

Doctrine of Equivalents (DOE) Affirmed Again for Vitamin D Manufacturing Method Patent in Japan

IP High Court, No. 2015(ne)10014 (March 25, 2016)

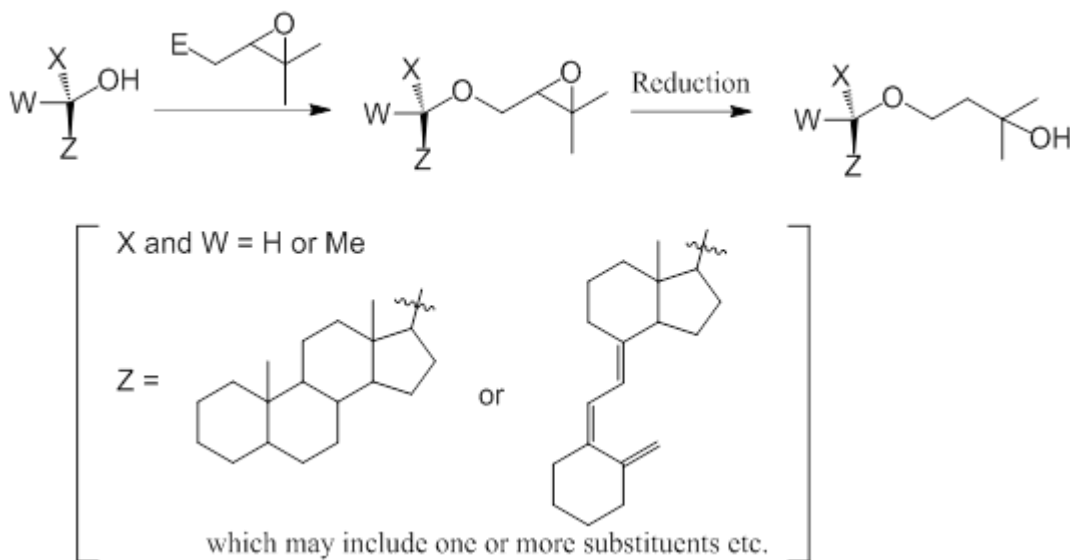
In *DKSH Japan, et. al. vs Chugai Pharmaceuticals* (IP High Court, No. 2015(ne)10014 (March 25, 2016)) ¹⁾, the Grand Panel of the Japan IP High Court affirmed the Tokyo District Court judgment (Tokyo District Court, No. 2013(wa)4040 (December 24, 2014)), and reiterated that the maxacalcitol manufacturing method patent was infringed under Doctrine of Equivalents (DOE).

Since the judicial precedent *Ball Spline* judgment (Supreme Court, No. 1994(o)1083 (February 24, 1998)) ²⁾, infringement has been denied in most of the cases, and no infringement has been affirmed in the fields of chemistry and life science. After this long dark age, the scope of DOE seems to be broadened by this judgment by the Grand Panel which is expected to create case laws as an IP specialized court.

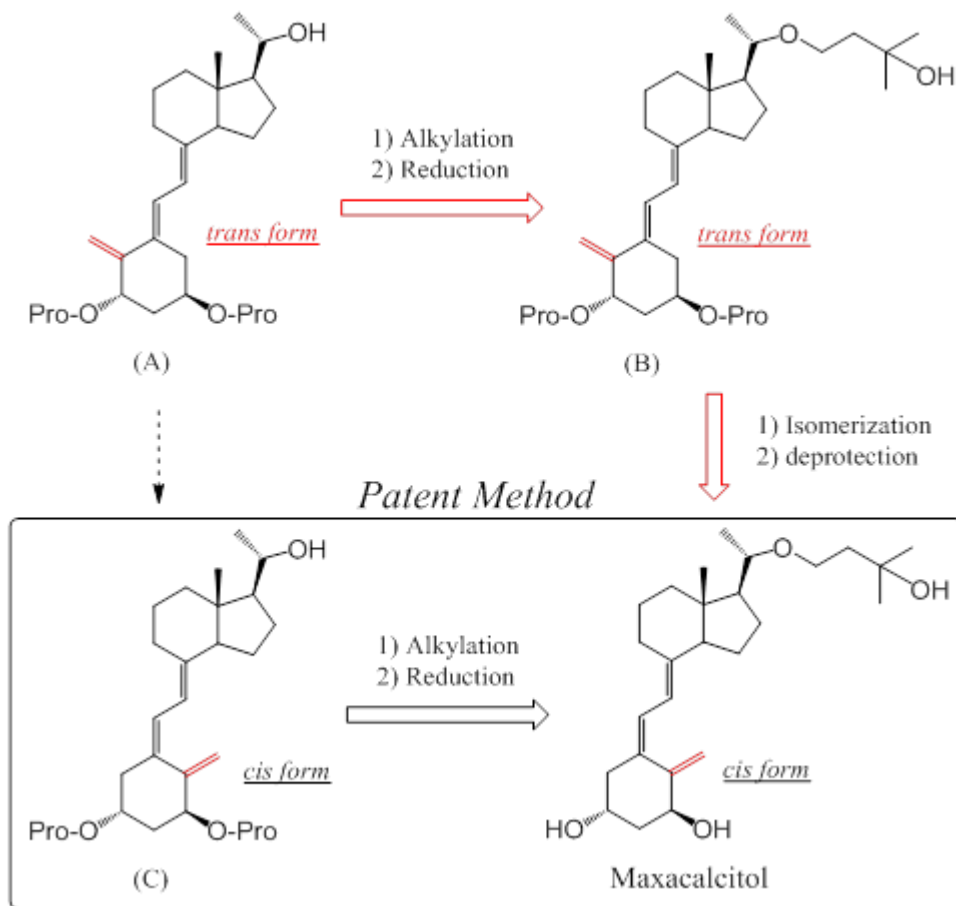
1. Background

Chugai jointly owns JP patent 3310301, claim 13 of which is directed to a maxacalcitol manufacturing method. The abstract of the claim 13 invention is as follows.

[Claim 13]



DKSH et.al. started to manufacture and sell maxacalcitol produced by the following method indicated in red arrow, starting material (A) to maxacalcitol through intermediate (B). The difference between the patent method and the DKSH's method is that the patent method uses "cis form", but the DKSH's method uses "trans form".



Chugai initiated litigation at the Tokyo District Court seeking an injunction against DKSH et.al. Tokyo District Court rendered the judgment¹⁾ on December 24, 2014, affirming infringement of DKSH et. al. under DOE and denying nullity of the patent. DKSH et al. appealed to the IP High Court, which selected this case as the 11th Grand Panel case, because five requirements for DOE²⁾ explained by the *Ball Spline* Supreme Court judgment have ambiguity.

2. Judgment of the Grand Panel of the Japan IP High Court

The Grand Panel affirmed the Tokyo District Court judgment, and declared that the patent was infringed under DOE and was valid. In the judgment, the court showed comprehensive guidance in “essential part” of the 1st requirement and “special circumstances” of the 5th requirement, both of which had been mostly argued and ambiguous.

(1) “Essential part” of the 1st requirement

The 1st requirement is that the part in the patented invention different from the product or method at issue is not the “essential part” of the patented invention.

The essential part should be recognized by determining a characteristic part in the patented invention constituting a unique technical idea not found in prior arts, based on the problem and its solution of the patented invention. Namely, the essential part should be recognized by the description of the claims and specification, in particular comparison with the prior art described in the specification, because substantial value of the patented invention is evaluated from the degree of contribution to prior arts. (i) In case of high contribution, a part of the patented invention is recognized broadly, and (ii) in case of low contribution, the

part is understood narrowly as the literal description of the claim.

The patented invention of the present case enables industrial production of maxacalcitol by a new manufacturing route for the first time. Thus, the patented invention has high contribution to prior arts. In light of the problem, its solution and effect of the patented invention, the essential part of the patented invention is introduction of the maxacalcitol's side chain to the OH group at 20 position in the vitamin D structure or steroid ring structure. The difference between "*cis form*" and "*trans form*" in the substituent "Z" is not an essential part. DKSH's method comprises the above essential part. Therefore, DKSH's method satisfies the 1st requirement.

(2) "Special circumstances" of the 5th requirement

The 5th requirement is that there are no "special circumstances" such that the product or method at issue was intentionally excluded from the scope of the claim during prosecution. When the patentee admitted once that the product or method was not included in the scope of the claims for example by intentionally excluding it during prosecution, the patentee cannot assert arguments contrary to this later in light of estoppel. When the patentee did not describe in the claim the other configuration of the product or method at issue, it comes under "special circumstances" of the 5th requirement, if it is recognized objectively and externally that the patentee acknowledged at filing the application, the other configuration as an alternative to the different configuration in the claim. Examples of such situations are (i) that the patentee described in the specification the invention comprising the other configuration; and (ii) that the patentee described in a scientific paper published around the filing date the invention comprising the other configuration. Because it should be protected that a third party has believed the patentee's intentional exclusion of the other configuration, it cannot be allowed in light of estoppel that the patentee asserts DOE concerning the product or method comprising the other configuration.

In the present case, there are no evidence sufficient to recognize objectively and externally that the patentee acknowledged at filing the application, "*trans form*" of vitamin D structure as an alternative to "*cis form*" of vitamin D structure in the starting material of the patented manufacturing method. Therefore, "special circumstances" of the 5th requirement are not admitted.

< The reporter's Comments >

This case may be appealed to the Supreme Court for further evaluation. I think this judgment was influenced by current discussion by Japanese governmental committee to improve court system in Japan, because not many infringement suits have been filed in Japan, and successful rate of infringement is not enough compared with those in other major countries. I think DOE in Japan will be broadened, and the Japanese patent system will be governed by pro-patent policy in future.

1) http://www.ip.courts.go.jp/eng/hanrei/g_panel/index.html

2) *Ball Spline* judgment (Supreme Court, No. 1994(o)1083 (February 24, 1998))

The *Ball Spline* judgment expressed five requirements for DOE, which are:

“Even if there is a part which is different from the product at question, the product should fall within the scope of the patented invention, if

(1) the different part between the product and the patented invention is not the “essential part” of the patented invention,

(2) the purpose of the patented invention can be achieved by replacing this part with the part in the product, and the identical function and effect can be obtained,

(3) a person skilled in the art could easily come up with the idea of such replacement at the time of manufacturing the product,

(4) the product is not identical to the technology in the public domain at the time of filing the patent application of the patented invention, and could not have been easily conceived at that time by a person skilled in the art, and

(5) there were no “special circumstances” such as the fact that the product had been intentionally excluded from the scope of the patent claim in the prosecution history.”

(Reported by Toshio Nakamura, Ph.D.)

SAKAMOTO & PARTNERS

Yamatoya Build. 6th floor, 2-13, Yotsuya, Shinjuku-ku, Tokyo, 160-0004,
JAPAN

TEL: +81-3-5919-3041 FAX: +81-3-5919-3042

Email: tsakamoto@sakamotopat.com

HP: <http://www.sakamotopat.com/eng/>