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**Israel  
Patent Office**

## **From Patent to Drug**

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Biotechnology Patent Examiner**





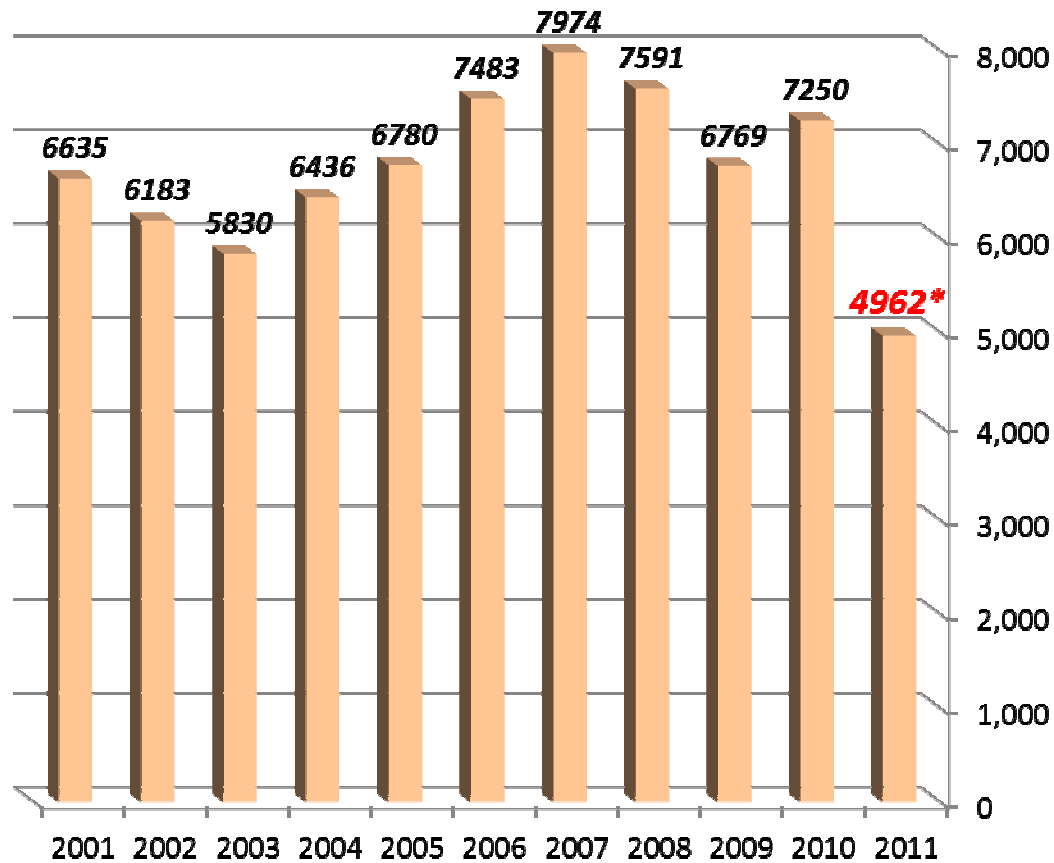
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- **Introduction to the patent examination process**
- **What is patentable (sections 3 & 13(b) of the Israel Patents Law)**
- **Patent requirements (sections 4, 5, 7 of the Israel Patents Law)**
- **Examples: from patent to drug**

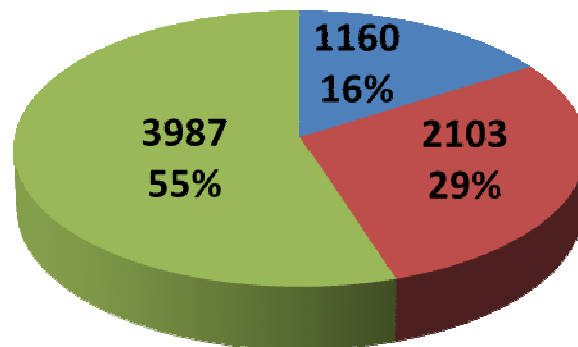
## Total number of patent applications submitted during the years 2001-2011



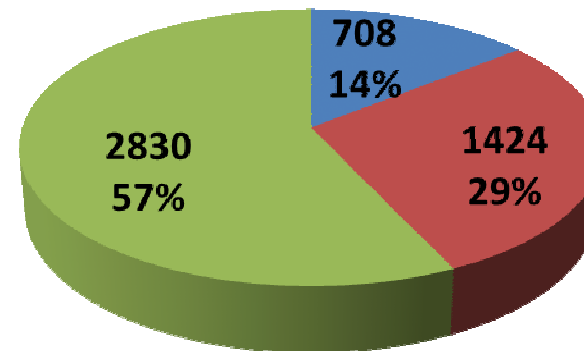
\*First nine months of the year

## Number & Percentage of applications by department (2010-2011\*)

**2010**



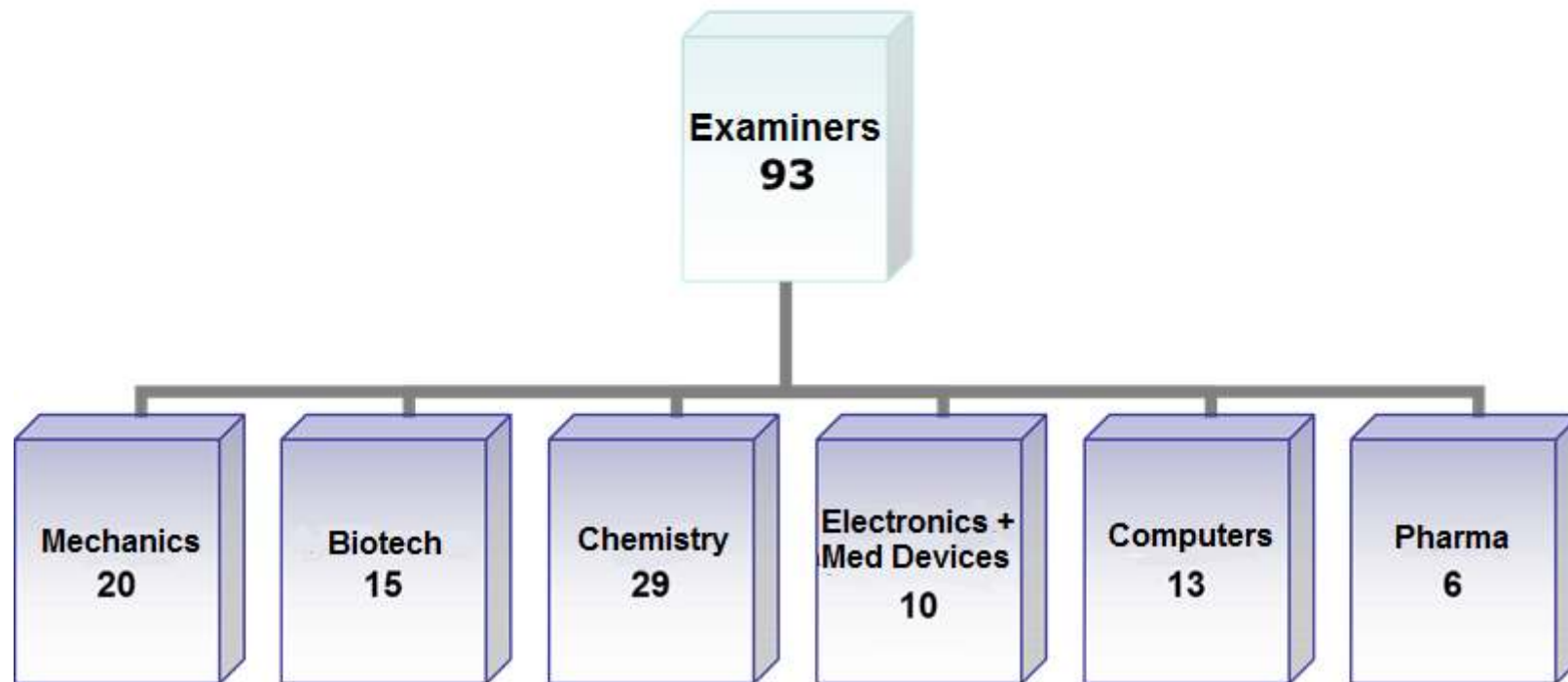
**2011\***



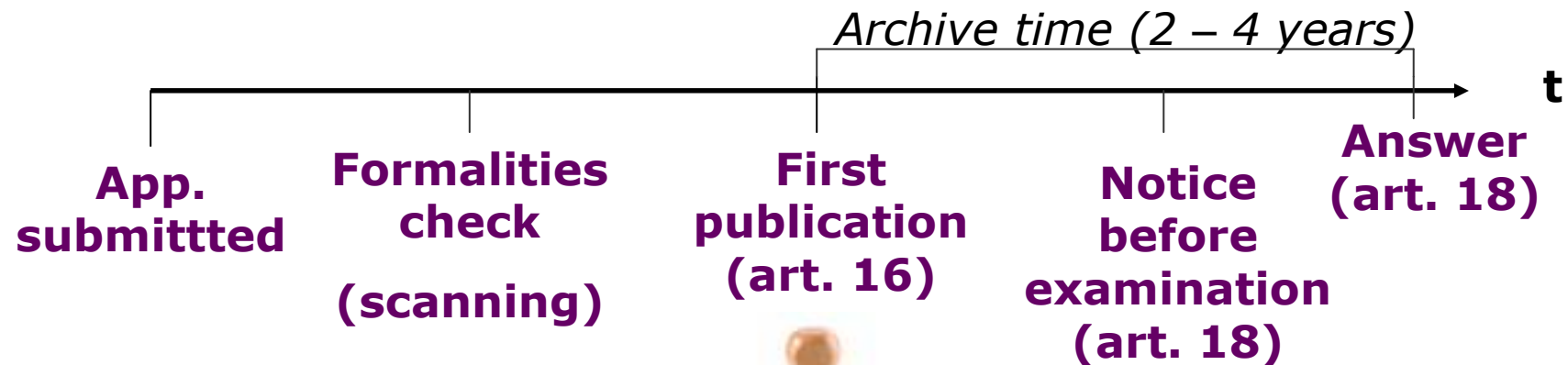
- Biotech
- Chem & Pharma
- Mechanics

\*First nine months of the year

## Number of ILPO Patent Examiners

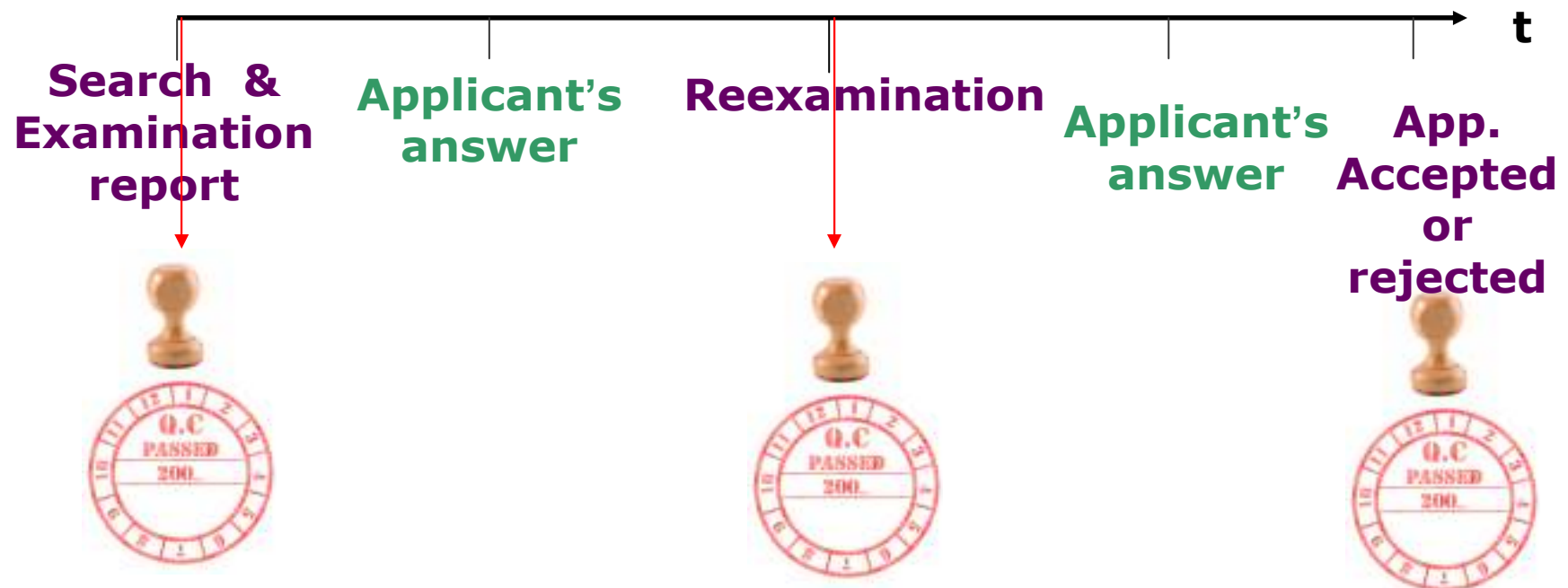


## Patent examination procedure



## Patent examination procedure

4 correspondences



## What is patentable?

**Section 3 of the Israel Patents Law states:**

***“An invention, whether a product or a process in any field of technology, which is new and useful, can be used industrially and involves an inventive step, is a patentable invention.”***

**Discoveries such as a mineral from the Dead Sea are not considered inventions and are therefore not patentable.**



## What is patentable?

**Section 13(b) of the Israel Patents Law states:**

***"It is permissible to express in the claim any of the basic elements of the invention as a means or a step for the performance of a certain act, and it is not necessary to specify the structure, the material or the acts required for the performance of that act; a claim expressed as aforesaid shall be deemed to include particulars of the relevant structure, material or acts, as described in the specifications."***

**Thus, Functional claims are allowed, as they are considered a product or a process**

## Patent requirements - Novelty

**Section 4 of the Israel Patents Law states:**

***“An invention is deemed new if it was not published, in Israel or abroad, before the application date –***

***(1) by written, visual, audible or any other description, in a manner that enables a skilled person to make it according to the particulars of the description;***

***(2) by exploitation or exhibition, in a manner that enables a skilled person to make it according to the particulars thus made known.”***

## Patent requirements – Inventive Step

**Section 5 of the Israel Patents Law states:**

***“An inventive step is a step which does not, to an average skilled person, appear obvious in the light of information published before the application date in ways said in section 4.”***

## Patent requirements – Restrictions

**Section 7 of the Israel Patents Law states:**

**“...no patent shall be granted for –**

**(1) a method of therapeutic treatment on the human body;**

**(2) new varieties of plants or animals, except  
microbiological organisms not derived from nature.”**

**Diagnostic methods are acceptable as  
they do not constitute treatment of  
the human body**



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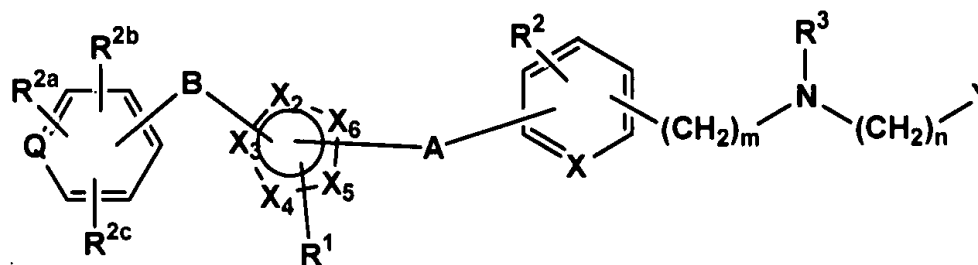
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# **From Patent to Drug: Examples**

## Example 1: Organic Chemistry (Markush Formula)

1. A compound which has the structure:



wherein m is 0, 1 or 2; n is 0, 1 or 2;

Q is C;

A is  $-(\text{CH}_2)_{x^2}-\text{O}-$  where  $x^2$  is 0 to 5;

B is a bond or is  $-(\text{CH}_2)_{x^4}$  where  $x^4$  is 1 to 5;

X is CH;



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**Multiple drugs can be derived from one markush formula and a single drug can have multiple patents (product, process, pharmaceutical composition, use)**

## Example 2: Pharma/Bio (Composition)

1. A transdermal hydroalcoholic gel composition for use in the treatment of type-2 diabetes in a subject in need thereof, wherein the transdermal hydroalcoholic gel composition comprises:
  - 5 a. 0.01% to 15% (w/w) of testosterone;
  - b. 0.01% to 50% (w/w) penetration enhancing agent;
  - c. 0.01% to 50% (w/w) thickening agent;
  - d. 30% to 98% (w/w) lower alcohol; and
  - e. the balance water;
- 10 wherein the serum testosterone concentration in the subject is at least 600 ng/dl to 1050 ng/dl after at least 30 days of daily administration of the composition.



## Example 3: Pharma/Bio/Chem (Use claims)

1. Use of a polynucleotide encoding an apoptosis-specific eIF-5A polypeptide for the manufacture of a medicament for inducing apoptosis in cancer cells.
2. The use of claim 1, wherein the polynucleotide encoding the apoptosis-specific eIF-5A polypeptide is comprised within an expression vector.
3. The use of claim 2, wherein the expression vector comprises a promoter sequence operably linked to the polynucleotide sequence encoding the apoptosis-specific eIF-5A polypeptide.

## Example 4: Pharma/Bio (Vaccine)

1. A vaccine composition comprising diphtheria (D), tetanus (T) and acellular pertussis (Pa) antigens and an adjuvant, wherein the concentration of D per 0.5 ml dose of bulk vaccine is 1-4 Lf; the concentration of T per 0.5 ml dose of bulk vaccine is 2.5 - 7.5 Lf and the Pa component comprises PT (pertussis toxoid), FHA (filamentous hemagglutinin) and pertactin (69K) wherein the concentration of PT per 0.5 ml dose of bulk vaccine is 2-10  $\mu\text{g}$ ; the concentration of FHA per 0.5 ml dose of bulk vaccine is 2-10  $\mu\text{g}$ ; and the concentration of 69K is in the range 0.5  $\mu\text{g}$  to 3  $\mu\text{g}$  per 0.5 ml dose of bulk vaccine.

## Example 5: Pharma/Bio (Diagnosis)

1. An assay for the diagnosis of a mental disorder in an individual, comprising:
  - (a) obtaining a sample from said individual, being a blood sample, a platelet-containing fraction thereof, or a fraction containing platelet-associated antibodies (PAA) shed from the platelets;
  - (b) contacting said sample with anti-human immunoglobulin antibody lacking the Fc domain (Fc-less anti-hIg antibody); and
  - (c) determining the degree of binding of said antibodies to the PAA in said sample, a degree of binding above that found in normal individuals indicating that said individual has a high likelihood of having a mental disorder.



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## Thank You

