

## Deposit of Biological Materials

In this issue of the WTS Legal Report we would like to discuss a matter of great practical significance: Polish and international regulations concerning the deposit of biological materials.

One of the grounds on which the Polish Patent Office can make a decision refusing patent protection is insufficient disclosure of an invention (Article 49 Section 1(2) of Act of June 30, 2000 on Industrial Property Law; hereinafter referred to as the IPL). A situation wherein an invention has not been disclosed in a manner sufficiently clear and complete to allow a person skilled in the art to carry it out, constitutes a ground for invalidation of a patent (Article 89 Section 1(2) of the IPL). **The question of insufficient disclosure is especially important when it comes to biotechnological inventions. Considering their specificity, submission of a drawing or a written description would often fall short of fulfillment of the sufficient disclosure requirement.**

In particular it pertains to biotechnological inventions which cannot be carried out without an access to a given microorganism. To address the case of such inventions, a special mechanism is provided in domestic and international regulations — it enables applicants to deposit samples of biological materials in so called collections.

### Definition of biological materials

Legal norms concerning the deposit of biological materials are closely tied, as one could easily guess, to regulations relating to biotechnological inventions. At the beginning let us remind you that a biotechnological invention, as defined by the Polish Act on Indu-

ustrial Property Law, is an invention in the meaning of Article 24, that concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Article 93<sup>1</sup>(1)). The definition of a biotechnological invention is therefore based on the general patentability criteria, complemented by specific terms, such as biological material and biological process. Biological process is the one that involves, is performed on or results in production of biological material (Article 93<sup>1</sup>(3)); whereas **biological material**, which is at this moment in the center of our attention, **shall be understood as a material containing genetic information and capable of reproducing itself or being reproduced in a biological system** (Article 93<sup>1</sup>(2)).

## The legal regulations in Poland

According to Article 93<sup>6</sup> Section 1 of the IPL, **if carrying out of an invention requires use of a biological material which is not available to the public and which cannot be presented in the patent description in such a manner as to enable the invention to be carried out by a person** skilled in the art, its disclosure might be realized by invoking a deposit, made at the latest on the date of filing of an application, of a material in a collection recognized by an international agreement or in a national collection, designated by the President of the Polish Patent Office through a promulgation in the Official Journal of the Republic of Poland “Monitor Polski”.

In such a case it is necessary to submit along with a patent application a document issued by a depository institution that shall include at least the name of this institution, the date of the deposit and the accession number (Article 93<sup>6</sup> Section 3).

It must be underlined that this rule shall not apply to every biotechnological invention — in a case of an application concerning a sequence or a partial sequence of a gene that reveals nucleotide or amino acid sequences, an applicant sends a sequence listing in compliance with the WIPO standard ST.25: in an electronic form that allows further processing of data (Article. 93<sup>2</sup> Sections 2 and 4); at the same time it is worth adding that an introduction of a new standard ST.26 is planned for the beginning of 2022 — nucleotide and amino acid sequence listings will be presented using eXtensible Markup Language (XML).

## The international legal regulations

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure along with the Regulations under the Treaty were

concluded in Budapest on April 28, 1977. A treaty is open for signature to any State member of the International (Paris) Union for the Protection of Industrial Property. The total number of states that are currently parties to the Budapest Treaty amounts to 82; Poland acceded to it on June 22, 1993.

Generally, **the principal idea of the Budapest Treaty comes down to the fact that all state-parties are obliged to recognize microorganism deposited for the purposes of patent procedure, irrespective of where a depositary authority is located.** Thus it is no longer necessary to deposit a material separately in every single state where a given subject seeks a patent protection.

### International Depositary Authority

The Polish legislation uses a term “collection” to designate an institution capable of receiving and storing biological materials. As stated in Article 93<sup>6</sup> Section 2 of the IPL, acquisition of a status of national collection is promulgated by the President of the Polish Patent Office who makes a decision after receiving, upon an institution’s request, a favorable opinion of a minister competent with regard to the type of deposited biological materials. At this moment there are 3 collections functioning in Poland:

- 1) Instytut Biotechnologii Przemysłu Rolno-Spożywczego im. prof. Waclawa Dąbrowskiego (*Prof. Waclaw Dąbrowski Institute of Agriculture and Food Biotechnology*), ul. Rakowiecka 36, 02-532 Warszawa;
- 2) Instytut Immunologii i Terapii Doświadczalnej im. Ludwika Hirszfelda, Polska Akademia Nauk (*Ludwik Hirszfeld Institute of Immunology and Experimental Therapy, the Polish Academy of Sciences*), ul. Rudolfa Weigla 12, 53-114 Wrocław;
- 3) Narodowy Instytut Leków (*National Medicines Institute*), ul. Chełmska 30/34, 00-725 Warszawa.

The first two collections have the status of international depositary authorities (IDA) in the meaning of the Budapest Treaty.

The provisions of the Treaty formulate a detailed conditions that have to be fulfilled in order to be eligible to acquire such a status. According to Article 6, a depositary institution must be located on the territory of a Contracting State and must benefit from assurances furnished by that State to the effect that the said institution complies and will continue to comply with the requirements specified in paragraph 2, which include: continuity of existence; possession of the staff and facilities necessary to perform its scientific and administrative tasks; impartiality and objectivity; availability, for the purposes of deposit, to any depositor under the same conditions. Moreover, the provision in question, listing

other conditions, indicates that an institution must accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations; it must issue a receipt to the depositor, and any required viability statement; comply, in respect of the deposited microorganisms, with the requirement of secrecy; as well as furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations (we will expand on this topic in a following section of the report). It should also be mentioned that the said assurance might be furnished as well by an intergovernmental industrial property organization, as long the depositary institution is located on the territory of a State member of such an organization.

The IDA acquires its status by virtue of a written communication addressed to the Director General of the World Intellectual Property Organization by the state-party on the territory of which the depositary institution is located or by an intergovernmental industrial property organization. If the Director General finds that the communication is complete and correct, it is published without any delays by the International Bureau of WIPO: the status is considered to be acquired as from the date of publication of the communication or another date indicated in the communication, provided that the latter is later than the former.

The most important consequence of acquisition of the status of an IDA is established by Article 3(1) of the Budapest Treaty. This provision resolves that the Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any IDA; such recognition shall include the recognition of the fact and date of the deposit as indicated by the IDA as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism. **In other words, a biological material deposited with such an authority shall be recognized by all the other state-parties for the purposes of patent procedures conducted in their jurisdictions.** The goal of the Treaty is a creation of a common standard — it must be noted that Article 3(2) of the Treaty expressly prohibits imposing requirements different from or additional to those which are provided in the Treaty and the Regulations.

## Making the deposit

As far as rules for making the deposit are concerned, the provisions of the Polish Act on the Industrial Property Law define a specific time frame to perform necessary actions. First of all, **a biological material shall be deposited at the latest on the day that application is filed** (Article 93<sup>6</sup> Section 1). Secondly, **an applicant shall submit a receipt issued by the depositary institution within 6 months following the application date;**

the legislator states at the same time that a submission of the receipt once the time limit expires, does not result in recognizing the deposit of biological material as equivalent to its disclosure in the application (Article 93<sup>6</sup> Section 4).

Far more detailed regulations can be found in the Regulations Under the Budapest Treaty. As indicated by Rule 6, the deposit transmitted to a depositary authority shall be accompanied by a written statement that shall contain, i.a., details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability, its identification reference (number, symbols, etc.) given by the depositor to the microorganism; as well as an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties. According to Rule 7, an IDA issues to a depositor a receipt that attests reception and acceptance of the microorganism (Rule 7 specifies also requirements with regard to form, language, signature and content of a receipt).

## **New deposits of biological materials**

Provision of Article 93<sup>7</sup> of the IPL states that if a biological material deposited in compliance with Article 93<sup>6</sup> ceased to be available in a collection, a new deposit can be made on conditions set out by the international agreement. The international agreement that a reference is made to is obviously the Budapest Treaty. Article 4 of the Treaty establishes a rule, according to which **making of a new deposit is required whenever the IDA cannot furnish samples of the deposited microorganism**, especially if such microorganism is no longer viable, or if the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions.

It should be added that every new deposit shall be accompanied by a written statement of the depositor, alleging that the newly deposited microorganism is the same as that originally deposited (Article 4(1)(c)). What comes to the fore in this context is a viability statement — **if all the preceding viability statements confirm that the microorganism was viable, and the new deposit is made within 3 months after the date of delivery of the appropriate notification, the new deposit shall be treated as if it had been made on the date on which the original deposit was made** (Article 4(1)(d)).

## **Viability test**

At this point it would be useful to explain what exactly the viability statement is.

Rule 10 of the Regulations under the Budapest Treaty obliges an IDA **to conduct a viability test of each microorganism deposited with it** — promptly after a microorganism is submitted to the deposit, as well as at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons (an assessment of necessity is left to an IDA's discretion); or at any time, on the request of the depositor. It is mandatory to inform the depositor about results of the test in writing through an international form BP/9. The viability statement is issued to the depositor, as well as to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples (you can find more information about furnishing of samples below). The crucial element of such a statement is the indication of whether the microorganism remains viable or is no longer viable.

In the *Guide to the Deposit of Microorganisms under the Budapest Treaty* the significance of this aspect of the procedure of making the deposit is strongly emphasized: “the whole point of deposit is to ensure that viable samples of the microorganism are made available at the appropriate time and under the requisite conditions to those entitled”. The viability statement issued along with a receipt that Rule 7 pertains to, confirms that a given microorganism has been deposited effectively. **This document plays a key role with regard to determining the date of deposit.**

### **Storage of the deposit**

Regulations under the Budapest Treaty specify the standard that applies to the storage of the deposited microorganisms. **An IDA is obliged to exercise all the care necessary to keep the microorganism viable and uncontaminated.** A time frame is also designated: the microorganism has to be stored for a period of **at least 5 years after the most recent request for furnishing its samples and, in any case, for a period of at least 30 years after the date of the deposit (Rule 9(1)).**

Another fact of great importance needs to be highlighted. As is written in the commentary to the IPL edited by professor Sieńczyło-Chlabicz, “depositing of a material with the depositary authority is effective with regard to all state-parties of the treaty, while a refusal of application or invalidation of a patent in one of the states do not necessarily entail a refusal in another state”. An effectively made deposit cannot be withdrawn, even if a patent is not granted; it does not expire in the event of subsequent invalidation of the patent (this is clearly confirmed by the aforementioned guide to the Budapest Treaty).

## Access to the deposit

Another issue that merits a profound consideration concerns secrecy: IDA shall not give information to anyone whether a microorganism has been deposited with it under the Treaty, nor any information concerning any microorganism deposited with it under the Treaty (Rule 9(2)).

The Polish Act on Industrial Property Law provides distinct legal regimes that are applied when it comes to the access to the deposit before and after a publication of a patent application. In the first case, the access is limited to persons enumerated in Article 251 Section 1 of the IPL, i.e.: the applicant and his or her plenipotentiary; law enforcement authorities and judicature — with regard to cases conducted by them; as well as other persons who present a written consent of the applicant; what is more, if the applicant submits a proper motion before application is published, this restriction could apply throughout the whole procedure of the application's review (Article 93<sup>6</sup> Section 5 of the IPL).

When it comes to the legal regime relevant to the period following the publication of the application (or the grant of the patent if the aforementioned motion was filed), a third party cannot be denied an access to the deposit if they agree in writing before the applicant or the patent holder that as long as the patent remains valid: 1) they will not share a sample or any substances derived from it with third parties; 2) they will use a sample or any substances derived from it only for experimental purposes. The applicant and patent holder can however release them from that obligation, but it is essential that they do so in an express manner (Article 93<sup>6</sup> Sections 6-7 of the IPL).

**A matter of the access to the deposit has also been elaborated on in Rule 11 of the Regulations under the Budapest Treaty. The Regulations provide specific solutions that shall apply depending on to whom a sample of a deposited microorganism is furnished.** If a request is made by **the industrial property office of any state-party** (or by any intergovernmental industrial property organization), they have to submit a declaration attesting that, (i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof; (ii) such application is pending before that office or has led to the grant of a patent; (iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State (or in the said organization or its member States); (iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure (Rule 11(1)).

An IDA furnishes a sample of a deposited microorganism also to **the depositor upon his or her request, as well as to any authority, natural person or legal entity authorized by the depositor** (Rule 11(2)).

The requests for furnishing samples can also be made by **“the certified parties”** — **this term shall be understood as referring to any authority, natural person or legal entity that present their requests with a use of a form whose contents are fixed by the Assembly of state-parties and which is accompanied by a certification of the relevant industrial property office**, confirming that: (i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof; (ii) publication for the purposes of patent procedure has been effected by that office; (iii) the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled (Rule 11(3)(a)). There also exists an alternative path of furnishing samples to the certified parties which is far less often used in practice: the industrial property office can periodically submit to the IDA lists of the accession numbers assigned by the depositary authority to the deposits of microorganisms referred to in patents granted and published by this office; in this case upon a request of a certified party, the IDA furnishes to it a sample of any microorganism where the accession number has been so communicated (Rule 11(3)(b)).

Trying to capture the essence of the mechanism provided for furnishing samples — taking into account what has been discussed before — we have to notice that the IDAs are not required to possess full knowledge of legal regulations binding in the state-parties to the Budapest Treaty. They are not obliged to conduct any examinations on their own to ascertain whether a given third party is in fact entitled to get access to a sample of a specific microorganism. Therefore **those authorities furnish samples only on the basis of a proper authorization by the depositor or a certification issued by a competent industrial property office.**

## Summary

In the order to recap our analysis of the deposits of biological materials, let us recall the key issues addressed in this report:



- The mechanism of deposits, regulated in the domestic law, as well as on the international level (The Budapest Treaty) allows patent applicants to fulfill a requirement of sufficient disclosure with regard to biotechnological inventions;
- The Budapest Treaty provides that all the contracting states have to recognize microorganisms deposited for the purposes of patent procedure, irrespective of where a depositary authority is located.
- The deposit must be made at the latest on the date of filing of a patent application, whereas the receipt issued by the IDA must be submitted within 6 months after the date of application;
- International depositary authorities are obliged to conduct a viability test of each microorganism deposited with them; the result is indicated in the viability statement;
- Samples of a deposited microorganism are issued by an IDA upon a request of: (i) industrial property office of any state-party or any intergovernmental industrial property organization; (ii) the depositor, as well as authorized authorities persons; (iii) the certified parties, as defined by Rule 11(3) of the Regulations under the Budapest Treaty.