MEDICAL USE PATENT IN JAPAN -TIPS FOR OBTAINING AND ENFORCING PATENT-

April 8-9, 2015
23rd Annual Intellectual Property Law & Policy Conference

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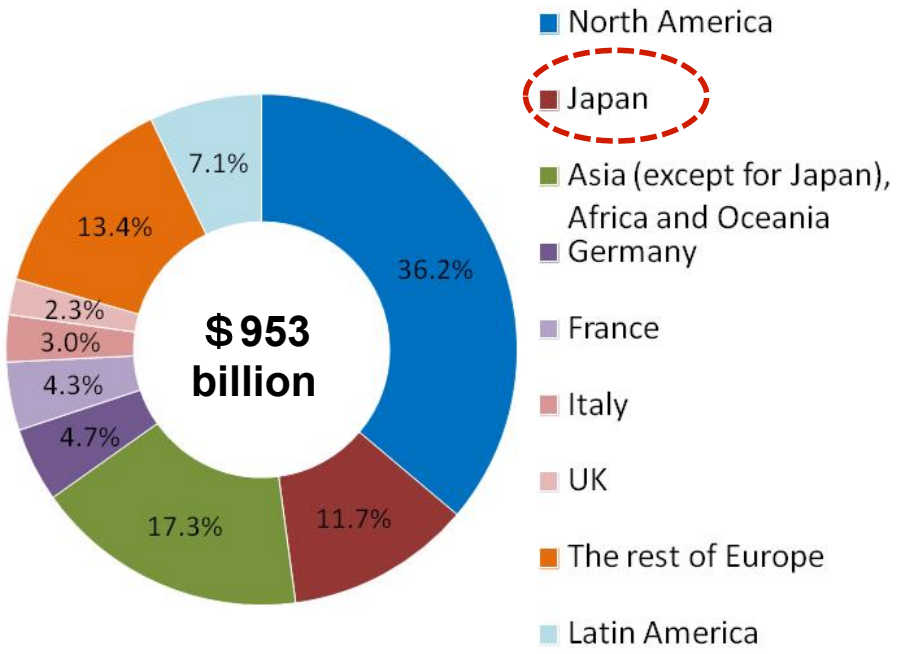
1. Basic Information

Market

Breakdown of the world pharmaceutical market



Pharmaceutical products (2011)

Source : “DATABOOK 2013”, Japan Pharmaceutical Manufacturers Association

Medical use Patent (Claim with limitation of Medical Use)(1)

Product with limitation of use (e.c. “Pharmaceutical compound for use of antiemetic”)

⇨ Invention of a product with limitation of use can be patentable as an “medical use invention” even on a condition that the product per se is already known to the public.

(Reason)

Such an invention provides a novel use of an product based on the discovery of an unknown property of the known product.

⇩

No problem for granting second medical use patent in Japan

Medical use Patent (Claim with limitation of Medical Use)(2)

Types* of claimed invention and their scope of exclusivity (prohibited act by a third party, Art. 2 of the Patent Act)

(1) Product (e.c."Pharmaceutical composition for use of antiemetic")

- Act of producing, using, assigning, exporting, or importing the product
- Act of offering for the assignment

(2) Method for manufacturing product (e.c."Method for manufacturing pharmaceutical composition for use of antiemetic")

- Act of using the process
- Act of using, assigning, exporting or importing the product produced by the process
- Act of offering for assignment, etc..

(3) Method (Method which does not produce any product ,e.c. "Use of a chemical compound X for checking the quality of a pharmaceutical compound Y for antiemetic")

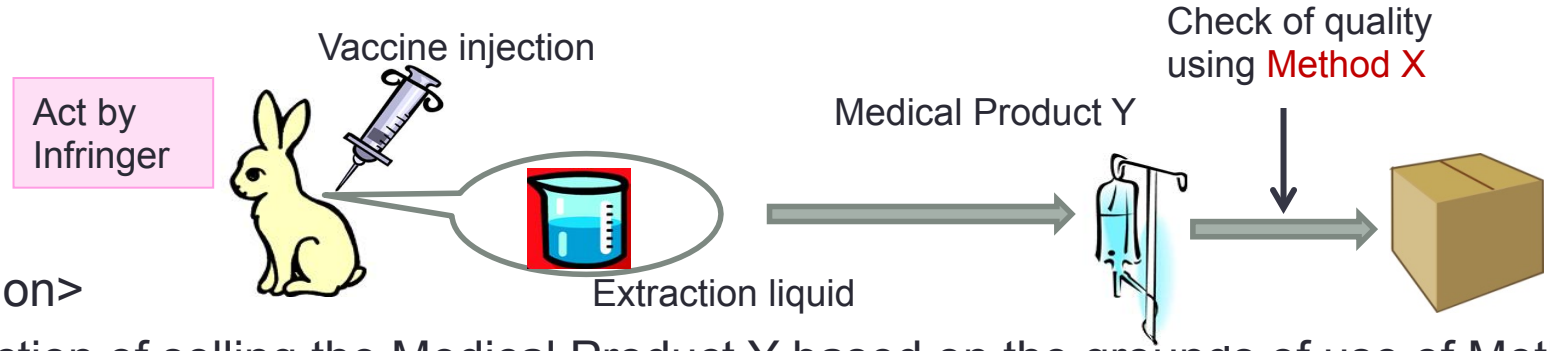
- Act of using the process

* The type is determined by contents of a claim as a whole

Medical use Patent (Claim with limitation of Medical Use)(3)

"Method of assaying inhibitory activity of generating kallikrein case"(The Supreme Court decision on July 16, 1999 /Heisei 10 (O) 604)

- Claimed invention: Method of assaying a physiologically active substance (Method X).
- Fact



<Question>

Injunction of selling the Medical Product Y based on the grounds of use of Method X is allowable?

<Findings>

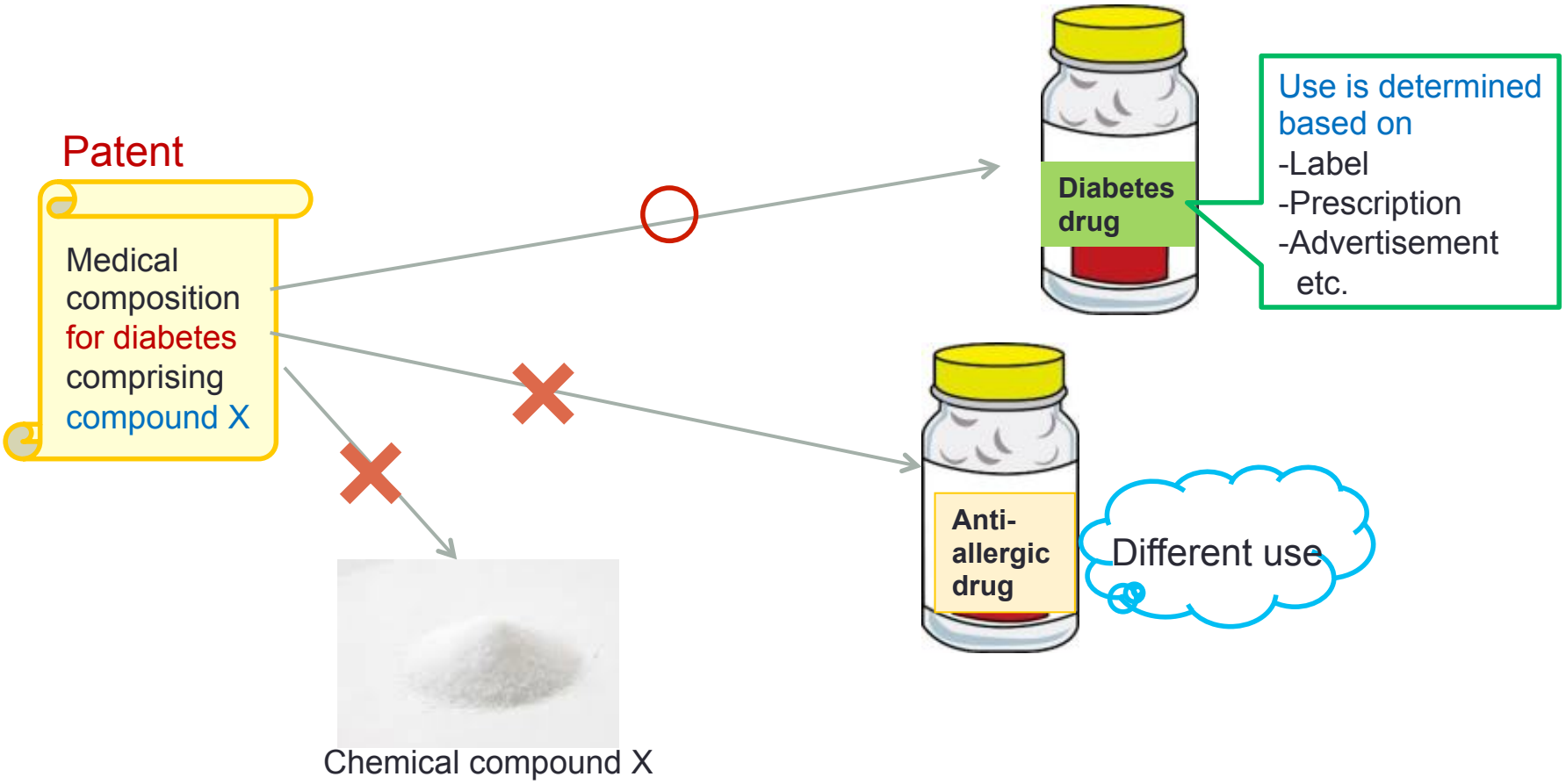
- The Osaka high court: YES. The method X has close relationship with the steps of manufacturing method of the Medical Product Y and the method X can be deemed as a method for manufacturing product.
- The Supreme Court: NO. The invention is NOT a method of producing a product and injunction of selling the Medical Product Y based on the use of Method X is groundless.

Basic Idea of “a patent with limitation of Medical Use ”(4)

Scope of the exclusivity: Within the limitation of Use

Example:

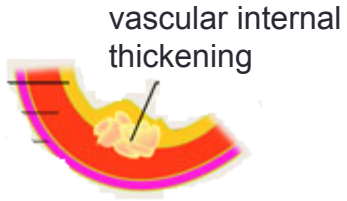
Patent : Medical composition for diabetes comprising compound X.



2. Recent Developments

Inventive step of medical use patent (1)

"Agent for suppressing vascular internal thickening case" (The IP High Court decision on September 10, 2014/Heisei25 (Gyo-ke)10209)



- Claimed invention : Agent for suppressing vascular internal thickening which includes peptide X as an active ingredient.

- Document 1(Prior art): Antihypertensive having ACE inhibitory activity which includes peptide X as antihypertensive peptide.

<Main issue of this case>

Use of peptide X for suppressing vascular internal thickening would have been easily conceived by a person skilled in the art based on the ACE inhibitory activity of peptide X ?

<Findings>

- JPO's finding: NOT inventive. There had been established knowledge at the time of priority date that ACE inhibitory activity has also effects on suppressing vascular internal thickening.

- The IP High Court's finding: Inventive. There had been various reports about the relationship between ACE inhibitory activity has an effect of suppressing vascular internal thickening but NO established knowledge at the time of priority date.

Inventive step of medical use patent (2)

"Ophthalmic formulations containing doxepin derivatives for treating allergic eye diseases case" (The IP High Court decision on July 30, 2014 /Heisei25 (Gyo-ke) 10058)

- Claimed invention : Ophthalmic composition which contains doxepin for treating allergic eye diseases.

- Document 1(Prior art):Experimental result which shows that doxepin has an strong suppression effects on allergic conjunctivitis in guinea pig.

<Main issue of this case>

Effect of treating allergic eye diseases for human would have been easily conceived by a person skilled in the art based on the knowledge based on effects in guinea pig described in D1?

<Findings>

- JPO: Inventive. Ophthalmic effect in human would NOT have been conceived from the data in guinea pig, because, at the time of priority date, medical efficacy about allergic eye diseases was reportedly different depending on spices.

- The IP High Court: NOT Inventive. A person skilled in the art who read the experimental result of D1 would have been motivated to try to apply doxepin to human. Further, he/she would have been motivated to check of the medical effect on human.

Enforcement : Medicinal drug vs. Supplement

"Composition for prevention and treatment of dementia case" (Tokyo district court decision on April 16, 2014/Heisei 24 (Wa) 24317, The IP high court decision on October 23, 2014 / Heisei 26 (Ne) 10051)

- Fact

  - Claimed Invention:

    "Composition for prevention and treatment of dementia comprising X"

  - Defendant's product : Dietary supplement for dementia comprising X

- Main Issue

  -Construction of "Composition for prevention and treatment of dementia"
  (Whether the claim covers dietary supplement.)

- Finding by the both courts

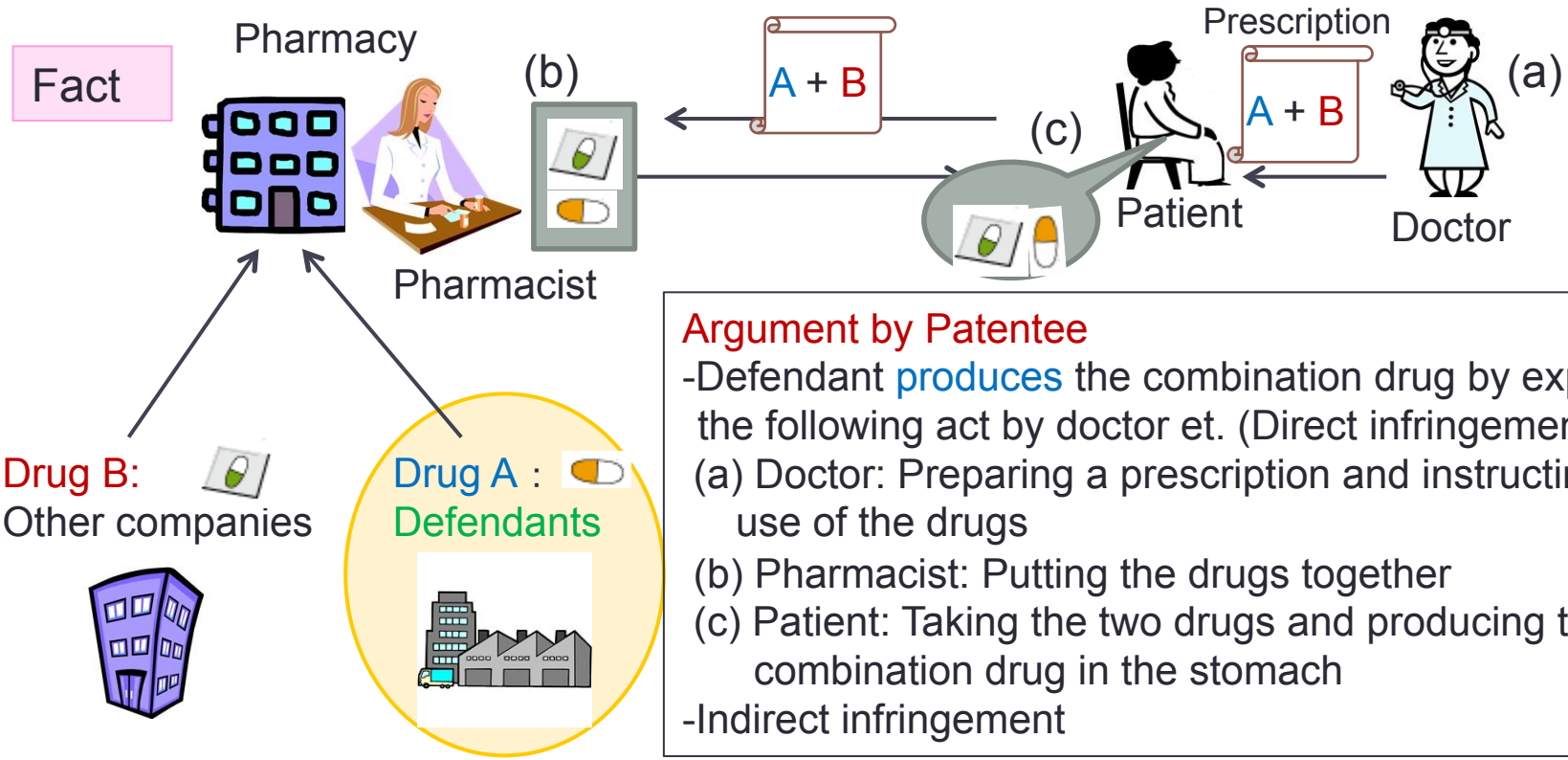
  - Generally "composition" can include composition of food , but taking the file history into account, "composition" of this patent does not include composition of food. (In the file history, the patentee deleted the claims of "composition of food" after the patent was rejected based on the prior art which shows "composition of food" for dementia.)

  - The Defendant's product does NOT fall within the scope of the claim, because it is dietary supplement.

Enforcement : Combination drug

"Pharmaceutical composition for diabetes case"(Osaka district court decision on September 27, 2012/Heisei 23 (Wa) 7576,7578 and Tokyo district court decision on February 28, 2013/ Heisei23(Wa)19435, 19436)

Patent: Pharmaceutical composition for diabetes which contains A in combination with B. (Both A and B had been known as a chemical compound for diabetes drug)



Argument by Patentee

-Defendant produces the combination drug by exploiting the following act by doctor et. (Direct infringement).

(a) Doctor: Preparing a prescription and instructing the use of the drugs

(b) Pharmacist: Putting the drugs together

(c) Patient: Taking the two drugs and producing the combination drug in the stomach

-Indirect infringement

Neither infringement courts find the direct/indirect infringement but based on the different reasoning. (Later, the patent was invalidated in other proceeding.)

3. Summary

Important points

1. Method Patent (which does not produce product, typically formulated as

" Use of X for…"

Point to be considered : Its scope of exclusivity is limited.

⇨ It is better to include a claim of method for manufacturing product instead of /in addition to a "use" claim.

2.Inventive step

(1) For obtaining second medical use patent, it is important to submit strong evidence, which shows that the use in the patent in question would NOT have been easily conceived by a person skilled in the art, especially the common technical knowledge of a person skilled in the art.

(2) The bar for inventive step with regard to combination drug invention seems to be getting higher .

3. Enforcement

(1) As to combination drug patent, exercise of a patent right on a party who just produce/assign one of the drug is difficult.

(2) More discussion is needed for Drug vs. Supplement issue?

Thank you!

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