

OPINION OF THE OFFICE OF THE OMBUDSPERSON OF THE REPUBLIC OF COSTA RICA REGARDING THE “BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE”, SUBMITTED TO THE LEGISLATIVE ASSEMBLY OF COSTA RICA, OCTOBER 2007.

(Reviewed, summarized and translated to English in July 2008¹)

Introduction

This document regarding the “Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure” (hereinafter the Budapest Treaty), was mainly written when Costa Rica was still deliberating its approval or disapproval, by referendum, of the “United States-Dominican Republic-Central America Free Trade Agreement” (hereinafter US-DR-CAFTA)². The research was conducted by the Office of the Ombudsperson of the Republic of Costa Rica (hereinafter the Office) before the contested referendum held in October 7, 2007 by which the free trade agreement was finally approved. The summary of the research remains the same with just a few annotations added in light of the post-referendum situation.

The Legislative Assembly did not solicit the Office's opinion on the Budapest Treaty. However, according to its competence stipulated in Article 1 of the Law, and Article 7 of the Regulations ruling its acts, the Office is allowed to study bills being considered by the congress and determine their possible implications on the lives of the citizens, as was the case with the Bill to Accede to the Budapest Treaty.

For further clarity on the competence of the Office of the Ombudsperson, the relevant provision is quoted below:

ARTICLE 7: OTHER FUNCTIONS.

The following are attributes of the Office of the Ombudsperson:

- a) To propose reforms or amendments to the rules, practices or behaviours that are harmful for the rights and interests of citizens, or otherwise, to recommend passing regulations in the case of some rules.
- b) To study bills in order to determine whether or not they harm the rights and interests of the inhabitants

Exercising this competence, the Office first proceeded to find out the arguments in favour and against the Bill on Costa Rica's Accession to the Budapest Treaty, in order to include some major considerations in its Annual Report for the Term 2006-2007. The sources of information of the Office at that time were the text of the Budapest Treaty, and the documents in the legislative file of the Bill on Accession (No. 16123).

In its Annual Report, the Office briefly pointed out some of the most relevant discussions recorded in that file which expressed the contrasting opinions of institutions and organizations consulted on the Bill by the Legislative Assembly. Likewise, it had in hand: motions and copies of the minutes of the Sessions of the Legislative Assembly where the Budapest Treaty was discussed; the

¹ The original opinion, in Spanish, is available online at <http://www.dhr.go.cr/descargas/CrDHR02.doc>.

² The results of the research on the Free Trade Agreement were presented to the Legislative Assembly, by the Ombudsperson, on March 30, 2006 (Document DH-158-2006, "*Report of the Office of the Ombudsperson in relation to Bill 16047, Free Trade Agreement between Central America, the United States y the Dominican Republic*").

parliamentary affirmative majority ruling and the negative minority ruling on the Bill; and the Juridical Technical Report of the Technical Services Department of the Legislative Assembly.

The recurring issues in those documents referred to contrasting views regarding the Budapest Treaty's:

- purpose;
- lack of compliance with the requirements of description and disclosure for patent granting;
- lack of foresight to require certificates of origin when the deposit is made;
- lack of definition of "microorganism", the subject matter of the treaty;
- supposed encouragement for scientific research;
- cost-benefit ratio in terms of its implementation both for patent applicants and the State;
- foresight or lack of foresight in domestic laws for microorganisms patenting; and
- likelihood to incorporate interpretative clauses in an international treaty

as well as the need and duty of the country to accede to or to reject it. Furthermore, those documents included diverse views regarding the economic, cultural and ethical implications of patents on microorganisms and other life forms.

The Office noticed that Costa Rican citizens had not had any real debate on this important Treaty, on the ethical principles implied by it, and on the possible impacts of its implementation in the social and environmental field or in scientific research.

In view of the right to information and the importance of patenting life forms, the topic should have been widely known to civil society so that the latter could have an informed participation when voting this treaty as an integral part of the US-DR-CAFTA as submitted to referendum.

On the other hand, the Office considered necessary to study some uses given to microorganisms, since such important life forms have fundamental functions in the life cycle, as transformers of organic matter and waste. Without them, the planet would be a garbage dump, and, therefore, life cycles would be interrupted. Also, the Office was aware of the opinion of US geneticist and businessman, J. Craig Venter, published in a local newspaper³ stating that there is scientific and commercial interest in sequencing the genomes of microorganisms, as they make up about one half of the planet's biomass.

Additionally, the Office reflected on the duty of taking care of other uses of biodiversity because Costa Rica has a little more than half a million species: *"This is approximately 3.6% of the planet's estimated biodiversity (between 13 and 14 million species). (...) It is also ranked among the nine countries on the planet with an extremely high microorganism diversity in its forest ecosystems."*⁴

The combination of all these factors — competence of the institution, lack of information and full debate on the Budapest Treaty, importance of biodiversity and its uses in Costa Rica — justified a more comprehensive and detailed analysis and encouraged the Office to advance further in the research started for its Annual Report (2006-2007).

This document presents a summary of the extended research⁵. Its exploratory goal was to know more about the Treaty and its possible implications for the country once the US-DR-CAFTA free trade agreement would be approved⁶. The following were the specific objectives:

³ La Nación. June 10, 2007

⁴ Obando, Vilma A. *Biodiversidad de Costa Rica en cifras*, Editorial INBio. Costa Rica, 2007.

⁵ The whole document was submitted to the Legislative Assembly on October 3, 2007 (Document DI-I-797-07) "*Opinion of the Office of the Ombudsperson regarding the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*".

- To contribute to the understanding of the Treaty as a legal instrument that modifies Costa Rica's current patent procedures facilitating the patenting of microorganisms and other life forms.
- To learn about the ongoing discussions at the national and international levels regarding intellectual property rights on life forms.
- To determine the possible impacts on our citizens and the country itself in case Costa Rica accedes to the Budapest Treaty.

The results are presented as follows:

- The first part describes the most important articles of the Treaty including the requirements of deposit. It also points out the Treaty's relationship with the US-DR-CAFTA.
- The second part analyzes the broad discussions and controversies in Costa Rica in relation to the Treaty, its contents and its omissions.
- Finally, the last part presents other issues closely related to the Budapest Treaty that are impossible to ignore.

The first part is introductory and descriptive.

The contents and omissions analyzed in the second part refer to the requirements of the Budapest Treaty, in contrast with patent procedures established in Costa Rica with regard to description, disclosure and certificates of origin. It also refers to the lack of definition of the term "microorganism" in the Treaty and, because of that vacuum, examines how any kind of biological material is in practice allowed to be deposited. This second part also introduces the controversy on the alleged need and obligation of Costa Rica to join the Budapest Treaty. Some other aspects are included such as the supposed promotion of scientific research, and the cost-benefit analysis of the implementation of the Treaty for patent applicants and for the State.

The third part refers to the implications of the patenting of life forms, including microorganisms.

Both the contents and omissions of the Treaty and other arguments in this paper were mainly analyzed in light of the discussions presented by national delegations at the Council for TRIPS of the World Trade Organization (WTO), and other related documents, such as:

- The examination of paragraph 3 b) of Article 27 of TRIPS (WTO document IP/C/W/369).
- *The examination of the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD)* (WTO document IP/C/W/368).
- The examination of concepts and positions: FAO. (2000) *Multilateral Trade Negotiations On Agriculture. A Resource Manual*. Food and Agriculture Organization. (FAO) Rome, 2000. www.fao.org/docrep/003/x7355s/X7355s04.htm
- Information on the procedures and requirements to deposit microorganisms, practical advices to depositors and for those interested to get samples from the deposit institutions, contained in *The Guide for the Deposit of Microorganisms*. www.wipo.int/treaties/es/registration/budapest.
- Information in the light of international instruments on human rights and the Costa Rican Constitution in relation with the patenting of life forms.

⁶ For a brief summary and outcome of the referendum see: Trejos, Ma. Eugenia et al. The opposition to CAFTA in Costa Rica: Institutionalisation of a social movement. In: bilaterals.org, BIOTHAI and GRAIN (editors), *"Fighting FTAs: the growing resistance to bilateral free trade and investment agreements"*. 2008. <http://www.fightingftas.org>

Part 1

Main contents of the Budapest Treaty and its Regulation

1.1. Relationship between treaties

The Budapest Treaty was one of the treaties that the Costa Rican State was compelled to join once the US-DR-CAFTA was approved in referendum (Art. 15.1, General Provisions).

Since in that context the Budapest Treaty is not independent of the US-DR-CAFTA, the process of denouncing⁷ it could not follow the procedures established in Article 17 of the Budapest Treaty. Costa Rica is now tied to the denouncing conditions established in general in the US-DR-CAFTA (Art. 22.7) and, especially, the consequences of doing so.

1.2. The Budapest Treaty

The Budapest Treaty was adopted on April 28, 1977 within the framework of the Budapest Diplomatic Conference and it entered into force on August 19, 1980. The Regulations were also adopted during the Conference.

The fundamental objective of the Budapest Treaty is that contracting States that allow or require the deposit of microorganisms for patent procedures will recognize the deposit made in an "*international depositary authority*" (hereinafter IDA) located within or outside of the territory of the contracting State (Article 3.1.a). It means that from the date of accession to the Treaty, a single deposit would be sufficient to start the patenting procedure before national agencies for patents, called "industrial property offices" in the Regulations of the Budapest Treaty (Rule 5, 5.1-b).

Another objective of the Budapest Treaty is to define the requirements for an agency to be granted the status of IDA (Article 6.1). This status demands the contracting State to offer assurance that the institution meets and will continue to meet the requirements set out in Article 6.2 and that it will be available for any depositor. The Treaty also points out that certain intergovernmental industrial property organizations may also furnish these assurances (Article 9.1.a).

Additionally to receiving the deposit, the IDA will store microorganisms and deliver samples only to those who are entitled to request them, for which the Regulations of the Budapest Treaty sets up the qualifications and conditions:

- All industrial property offices of any contracting State or intergovernmental industrial property organization, when such request is accompanied by a statement for which conditions are stipulated (Rule 11.1);
- The depositor (Rule 11.2, (i)); Any authority or natural person or legal entity (referred to as "the authorized party") if their request is accompanied by a statement of the depositor authorizing the requested delivery of samples (Rule 11.2 (ii)); and
- Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (referred to as "the certified party"), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and certified by the industrial property office according to several conditions established in Rule 11.3 a), paragraphs (i, ii, and iii). One of such conditions is to certify that publication for the purposes of patent procedure has been effected by that office.

⁷ To denounce a treaty means to make it ineffective.

According to the Common Rules, delivery of sample is free (Rule 11.4 h) for the concerned parties listed in Rule 11.1. Furnishing of samples under Rule 11.2 and 11.3 shall be chargeable to the depositor, to the authorized party, to the certified party or to the requesting party at the rate defined by the IDA, before or at the time of the request.

In the event that it is not possible for the IDA to deliver samples of the first deposited microorganisms, the Budapest Treaty (Art. 4 a-i, a-ii) and its Regulations (Rule 6.2) set out the definition of "new deposit". This new deposit is applicable when the microorganism is no longer viable or when delivery of the sample requires it to be sent abroad and the shipments are prevented by export or import restrictions.

The Treaty stipulates that if that is the case for certain types or microorganisms in the contracting State, those restrictions should not be applied to microorganisms that are deposited or will be deposited according to the Treaty. The contracting States can set such limitations only if national security is affected or in view of national security or the dangers for health or the environment (Article 5).

The Budapest Treaty authorizes the IDA to charge a fee for every deposit and its storage. This storage has a minimum term of 30 years (Rules 9 and 12 of the Regulations). For example, according to the Guidelines for Microorganism Deposits of the Budapest Treaty, the deposit of a sample has a cost of US \$500 at the Agricultural Research Service Culture Collection (NRRL), which is an international depository authority of the Department of Agriculture of the United States of America (a public IDA). On the other hand, at the American Type Culture Collection (ATCC), a private international depository authority, the cost of deposit and storage is US \$2,500. By the way, Rule 2.1 of the Treaty Regulations⁸ established that an IDA can be a public organization or a private enterprise.

Under the Budapest Treaty, there are presently 37 public or private IDAs distributed in the following countries: Germany (1), Australia (1), Belgium (1), Bulgaria (1), Canada (1), China (2), Slovakia (1), Spain (2), United States of America (2), Russian Federation (3), France (1), Hungary (1), India (1), Italy (2), Japan (4), Latvia (1), The Netherlands (1), Poland (2), United Kingdom (7), Czech Republic (1) and Republic of Korea (3)⁹.

In relation with the administrative provisions of the Treaty, the State parties are constituted into the Union for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedures or "the Budapest Union" (Article 1). This Union is governed by an Assembly made up of all the member States, whose objective is to maintain and develop the Union and the implementation of the Treaty. Likewise, this Assembly has the power of amending the Treaty, the Regulations and, additionally, it can eliminate or limit the status held by the IDAs with regard to its guidelines and the type of microorganisms that are deposited (Articles 6, 10, 12, and 14).

The International Office is responsible for the administrative functions that are the competence of the Union and, particularly, those specifically assigned by the Treaty or by the Assembly.

1.3. What is the deposit procedure like?

The Treaty Regulations describe in detail the procedures that depositors and the IDA should follow. Some of them are here briefly summarized.

Rules 6.1 and 6.2 state what should happen in the event of an initial deposit or a new deposit.

⁸ IDAs are understood as scientific institutions with the ability to collect microorganisms.

⁹ WO/INF/12 Rey. 14, dated January 31, 2007. World Intellectual Property Organization, Geneva.

With respect to the initial deposit, it is stipulated that the microorganisms delivered by the depositor to the IDA will be accompanied by a written statement signed by the depositor, which must include:

- indication that the deposit is made by virtue of the Treaty and the commitment of not withdrawing it during the time established under Rule 9.1;
- the name and address of the depositor;
- details of the conditions for the cultivation of the microorganism, for its storage, and for testing its viability. When the deposit consists of a mixture of microorganisms, a description of the components, and at least one of the methods to verify their presence;
- the identification reference (number or symbols) that the depositor has assigned to the microorganism¹⁰.
- the indication of any properties of the microorganism that pose or may pose some danger for health or the environment, or the indication that the depositor is not aware of such properties.

Moreover, Rule 6.1 (b) states that it is highly recommended, but not a duty, that the written statement include a scientific description and/or proposed taxonomic designation of the deposited microorganism.

Rule 6.2 for new deposits indicate what should be included in the written statement, for example:

- some indications referred to in Rule 6.1 for a new deposit
- reasons for making the new deposit;
- a statement alleging that the microorganism which is the subject of the new deposit is the same as that which was the subject of a previous deposit; and the most recent scientific description and/or taxonomic designation in connection with the previous deposit.

It is important to note that the indication of the properties of the microorganism which may be dangerous to health or the environment is not mandatory as long as the depositor gives a notice of not being aware of such properties (Rule 6.1) (a-5). It is also important to remark that, according to Rule 6.1 (b), it is not mandatory to include the scientific description and/or proposed taxonomic designation of the deposited microorganism as part of the written statement referred to in Rule 6.1 (a). It is only a strong recommendation.

In other words, the non-obligatory requirement of describing the risks of the microorganisms, the lack of knowledge of their dangerous properties as a valid argument, and the fact that the other documents attached to the statements focus on the management of the microorganism in the laboratory, show the limited information involved in the deposit.

Rule 6.3 refers to the requirements of the IDA in relation to the initial or new deposit, among which it is worth pointing out the necessary form and quantity of the deposited microorganism, payment of the stipulated maintenance fee and, to the extent permitted by the applicable law, a contract defining the responsibilities of the depositor.

Rule 6.4 states the reasons of the IDAs to reject the deposit of a microorganism. According to this rule, it is the IDA which defines what type of microorganisms it accepts or rejects. The list of accepted microorganisms can be limited or extended under the prerogative of the IDA, provided that the contracting State is properly notified. It is important to clarify that the IDA is obliged to reject the deposit of microorganisms that are not included in the list delivered to the World Intellectual Property Organization (WIPO). IDAs can also reject the deposits of microorganisms which, although included in the list, cannot be conserved due to their difficult genetic manipulation.

¹⁰ Such indication assigned to the microorganism is part of the accrediting receipt that the IDA will issue to the depositor on receiving and accepting each deposit of microorganisms.

Rule 6.4 sets up the acceptance procedure. Among the conditions, paragraph ii) establishes that an IDA can refuse to accept a microorganism if it cannot meet the relevant tasks with regard to the deposit.

Once the microorganism has been accepted, the IDA must deliver a suitable document as proof of receipt and acceptance of the deposit (Rule 7). The receipt is important because it constitutes the written document indicating that the microorganism was deposited on a given date, which is an essential piece of data for patent matters. This is also important because, in spite of the little information it contains, it is the official document that the depositor keeps after the IDA receives the deposit.

Rule 9.1 establishes that a deposited microorganism shall be carefully stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the IDA and, in any case, for a period of at least 30 years after the date of the deposit.

Rule 9.2. says that IDAs shall not give information related to any microorganism deposited with them under the Treaty except in the case of an authority, natural person or legal entity entitled to obtain a sample of the microorganism under Rule 11.

1.4. Findings related to the understanding of the Budapest Treaty and its relations to patent procedure

The documents reviewed and interviews conducted show a prevailing difficulty to understand that the Budapest Treaty does not grant patents as such; rather, it only facilitates patent procedure. Its objective is the *“recognition of the deposit of microorganisms for the purposes of patent procedure”*. The deposit of microorganisms in an IDA facilitates that procedure, but each country will grant a patent only upon the request of the concerned party. In Costa Rica, this would correspond to the Registry of Industrial Property of the National Registry. Specifically, the Treaty only regulates one of the steps in the procedure to patent a microorganism: the deposit. However, in the case of Costa Rica, it would have an impact on the entire patenting procedure, as will be demonstrated below.

It has been pointed out that the member states of the Budapest Treaty accept the deposit of a microorganism in an IDA as the first step in the patenting process. This acceptance implies in itself a change in the patent procedures established in Costa Rica. Up to now, our national law on patents did not allow the deposit of microorganisms or any other biological materials. Now that the US-DR-CAFTA has been adopted, it is mandatory to determine the way it would affect our patenting procedure, its different stages and the compliance with the provisions set out therein.

It is worth pointing out that the Office of the Ombudsperson also found favourable opinions regarding the Budapest Treaty. Among other arguments, proponents expressed that there is no relationship between the deposit and the patenting procedure and, because of that, they believe there will be no change in our law upon accepting deposits. Such a position is untenable and leaves the Budapest Treaty -- as well as intellectual property rights on biological material, the ultimate goal to which the Treaty contributes significantly -- void of content. The name of the Treaty, its Article 1, and even the substantive provisions contained therein account for that relationship.

Part 2:

Contents and omissions of the Budapest Treaty

This section contains the most relevant aspects of the controversies surrounding Costa Rica's accession to the Budapest Treaty. It is important to know the patenting procedure established in Costa Rica¹¹ to understand these controversies.

Since the Treaty regulates the deposit of microorganisms for the purposes of patent procedure, and not the patenting procedure as a whole, once deposit becomes an integral part of the procedure, the Treaty will affect Costa Rica's patent law. Up to now, this law establishes conditions for the **description, publication and presentation of a certificate of origin for patents related to biological resources** which will be difficult to fulfil once an IDA accepts a microorganism without the need to comply with Costa Rica's conditions. (Emphasis added.)

Some other limitations are connected with: **the right to opposition; the lack of definition of the subject matter of deposit (what is considered a microorganism?); the amendments to current regulatory provisions on patenting procedures not considered before in Costa Rica; and the fact that debates in the international arena on patents on life have not been settled.** (Emphasis added.)

This section reviews these limitations as well as the considerations provided by some sectors in favour of the accession of Costa Rica to the Budapest Treaty because, in their vision, it would promote scientific research at no extra expense for the depositor and for the State.

2.1 The description requirement

In Costa Rican law, the description of an invention is an essential requirement to apply for a patent, as this description will eventually be published. The description is a necessary element of the disclosure of an invention but does not constitute disclosure itself; clearly, the description is different from disclosure and, in turn, description and disclosure are parts of the patenting procedure. According to this procedure, the description accompanies the application, the application is afterwards published, and from that point on opposition is feasible. If there is no opposition, the examination of the content of the application follows, and if the resolution is favourable, the patent is registered, a certificate is delivered to the applicant and a brief description of the resolution is published.

Article 6 of the Patent Law establishes that the patent application shall be filed with the Industrial Property Registry accompanied by a description, the claims determining the scope of protection sought, the necessary drawings to understand the invention, a summary of these documents and the receipt of payment.

Article 6 paragraph 4 sets out that the description should specify the invention in a sufficiently clear and complete manner so that a person knowledgeable in the technical matter can execute it.

Furthermore, it should describe the best method known by the applicant to operate the invention, citing one or more concrete examples whenever possible, and identifying the particular one that would yield the optimum results in its industrial application.

Article 7 cites the information to be included in the description: the sector wherein the invention is applied, a description of the former technology used insofar as it may assist in understanding the

¹¹ *Law of Patents of Invention, Industrial Drawings and Models and Utility Models* (No. 6867) (hereinafter Law of Patents). Articles 6 to 15, establish the conditions of the patent procedure.

invention's application, as well as a description of the proposed procedure, pointing out its advantages over any previous ones.

In short, in Costa Rica, a clear and complete description of the invention and its advantages is mandatory to apply for a patent.

In Part I of this report, under the heading "*What is the deposit procedure*" (of a microorganism) according to the Budapest Treaty, we made ample reference to the information required for its initial deposit, as well as for subsequent deposits (see Rules 6.1 and 6.2 respectively). The written description should include, among other information, a scientific or taxonomic designation proposed for the microorganism being deposited. Rule 6.1 b) specifically recommends inclusion of a proposed designation or description in the initial deposit, and Rule 6.2 iii) indicates that new deposits should contain updated descriptions when these have been included in the previous deposit. Inclusion of the description or designation is expressed as **a special recommendation and not a condition for deposit**. Accordingly, if the depositor has not included this designation in his initial deposit, he is exempt from doing so in any subsequent deposit. Since this inclusion is not obligatory for the initial deposit, nor is it for new deposits. (Emphasis added.)

According to the Treaty Regulations and the Guide for Deposit of Microorganisms, presentation of a scientific description or taxonomic designation is not obligatory. We may affirm that this is the case not only for the initial deposit but also for subsequent deposits of the same microorganism, and although Rule 8.1 a) indicates that these attributes may be submitted afterwards, or modified if previously indicated, the term "*may*" allowing for the possibility but not requiring it.

Rule 6.4 (b) of the Budapest Treaty indicates that the IDA shall accept the microorganism when all demands of Rules 6.1 (a) or 6.2 (a) and 6.3 (a) are satisfied. However, insofar as Rule 6.4 (b) does not include the conditions of Rule 6.1 (a), **the special recommendation — NOT the obligation — is left untouched**. Rule 6.4 (b) then also confirms the optional character of including the description and/or designation in the written statement and, not having done so initially, the depositor is exempted from updating this information, none of which puts him in violation of Rule 6.4 (b). (Emphasis added.)

Receipts issued by an IDA in acceptance of each microorganism deposit shall also reflect the absence of its description and/or designation. Budapest Treaty Rule 7.3 (vi) provides that IDA receipts should make mention of the description and/or designation when included in the declaration, and also in case the deposit is transferred to another IDA agency. Should the initial declaration include no description, none may be mentioned on receipts of subsequent deposits, **so no mention of the description may appear in the receipt**. (Emphasis added.)

Rule 7.6 stipulates that an IDA shall, upon request, inform all entities entitled to receive a microorganism sample of the most recent scientific description and/or taxonomic designation proposed, as provided in Rules 6.1 (b), 6.2 (a. iii), or 8.1 (b. iii). If we consider that

- no such description or declaration of the microorganism deposited is obligatory,
- subsequent deposits include such information only if the initial deposit did (Rule 6.2 a. iii), and that according to Rule 8.1 it is not compulsory to provide such information after having completed the deposit,

we conclude that it is impossible to deliver the descriptive information, in its most recent version, to interested entities unless this information was provided with or after delivery of the initial deposit. This inadequacy is a matter of concern for governmental, industrial and other authorized subscribers or certified entities, **and confirms that under the Treaty, description is substituted by deposit**. (Emphasis added.)

While it has been argued that deposit is acceptable for patent purposes because describing a microorganism is not a simple matter, this statement should be delimited to define whether such description is really difficult or simply wielded to evade compliance with established legislation.

In relation to the information related to the description or designation accompanying the declaration of a microorganism deposit¹², and the receipt for it¹³, the preceding paragraph calls our attention to the fact that failure to include the description and/or designation of the microorganism is acceptable. Furthermore, by Rule 6.1 (a.v), it is likewise possible to claim ignorance of the dangers these microorganisms may pose to health and the environment.

It is also possible that those responsible for the handling of microorganisms will be exempt from accountability on both health and the environment. In such cases, the State may consequently be hindered from fulfilling its obligation to avoid risks or dangers to life, or deteriorate its quality, all of which stand contrary to Article 45 of Costa Rica's Biodiversity Law, the Convention on Biological Diversity, and the Cartagena Protocol. All of these have urged countries to adopt protection measures relating to the transfer, manipulation and use of modified life forms because of potential adverse effects on biological diversity and its conservation.

The receipts, moreover, will contain neither the description nor designation of the microorganism unless this appears in the initial deposit, and this also applies to subsequent deposits and sample transfers to other IDA. Further, the "*deposit order number assigned by the international authority*" is merely symbolic, as is the "*identification reference*", which is a mere administrative tool revealing nothing truly significant about the deposited microorganism.

If in addition to the non-compulsory requirement of a description and to the acceptance of ignorance about dangers in handling the microorganisms we consider that the remaining items contained in the written declaration are obvious and only intend to assure the laboratory handling of the microorganism, it is evident that no meaningful information accompanies initial and subsequent deposits under the Budapest Treaty.

Neither scientific description nor taxonomic designation is required for deposit, for receipt issue, or for sample delivery. Moreover, the information associated with the deposit and the receipt is meagre, and descriptions are missing from the IDAs' microorganism deposits. We must conclude, then, that the Budapest Treaty not only supplants the description by the deposit, but also effectively exempts the depositor and the IDA agencies from having such information available even for authorized recipients.

While IDAs could argue their inability to provide descriptive information that they do not have, the depositor may claim that the Treaty poses no obligation to provide it. In other words, the Budapest Treaty not only fails to encourage description but also, by these rules, effectively discourages it.

Evidently, the intent of the Budapest Treaty regarding microorganism description goes deeper. We have seen that microorganism deposit information is ineffective, and that IDA-requested data is aimed merely to facilitate inter-agency exchanges. One example is that an IDA may deliver a microorganism sample to an authorized recipient without description or designation, nor any indication of potential health or environmental hazards, insofar as the depositor, sheltered by the Budapest Treaty, did not provide it.

Microorganism description is not required for deposit in the Treaty. However, if the Costa Rican patent law¹⁴ demands a more detailed description, the Treaty falls far short of compliance with

¹² Rule 6.1 (a)

¹³ Rules 7.3, 7.4, and 7.5

¹⁴ Article 9 of the Patent Law states that the Industrial Property Registry shall define whether the application complies with its several requirements, including a description, and should omissions or other discrepancies

those requirements. Since the Budapest Treaty does not oblige description, the means for dispute under Costa Rican law are not evident. Bearing in mind that the sample is for a patent application, would the deposit itself then supersede compliance with the description requirement established in Costa Rican patent application procedure?

The key question, now that Costa Rica has joined the Budapest Treaty, is how might we demand compliance with our legislation regarding description of an invention, given the omissions and insufficiencies contained in the Treaty? The answer to that question should consider that the Treaty demands no description but rather supplants it with deposit of the microorganism. Likewise, patenting procedures might degenerate once the argument of difficulty to describe the microorganism is settled to evade compliance. We, therefore, cannot expect to compensate for this omission in our patent application procedure.

If the description requirement, as set forth in national legislation, is not met, then the invention cannot be evaluated. And if the public cannot understand the object of the patent nor the utility of the invention, the patenting process itself will be pointless. In other words, protection would be given to biological material without public knowledge of its being patented, nor understanding its use. (Emphasis added.)

It was remarkable for the Office of the Ombudsperson to note that the competent local authorities in patent procedures have not visualized the risks inherent to the Budapest Treaty. The assistant director of the Industrial Property Registry asserted that with the Treaty: *"the description of the object to be applied for patenting will not be eliminated"*. She insisted that *"... the description is the technical body of the invention; a clear description has always been required."*¹⁵ It is evident that this local authority has not realized that the implementation of the Budapest Treaty neither facilitates nor contributes to compliance with this requisite, but rather restricts or virtually derogates it.

According to Article 12 of the Patent Law¹⁶, an application may be rejected if it is incomplete or otherwise lacking in any of the prescribed requisites. Should no description be attached, or an accompanying description is inadequate or insufficient, the right to exercise a properly founded opposition is inexistent or at least very limited.

2.2. The publication requirement (disclosure)

Patent application procedures in force in Costa Rica include publication¹⁷ of the description attached to the application so that opposition may be possible. Such publication shall include the applicant's name and relevant data concerning the applicant, the inventor and his representative, and thence the name and a summary of the invention indicating clearly what is to be patented and its use. Article 10 of the Patent Law, states that patent application files may not be opened prior to their publication, except by express written consent of the applicant. If the patent is granted, a brief account of the decree should be published as well.

None of these requirements are present in the Budapest Treaty or its Regulations.

be encountered, the applicant shall be so notified and if corrections are not submitted within the established term, the application shall be voided. Article 15 of the Regulations states that patent applications shall be accepted only when containing, among other requirements, a clear description of the invention and its claims. There can be no doubt that description is obligatory.

¹⁵ Interview with Catalina Monte, assistant director of the Industrial Property Registry, of the Public Registry. July 25, 2007.

¹⁶ Article 12 of the same law provides for appeal for denial by anyone who considers that granting the patent would run contrary to the basic requirements prescribed therein.

¹⁷ This implies publication in the Official Gazette of the patent application or its grant.

Those in favour of the Budapest Treaty argued that it facilitates compliance with the disclosure requirement. In fact, nothing related to an official publication of the deposit appears therein. Rather, Treaty Article 9.2 clearly prohibits IDA agencies' disclosure of any information whatsoever regarding microorganism deposits in their custody, or even regarding the microorganisms in themselves, except to those persons or entities authorized to receive microorganism samples. Such information is therefore secret.

Those in favour of the Budapest Treaty argued that it facilitates compliance with the disclosure requirement. Nonetheless, nothing related to an official publication for the purpose of patenting procedure appears therein. Moreover, Art. 9.2 of the Regulations, in consideration of matters of secrecy of the microorganisms being stored, clearly prohibits IDAs to give any information to anyone concerning the material kept, except to the entitled authorities, natural persons or legal bodies.

Costa Rican patent law states that an invention is eligible for patent protection if it has not been disclosed anywhere in the world prior to its date of application. If added to that Article 10.4 of the same law explicitly mentions that patent application files shall not be opened except by written consent of the applicant, so that the invention is not disclosed until its patent application has been published, we could think that a similar provision of non early disclosure would be included in the Budapest Treaty.

If this were the case, the Budapest Treaty would apparently not contradict our law. Nevertheless, in the case of the Treaty, the knowledge about the characteristics of the deposit is very limited. One thing is to know of the existence of a deposit; another is to get to know the deposit itself. In this last case, the Treaty provides scarce and meaningless information (e.g., symbols, numbers, terms of reference). The Office then affirms that, under the Budapest Treaty, no duly founded opposition to patent application may be made following its publication. Quite contrary to facilitating disclosure of the invention, the Budapest Treaty rather obstructs it.

All patenting procedures should entail some degree of restriction in benefit of the inventor, as the Office readily agrees. Notwithstanding, the improbability of receiving deposit information even after patent application publication is a real obstacle to the right of information and consequent decision making in public matters.

2.3. The requirement of a certificate of origin for access to biological material

In any process of access to biological material, the interested party must ask for permission. Inspired by the Convention on Biological Diversity (CBD)¹⁸, the Costa Rican Biodiversity Law (Article 63.1) establishes as the first requirement for access to genetic and biochemical biodiversity elements *prior informed consent*¹⁹. The local representatives where the access will take place, be they regional councils of conservation areas, farm owners or indigenous authorities, when it is in their territories, are the subject of this consent which must be approved by the Technical Office of the National Commission on Biodiversity (Conagebio) (Art. 63.2).

Additional requirements for access are: technology transfer and the fair and equitable sharing of benefits, if any; protection of the traditional associated knowledge; and definition of the ways in which the said activities will contribute to the conservation of species and ecosystems.

¹⁸ CBD objectives include the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. (Article 1).

¹⁹ Prior informed consent: Procedure through which the State, private owners or the local or indigenous communities, as the case may be, properly supplied with all the required information, allow access to their biological resources. *Costa Rica Biodiversity Law*. Art. 7.9.

Applications for an access permit should be accompanied by evidence of prior informed consent, as required in the certificate of origin²⁰, which is a condition to access for research or bioprospecting²¹.

The Biodiversity Law (Article 80) states that both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Conagebio before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by that Technical Office and the prior informed consent. Justified opposition from the Technical Office will prohibit registration of a patent or other form of protection of the innovation.

Those against the Budapest Treaty pointed out that it ignores the requirements of both the Convention on Biological Diversity and the Costa Rican Biodiversity Law. In their opinion, such omissions render microorganism registry procedures meaningless. They further contend that exclusion of the certificate of origin would encourage biopiracy²². This position was upheld with the presentation of several cases of great concern all over the world about the biopiracy of biological material including human cell lines²³.

The Budapest Treaty, we concur, favours the deposit requirement, excludes the certificate of origin, and thus thwarts international and national biodiversity protection laws.

In view of its undesirable consequences, the Office of the Ombudsperson considered that accession to the Budapest Treaty be studied and decided with great precaution since:

- The information linking the deposit of the microorganism to its place of origin would be lost.
- Unauthorized and uncontrolled misuse of the deposit and its resources will be facilitated.
- Intellectual property rights are monopolies of developed countries, which once obtained thwart technology transfer and the distribution of benefits to biodiversity-rich countries²⁴.
- The right to objection is effectively annulled, leaving natural resources unprotected against arbitrary and illegal use, and providers defenceless regarding their associated traditional knowledge.

All of the foregoing implies that the requirements for access to biological materials defined in the Costa Rican law shall go unimplemented.

2.4. Microorganism: an undefined term

The Budapest Treaty does not define the term microorganism, neither in its Articles 2 (definitions), 3 and 4 (deposits), nor in its Regulations (6-11).

²⁰ According to the *General Rules for the Access to the Genetic and Biochemical Elements and Resources of the Biodiversity* (Decree N° 31514-MINAE, Art. 6.f), the certificate of origin is an official document issued by the Technical Office of the Conagebio, which certifies the legality of access to genetic and biochemical elements and resources of biodiversity and the observance of the terms on which the corresponding access permit was granted to the interested party.

²¹ Bioprospecting is the systematic search, classification, and research for commercial purposes of new sources of chemical compounds, genes, proteins, and microorganisms, and other products with actual or potential economic value, found in biodiversity (*Decree No. 31514-MINAE, Art. 6.d*). According to the Biodiversity Law (Art. 78.3) the State shall not grant intellectual property rights to non genetically modified microorganisms.

²² Private misappropriation of genetic resources and knowledge for profit. See more at: www.laneta.apc.org/biodiversidad/biopirat.htm.

²³ Some of these examples were taken from: Grain. *Of Patents and Pirates. Patents on life: the final assault on the Commons*. 2000. <http://www.grain.org/briefings/?id=141>

²⁴ FAO. (2000) *Multilateral trade Negotiations On Agriculture. Op. cit.* Módulo 4.3.2.

The Guide to Deposits under the Treaty describes the material to be deposited and possibly patented as follows:

The term “microorganism” **is not defined in the Treaty** so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. **Whether an entity technically is or is not a microorganism matters less in practice than whether the deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it.** Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word ²⁵. (Emphasis added.)

This lack of clear definition begs the question: What is really deposited in the IDAs under the Budapest Treaty? Microorganisms or biological material in general?

The Guide to Deposits lists the types of samples accepted by the different IDAs. Not only microorganisms such as algae, bacteria, fungi, mildew, yeasts and virus are deposited, but also embryos, DNA, human and animal cell cultures, RNA, endogens, plasmids, seeds, mice and rat embryos and micoplasmas²⁶.

The US IDA, the American Type Culture Collection (ATCC), *“accepts microorganisms for patent purposes”* including bacteria, cellular lines, genes, purified DNA, and others. Other IDAs have documented their acceptance of similar types of biological material, thus exceeding by far what is understood by microorganism.

Differing from the Guide to Deposits and the International Patent Classification's lack of precise definition of the term, an FAO Manual accepts that

The term microorganism may be understood to include any microscopic organism, including bacteria, virus, algae, unicellular protozoa and microscopic fungi. It is considered that these organisms pertain to a different life category than animal and plant. Although plant and animal tissues and cells may be studied microscopically, they are not microorganisms.²⁷

As shown above, this manual limits the term to five organisms. The Costa Rican botanist Rolando Mendoza²⁸ points out:

Plant and animal cells, although microscopic, may not be called microorganisms insofar as they are part of the tissues of more complex forms of life, and thus may not be patented, but if patented, it is because the concept of microorganism has been altered. It is therefore false to maintain that an isolated human or plant cell is a microorganism, since it constitutes part of a higher being.

It is clear that it is not so difficult to agree on a definition of microorganism, but the Budapest Treaty deliberately leaves this term open, promoting in this way the deposit of all types of biological material.

We are not dealing here with a protocol or a declaration of principles that, given its characteristics, normally does not need to precisely define what is regulated or protected. We are dealing with an international treaty of procedures and regulations whose importance demands clear definitions for proper application. In this case, concepts should not be left loose or delegated to some other instruments for clarification. The lack of certainty of the subject matter of this international piece of international law violates the right to legal certainty, i.e. to know where we stand.

²⁵ *Guide to the deposit of microorganisms*, WIPO.

<http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/introduction.pdf>

²⁶ *Guide to the deposit of microorganisms*. WIPO, Op. Cit. Part II, pages 3-6.

²⁷ FAO. (2000) Op. cit.

²⁸ Interview on concepts of natural sciences, August 26th 2007

2.5. What is patentable and what is not?

As we have seen, leaving the key term "microorganism" undefined clears the way for deposit of all types of biological material in the IDAs. Given this situation, what material is patentable under Costa Rican law?

Costa Rica's Biodiversity Law defines microorganism as a single-celled or multicellular organism capable of carrying out its vital processes, independently of other organisms (Art. 7.23).

Although this definition does not expressly exclude cells and tissues, Articles 77 and 78 do delimit patentable and non-patentable materials: cells, plants, animals, and unmodified microorganisms are not patentable. Article 4 expressly states that the Law does not apply to human biochemical and genetic material.

Under the Budapest Treaty, it is impossible to distinguish between genetically modified, and genetically unmodified microorganisms. Since the deposit of "microorganisms" according to the Treaty is done "for the purpose of patenting", then all biological material in custody in the IDAs is patentable. That is in blatant contradiction with our legislation. Further, Articles 20 and 21 of our Political Constitution are incompatible with private appropriation of human life, including its genetic material.

2.6. Why were we compelled to accede to the Budapest Treaty?

In spite of the fact that the Treaty exists since 1980, Costa Rica had never deemed it necessary to join. According to the minutes of public appearances at Congress, even research institutions with the technical characteristics to be interested in membership had never pushed for it. On the other hand, FAO defends the idea²⁹ that national legislation should establish where and how biological materials are deposited, the conditions for the maintenance of such samples and the modalities of access to the products of interest.

The Office agrees with the opinions given at the Legislative Assembly that there was no obligation on our country to accede to the Budapest Treaty. According to international fora, even in the eventuality that a country accepts the patenting of microorganisms at the national level, the State is the one responsible for determining which system of deposit is suitable for it, including Costa Rica. The same would apply to determining whether deposit is an acceptable replacement for description.

Another argument made in favour of our accession to the Budapest Treaty held that it is our obligation to patent microorganisms because it is so established in the TRIPS Agreement, approved by the Costa Rican State. The Agreement establishes in its Article 27.3 b):

Members may also exclude from patentability: a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; **b) plants and animals other than micro-organisms**, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. // (...) **The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO (World Trade Organization) Agreement**". (Emphasis added.)

As can be observed, the last sentence mandates a review of this provision of the TRIPS Agreement. This is because of the polemic which arose over this multilaterally-imposed obligation to recognize and grant, for the first time, rights of proprietorship over life forms.

²⁹ FAO. (2000) Op. cit.

The Council for TRIPS has been reviewing this subparagraph of the Agreement, and the discussions in that regard are not yet closed. In a recent meeting of the Council, the parties reported that³⁰:

(...) concern has been expressed by the fact that the examination of paragraph 3 b) of Article 27 of the TRIPS Agreement, which started in 1999, has not concluded

From the logical and legal point of view, it is not coherent to demand that countries fulfill this obligation since such subject matter is still under discussion. These regulations have been pointed out as inaccurate and ambiguous. Added to that is juridical uncertainty because of the lack of definition of the object of patenting: microorganisms.

The Office considers that, while these discussions continue and there is no agreement in the subject matter to be patented, Costa Rica should not have adhered to a Treaty which precisely facilitates the patenting of life forms.

2.7. Other aspects of the discussion about accession to the Budapest Treaty

a) Scientific research on biological material

Some scientists interviewed in the course of this investigation expressed the opinion that research on biological resources cannot be performed if its results are not commercialized to cover expenses. A way to assure this, they said, is through intellectual property.

During the research process, a scientist must use materials, information and procedures which could be already patented. In case of using a patented technology or biological resource, the researcher is compelled to pay royalties to the proprietors. That is to say, the research is born tied to pre-existing patents.

It is a platitude to say that the industrialized countries are the ones called to take advantage of the intellectual property system. On the contrary, the capacity of developing countries to obtain and use modern foreign technologies is at present conditioned by international treaties that work against them.

Nowadays, patents are granted, at least in the case of biological material, in a way that "inventiveness" or a step forward in the state of the art is very limited. Patents are also non-specific, such that when they are awarded they cover all or many functions of the substance, even those unknown at that moment. This trend inhibits research and innovation, not only because a new researcher must pay a large amount of royalties, but because he or she will be obstructed from seeking a patent him/herself as the field is already taken³¹.

In the case of the Budapest Treaty, the deposit of a microorganism — or a biological material — will constitute the first step in the procedure for a patent application. If it is granted as per current circumstances, it will eventually generate rights over the microorganism's known but also unknown functions with the consequences already mentioned, contrary to the promotion of research and innovation.

Another aspect which generated great concern to the Office was that some of the scientists interviewed for the purpose of the present report agreed that there is a tendency to ignore the value of publications in journals or books, and to over-value the acquisition of a patent. The following excerpt is illustrative of that situation:

³⁰ Document IP/C/W/369/Rev. 1 of March 9, 2006. World Trade Organization.

³¹ See: Sangeeta, Fager. El debate biopolítico en el ámbito europeo y alemán. Bio-Politics Conference. Fundación Heinrich Boell. México City. October 22-23, 2004.

The publishing of papers in academic journals or at scientific conferences is now a formality without real significance. The real event is the patent application. And even more strikingly, the continuous informal sharing between research groups which was so important for the efficiency of the system has all but ceased. Nothing can ever be shared for fear that a future patent might be compromised.³²

The Universal Declaration on Bioethics and Human Rights promotes the shared utilization of knowledge related to scientific and technological progress. That goal seems to be far away vis-a-vis the expectations of patenting and the implementation of the Budapest Treaty.

b) Costs for the country

The ones in favour of the Treaty argued that accession to it would not generate extra costs for the State. That position does not match the Regulations of the Treaty.

Rule 14.1 specifically mentions that the expenses of each delegation participating in any session of the Assembly and in any committee, working group or other meeting dealing with matters of concern to the Union shall be borne by the State or organization which has appointed it

Rules 5.1 mentions that in the case of interruption or cessation of the services of an IDA, the contracting State or legally approved intergovernmental industrial property organization must, among other things:

- (i) ensure, to the fullest extent possible, that samples of all such microorganisms are transferred promptly and without deterioration or contamination from the "the defaulting authority" to the "substitute authority";
- (ii) ensure, to the fullest extent possible, that all mail or other communications addressed to the defaulting authority, and all files and other relevant information in respect of the said microorganisms are promptly transferred to the substitute authority;
- (iii) ensure, to the fullest extent possible, that the defaulting authority promptly notifies all depositors affected of the discontinuance of the performance of its functions and the transfers effected;

Aren't all these commitments a clear proof of extra personnel and extra costs for the contracting State?

The ones in favour of the Treaty further argued that it has the advantage of preventing multiple deposits in all the countries where the depositor would aim to obtain a patent. With the Treaty, all members are compelled to accept the deposit at any IDA. This, nevertheless, mainly represents an economic advantage for the depositor.

Although the Treaty does not compel a contracting State to establish an IDA, some organizations and individuals consulted in Costa Rica did not discard such a possibility. Some considered that there are entities in the country that have the technical capacity and will be willing to become an IDA. Nevertheless, they also recognized the complex and expensive procedures involve in the deposit of microorganisms, including maintenance, which are very difficult to assume without the support of the State.

Indeed, the protection of intellectual property rights is going far beyond what could benefit the citizens. Costa Rica's current Vice-President and Minister of Justice, Laura Chinchilla, recently declared in an interview³³ that if the Government would enforce the law related to software licensing it would run out of money needed to build social housing or to finance public schools. If that is so, expenses to be party to the Budapest Treaty to facilitate patents on biological resources would add to that problem, without a real need for it.

³² GRAIN. Community or commodity: What future for traditional knowledge? In: *Seedling*, July 2004. <http://www.grain.org/seedling/?id=291>.

³³ La Nación. February 14, 2007

On the other hand, the Budapest Treaty, as we explained, does not recognize basic requirements for access to genetic resources, among which are the transfer of technology and the fair and equitable sharing of benefits.

We are certain that Costa Rica recognizes the right of intellectual property "protection". However, the Office considers that this cannot be superimposed over human rights. That is to say, human rights should be guaranteed over private ones. Human rights are the cornerstone of social ethics which guarantees just and solidarity relationships among all human beings.

Part 3.

Consequences of the patenting of life forms

The Office consulted the minutes of the TRIPS Council and could identify some consequences produced by the implementation of intellectual property rights which we cannot ignore in this report in as much as the Budapest Treaty facilitates the patenting of life forms. The Office detected in those minutes contrasting opinions held by two different groups of countries. One is constituted by industrialized countries (United States, Japan, China, Singapore, European Union, Norway, Australia, Switzerland, Korea); the other comprised by developing ones (India, Kenya, Brazil, Peru, Zambia and the African Group).

A general overview of the different positions allowed us to summarize the following considerations.

- The developing countries are opposed to the patenting of life forms for several reasons among them for ethical considerations.
- Some developing countries attribute to life forms a superior value above their commercial interest. The extent of the commoditisation of life forms must be defined by national legislations in consideration of those values.

The Office considers important to add that the value system of each country must be respected by international instruments and national legislation. In our case, it is the Costa Rican State, based on an ample social consultation, who should freely decide if life forms are patentable or not. It would not be coherent with the principle of free determination to adhere to treaties and trade agreements which would trigger a change in standing legislation based on a value system that a few years ago did not allow the patenting of life forms.

- Governments of industrialized countries affirm that research on biological material would not be possible without intellectual property and trade secrets.
- Japan and Australia showed interest to extend patents to all kinds of biological material, including non-modified resources merely isolated from their natural state.

In Costa Rica, the current legislation does not provide patents to non-modified micro-organisms. This position is similar to the one defended by a group of developing countries at the Council for TRIPS.

The Office now centers attention on the topic of values behind the positions against or in favor of the patenting of life forms. The Budapest Treaty facilitates this procedure and in that context several questions are raised: To whom does life belong? Is it ethical to appropriate and monopolize any type of life form including its smallest components? What use will be made of the

products, procedures, services and knowledge derived from the patenting of microorganisms in the IDAs?

The answer to the first question differs according to each person if he/she is a believer and according to the values of each one's belief. In answer to the other two questions, the Office establishes that both the deposit of microorganisms and any other type of biological material under the Budapest Treaty, and any kind of use made of them after the patents are granted, could bring ethical dilemmas especially, but not only, when they deal with human components.

Bioethics deals with human behaviour and all the aspects connected with life and health from the point of view of values. That is why the Office would expect that the patenting of life forms would give rise to a bioethics dialogue among different religious denominations and all the people of good will concerned with it.

The Office is aware of the bioethics debates surrounding biotechnologies and genetic interventions. The philosopher Antonio Marlasca points out that:

...the great topics and great debates of bioethics are product and consequence of the so called "biological revolution". This revolution started with the discovery of the Desoxyribonucleic Acid (DNA) structure by Crick and Watson in 1953. From there on a series of spectacular interventions over the life started, especially over the human life, and ever since diverse ethical orientations appeared³⁴.

Marlasca has also mentioned that the ethical valuation of facts such as intervening in genetic heritage and the improvement of the hereditary qualities of human beings (in the physical and mental aspects) vary depending upon religious beliefs or the lack of them, and with the anthropological assumptions behind them.

It seems to us, then, that the different faiths and congregations, the scientific community and civil society in general have much to contribute even to the bioethics dialogue about the patenting of life forms and its consequences.

The geneticist Francis Collins³⁵ states that every day new ethical dilemmas associated with advances in the genomics arise. It would be a mistake, he continues, to leave the real ethical challenges only to scientists; they cannot be the only ones at the discussion table.

Scientific progress is in itself a matter to improve the conditions of the environment, human beings individually and humankind in general. However, the advances of science raise numerous and serious ethical queries. Such queries will be answered at the level of theoretical reflection and at the level of action. What is true is that this is a question whose answer cannot be given by science alone.

The Office considers that we must be careful with research on biological material in general and on human beings in particular. It is also necessary to be aware of proposals like accession to the Budapest Treaty whose final objective is to facilitate the patenting of life forms. We should seek the best protection for those life forms and be aware of their uses. In this matter the different denominations, congregations, civil society and the scientific community have the final say.

³⁴ Marlasca, Antonio. *Introducción a la Bioética*. Facultad de Filosofía. Universidad Nacional. Heredia, Costa Rica. Pág. 14.

³⁵ Collins, Francis S. *The Language of God*. Free Press. 2006.

Conclusions

- Accession to the Budapest Treaty was one of the commitments that the Costa Rican State acquired once the US-DR-CAFTA was approved.
- The Treaty does not grant patents. It rather facilitates the procedure in matter of patents allowing the deposit of microorganisms in one of the currently 37 International Deposit Authorities.
- The Treaty does not require the depositor to indicate the source or the origin of the material in custody. This means that it does not demand proof of either the prior informed consent of the supplier of the material nor the certificate of origin.
- The Treaty prohibits the IDA from providing information about the deposited materials. That means that interested third parties, indigenous people, rural communities and other suppliers of biological resources will see limits on the exercise of their right of opposition if their natural resources, or even their own genes, are deposited for patenting purposes.
- The Treaty will consequently contribute to the lack of protection for biodiversity and will prevent the eventual sharing of benefits mandated by law to the providers of deposited biological materials.
- The Budapest Treaty neither facilitates a detailed description of the deposited material nor, as a consequence, contributes to the full disclosure of the invention. The incomplete information will be insufficient, under national legislation, to exercise the right of opposition to a patent application.
- The arguments given in the affirmative verdict of the majority at the Legislative Assembly of Costa Rica on the bill for Accession to the Budapest Treaty to defend the notion that the Treaty promotes the description and disclosure of inventions are not supported.
- The Budapest Treaty does not define its subject matter, i.e. the word "microorganism", for the purpose of allowing the deposit of biological materials in general and expanding their protection through proprietary rights.
- Some of the deposited biological materials do not qualify as microorganisms.
- The WTO Council for TRIPS and several branches of WIPO continue discussing to what extent life forms are patentable or not. That means that, worldwide, the discussion is open. Therefore, the obligations regarding intellectual property rights at those multilateral fora are still uncertain. Meanwhile, bilateral and regional free trade agreements are compelling developing countries to approve more intellectual property treaties, such as Budapest, and more rigid clauses not yet completely accepted at the multilateral level.
- Costa Rica's national legislation does not allow the patenting of genetically unmodified microorganisms. Notwithstanding, because of the lack of definition of "microorganism" in the Budapest Treaty and the consequent lack of distinction between "not genetically modified" and "genetically modified" microorganisms, it can be understood that the Treaty includes all types of microorganisms.
- In Costa Rica, private entities have never been involved in the registry procedure of industrial property. According to Rule 2.1 of the Regulations of the Budapest Treaty, private entities are allowed to have the custody of microorganisms; therefore, now that Costa Rica was compelled to adhere to the Treaty our national law must be changed.
- There has been a worldwide debate related to the economic, environmental and ethical impacts of the patenting of life forms. That debate seems to have been ignored with the imposition of the Budapest Treaty.
- No member can unilaterally modify the Budapest Treaty. Every modification must be done through the Assembly and agreed to by all signatory countries of the Treaty. Therefore, any unilateral declaration made, for instance, by Costa Rica in order to clarify or redefine the scope of the Treaty does not have any validity. International treaties do not allow reservations or interpretive clauses.
- What is worse, now that the US-DR-CAFTA has been approved, any modification of the subordinate treaties, i.e. Budapest and the UPOV Convention (1991 Act) will be much more complex.

- The Office of the Ombudsperson concludes that the Budapest Treaty is not in line with the norms and ethical principles of Costa Rica. Therefore, it considers that civil society, the scientific community and the different congregations should have had a more broad discussion on this Treaty including its ethical, environmental, social, economic and legal implications. Unfortunately, this did not happen and the decision to vote the US-DR-CAFTA, with its obligation for Costa Rica to accede to the Budapest Treaty, at referendum was not taken with a generalized prior informed consent.
- Accession to the Budapest Treaty has implications in the economic, legal and cultural fields and contravenes the human right to life, the human right to information and participation, and the human right to legal security.

Glossary

DNA	Desoxyribonucleic Acid
TRIPS	Trade-Related Aspects of Intellectual Property
IDA	International Depositary Authority
CBD	Convention on Biological Diversity
IPR	Intellectual Property Rights
FAO	Food and Agriculture Organization
WTO	World Trade Organization
WIPO	World Intellectual Property Organization
UPOV	Union for the Protection of New Plant Varieties
US-DR-CAFTA	United States-Dominican Republic-Central America Free Trade Agreement

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