

**The 9<sup>th</sup> Annual International Seminar in at Ahmedabad, INDIA**

**PATENTABILITY OF SUBJECT MATTERS IN  
THE FIELDS OF BIOTECHNOLOGY AND  
COMPUTER PROGRAM  
IN JAPAN**

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**HASEGAWA PATENT LAW FIRM**

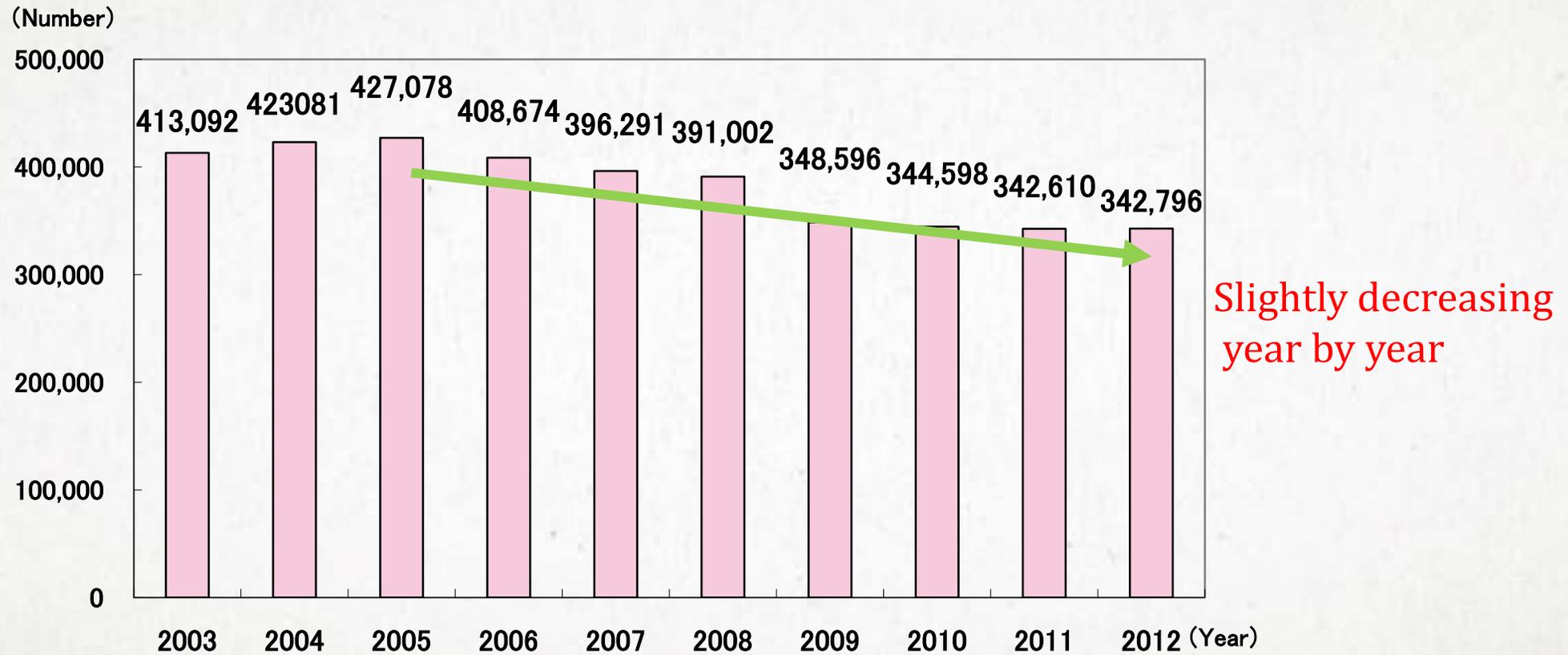
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## TOPICS

1. Japanese Patent Applications Statistics
2. Computer Program itself is patentable in Japan?
3. Patentable subject matters with regard to Biotechnology

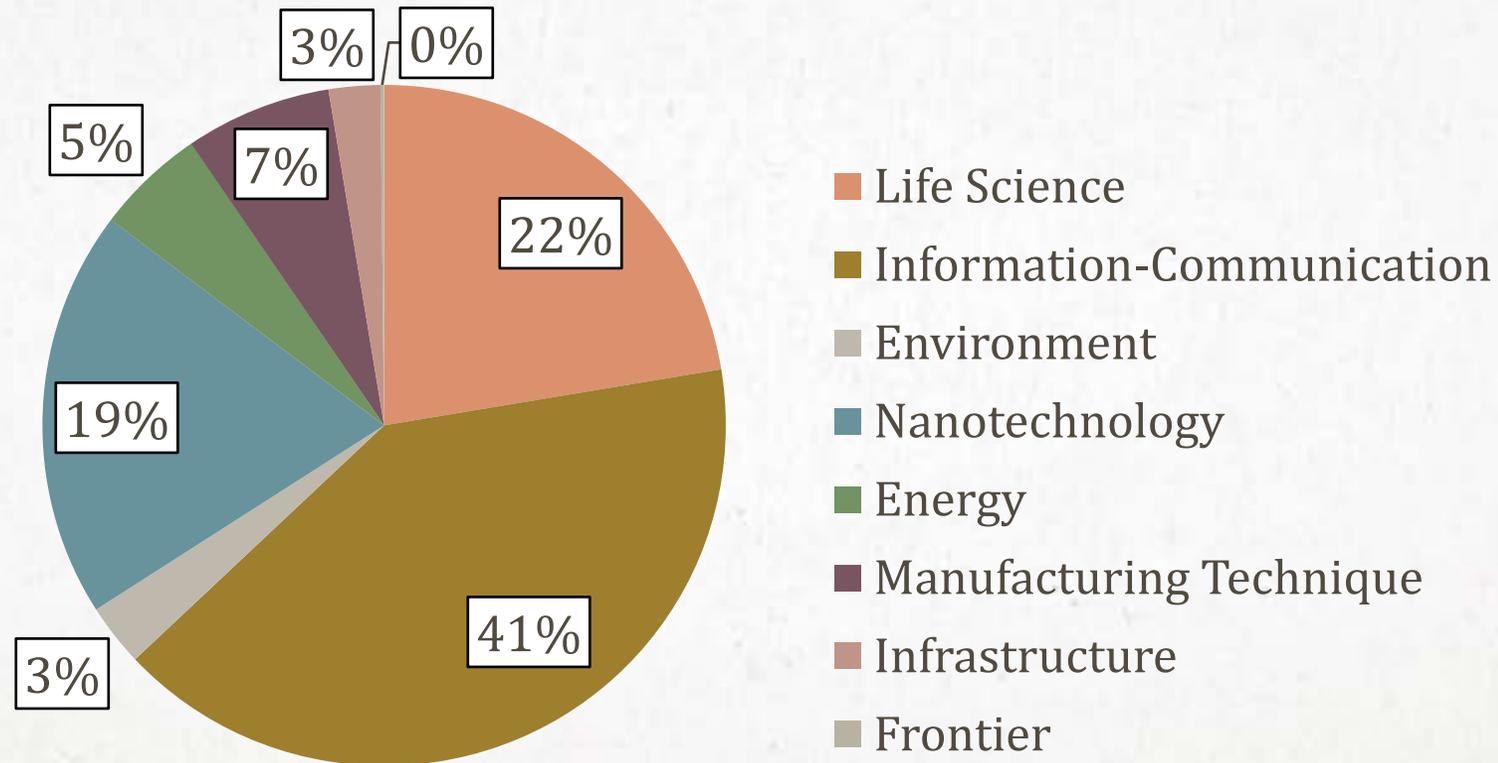
# **1. Japanese Patent Applications Statistics**

# Japanese Patent Applications Statistics



# Japanese Patent Applications Statistics

Rate of Major 8 Technical Fields in patent applications published in 2009



## **2. Computer Program itself is patentable in Japan?**

# Computer program itself is patentable in Japan?

- Present-2000           “YES”  
even if there is no storage device
- 2000-1997   “YES”  
if the program is stored in a storage device
- 1997-   “NO”

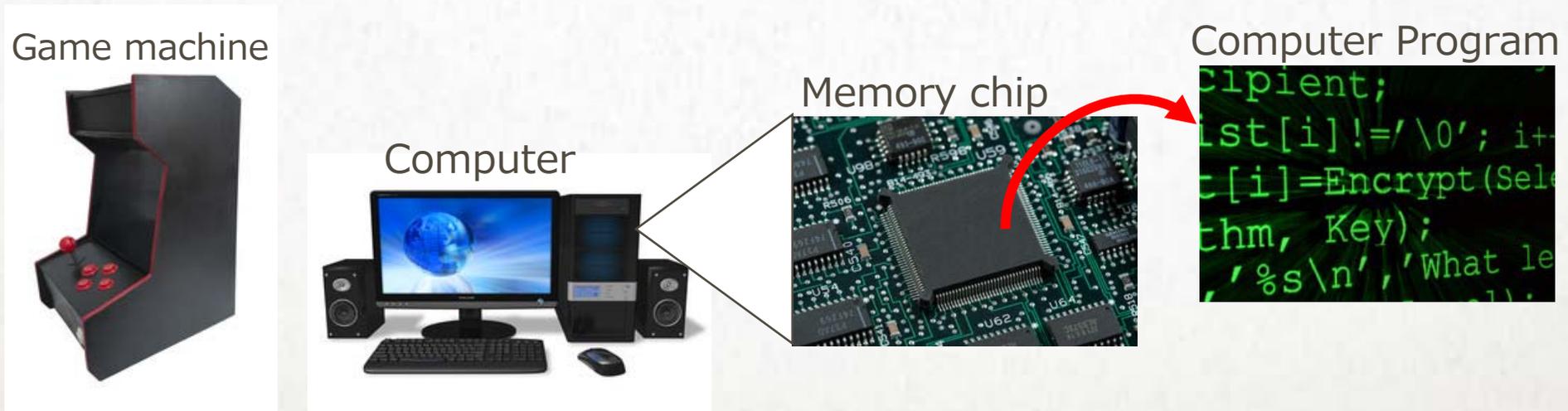
# Computer program itself is patentable in Japan?

## HISTORY

- Before 1990

Hardware like computer was sold to consumer.

Computer program was originally stored in the hardware.



# Computer program itself is patentable in Japan?

## HISTORY

- After 1990

Computer program itself has been directly sold to a consumer since 1990.

But, Japanese patent law defines that patentable subject matter is “**Tangible Object**” or “Method” used natural law.

Computer program is an aggregate of digital data like formulas and commands and is intangible.

# Computer program itself is patentable in Japan?

## HISTORY

- In 1997

Japan Patent Office decided that

Computer program itself was NOT patentable due to intangible object BUT a storage device like CD-R stored the computer program would be patentable.

# Computer program itself is patentable in Japan?

## HISTORY

After that,

By large expanding of Internet, a consumer began to obtain the computer program itself via internet directly without any storage devices.

Consumer



INTERNET



Computer Program

# Computer program itself is patentable in Japan?

## HISTORY

- In 2000

Finally, Japan Patent Office decided that

Computer Program would be a patentable subject matter even it was intangible.

## Computer program itself is patentable in Japan?

- Other countries except Japan
  - (1) India, U.S., China, countries in EU, Korea:  
the program itself is **NOT** patentable
  - (2) Even if New Zealand:  
recently decided **NOT** to  
patentable

We don't know any countries that admit the computer program itself as patentable subject matter.

## Computer program itself is patentable in Japan?

- Note

Japan Patent Office requires a computer program in a claim is described so that the program works by using hardware like computer.

Accordingly, if no hardware is described in a program claim, the claimed program is not patentable.

# Computer program itself is patentable in Japan?

How to prepare claims is important

- Example (GOOD)

A computer program readable by **computer**, wherein the computer program makes the **computer** perform

A step,

B step and

C step.

Example (BAD)

A computer program performing

A step,

B step and

C step.



No Hardware

## Computer program itself is patentable in Japan?

What advantage does a computer program's patent deliver to the patent owner?

In Japan:

The patent owner can attack a third party providing users with accused program itself without any storage devices due to **direct infringement**.

In other countries:

Since the patent owner can get just a machine, storage device or process patent, the patent owner can **NOT** attack above-mentioned third party due to direct infringement.

The only way to accuse the third party is to claim **an indirect infringement**.

## Computer program itself is patentable in Japan?

What advantage does a computer program patent deliver to the patent owner? (Cont.)

Even if the third party stays servers to provide the consumer with the computer program in any patent free countries, the third party will become an infringer as long as the Japanese consumer gets the program in Japan.

### 3. Patentable subject matters with regard to Biotechnology

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

- Ethical problems in Patenting Biotech/Medical inventions are solved with "Industrial applicability" under Article 29 main paragraph  
"Public order and Morality" under Article 32

According to Japanese Patent Law

Article 29 An inventor of an invention that is **industrially applicable** may be entitled to obtain a patent for the said invention...

Article 32 Notwithstanding Article 29, any invention that is liable to **injure public order, morality** or public health shall not be patented.

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY



NON-APPLICABLE

## BASIC IDEA

Medical activities conducted against human by Doctor or under instruction of doctor should not be patented

Method of surgery, treatment and diagnostics

## EXAMPLES

- Administration of drug
- Disinfection of skin for injection
- Use of medical device in human body
- Cosmetic operation
- Applying medical device on human body



# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY



## APPLICABLE

### Not including doctor's activity

- Drugs and medical device
- Method of operating medical device **without action against human body**

### Collecting information without medical purpose

Collecting sample or data from human body without determining step for medical purpose

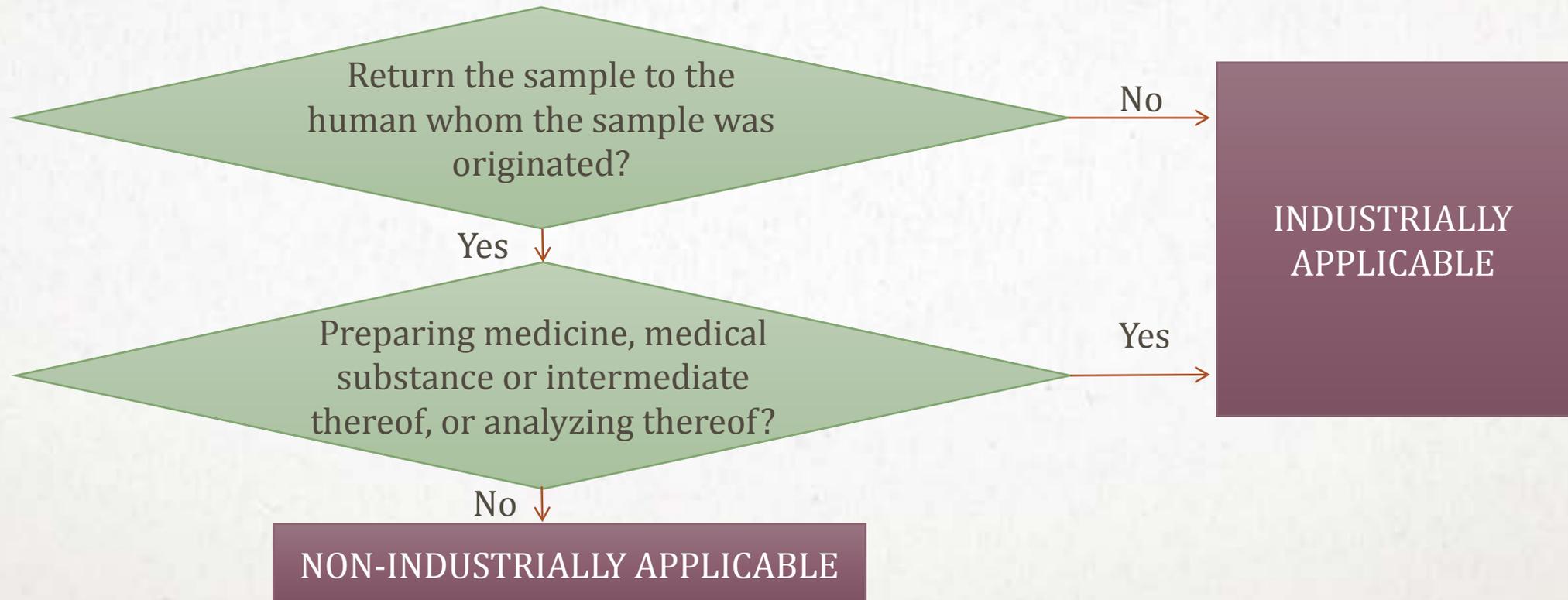
#### EXAMPLES

Method of obtaining oral mucosa for flu test

Method of shooting lung by irradiating X-ray on breast

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

A method of processing or analyzing a sample obtained from a human  
e.g. in the field of regenerative medicine



# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## PUBLIC ORDER AND MORALITY

### INDUSTRIALLY NON-APPLICABLE

A method for blood purification

A method for detecting hematocrit of blood during extracorporeal circulation

### INDUSTRIALLY APPLICABLE

A method for preparing medicine such as blood derivative, vaccine, recombinant preparation, or cell medicine which uses materials obtained from human

A method for preparing medical material such as artificial bone, cultured skin substitute which uses materials obtained from human

A method for preparing intermediate product for medicine or medical material which uses materials obtained from human (e.g. a method for differentiation of a cell, a method of separating or purification cells)

A method for analyzing medicine or medical material or intermediate product thereof.

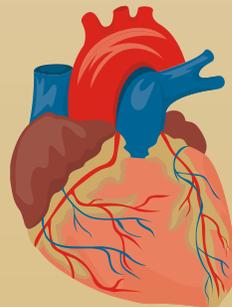
# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## PUBLIC ORDER AND MORALITY (CONT.)

### NOT-PATENTABLE

Liable to injure public order or morality

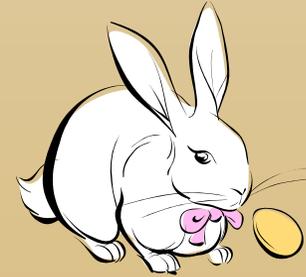
- Human
- A part of human without separating from human body



### PATENTABLE

Not Liable to injure public order or morality

- Animals other than human
- Plants and seeds
- Animal cells and plant cells including ES cells



# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## PUBLIC ORDER AND MORALITY - ES CELL

No specific clause, guideline or case for ES cells.  
Preceding prosecutions available.  
ES cell originated from animal other than human is patentable.  
Processing method conducted on already separated ES cell is patented.  
However, a method for preparing or separating ES cells cannot be patented.

### NOT-PATENTABLE

**Liable to injure public order or morality**

- Human ES cell
- Method of **obtaining** human ES cell

### PATENTABLE

**Not Liable to injure public order or morality**

- Method of **processing** ES cell

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## SECOND MEDICAL USE AND COMBINATION

- New use for known compound can be patented as "a pharmaceutical composition for such new use" claim if such new use is novel and inventive (Second medical use)
- New administration regimens such as administration route, dosage, and frequency or number of times can be patented as "a pharmaceutical composition to be used in such administration regimens" if such new administration regimen is novel and inventive
- Combination of new compounds is patented as " a pharmaceutical composition comprising combination of A and B" usually if such combination is novel and inventive

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## SECOND MEDICAL USE AND COMBINATION (CONT.)

### NOTE for "a pharmaceutical composition claim"

Claimed use (application) should be supported by a data in

Example in the specification.

Additional data will not be taken into consideration during prosecution stage.

# PATENTABLE SUBJECT MATTERS WITH REGARD TO BIOTECHNOLOGY

## OTHER PATENTABLE SUBJECT MATTERS

- DNA/RNA as far as its function is known and novel
- Antibody
- Pro-drug
- Isomer/polymorphism of known compound
- Subject matter can be defined by its function or result but the scope of invention should be clear and enabled by the specification

# CONCLUSION

- The computer program itself is patentable in Japan.
- That brings a large advantage to a patent owner.
- Human himself or herself, a part of human without separating from human and medical actions to human are not patentable in Japan.
- Human ES cell is not patentable, but iPS cell is patentable in Japan.

**Thank you so much.**

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