KTK 関西特許研究会
特実部会、医薬・バイオ特許研究班合同会合

Pharma Patent Basics

6:30-7:30 pm, July 7, 2020 @ZOOM

Yasuko Tanaka
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S-Cube Corporation / S-Cube International Patent Firm

Agenda

- Introduction and warm-up (Breakout session)

1. Pharmaceutical Overview

2. Pharmaceutical IP Protection

- Group discussion (Breakout session)

3. Recent IP Court developments in Japan (if possible)

Tonight’s goal:

To become better prepared to Zoom with English speaking counter parts and discuss patent issues in English

Ice break & self-introduction

Name（氏名）, Organization（所属）

- My name is….., I am from…./ I work for …

Greetings:

How are you? / How have you been?

Do you work from home?

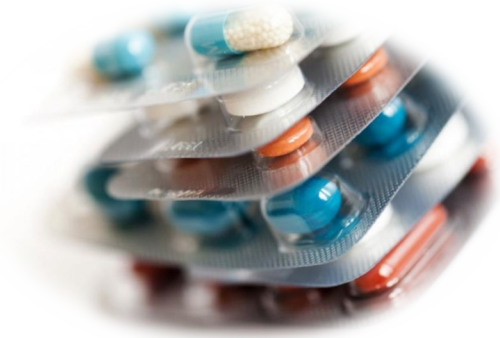
Current assignment（担当業務）

Reasons for participating in this seminar（このセミナーに参加した理由）

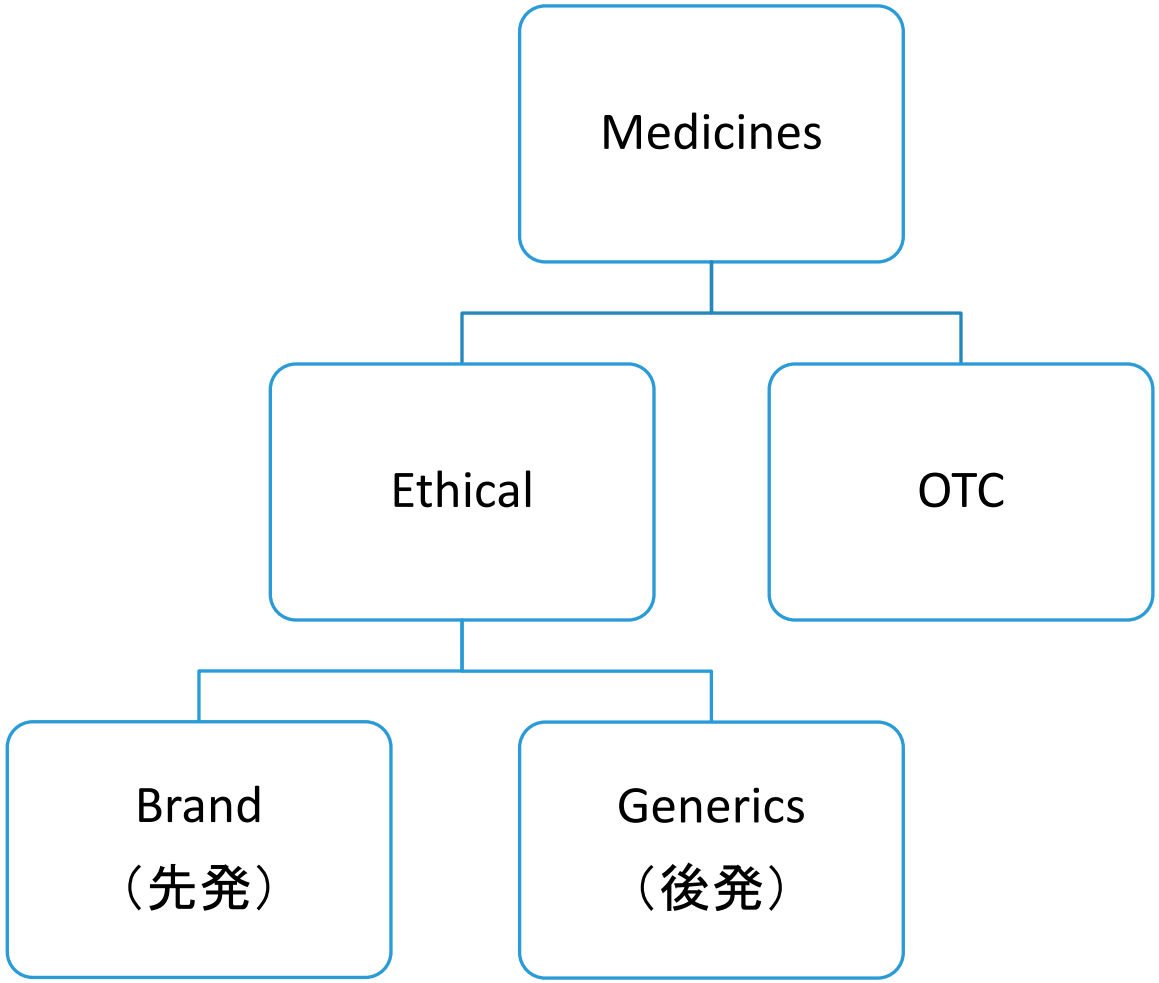
What do you expect from this seminar?

1. Pharmaceutical Overview

- Medicine categories
- Brand and Generics
- Industry Trends



Medicine Categories

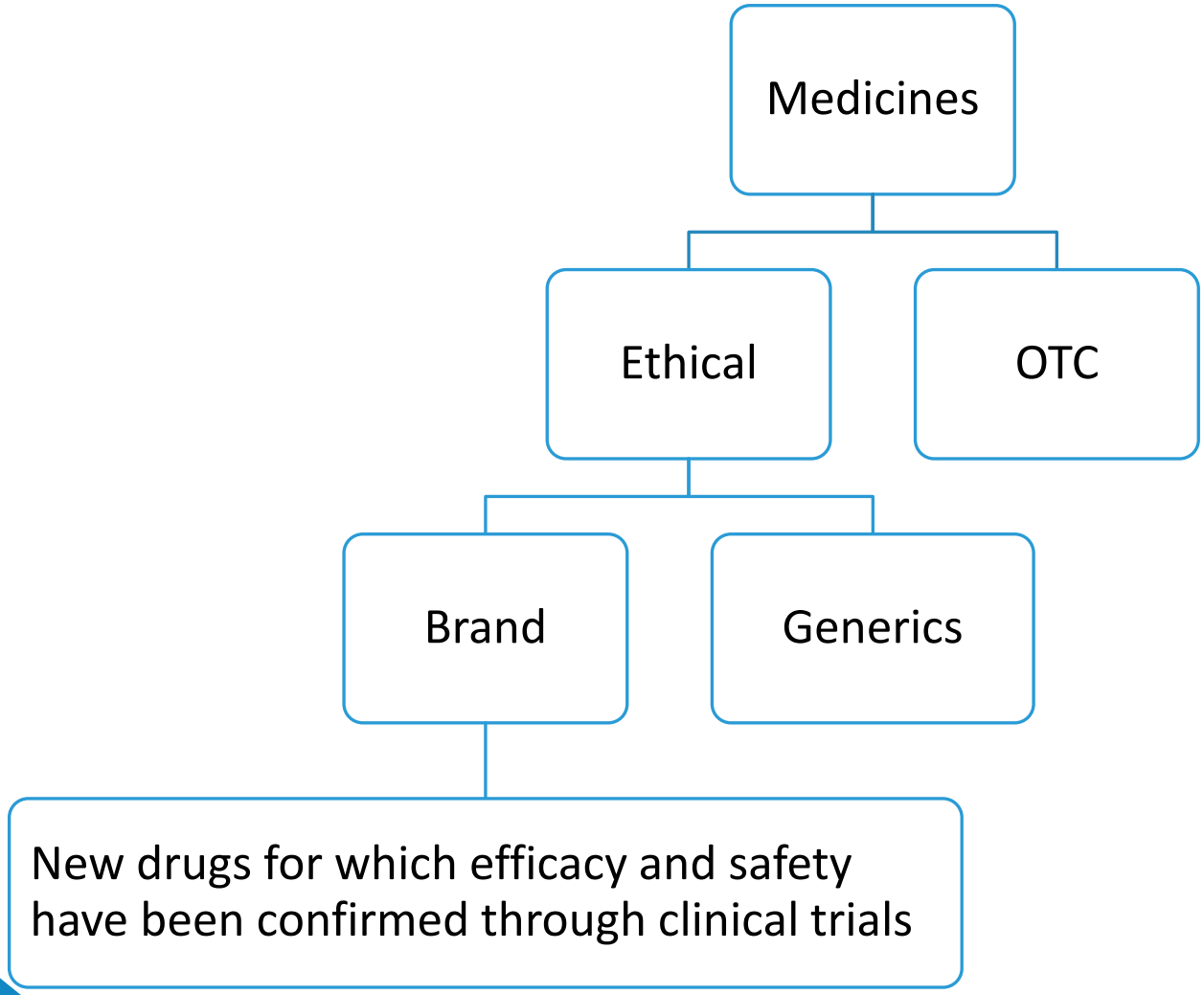


Ethical drugs are regulated by the Health Ministry*

- Marketing approval (MA)
  - Manufacturing and marketing
- Drug price
  - Drug prices are listed in the National Health Insurance Drug Price Standard

* Ministry of Health, Labor and Welfare

Medicine Categories



Source: Ministry of Health, Labor and Welfare website (J) http://www.mhlw.go.jp/topics/2014/03/tp0305-01.html

Pharmaceutical R&D - Brand

Basic Research → Non-clinical trials → Clinical trials → NDA & Review → Marketing Approval → Launch

R&D term: 9 to 17 years

R&D cost : $1.3 Billion USD* (Avg.)

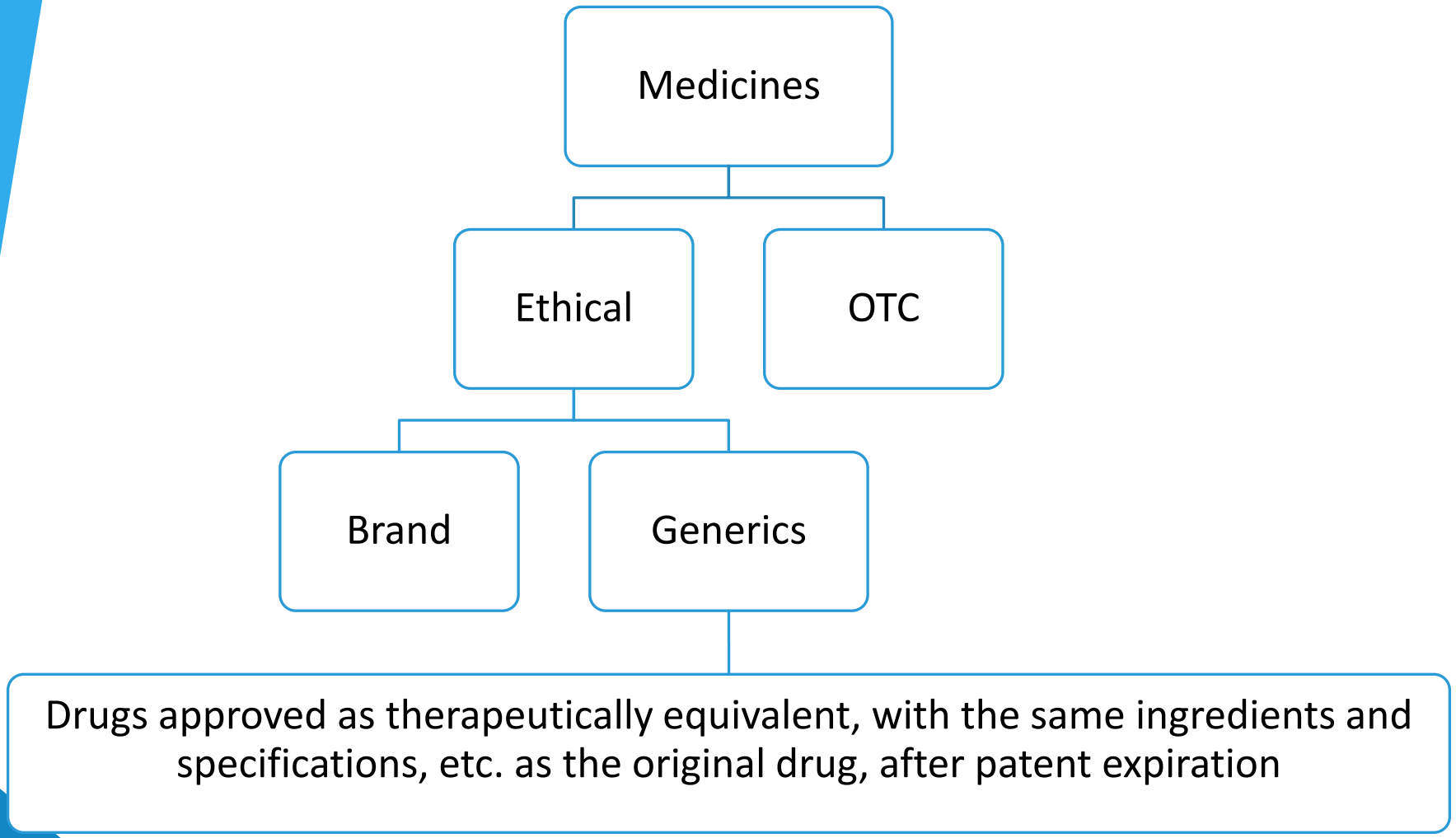
Clinical trials :臨床試験

NDA : 新薬の薬事申請（New drug application）

Marketing Approval : 承認

*Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA. 2020;323(9):844–853. doi:10.1001/jama.2020.1166

Medicine Categories



Source: Ministry of Health, Labor and Welfare website (J) http://www.mhlw.go.jp/topics/2014/03/tp0305-01.html

Pharmaceutical R&D - Generics

Selection → Formulation research → Equivalence tests → GE application & review → Marketing Approval → Launch

R&D term: 3 to 4 years

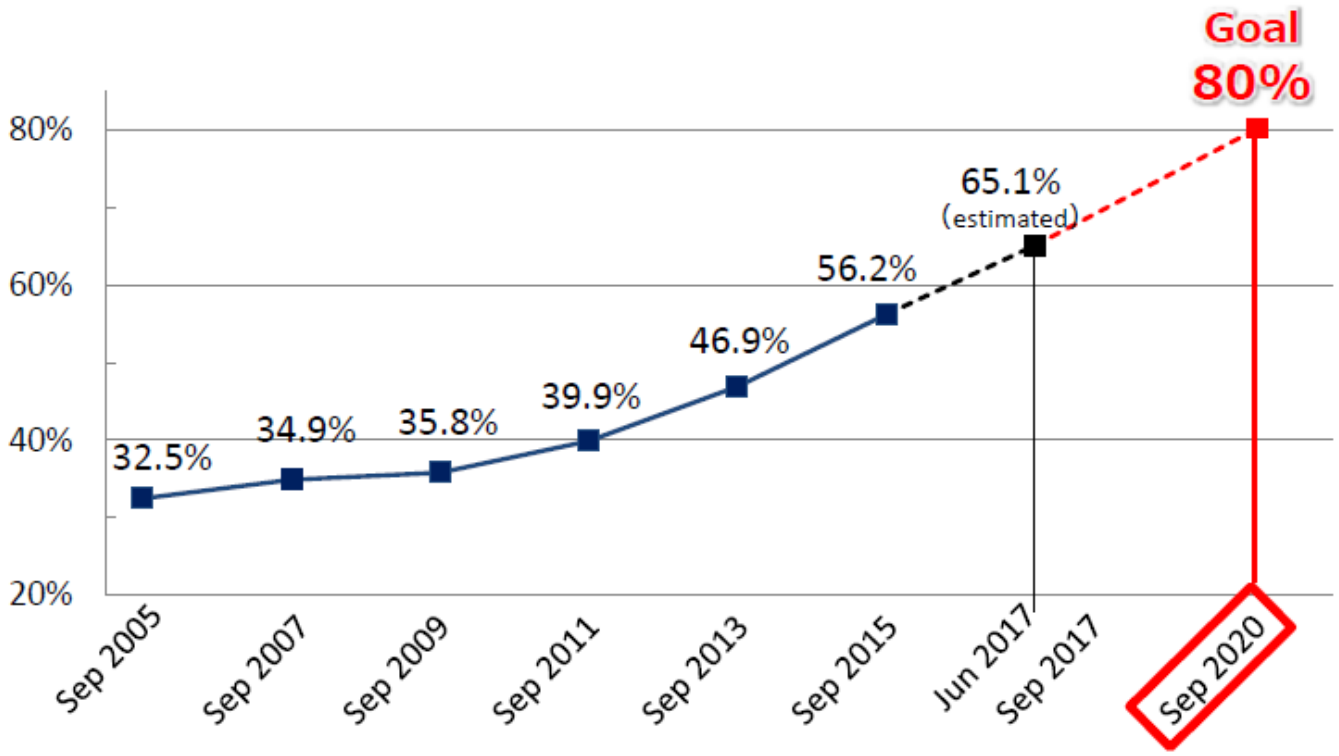
R&D cost : One million USD

Equivalence tests :同等性試験

Japanese Gov't promotion of Generic drug use

Transition of Generic Drugs Market Share in Volume and its Goal

Goal of share in volume (Basic Policy in 2017)	By September 2020, the ratio of generic drugs use in volume should be 80% and further promoting measures are studied to enable the goal as early as possible



78.5% as of 4Q FY2019

Quoted from PMDA materials: https://www.pmda.go.jp/files/000221883.pdf

One pharma product consists of far fewer patentable components than other retail products

Pharmaceutical products:

Compound (API), process, formulation, package …

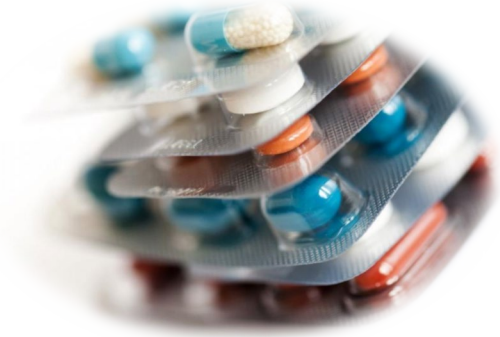
API: Active Pharmaceutical Ingredient

Cars:

Engine, tire rubber composition, window, cup holder, bumper material, navigation system, electronics, headlight, etc.・・・・・

2. Pharmaceutical IP Protection

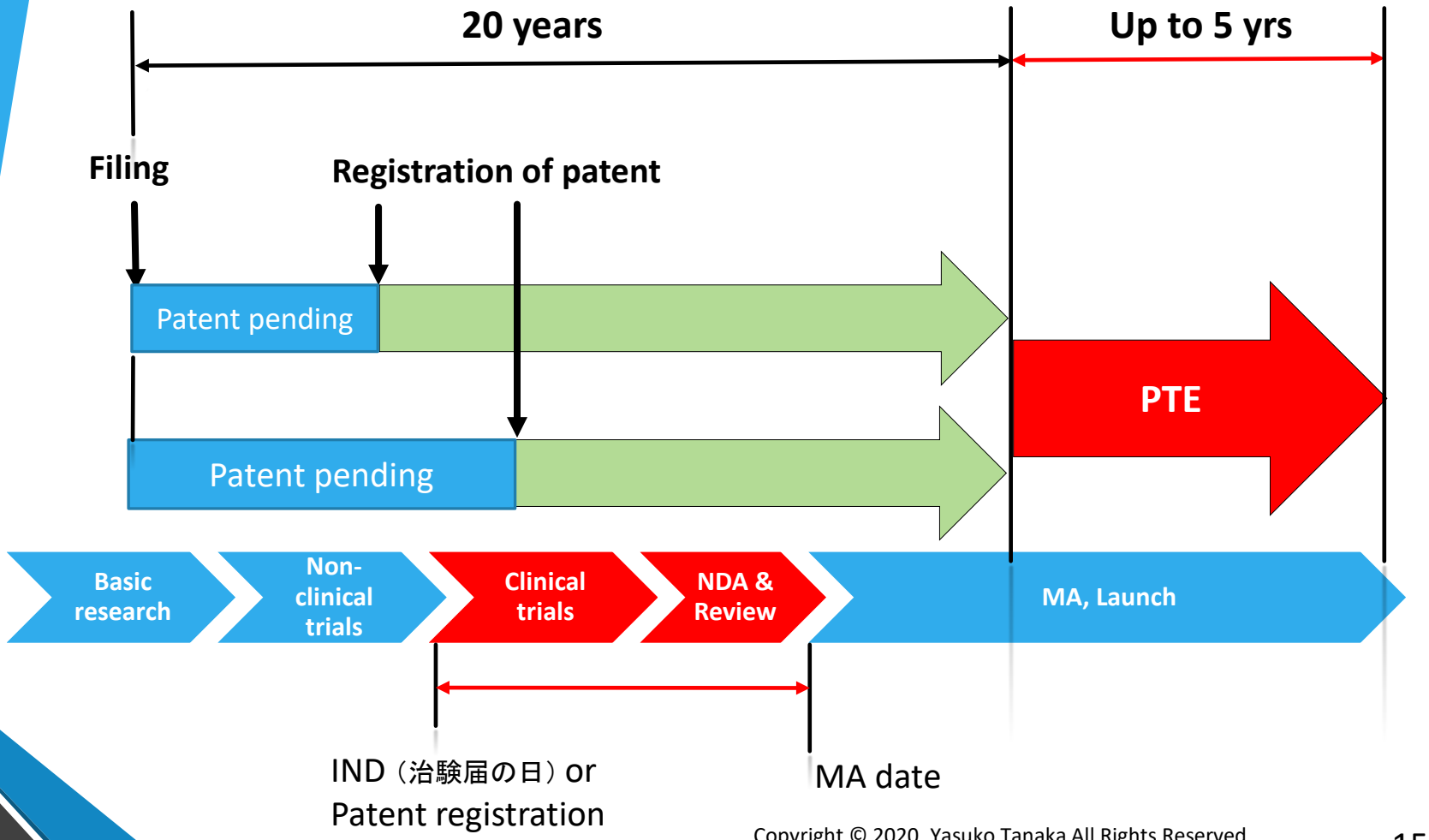
1. Patent Term Extension
2. Data Protection
3. Patent Linkage
4. Experimental Use Exemption



1. Patent Term Extension (PTE)

S-CUBE IP Business Consulting

The patent term can be extended up to five years



PTE in Japan is unique

The following conditions can be the basis for PTE:

1) The MA is the first one with respect to the API

2) After the first approval

- ✓ additional indication approval （効能追加）
- ✓ additional formulation approval （剤形追加）
- ✓ additional usage and dosage approval（用法・容量変更）

PTE system in JP/US/EU/KR

	Japan	USA	EU (SPC)	Korea
Extended Period	Up to 5 yrs	Up to 5 yrs	Up to 5 yrs	Up to 5 yrs
Multiple extensions on the same patent	✓	✗	✗	✗
Multiple patents can be extended based on one MA	✓	✗	✗	✓
Scope of the extended patent right	Complicated	Approved API	Approved API and all uses	Approved API and all uses

2. Data Protection

The protection of clinical trial data:

- legally required and economically necessary
- provides incentives for the development of innovative pharmaceutical products

- Generics may file a request for MA after the data protection period
- Legislation and term differ by country
- New medicines are protected by patent and data protection systems

Data Protection in JP/US/EU

- **Japan : Re-examination period**

  8 years from the MA for new drugs

- **US : Data exclusivity**

  5 years from the MA for new small molecule drugs

  12 years from the MA for biologics

- **EU: Data protection or regulatory data protection**

  8 years from the MA for new drugs

3. Patent Linkage

The system or process by which a country links drug marketing approval to the status of the patent(s) corresponding to the brand product.

- *Link between patent and drug approval systems*

Yes: US, Canada, Singapore, Korea, Taiwan, Australia …

(JP system is unique.)

No : EU, Switzerland

4. Experimental Use Exemption

Japan

Patent Act Art 69(1) : The effects of the patent right shall not extend to the working of the patented invention for the purposes of experiment or research.

Supreme Court Case H10 (Uke) No. 153 (April 16, 1999)

Equivalence test to obtain information to be attached to a request for MA of generic drugs falls under the category of “working of the patented invention for the purpose of experiment and research.”

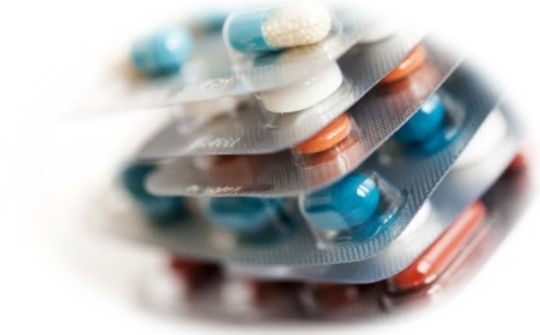
Group Discussion

Is the protection for new drugs too weak, fair or excessive?
In which aspect: PTE, data protection, others?
Give reasons for your opinions.

5-minute discussion
One group will be asked to share discussion outcome

3. Recent IP Court developments in Japan

1. New battle between brand and generic makers
2. IP High Court decision after the Supreme Court rejected their initial finding on inventive step
3. Cholesterol lowering drug discontinued due to patent infringement



1. New battle b/w brand & generic makers

Chugai sued generic makers in the
Tokyo District Court on May 29, 2020

Brand product: Edirol ® Capsule Re-examination period -Jan. 21, 2019

(eldecalcitol, active vitamin D3 derivative for Osteoporosis)

Defendants: Sawai and Nichi-Iko

- Defendant product was approved on Feb. 17, 2020
- Drug price was listed on June 18, 2020

Patent at issue: JP 5969161 (Use patent) -April 28, 2030

Check! :

- Validity of the patent (Muko 2019-800112)
- Patent linkage???

2. IP High Court decision after the Supreme Court rejected their initial finding on inventive step

Supreme Court	**Aug. 27, 2019: Supreme Court Case 2018 (gyo-hi) 69** Revoked the original judgement and remand the case to the IPHC	
IPHC	**Nov. 21, 2017: IP High Court Case 2019 (gyo-ke) 10118** Found invalid due to lack of inventive step (no remarkable effect was observed)	**June 17, 2020: IP High Court Case 2019 (gyo-ke) 10118 Remand Trial** Found inventive step Unexpected remarkable effect was observed
JPO	**Dec. 1, 2016: Muko 2011-800018 (JP 3068858)** Found invalid due to lack of inventive step (no remarkable effect was observed)	

3. Cholesterol lowering drug discontinued due to patent infringement

The Supreme Court upheld an **IP High Court** ruling by dismissing an appeal by the defendant (Sanofi) on April 24, 2020

As a result, the defendant was required to stop selling its drug “Praluent®”

The plaintiff (Amgen) claimed the defendant’s drug infringed on patents related to antigen-binding proteins (antibodies) for PCSK9

Takeaways:

- Brand bio-drug from Sanofi discontinued after patent dispute with Amgen
- Represents a new trend on the functionally defined antibody claim
- US and EU courts think differently

IP High Court Case No. 2019 (ne) 10014 on Oct. 30, 2019

Tokyo District Court Case No. 2017 (wa) 16468 on Jan. 17, 2019

Summary

1. Pharmaceutical Overview
2. Pharmaceutical IP Protection
3. Recent IP Court developments in Japan

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Ms. Tanaka graduated from Chiba University (Biochemistry) in 1990. She has worked in the IP Dept. of Teijin, Pfizer Japan and 3M Japan dealing with global patent prosecution both in English and Japanese, IP clearance and dispute, IP strategy/consulting, transactions, patent search, and IP education. While working for the American multinationals, she worked closely with her English-speaking local representatives/counterparts on a daily basis.

In April 2013, Ms. Tanaka ventured out on her own founding “S-Cube Corporation” (IP Business Consultancy) and soon after expanded her business by establishing S-Cube International Patent Firm. (https://www.english.s-cubecorp.com/).

She was a part-time lecturer at the University of Toyama in 2016 and has been a part-time lecturer at Tokyo University of Agriculture and Technology since 2017.