

Recent Decision of “Doctrine of Equivalents” in Japan --Maxacalcitol Case--

New Criterion of Requirement 1
of Doctrine of Equivalents

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Chemistry & Materials Science

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Summary

- Two Important Decisions of Doctrine of Equivalents in Japan

(Decision 1)

Supreme Court Decision (1998) Case No.1994(O)1083

“Ball Spline Case”

(Decision 2) <Today's main topic>

IP High Court En Banc Decision (2016) Case No. 2015 (Ne) 10080

“Maxacalcitol Case”

- Interpretation of an Essential Part, - Application of DOE to Medicament Invention

Decision 1: Ball Spline Case

- Summary:

The Supreme Court Decision

Doctrine of Equivalents: **five requirements** must be satisfied

1. Non-essential Part
2. Possibility of Replacement
3. Ease of Replacement
4. Non-obviousness
5. Special circumstances

Ball Spline Case (Cont.)

- Requirement 1: Non-essential Part

The part replaced is not an essential part of the patent invention.

“The essential part” = a characteristic part of:

- the unique technical idea, and
- not found in a prior art

- If the essential part is replaced...
- Interpretation of “the essential part”

Ball Spline Case (Cont.)

- Requirement 2: Possibility of Replacement

The replacement of the part **achieves the object** of the claimed invention and produces **the same result** as the claimed invention.

- if the same result cannot be obtained...

Ball Spline Case (Cont.)

- Requirement 3: Ease of Replacement

The replacement of the part would have been **obvious** to a skilled person at the time of **making** the defendant's product.

- new technique (not known at the time of filing)
- not “at the time of filing the application”

- Requirement 4: Non-obviousness

The defendant's product was not **novel and non-obvious** at the time of **filing** the patent application.

- not “at the time of making the defendant's product”
- invention should not be granted

Ball Spline Case (Cont.)

- Requirement 5: Special circumstances

There is no proof showing that the applicant **intentionally excluded the defendant's product** from the claimed invention.

- ex) “file wrapper estoppel”

Decision 2: Maxacalcitol Case

- Two Important Decisions of Doctrine of Equivalents in Japan

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(Decision 2) <Today's main topic>

IP High Court En Banc Decision (2016) Case No. 2015 (Ne) 10080

“Maxacalcitol Case”

Decision 2: Maxacalcitol Case

Summary:

- **Patentee:**
Chugai Pharmaceutical Co. Ltd
- **Defendants:** (four companies)
DKSH Japan Stock Company, Iwaki Seiyaku Co. Ltd, Takada Pharmaceutical Co. Ltd, and POLA-Pharma Inc.

Maxacalcitol Case (Cont.)

Summary (Cont.):

- Claim:

A method of manufacturing maxacalcitol

Two steps:

- reacting starting material with agent
- opening epoxy ring in agent

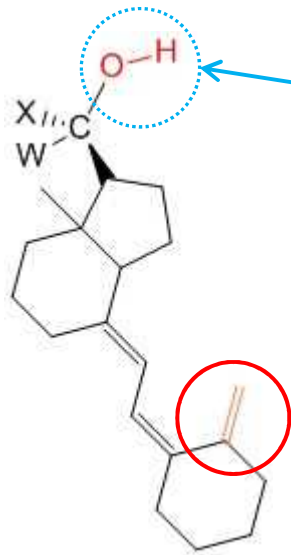
- A defendant's method of manufacturing a maxacalcitol drug substrate ("a defendant's product") satisfies features in the method of the claim, except a starting material.

Maxacalcitol Case (Cont.)

- Starting Material: vitamin D structure

the claim:

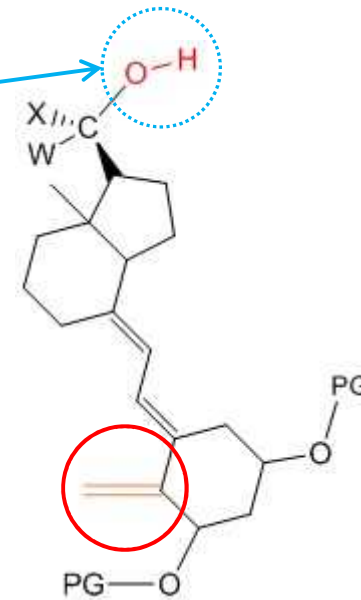
cis-type vitamin D structure



Reaction site

the defendant's method:

trans-type vitamin D structure



≠

Note:

Starting material may include one or more protective groups (PG) or non-protective groups.

Maxacalcitol Case (Cont.)

	The Claim	The Defendant's Method	Identical
Starting Material	<u>Cis</u> -type VD structure	<u>Trans</u> -type VD structure	NO
Finished Product	Maxacalcitol	the same	YES
Steps of the method	Two Steps	Four Steps (include two steps of the claim)	YES



Not Literal Infringement

Is the defendant's method Equivalent to the claim?

Maxacalcitol Case (Cont.)

- As to satisfaction of Requirements 1 to 5,

The IP High Court Decision shows New Criteria of Requirements 1 and 5 of Doctrine of Equivalents.



A new criterion of **Requirement 1** will now be explained.

*A new criterion of Requirement 5 → the next presenter, Mr. Takeuchi.

Maxacalcitol Case (Cont.)

- Requirement 1

“The part replaced is not *an essential part* of the patent invention.”



- The IP High Court Decision shows the new criterion for deciding “*an essential part*” of a claim

- 1) How to decide the essential part of a claim?

- Step i) Deciding “degree of contribution” of a claimed invention

- Step ii) Deciding “prior art” to be compared with a claim

- 2) Comparing the claim with the defendant’s product based on the decided essential part

1.1) - pioneer invention...broad - improvement invention...narrow

Maxacalcitol Case (Cont.)

1) How to decide the essential part of a claim?

- Step i) Deciding “degree of contribution” of a claimed invention
- Step ii) Deciding “prior art” to be compared with a claim

“The essential part” = a characteristic part of:

- the unique technical idea, and
- not found in a prior art



contributes to the prior art

Maxacalcitol Case (Cont.)

Step i)

Deciding “degree of contribution” of a claimed invention

If the degree of contribution of a claimed invention to the prior art is large, a part of a claim can be recognized **broadly**.

Degree of Contribution	Recognition of the part	scope of equivalent
Large	Broad	Broad
Small	the same as claimed	Narrow

- pioneer invention - improvement invention

Maxacalcitol Case (Cont.)

Step ii)

Deciding “prior art” to be compared with a claim

determine “the degree of contribution” → compare with the prior art

When comparing,

- a prior art described in **the specification** should be used.

Maxacalcitol Case (Cont.)

2) Comparing the claim with the defendant's product based on the decided essential part

(Requirement 1)

“The part replaced is not *an essential part* of the patent invention.”

- Whether or not the part replaced is *an essential part*.

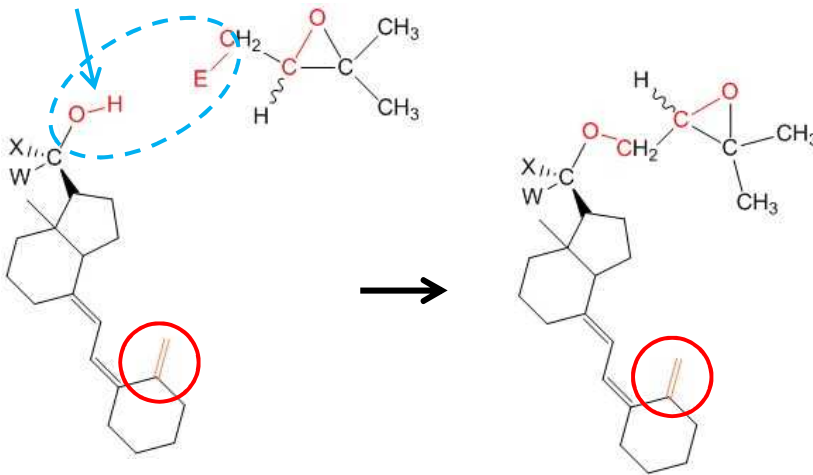
That is...

- Whether or not the defendant's product includes *the same essential part* of the claim.

Maxacalcitol Case (Cont.)

- First Step : Starting Materials are different, but, the **Reaction Mechanisms are the Same.**

Reaction site

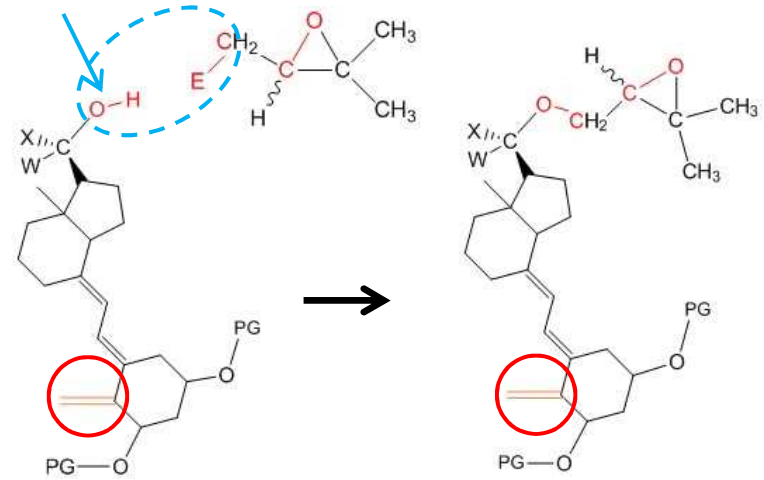


Starting Material
(**Cis-type** VD)

Intermediate
(inc. **Cis-type** VD)

The Claim

Reaction site



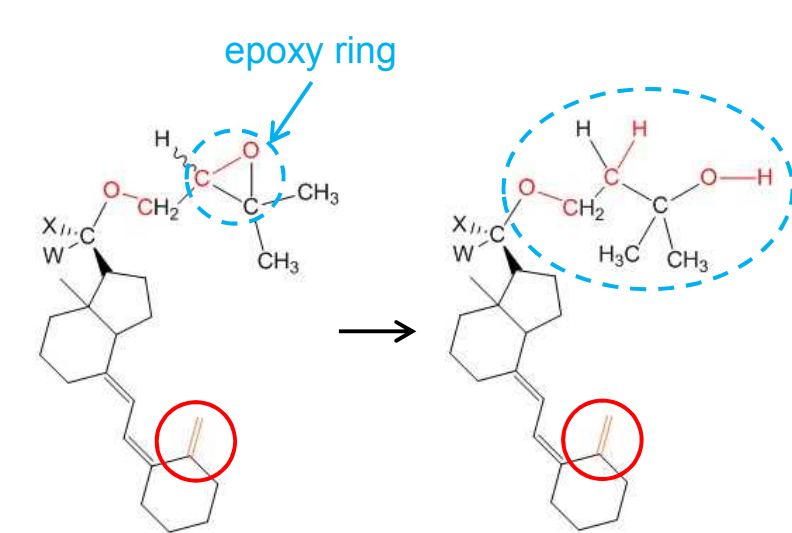
Starting Material
(**Trans-type** VD)

Intermediate
(inc. **Trans-type** VD)

Defendant's Method

Maxacalcitol Case (Cont.)

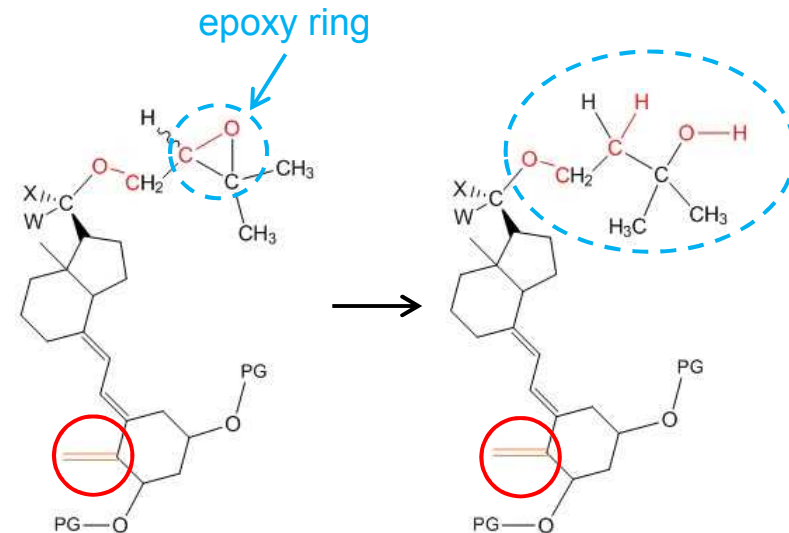
- Second Step: Intermediates are different, but, the **Reaction Mechanisms are the Same.**



Intermediate
(inc. **Cis-type** VD)

Maxacalcitol

The Claim



Intermediate
(inc. **Trans-type** VD)

Intermediate 2
(inc. **Trans-type** VD)

Defendant's Method

Maxacalcitol Case (Cont.)

The IP High Court Decision Indicates that:

- The claim provides **a new manufacturing route** which can synthesize large quantities of Maxacalcitol by simple steps.



The essential part of the patented invention is the “**manufacturing route**” itself.

- The claim allows Maxacalcitol to be produced industrially by this **new, non-conventional** manufacturing route. *<pioneer invention>*



The degree of the contribution of the claimed invention to the prior art is large, so a part of the claim can be recognized **broadly**.

Maxacalcitol Case (Cont.)

- The Starting material of the claim of a “cis-type vitamin D structure” is recognized **broadly** as a vitamin D structure.
- **The essential part** of the claim is the new manufacturing route including:
 - Reacting 20-position alcohol compound of the vitamin D structure and an epoxy hydrocarbon compound to introduce a side chain with an epoxy group to the vitamin D structure; and
 - Opening an epoxy ring of the epoxy group to obtain Maxacalcitol.

Maxacalcitol Case (Cont.)

- Both methods of the claim and the defendant use a starting material of the vitamin D structure and use the “first step” and the “second step” ,i.e., have a common important part for means to solve the problem.
- It is not important whether the starting material is “cis-type” or “trans-type”.



- It is **not essential** whether the starting material is “cis-type” or “trans-type”.



The essential parts are the SAME!!

The Defendant's method satisfies Requirement 1.

Maxacalcitol Case (Cont.)

Summary of the Maxacalcitol Case:

New Criterion of Requirement 1

“An essential part” of an Invention is recognized **more broadly** when the invention is a large contribution to a prior art.

In addition....

This decision is a very rare case in which IP High Court allowed a method claim of manufacturing a **medicament** to apply Doctrine of Equivalents.



Thank You !