members representing more than 125 countries. The objective of AIPPI is to improve and promote the protection of IP on both international and national bases. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and national laws relating to IP. It operates by conducting studies of existing laws and proposes measures to achieve harmonization of these laws on an international basis. Where appropriate, AIPPI intervenes with submissions before major courts and legislative bodies to advocate for strengthened IP protection.

AIPPI has numerous Standing Committees that specialize in various areas of law or technology relating to IP. Each committee is composed of intellectual property professionals

with expertise in the Committee subject. The members of AIPPI's Standing Committees reflect the geographic diversity of AIPPI.

AIPPI's Standing Committee on Pharma and Biotechnology was established to monitor, comment and advise AIPPI on policy and legal issues relating to IP protection for pharmaceutical and biotechnology inventions. The Committee currently has 60 members, from over 25 countries.

Executive Summary

The AIPPI Standing Committee on Pharma and Biotechnology (Biotechnology Sub-Committee) has carried out an international study to identify the discrepancies between procedures before national and regional patent offices with regard to the deposit of microorganisms for patent purposes. The study has been carried out with a view to make a recommendation for a common optimum procedure which allows the patentability requirement of sufficiency of disclosure of an invention to be met but which does not leave the patent applicant or owner vulnerable to abuses of the deposited sample when released to third party requesters. The recommendations of the Standing Committee are that a microorganism or other biological material must be deposited at a recognised International Depository Authority (IDA) not later than the earliest priority date of the patent application and as a minimum, the identity of the IDA and the accession or reference number of the deposit must appear in the published patent application. Following publication of the application, or in the case of an International application under the Patent Cooperation Treaty, after entry into the national phases of the application, the deposited sample may be released to the third party requester. Such a release should take place under tight restrictions. Intention to release should be notified to the patent applicant or owner who should have the right to object to the release to any specific requester, the dispute to be settled by the relevant national or regional patent office. Further, release must be accompanied by restrictions as to acts the requester may do with the released sample. In particular the requester may not: make available the sample or any biological material derived therefrom to any third party, export the sample from the country of release or use the sample for anything other than experimental purposes relating to the invention. The restrictions upon the requester will expire (1) upon grant of the patent (2) upon withdrawal or refusal of the patent application. Procedures must be in place to address breach of these restrictions by the applicant regardless of whether the application is still pending or granted including the option of requiring the requester to give security for damages in the event of breach. The applicant should have the option to implement the “expert solution” by requesting before publication of the application that the deposited sample be released upon request only to a nominated expert of the requester, the expert requiring the approval of the applicant and being bound by the same restrictions as would the requester with regard to acts which may be carried out by the sample.

1. Budapest Treaty and Regulations thereunder

To obtain grant of a patent it is a requirement that the invention be described in a manner clear and complete enough for it to be reproduced by a person skilled in the art. This is

variously described as the sufficiency of disclosure or enablement requirement. When the invention pertains to a microorganism or biological material it is not always possible merely by written description of the microorganism or material, for this requirement to be met. Access to a sample thereof is required. The patent laws of most territories provide for the patent applicant to be able to deposit the microorganism or material at a recognised Depository Authority, typically a cell-culture collection, whereby samples can be released to requesting third parties.

The Budapest Treaty is a union of contracting states which provides for the International recognition of the deposit of microorganisms for the purposes of patent procedure. It eliminates the need for a patent applicant to deposit the microorganism (a term construed in practice to cover all forms of biological material) in each country in which a patent is sought. Rather, it can be deposited with a single International Depository Authority (IDA) accorded such status under the Treaty and this is deemed to suffice for the purpose of meeting the sufficiency of disclosure requirement before the national Patent Offices of any contracting states and participating regional Patent Offices. Such IDA's are located throughout the world although there are currently only 80 contracting states to the Treaty.

The Budapest Treaty is principally concerned with the criteria to be met to be designated an IDA and the duties and the obligations upon the IDA, in particular, regarding testing the viability and facilitating the maintenance of cultures, arranging replacement of non-viable deposits, duration of storage, issuance of deposit certificates and procedure for the release of samples to third party requesters.

The Treaty does not address Patent Office requirements concerning the deposit such as when a deposit must be made, what information about the deposit must appear in the patent specification, when it must be supplied, any rights conferred on the patent applicant to restrict availability, nor any rights or obligations upon third parties to whom the sample is made available upon request. All of these are determined by national law of the contracting states party to the Treaty. Accordingly, the Budapest Treaty, while providing for harmonisation of recognition of a microorganism deposit for the purposes of patent procedure, does not provide harmonisation of patent laws and procedures regarding the requirements for sufficient disclosure or enablement for which reliance is placed on the deposit.

2. Study by the AIPPI Standing Committee on Pharma and Biotechnology

In the light of the scope for lack of harmonisation of rules and procedures before national or regional Patent Offices in connection with microorganism deposit, the AIPPI Standing Committee on Pharma and Biotechnology (Biotechnology Sub-Committee, hereinafter "COMMITTEE") has carried out an International study to determine where such rules and procedure coalesce and where they diverge among contracting states to the Budapest Treaty or states which otherwise allow for microorganism deposit, with a view to recommending a common optimum position which does not leave the patent applicant vulnerable to abuses of the deposited sample by said third parties but by which the requirement for sufficiency of disclosure can nevertheless be regarded as met.

The study covers the UK, Italy, Sweden, US, Canada, Mexico, Brazil, Australia, Japan, China, Korea, Philippines, Israel and the European Patent Office. The issues considered were, *inter alia* (i) at what point in the patenting procedure should a microorganism deposit be made for the purposes of sufficiency of disclosure, (ii) when should information about the deposit (name of IDA and accession no) appear in the patent specification, (iii) to whom should a third party make a request for a sample of the deposit, the national or regional Patent Office or the IDA, and when, (iv) to whom may the deposit by released and (v) what obligations does the requester have to meet in order for a sample of the deposit to be released to them.

3. Results of Study

(i) Date for Deposit

All of the territories studied are signed up to the Budapest Treaty except Brazil. However, Brazilian Industrial Property Law allows for supplementation of disclosure by deposit of biological material at an IDA recommended under the Budapest Treaty or otherwise authorised. All territories rely on the deposit system as necessary to secure sufficiency of disclosure. The study has shown that, it is predominantly the case that any microorganism deposit must be made no later than the filing date of the application or any claimed priority date, if reliance is to be placed upon it. The United States is an exception to this principle where a deposit can be made at any time before a patent is issued.

(ii) Provision of Deposit Information

It is a requirement across all the territories studied that reliance on a microorganism deposit requires the inclusion in the patent specification of sufficient information to allow third parties to identify and locate the deposited sample. At a minimum, this is the name of the IDA and the accession number or reference number, accorded to the deposit, although some Patent Offices require the date as well. However, there is variation as to when this information must be provided during the patenting procedure. The options include (a) at the filing date (China, Japan, Korea, Philippines), (b) after the filing date but before the application is put into the public domain by publication, usually by 18 months from the priority date (UK, Italy, European Patent Office, Canada, Australia), (c) on request from the National Patent Office if the information is missing on filing (Brazil) (d) six months after the date on which the applicant submits the corresponding patent application (Mexico) and (e) up to the point of grant (USA). In general, failure to meet this formal requirement does not, of itself, result in refusal of the patent application but renders the application vulnerable to refusal for lack of sufficiency of disclosure on substantive examination of the application for patentability.

(iii) Where should a third party lodge a request for sample of deposit and when?

Rule 11.3 of the Implementing Regulations of the Budapest Treaty requires that an IDA shall furnish a sample of the deposit to any natural person or legal entity upon making a request. The request must include a certification from the National Patent Office that (1) an application referring to the deposit has been filed for grant of a patent (2) the subject matter

of the application involves the microorganism or use thereof, (3) publication for the purpose of patent procedure has been effected by that Office and (4) the requesting party has a right to the sample under law governing patent procedure before the National Office and where National law applies any conditions on the requester upon release of the sample, those conditions have been met.

Consistent with this provision, most territories, party to the Budapest Treaty studied, have implemented provisions that require the release of a deposited sample to a third party to be authorised by the National Patent Office, at least requests made after the patent application is published but before grant. These are Canada, Australia, Korea, China, Japan, Italy, UK and European Patent Office. The applicant is duly notified of the request.

However, given the flexibility enshrined in Rule 11.3 to apply national law to the conditions of release, the study identified particular variations on the approach above. Mexico, the Philippines and Israel are all contracting states of the Budapest Treaty and are bound thereby but have not enacted specific provisions concerning release of deposited samples to third parties.

In Japan, although deposit information must be supplied on filing, Japanese National Law does not allow release of a sample to a requester until the patent is granted, except in specific circumstances, in particular, where an applicant for a patent is notified of the rejection of the application on the basis of an earlier filled application referring to a deposited microorganism or where a person receives a threat of later infringement proceedings under an application referring to a deposited microorganism.

In China, The State Intellectual Property Office (SIPO), upon receiving a request for release of a microorganism, duly notifies the applicant who is given the opportunity to provide comments as to why the sample should not be released to the requesting party. SIPO then makes a decision as to whether the release of the sample should be authorised or not.

It should be noted that the principle that a sample may be released to a requester following publication of the application is different where the national application arises from an International application under the Patent Cooperation Treaty. In this case, even though the eighteen month publication of the International patent application may take the place of a national publication, no microorganism deposit can be released until the application has proceeded to the national application phase (see Rule 13bis.6 PCT).

By contrast to the territories discussed above, the USA consistent with its position that a deposit to be relied on may be made at any time up to grant of the patent, does not allow release of the deposit until after grant.

Finally, Brazil, which is not a party to the Budapest Treaty, allows release of a sample of a deposit to a third party on request to an IDA or other authorised depository institution.

(iv) To whom may the deposit be released

As recited under (iii) above, Rule 11.3 of the implementing regulations of the Budapest Treaty requires an IDA to release samples to "any authority, natural person or legal entity" on verification from the National Patent Office that the deposited material is referred to in at least a pending and published patent application and any restrictions placed upon the character or actions of the requester set forth in national law are met. Conscious that release of a deposited sample to any requester could result in abuse of this right to the detriment of the patent applicant or patent holder, some of the studied territories have made use of the flexibility provided by Rule 11.3 to restrict availability of the sample to a "nominated expert", rather than the requester themselves. Amongst the studied territories, this option is available before the European Patent Office, UK, Italy, Sweden and in other European countries as well as Canada and Australia.

Under Rule 32 of the European Patent Convention the applicant for a patent where the invention relates to a deposited microorganism or the use thereof, may inform the EPO that until publication of the mention of grant or where an application is refused or withdrawn for 20 years from the filing date, a sample of the deposit be made only available to an independent expert nominated by the requester of the deposit. The patent applicant must request this "expert solution" before publication of the application such that the request will appear on the published document. Any expert nominated by a third party requester of the deposit must fulfil the requirements and obligations laid down by the President of the EPO. In particular, the nomination shall be accompanied by a declaration from the expert that they undertake to comply with the aforementioned requirements and obligations and that they know of no circumstances which might give rise to justified doubts as to their independence or which might conflict in any other way with their function as expert.

The expert must give undertakings not to make the deposited material available to any third party, including the requester and to use the material for experimental purposes only. These undertakings must apply until the patent expires or, in the case of an application being refused or withdrawn, for 20 years from the filing date.

The expert solution as set forth above applies in contracting states of the European Patent Convention as of 1st October 2017.

In Canada, a patent applicant is entitled to restrict access to an independent expert nominated by the Commissioner of Patents. The request to institute restricted access must be made by the applicant before the application is open to public inspection and the appointed expert is subject to the applicants' agreement. If agreement cannot be reached within "reasonable time", the request for restricted access is deemed never to have been made. The restricted access lasts until the patent is granted but does not apply following refusal, withdrawal or lapse of the application. The expert must give undertakings not to make the sample available to any other person and to only use the sample for experiments relating to the subject matter of the application.

Similar arrangements exist in Australia where appropriate notification by an applicant that any deposited microorganism be made available to an expert, before the first publication of the application, results in restricted access to said expert who must give undertakings not to

make the sample available to another person and use only for experimental purposes or in relation to opposition proceedings or other relevant proceedings pertaining to the patent.

(v) Obligations on requester of the sample

As set forth in (iii) and (iv) above, Rule 11.3 allows for the possibility that certain conditions may be applied by national law to a third party requester's right to a sample of the deposit. Such conditions include the "expert solution" as discussed under (iv) above. However, where the applicant for the patent has not instituted the expert solution, then the requester themselves will have direct access to the sample. Many of the studied territories, in particular, Europe, Canada, Australia, China, Korea, and Japan do apply conditions as envisaged by Rule 11.3, which restrict what the requester may do with the sample. These are that the sample or any biological material derived therefrom must not be made available to another party and the sample is to be used for experimental purposes only. In many of the studied territories express provisions in national laws for breach of these conditions while the application is pending are not present but it is widely assumed that normal judicial remedies would apply.

In Australia, additional conditions may be applied by the Commissioner of Patents, when a request for release is granted, for example, the requester may have to give security for damages in case of any breach of the undertaking.

In Brazil, Mexico, Israel, and the Philippines no conditions are recited expressly in law to be applied to the requester and so once a sample is released the requester is under no particular express obligation to avoid commercial uses of the sample obtained.

In general, the conditions applied to requesters remain in force until the patent expires or is revoked or, in the case of a pending application, until withdrawn, lapsed or refused. In Japan the undertaking lasts until the requester destroys the sample after the relevant experiments have been completed and in Canada the undertakings expire on grant of the patent, whereby patent infringement proceedings would then be available for breach thereof.

4. Previous AIPPI Resolution

An AIPPI Resolution was passed at the Rio de Janeiro meeting in 1985 (Question 82) concerning patent protection for biotechnological inventions. It was duly resolved that:

- If a written description is sufficient to make the living organism, or other biological material available to a person skilled in the art, then deposit should not be required, but nevertheless, deposit should always be considered as completing the requirement of sufficient disclosure particularly in relation to the repeatability of the invention, recognising that practical problems in relation to some organisms will have to be solved.
- Since the release of deposited material could be abused, the conclusions of AIPPI at the congress of San Francisco and Munich in relation to microorganisms, namely that:

a) a microorganism should not be accessible to the public until an enforceable right exists,

b) release should be for research only,

c) the organism should not be passed to third parties,

d) the organism should not be exported from the country of release,

e) in the event of a violation of the undertaking, the burden of proof should be upon the receiver of the organism, should be applicable to microorganisms and other biological material.

5. Position of AIPPI

Following consideration of the divergences which the COMMITTEE study has identified in procedures before national intellectual property offices as of 2017, with regard to microorganism deposit requirements and third party availability, the COMMITTEE considers the harmonised position set forth below would be optimum for securing enablement of microorganism-related inventions, but without leaving the patent applicant or proprietor vulnerable to abuses of the deposited sample by third parties.

It is agreed that, as concluded in the 1985 resolution, in a situation where a written description of the invention is sufficient to make a microorganism or biological material or the use thereof available to a person skilled in the art, then deposit of the material should not be required. This will often be the case where full nucleic acid and amino acid sequences are available for claimed biological material, regardless of the microorganism used as a vehicle to produce it. However, deposit should always be considered as completing the requirement of sufficiency of disclosure and must be regarded as essential if the invention described in a patent application cannot be reproduced without access to the actual material.

It was the prevailing position amongst the territories studied by the COMMITTEE that an application for a patent must provide a sufficient disclosure of the invention in the application as filed and also in any application from which it claims priority. This principle is provided by many national laws and supported by decisions of their national courts. In the view of the COMMITTEE, this principle is correct and it follows logically therefore, that where a microorganism or biological material is required for reproduction of an invention, the deposit must be made by the date by which the sufficiency of disclosure requirement must be met, which is the filing date or claimed priority date. Further, information as to the location and identity of the deposit as a minimum, the name of the IDA and the accession number, must be public at the point at which the specification first enters the public domain by publication of the application at 18 months. Therefore, this information should be provided soon enough to be included in the published application. A period of 16 months from the priority period is provided under the Patent Cooperation Treaty, the European Patent Convention and in other territories and the COMMITTEE agrees is an entirely reasonable approach, as it gives an adequate opportunity for the deposit to be processed by the IDA and an accession no/deposit certificate issued.

The point at which the deposit may actually become available to third parties is more controversial and has required very thorough consideration by the COMMITTEE. As is expressed in the 1985 AIPPI resolution, one form of protection for the depositor is to prevent access to the sample by third parties until an enforceable patent right exists and a remedy is open to the depositor should the requester engage in commercial activity with the sample. Such an approach is adopted by the US and Japan (except in certain specified circumstances – see 3(iii) above). An alternative position is adopted by other territories, including the studied territories of Europe, Canada, Australia, China and Korea, whereby a third party may request access to the deposited sample after publication of the pending patent application but conditions are applied which restrict what the requesters may do with the sample. These include, that the sample must not be made available to another party and the sample is to be used for experimental purposes only, at least until an enforceable right does exist.

Both options have been born of the understood commercial and economic role of patents in society, an understanding which has been evolving over several hundred years and continues to evolve. An early principle dating back to the seventeenth century is that an inventor is rewarded with a patent for disclosure of the invention, with a view to it being reproduced by others on expiry of the patent. As such, publication of the invention occurred only on expiry of the patent. By the mid-eighteenth century it was recognised there were practical advantages to publication of the invention on grant. Third parties would be advised of the existence of the right earlier and technological innovation could be accelerated by others making further developments of the technology, the notion of experimental use of the invention also being born.

The reward principal, whereby no disclosure to the public was made until a patent was awarded, was seen as satisfactory until the mid-twentieth century, when certain practical problems started to emerge. In particular, huge backlog in examination of patent applications at national patent offices was delaying the introduction of the inventions into the public domain. This was seen as hampering innovation and, in particular, preventing third parties understanding what they may do free of patents, thus restricting their development activities. It appeared the commercial and economic goals of the patent system were not being met.

Reluctantly, a somewhat pragmatic solution has been adopted in most territories whereby the patent application is published at 18 months from the priority date regardless of its examination status. Thus gives potential for yet faster technological innovation and protects the interests of third parties from inadvertently being caught by a patent monopoly. These advantages have been considered to justify the breach of the historic so called “patent bargain” whereby a patent is a reward for disclosure, although, dissenters still exist.

It is against this historical background that the appropriate date of release to a third party of a biological sample deposited for the purposes of sufficiency of disclosure comes to be considered. Again there are conflicting legal views. For example, it is the Japanese position that publication of a pending patent application is a procedural step merely for the purpose

of informing the public of the existence of the application. It does not have a legal relationship to the issue of whether the invention can be reproduced by a person skilled in the art. Thus, there is no requirement for third party access to a deposited sample at the time of publication of the application and release only after patent grant is thus appropriate. Likewise, the US does not provide for release of any deposited sample to a third party until after grant, notwithstanding the adoption of early publication. As aforesaid, the other studied territories have provision allowing third parties to request a deposited biological sample from the IDA from the date of publication of the application. This approach follows from the accepted modern practice of putting the invention into the public domain prior to grant of the patent and the adoption by national laws and courts of the principle that a patent specification must provide a sufficient disclosure as of the filing date and hence also at the date of its first publication. The deposited sample would be required for the skilled person to reproduce the invention.

Following consideration of the various positions the COMMITTEE considers there is conflict between the position that no sample may be released to a third party until grant of a patent and the well-adopted principle that sufficiency of disclosure must be achieved at the filing date and thus by the publication date of the application, the first opportunity for one skilled in the art to reproduce the invention. To meet this latter requirement, it follows that access to the deposited sample should be allowed as of the publication date.

Such access, completely unfettered at the point of publication before any enforceable right exists, clearly leaves the depositor vulnerable to possible abuses of the sample by way of commercial activity by the requester. The COMMITTEE considers such a position entirely unacceptable, since damage which may be caused by early dissemination of microorganisms or biological material years before a patent is granted, may be greater than can be compensated for when a granted patent actually exists. Furthermore, the sample must remain available at the IDA for a period of 30 years after the date of deposit (Rule 4, Rules of Budapest Treaty), even if a patent does not grant, which could be equally undesirable for the depositor. If the existence of possible patent protection is a driver of innovation but such protection for inventions involving microorganisms is compromised by the need to deposit the relevant material in an IDA, and the subsequent unconditional availability, this could be having a negative impact on the development of certain technologies.

As reported herein, a majority of the studied territories require that a sample may only be available to a third party requester upon condition that the requester does not pass on the sample to any other party and uses the sample only for experimental purposes in relation to the invention. The COMMITTEE concludes that such restrictions upon the requester are essential and should be in effect until the expiry of the patent or until the application is withdrawn, refused or otherwise lapsed. In the 1985 resolution it was concluded that the organism should not be exported from the country of release. The COMMITTEE considers this to be a reasonable restriction once the sample is in the hands of the requester but should not be applied in a way as to prevent requesters domiciled outside the country where the IDA is located from obtaining a sample as this would be contrary to the aims of the Budapest

Treaty, whereby a single deposit in one IDA secures sufficiency of disclosure for a family of patent applications around the world. Availability of the sample in the territory covered by the eventual patent should be essential. The applicant must always be promptly notified by the national patent office that a request has been lodged and who by. In addition the COMMITTEE considers the patent applicant/proprietor must have the right to object to the release of the sample to any given requester and national and regional patent offices should determine the matter as between the parties. The applicant should have the right to protect suspected future abuse of the sample, notwithstanding any implications for validity of the corresponding patent or application. Further, procedures in each country which is a member of the Budapest Treaty, should be established to ensure that the third party requester is aware of and signs up to the conditions to be applied to the release of the sample and which allow action for breach of the conditions by the requester, regardless of whether the patent is granted or still a pending application. It is suggested that a system such as applied in Australia where the requester may be required to provide security for damages in the event of breach of the release conditions should be adopted.

Finally, the AIPPI supports in general the availability of an Expert Solution as discussed for the studied territories Europe, Australia and Canada. This provides an additional layer of protection for patent applicants against abuses of the sample by third parties, should the applicant choose to adopt it.

As discussed in 3(iv) above, before a patent application is published, an applicant should be able to request that the sample of the deposited material be made available only to an expert nominated by the requester. That such a request has been made must appear in the published application. In the view of the COMMITTEE this expert must be approved by the applicant. Furthermore, the independent expert must give the same undertakings as the requester that the sample will not be made available to any other party, including the requester and that the sample must be used for experimental purposes in relation to the invention. Thus, while the expert may not provide the sample to the requester, they are able to carry out experimental work on the sample of no more broad scope than would be allowed to the requester themselves and to pass the findings back to the requester. The COMMITTEE is of the opinion that by exercising such an option the requirement for sufficiency of disclosure is met, since the expert merely stands in the shoes of the requester, so long as there is no restriction as to the number of requesters and therefore the number of individual experts appointed.

Further the COMMITTEE also supports the provisions of Rule 32 of the European Patent Convention that the sample should be available to only the nominated expert under the specified conditions until the application is granted or where the application is refused or withdrawn for 20 years from the date of filing the application. Thus, applicants with commercial concerns about the fate of the deposited material in the event that an enforceable patent right does not materialise, should be able to opt for the expert solution wherein action for breach of the conditions of release could be brought independently.

6. Summary of Recommendations

The recommendations of the COMMITTEE for harmonisation of national laws of those countries which are member states of the Budapest Treaty are as follows:

- In order to ensure requirements of sufficiency of disclosure are met for a patent application, a microorganism or other biological material necessary for reproduction of the invention must be deposited at an IDA recognised under the Budapest Treaty not later than the filing date or where an earlier priority is claimed, the priority date of the application.
- As a minimum, the identity of the IDA and the accession or reference number of the deposit must be supplied for inclusion in the published application, ideally by sixteen months from the priority date and in any case before the preparations for publication are complete.
- Following publication of the application at eighteen months from the priority date, or in the case of an International application under the Patent Cooperation Treaty, after entry into the national phases of the application, subject to securing the interest of the patent applicant that the deposited sample is not abused, may be released to a third party requester, upon a request to the IDA duly authorised by the national patent office.
- Intention to release and identity of the requester must be notified to the applicant, wherein the applicant must have the opportunity to object to the release, the matter to be determined by a national or regional patent office.
- Release must be accompanied by certain restrictions as to the acts the requester may do with the released sample. The requester must not
    - Make available the sample or any biological material derived therefrom to a third party.
    - Export the sample from the country of release (although the IDA may do so).
    - Use the sample for anything other than experimental purposes relating to the invention.
    - The restrictions upon the requester will expire (1) upon grant of the patent (2) upon withdrawal or refusal of the patent application.
    - Procedures must be in place to address breach of these restrictions by the applicant regardless of whether the application is still pending or granted including the option of requiring the requester to give security for damages in the event of breach.
    - The applicant must have the option to implement the “expert solution” by requesting before publication of the application that the deposited sample bye released upon request only to a nominated expert of the requester, the expert requiring the approval of the applicant and being bound by the same

restrictions as would the requester with regard to acts which may be carried out by the sample.

- The deposited sample can be released to the nominated expert and the restrictions as to actions which can be carried out should remain in place until patent expiry or it the application is refused or withdrawn, for 20 years from the filing date.

The COMMITTEE has also considered how International harmonisation might most practically brought about and whether amendment of Rule 11.3 of the Budapest Treaty to specify release conditions would be appropriate. Drawbacks to such an approach are that (I) the number of countries signed up to the treaty is less than would ideally be desired and (2) even existing contracting states would be required to sign up to the amended Treaty leaving the possibility of greater disharmony . Thus, the COMMITTEE suggests rather the encouragement of individual contracting states to provide a harmonised international environment for the recognition of deposit of microorganisms for the purpose of patent procedure by introducing common restrictions upon the requesters as to the activities they may undertake with the released sample. Encouragement of current non-contracting states to join the Budapest treaty should also be provided.

December 6, 2018