Selected points regarding eligibility of claims according to Article 7(2) of the Israeli patent law
Art. 7(2)
• States that **a patent will not be issued to new kinds of plants or animals except for microorganisms which were not obtained from nature.**

• I would like to concentrate on the microorganism part of Art. 7(2).
• I will give an example of an application I examined and the relevant claim, and compare way of examining of said claim in the IPO versus examinations in the EPO or in the USA.
• Reading above article again:
• **Thinking points:** 1. what are new kinds of microorganisms?
• 2. What is considered natural?
• Let me point out that microorganisms are usually found in nature in small concentrations and usually as a mixed population with other microbs.
The application is related to Influenza A virus which infects dogs. A new phenomenon in racing dogs in the USA who had hemorrhagic pneumonia.

Relevant claim:

An isolated influenza virus that is capable of infecting a canid animal.

Examiner’s remark:

The claim opposes Art. 7(2) and can not be accepted because the virus is obtained from nature.
Sum of arguments

- Applicant’s response:
  - We are claiming a virus and not a **kind** of animal or plant. The argument is based on semanthics.

- Communication with applicant went back and forth several times and even after I substantiated my arguments by including the Registrar’s decision in a similar matter, it took another communication from the applicant to settle on an acceptable claim which was:

- 
CLAIM:
1. An isolated canine influenza virus, which is a type A influenza virus wherein said influenza virus is inactivated or attenuated and wherein said influenza virus comprises a polynucleotide which encodes a polypeptide having the amino acid sequence shown in any of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 33, or 34, or a functional and/or immunogenic fragment thereof, or said polynucleotide encodes a polypeptide having 99% or greater sequence identity with the amino acid sequence shown in any of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 33, or 34.

This claim is acceptable because the virus is inactivated or attenuated and is not in its state found in nature.
The Registrar Dr. Michael Ofir Ruled in a case where the applicants claimed a pure culture of microorganisms isolated from a sewage tank (11/1991).

After a debate, his decision was, that the specifically claimed microorganisms were patentable because they were isolated from a sewage tank which is not a natural environment. He also referred generally to patenting microorganisms isolated from nature, in the sense of Art. 7(2) of the Israeli patent law. This is summed up below:

Registrar’s ruling:
- A pure culture of microorganisms which is obtained from nature is not entitled to a patent even though the culture is not present in nature and although isolation and production may require special skills and talents, expertise and effort during the process. A pure culture as such, is considered a microorganism obtained from nature in the sense of Art. 7(2) and so, it is not entitled to a patent. Without scientific evidence it cannot be stated, that a pure culture of a microorganism is new end different from what is found in nature. But if it can be proven that the microorganism claimed was not isolated as such from nature, i.e. that there was some human intervention, it may be patentable.
In the EPO the claim that was submitted was:

- An isolated canine Influenza A virus that is capable of infecting a canid animal.

The examiner objected to the claim, worded as “a result to be achieved” and because it does not include the technical features that enable the production and identification of distinguishing features of the specific canid virus. Since the technical effects as said are missing, there is undue burden on someone trying to determine the limits of the invention.

Accepted claim:

1. An isolated canine influenza A virus that is capable of infecting a canid animal, wherein the influenza virus comprises a hemagglutinin (HA) polypeptide or a polynucleotide which encodes an HA polypeptide, wherein the HA polypeptide comprises:

   (a) the amino acid sequence shown in any of SEQ ID NOs: 16, 32, 33 or 34; or
   (b) an amino acid sequence having 95% or greater sequence identity with the sequence shown in SEQ ID NOs: 33 or 34, wherein the amino acid sequence comprises a serine at amino acid position 82, a leucine at amino acid position 221, a threonine at amino acid position 327, and a threonine at amino acid position 482.
Aticle 52

Patentable inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;
• **3.1 Discoveries**

• If a new property of a known material or article is found out, that is *mere discovery* and *unpatentable* because discovery as such *has no technical effect* and is therefore not an invention within the meaning of Art. 52(1).....

• ... However, if a substance found in nature can be shown to produce a technical effect, it may be patentable... In addition, if a *microorganism is discovered* to exist in nature and to produce an *antibiotic*, the *microorganism itself may also be patentable* as one aspect of the invention.
5. Exclusions and exceptions for biotechnological inventions

5.1 General remarks and definitions

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

5.2 Patentable biotechnological inventions

In principle, biotechnological inventions are patentable under the EPC. Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:

(i) Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.....

A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

"Microbiological process" means any process involving or performed upon or resulting in microbiological material.
5.5 Microbiological processes

5.5.1 General remarks

- The product of a microbiological process may also be patentable *per se* (product claim). Propagation of the microorganism itself is to be construed as a microbiological process for the purposes of Art. 53(b). Consequently, the microorganism can be protected *per se* as it is a product obtained by a microbiological process (see G-II, 3.1).

- The term "microorganism" includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory (see T 356/93), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells.
Claim submitted to the USPTO

We claim:

1. An isolated influenza virus that is capable of infecting a canid animal.

The main arguments against the claim were that it did not comply with the requirements for novelty and inventive step.

The claim that was accepted was:

We claim:

1. An isolated canine influenza virus wherein said influenza virus comprises a polynucleotide which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:33, or a polynucleotide encodes a polypeptide having 99% or greater sequence identity with the amino acid sequence of SEQ ID NO:33.
In the USPTO, instructions for evaluating microorganisms as patents are based on the ruling of Diamond vs. Chakrabarty (some general facts from Wikipedia)

Genetic engineer Ananda Mohan Chakrabarty, working for General Electric, had developed a bacterium (derived from the Pseudomonas genus and now known as Pseudomonas putida) capable of breaking down crude oil, which he proposed to use in treating oil spills. General Electric filed a patent application for the bacterium in the United States listing Chakrabarty as the inventor, but the application was rejected by a patent examiner, because under patent law at that time it was generally understood that living things were not patentable subject matter under Section 101 of Title 35 U.S.C.

The Board of Patent Appeals and Interferences agreed with the original decision; however, the United States Court of Customs and Patent Appeals overturned the case in Chakrabarty's favor, writing that "the fact that micro-organisms are alive is without legal significance for purposes of the patent law." Sidney A. Diamond, Commissioner of Patents and Trademarks, appealed to the Supreme Court.

The Supreme Court case was argued on March 17, 1980 and decided on June 16, 1980. The patent was granted by the USPTO on Mar 31, 1981.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2105   Patentable Subject Matter — Living Subject Matter [R-07.2015]

I. INTRODUCTION

The decision of the Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from Chakrabarty and subsequent judicial decisions that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. Note, however, that Congress has excluded claims directed to or encompassing a human organism from patentability. See The Leahy-Smith America Invents Act (AIA), Pub. L. 112-29, sec. 33(a), 125 Stat. 284 (September 16, 2011). sec. 33(a), 125 Stat. 284 (September 16, 2011).

II. LIVING SUBJECT MATTER MAY BE PATENTABLE

A. Living Subject Matter May Be Directed To A Statutory Category

In Chakrabarty, the Supreme Court held that a claim to a genetically engineered bacterium was directed to at least one of the four statutory categories, because the bacterium was a “manufacture” and/or a “composition of matter.”
The Supreme Court made the following points in the Chakrabarty opinion (relating to 35 U.S.C section 101):

- “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”

- “Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent’s microorganism is the result of human ingenuity and research.”
B. Living Subject Matter May Be Eligible for Patent Protection

The Supreme Court in Chakrabarty held a claim to a genetically engineered bacterium eligible, because the claimed bacterium was not a “product of nature” exception. In so holding, the Court made the following point:

“This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”

A more recent judicial decision from the Federal Circuit indicated that “discoveries that possess ‘markedly different characteristics from any found in nature,’ ... are eligible for patent protection.” In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1336, 110 USPQ2d 1668, 1671 (Fed. Cir. 2014), quoting Chakrabarty, 447 U.S. at 310. In Roslin, “ Roslin, 750 F.3d at 1337, 110 USPQ2d at 1671
## Comparison of examination in IPO, EPO, USPTO

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<thead>
<tr>
<th>USPTO</th>
<th>EPO</th>
<th>IPO</th>
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<tr>
<td>Invention is entitled to any new... manufacture or composition of matter. The distinction is made between products of nature and human-made inventions.</td>
<td>Mere discovery is unpatentable because a discovery has no technical effect.</td>
<td>A pure culture of microorganisms which is obtained from nature is not entitled to a patent.</td>
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<tr>
<td>A genetically engineered bacterium is a “composition of matter “or is due to “manufacture”. It is not a product of nature.</td>
<td>A <strong>product</strong> of a microbiological process may be patentable per se. Microb. process means any process involving or resulting in microb. Material.</td>
<td>Microorganisms for which there is evidence that are not isolated from nature, i.e. that there was some alteration by human intervention, may be patentable.</td>
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<td>Recent decision: discoveries that possess markedly different characteristics from any found in nature, are patentable.</td>
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