

Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977

National Interest Analysis, 25 January 2016

Executive Summary

It is proposed that New Zealand accede to the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977 (the Budapest Treaty) as a requirement under the Trans-Pacific Partnership Agreement (TPP). The Budapest treaty provides an internationally harmonised regime for the recognition of micro-organism deposits where such deposits are required by Contracting Parties' patent legislation. The New Zealand Patents Act 2013 requires micro-organism deposits.

The main obligation imposed on Contracting Parties by the Budapest Treaty is that they recognise, for the purposes of patent procedure, the deposit of micro-organisms in 'International Depositary Authorities' (IDAs) established under the Treaty. There is no obligation for Contracting Parties to establish an IDA on their Territory.

As the Patents Act 2013 already recognises deposits in IDAs no amendment to the Patents Act 2013 would be required for New Zealand to accede to the Budapest Treaty.

Most, if not all, applicants for New Zealand patents for inventions involving micro-organisms also apply to patent the same inventions in another country or countries already Party to the Budapest Treaty. These applicants would therefore already be required to make a deposit in an IDA established under the Treaty of the micro-organism involved.

Accession to the Budapest Treaty would impose no additional costs on patent applicants, businesses in general or on government or the public. The prime benefit from accession is that it would enable an IDA to be established in New Zealand under the Treaty. If an IDA was established in New Zealand this may benefit local researchers who would otherwise have to use an IDA in another Budapest Contracting Party. Note, however, that the establishment of an IDA would be a commercial decision by a private entity. There would be no guarantee that an IDA would be established in New Zealand.

Date and Nature of Proposed Binding Treaty Action

It is proposed that New Zealand accede to the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977 (the Budapest Treaty).

The Budapest treaty was concluded on 28 April 1977 and entered into force on 19 August 1980. If New Zealand acceded to the Budapest Treaty it would enter into force for New Zealand three months after the date of deposit of the instrument of accession, or such later date as may be indicated in the instrument.

Accession would not require any amendments to the relevant legislation (the Patents Act 2013) and could take place once the parliamentary treaty examination process has been completed.

Consultation will be undertaken with Tokelau to determine whether New Zealand's accession to the Budapest Treaty will extend to Tokelau as a non-self-governing territory of New Zealand.

Reasons for New Zealand to Become Party to the Treaty

Background

It is a requirement of New Zealand's patent legislation (and that of all other countries) that patent applicants provide a full and complete description of the invention for which they seek patent protection. The description must be sufficiently detailed that a suitably skilled person could duplicate the invention without undue experimentation. For most inventions, this can be done through the provision of a written description.

Where a patent application claims a micro-organism as the invention, or where the invention involves the use, modification or cultivation of a micro-organism, it may not be possible to provide a written description of the micro-organism that would enable a skilled person to duplicate the invention.

As a result, many countries developed requirements that the written description in patent applications involving micro-organisms may be supplemented by depositing a sample of the micro-organism in a specialised institution recognised by the relevant patent granting authority.

There was, however, no system of international recognition of deposits or of the specialised institutions. That is, an institution recognised by one country's patent granting authority might not be recognised by authorities in other countries. Consequently applicants for patents for inventions involving micro-organisms might have to make several deposits, one in each country where the applicants wanted patent protection and micro-organism deposits were required. In addition, there was no harmonised procedure by which institutions would make samples of deposited micro-organisms available to interested parties.

These difficulties led the World Intellectual Property Organisation (WIPO) to conclude the Budapest Treaty in 1977. The text of the Budapest Treaty and Regulations and list of Contracting States is annexed to this National Interest Analysis and can also be found at:

<http://www.wipo.int/treaties/en/registration/budapest/>

The Treaty provides that certain specialised institutions be recognised as international depositary authorities (IDAs), and Parties to the Budapest Treaty agree to recognise a deposit made in an IDA for the purposes of patent procedure. The Budapest Treaty also sets out procedures by which institutions can become IDAs under the Treaty, and also the procedures for obtaining a sample of a micro-organism from an IDA.

The Budapest Treaty entered into force in 1980, and to date (June 2015), 79 states have acceded to it, including Australia, Canada, the United Kingdom, Japan, China and the United States. There are currently 42 IDAs recognised under the Treaty. The nearest authorities to New Zealand are the Lady Mary Cellbank Australia and the National Measurement Institute, both in Australia. A full list of Contracting states and depositary authorities can be found at: <http://www.wipo.int/treaties/en/registration/budapest/>

The current situation in New Zealand

The Patents Act 2013, which entered into force in September 2014, provides that micro-organism deposits be made in a depositary prescribed in the regulations. All, or nearly all, New Zealand patent applications for inventions involving micro-organisms will also be the subject of corresponding patent applications in Contracting States of the Budapest Treaty. Most of these applications originate from foreign applicants. As a result, patent applicants will have deposited a sample of the micro-organism in an IDA.

This effectively means that IDAs have to be recognised as prescribed depositaries under the Patents Act 2013, regardless of whether or not New Zealand accedes to the Budapest Treaty. Otherwise it might be

impossible for applicants to comply with the deposit requirements under the Patents Act 2013. In any case, there may be few, if any, other institutions capable of accepting micro-organism deposits that could be recognised under the Act.

As a consequence, the Patents Act 2013 is consistent with the Budapest Treaty as the only substantive obligation on Parties to the Budapest Treaty is that they recognise micro-organism deposits in IDAs. No amendment of the Patents Act 2013 is required for accession.

Advantages and Disadvantages to New Zealand of the Treaty entering into force and not entering into force for New Zealand

The main obligation imposed on Contracting Parties by the Budapest Treaty is that they recognise, for the purposes of patent procedure, the deposit of micro-organisms in 'International Depository Authorities' (IDAs) established under the Treaty. There is no obligation for Contracting Parties to establish an IDA in their Territory.

Most, if not all, applicants for New Zealand patents for inventions involving micro-organisms will have also applied to patent the same inventions in Budapest Treaty Contracting States. These applicants will therefore have had to make a deposit of the micro-organism involved in an IDA. As there are few, if any, other depository institutions that patent applicants could use, the Patents Act 2013 recognises deposits in IDAs. No amendment to the Patents Act 2013 is therefore required for New Zealand to accede to the Budapest Treaty.

Accession to the Budapest Treaty would impose no additional costs on patent applicants, businesses in general or on government or the public. The prime benefit from accession is that it would enable an IDA to be established in New Zealand and be recognised by the patent granting authorities in other Budapest Treaty Contracting Parties. If an IDA was established in New Zealand this may benefit local researchers who would otherwise have to use an IDA in another Budapest Contracting Party. This could reduce costs for New Zealand resident patent applicants, which could encourage more research involving micro-organisms to be carried out in New Zealand. However, there is no certainty that a depository would be established in New Zealand if New Zealand were to accede to the Budapest Treaty.

In addition, if New Zealand is a Contracting Party to the Budapest Treaty, New Zealand would have a voice in any future amendments or revisions of the Treaty. Such amendments or revisions could affect the interests of New Zealand researchers who apply for patents in Budapest Treaty Contracting States.

No disadvantages have been identified.

Legal obligations which would be imposed on New Zealand by the Treaty action, the position for reservations to the Treaty, and an outline of any dispute settlement mechanisms.

The main legal obligation imposed by the Budapest Treaty is that Contracting States that allow, or recognise, micro-organism deposits for the purposes of patent procedure, must recognise micro-organism deposits made with IDAs recognised under the Treaty (see Art.3). There is no obligation for a Contracting State to establish IDAs in its territory.

Article 7 of the Budapest Treaty sets out the mechanism by which an institution in a Contracting State can become an international depository authority. This requires the Contracting State in whose territory the IDA is situated to provide assurances that the institution complies with the requirements for IDAs set out in Art. 6(2) of the Treaty.

The requirements set out in Article 6(2) are as follows:

The depositary institution must, in its capacity of international depositary authority:

- i. have a continuous existence;
- ii. have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty;
- iii. be impartial and objective;
- iv. be available, for the purposes of deposit, to any depositor under the same conditions;
- v. accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations;
- vi. issue a receipt to the depositor, and any required viability statement, as prescribed in the Regulations;
- vii. comply, in respect of the deposited microorganisms, with the requirement of secrecy, as prescribed in the Regulations;
- viii. furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations.

The assurances required by Article 6(1) must be communicated to the Director-General of WIPO through diplomatic channels (Rule 3.1).

Rule 3.1 states:

- a. The communication referred to in Article 7(1) shall be addressed to the Director General, in the case of a Contracting State, through diplomatic channels or, in the case of an intergovernmental industrial property organization, by its chief executive officer.
- b. The communication shall:
 - i. indicate the name and address of the depositary institution to which the communication relates;
 - ii. contain detailed information as to the said institution's capacity to comply with the requirements specified in Article 6(2), including information on its legal status, scientific standing, staff and facilities;
 - iii. where the said depositary institution intends to accept for deposit only certain kinds of microorganisms, specify such kinds;
 - iv. indicate the amount of any fees that the said institution will, upon acquiring the status of international depositary authority, charge for storage, viability statements and furnishing of samples of microorganisms;
 - v. indicate the official language or languages of the said institution;
 - vi. where applicable, indicate the date referred to in Article 7(1)(b).

If the communication complies with the requirements of Rule 3.1, the Director-General of WIPO will notify all Contracting States and it will be published by the International Bureau of WIPO.

If an IDA ceases to meet the requirements of an IDA as set out in Art. 6(2), the Contracting State that made the declaration under Art. 6(1) in respect of the IDA must take steps to ensure that the samples of micro-organisms deposited with the IDA under the Budapest Treaty are transferred to another IDA (see Rule 5).

There are no provisions allowing states to make a reservation upon accession.

The Budapest Treaty does not contain any dispute resolution provisions.

Measures which the Government could or should adopt to implement the treaty action, including specific reference to implementing legislation

No amendments to the relevant legislation, the Patents Act 2013, would be required to accede to the Budapest Treaty. The Patents Act 2013 contains provisions that require patent applicants to make micro-organism deposits in appropriate cases. The provisions require that the deposits be made in depositaries prescribed in the Act.

Most, if not all, applicants for New Zealand patents for inventions involving micro-organisms would have also applied to patent the same inventions in Budapest Treaty Contracting States. These applicants would therefore have had to make a deposit of the micro-organism involved in an IDA.

On this basis the prescribed depositaries would have to include IDAs established under the Budapest Treaty. The effect of this is that the Patents Act 2013 and associated regulations will be consistent with the Budapest Treaty whether or not New Zealand accedes to the Budapest Treaty.

Economic, social, cultural and environmental costs and effects of the treaty action

Accession to the Budapest Treaty will not impose any environmental, cultural or social costs on New Zealand.

Economic costs to New Zealand of compliance with the Budapest Treaty

Costs imposed on Business

Most, if not all applicants filing patent applications for micro-organism related inventions in New Zealand would also be applying for patents for the same inventions in other countries party to the Budapest Treaty. Such applicants would already have to bear the costs involved in making a micro-organism deposit and providing documentation to the patent granting authorities in those countries. On this basis, few, if any, additional costs would be imposed on patent applicants.

Costs imposed on government

Accession to the Budapest Treaty would not impose any significant additional administration costs on government agencies. The only government agency that would be affected is IPONZ, but this will not have fiscal implications.

If New Zealand accedes to the Budapest Treaty, there would be no obligation for the government to establish an IDA.

The Budapest Treaty does not require New Zealand to make any financial contribution to the Budapest Treaty Assembly established under Article 10 of the Treaty.

Costs imposed on society

Accession to the Budapest Treaty would impose no additional costs on society.

Completed or proposed consultation with the community and parties interested in the treaty action

Consideration was first given to New Zealand's accession in 1988 by the then Industrial Property Advisory Committee (IPAC). IPAC recommended that New Zealand accede to the Budapest Treaty. The issue was also canvassed as part of a review of the Patents Act 1953 carried out by the then Ministry of Commerce in 1992. The review of the Patents Act 1953 eventually resulted in the introduction of a Patents Bill, enacted as the Patents Act 2013, to replace the Patents Act 1953

Submissions to the review of the Patents Act 1953 supported New Zealand's accession to the Budapest Treaty. None of the submissions to the Commerce Select Committee, which considered the Patents Bill, opposed New Zealand's accession to the Budapest Treaty. Where submitters raised concerns regarding the requirement for micro-organism deposits, these related to the procedures set out in the Bill for making and documenting the deposits. Such procedures are not regulated by the Budapest Treaty.

Maori groups, including those involved with the WAI 262 claim, were consulted as part of the development of the Patents Act 2013, and also made submissions to the Commerce Select Committee that considered the Patents Bill. While some Maori (and others) have concerns regarding the granting of patents for life-forms in general, there was no opposition to accession to the Budapest Treaty.

Subsequent protocols or amendments to the treaty and their likely effects

Future Protocols

There is no provision in the Treaty regarding the negotiation of future related legally binding instruments.

Amendment Procedure

Procedures for amending the Budapest Treaty are set out in Articles 13 and 14. According to Article 13, the Articles of the Treaty may be revised by diplomatic conferences of the Contracting States. Articles 10 and 11 of the Treaty, which relate to the Budapest Union Assembly and the International Bureau of the Budapest Treaty Union, respectively, may also be amended according to the procedure set out in Article 14.

Article 14 allows Articles 10 and 11 to be amended by the Budapest Union Assembly, rather than by a diplomatic conference. Adoption of any amendments to Article 10 requires four-fifths of the votes cast in the Assembly; adoption of amendments to Article 11 requires three-fourths of the votes cast. In both cases a quorum of half of the Contracting States is required for the amendments to take effect. Amendments adopted under Article 14 become binding on all Contracting States once three fourths of the Contracting States that were members of the assembly when the amendments were adopted have accepted them.

Amendments to the Budapest Treaty are infrequent. Since the Treaty was concluded in 1977 there has been only one amendment, in 1980.

The Budapest Union Assembly meets every second calendar year, as part of the WIPO General Assembly which meets in September or October of each year. The last meeting of the Budapest Assembly was in September 2013. As a member of WIPO, New Zealand is entitled to attend meetings of the Budapest Assembly as an observer. Therefore, New Zealand could become bound by an amendment to Articles 10 or 11 without having taken any positive action to accept the amendment. However, any amendment to Articles 10 or 11 that would create financial obligations for New Zealand or that would increase such obligations will only bind New Zealand if New Zealand notifies its acceptance of such amendment (i.e. taken a positive treaty action). Any amendments to the other Articles of the Budapest Treaty would be required to be approved by Cabinet.

Binding standards

The Budapest Treaty does not provide for the introduction of future rules or standards automatically binding on states party to the Treaty.

Withdrawal or denunciation provision in the treaty

Any Contracting State may denounce the Budapest Treaty in a notification to the Director-General of WIPO. This denunciation takes effect two years after the date of receipt of the notification by the Director-General. A Contracting State cannot denounce the Treaty until at least five years have passed since the date on which it became party to the Treaty.

The reasons for the notice provisions are not known. One possible reason is that if a Contracting State denounces the Treaty, any IDAs on its territory lose their status as IDAs one year after the Director General of WIPO is notified of the denunciation (Art. 17(4)). The notice provisions would give time for patent applicants and patent owners which had made deposits in the IDAs to transfer their deposits to IDAs in other Contracting Parties.