Recent IP High Ct. Grand Panel Judgment on Product-by-Process Claims

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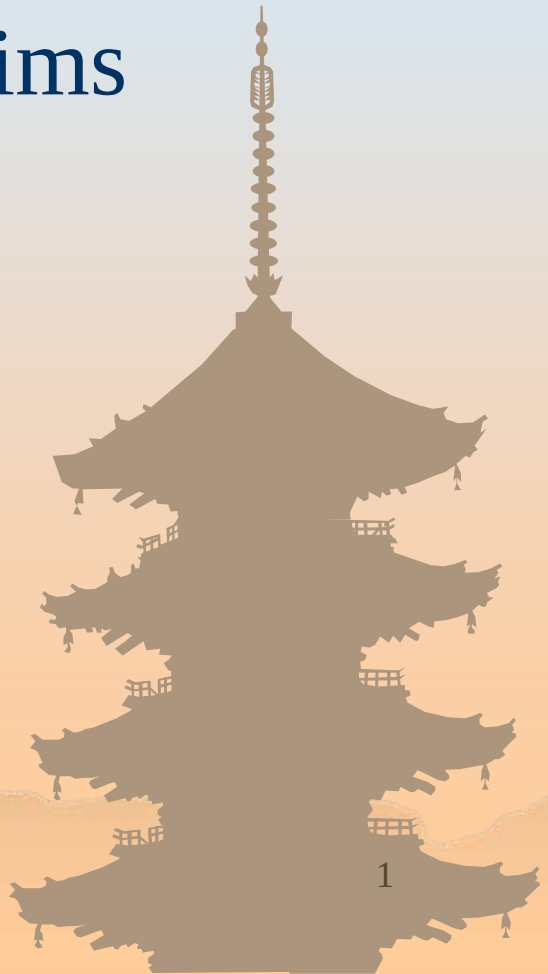
Japan



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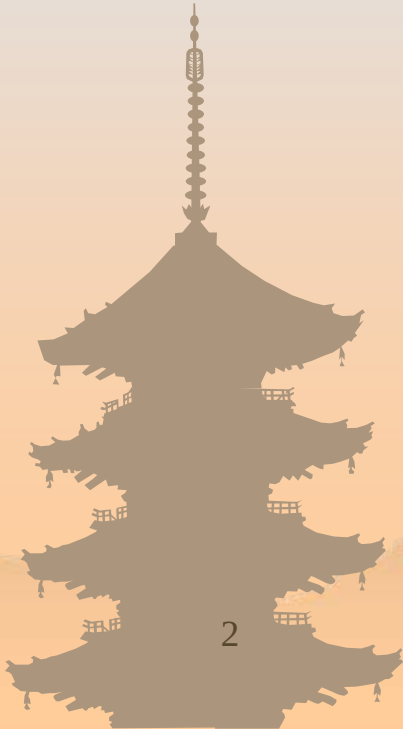


1. Background

1-1 Court Precedents

- “Technical scope of a product-by-process (p-b-p) claim shall be determined by the product itself, and not be limited to the product prepared by the claimed process, in principle.”
- “Technical scope of a p-b-p claim shall be limited to the product manufactured through the process stated in the claim, in principle.”
- There is no Supreme Ct. ruling that gives clear answer to this issue.

1-2 Practice of Japan Patent Office (JPO)

- The claimed product may be defined by the manufacturing process when it is impossible, difficult or inappropriate for the product structure of the invention to be directly defined by the characteristics or others independently of the manufacturing process
- A p-b-p claim shall be construed to refer to the final product itself, unless it should be construed as different meaning
- If an identical product can be obtained by a different process from the one stated in the claim, the claimed invention is not novel where the product is publicly known prior to the filing

Examination Guidelines for Patent and Utility Model
http://www.jpo.go.jp/cgi/link.cgi?url=/shiryou/kijun/kijun2/tukujitu_kijun.htm

2. Judgment of Grand Panel

- Date of Judgment Jan. 27, 2012

  2010(Ne)10043

  http://www.ip.courts.go.jp/eng/documents/g_panel.html
- Parties

  [Appellant-Plaintiff] (patent holder) Teva Gogyszergyar Zartkoruen Mukodo Reszvenytarsasag

  v.

  [Appellee-Defendant] Kyowa Hakko Kirin Co. Ltd
- Appealed from Tokyo District Ct.

2-1 Appellant's Patent (Patent No. 3737801)

"Pravastatin Sodium substantially free of Lactone and Epi-Pravastatin, and compositions containing same"

Claim 1

The pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava prepared by process comprising the steps of:

a) process A

b) process B

c) process C etc.

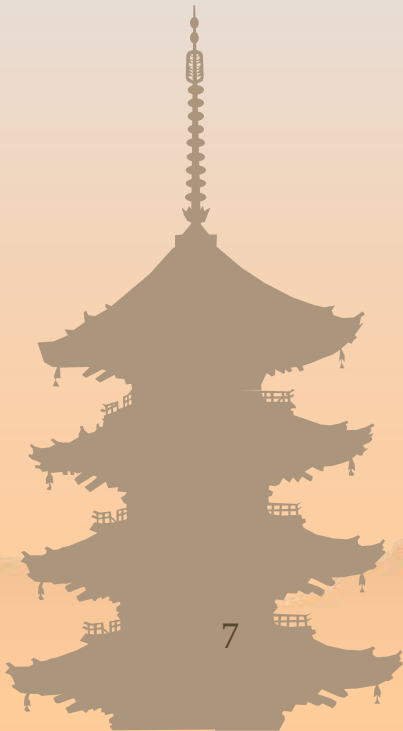
➡ Invention 1

2-2 Appellee's Product

The pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava,

of which manufacturing process does not fulfill process A.

Do appellee's products fall within the technical scope of Invention 1 ?



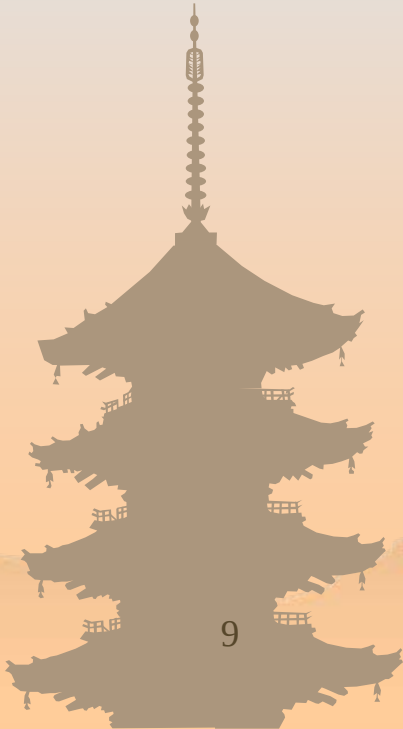
2-3 Judgment

The appellee’s pruducts are recognized as not falling within the technical scope of Invention 1.

➡ Dismissed the appeal.

2-3-1 Principle of interpreting claims

- It is impermissible to interpret or definitely determine the technical scope of the invention as including other manufacturing process beyond the manufacturing process stated in the scope of claims, in principle.



2-3-2 As to P-B-P Claims,

- There are two types,

Type A

Claims in which a product is specified by means of a process to manufacture the product because there are circumstances where “it is **impossible or difficult** to directly specify the product by means of the structure or feature of the product at the time of filing an application.”

Type B

Claims in which a process to manufacture the product is stated in addition to a product, though it cannot be said that there are circumstances as described above.

- The technical scope of the invention shall be interpreted as,

Type A

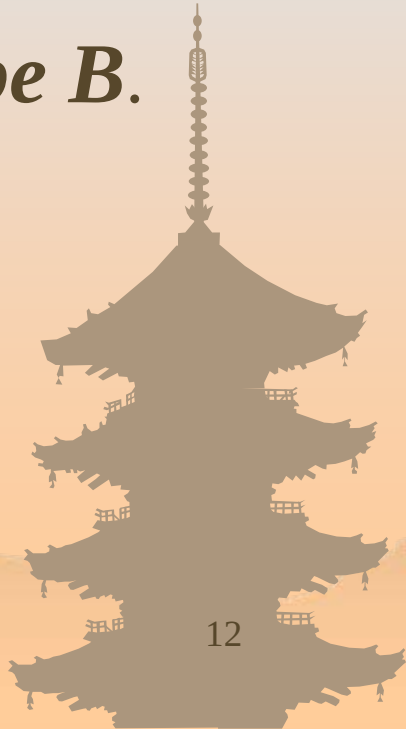
Not being limited to products manufactured through the process stated in the scope of claims but also covering any products that are identical to the products manufactured through said process

Type B

Being limited to product manufactured through the process stated in the scope of claims

2-3-3 Burden of Proof

- A person who asserts that the claim falls within ***Type A*** should prove that “it is **impossible or difficult** to directly specify the product by means of the structure or feature of the product at the time of filing an application.”
- Otherwise, the claim shall be regarded as ***Type B***.



2-3-4 Conclusion

- The court found no circumstance where “it is **impossible or difficult** to directly specify the product by means of the structure or feature of the product at the time of filing an application”
- Therefore, Invention 1 should be understood as being stated in ***Type B*** claim.

Appellee’s products are not infringing the appellant’s patent.

3. Comparing with Abbott v. Sandoz Case

En banc panel of CAFC held that a p-b-p claim is not infringed by products manufactured through the processes other than the one stated in the claim.

Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282,1293 (Fed Cir. 2009)

IP High Ct. Grand Panel judgment differs from CAFC judgment in some points.

- IP High Ct. ruled that ***Type A*** claims shall cover any products that are identical to the products manufactured through the claimed process, while CAFC didn't allow such exception.
- IP High Ct. held that in determining validity of a patent including p-b-p claims, the gist of the invention should be recognized in the same manner as recognizing the specific content of the claims, while CAFC majority didn't state how p-b-p claims should be recognized in determining validity.

cf. Amgen Inc. v. F. Hoffmann-La Roche Ltd.(Fed. Cir. Sept. 15, 2009)

4. Conclusion

- IP High Ct. made it clear that, when interpreting p-b-p claims, statements in the scope of claims should be used as standards in determining the technical scope of the patented invention,

  and that, p-b-p claims should be recognized in the same manner in determining validity or infringement of the patent.

- The court decided that ***Type A*** claim shall be treated as exception.

  - Legal stability
  - Benefits of patent holders

Thank you very much!