



# WINDS FROM JAPAN

The Licensing Executives Society Japan

## *IP High Court Applied Doctrine of Equivalents in Pharmaceutical Field First Time Ever*

*– IP High Court Grand Panel Judgment of March 25, 2016*

By Hiroki Saito\*

### (1) Outline of the Case

On December 26, 1985, Chugai Pharmaceutical (“Chugai”) filed a patent application for a substance containing maxacalcitol, an active ingredient of a curative medicine for keratoma (Product Name: Oxarol), and obtained a substance patent. This patent expired on December 26, 2010.

On September 3, 1997, Chugai filed a patent application for a method of producing maxacalcitol and obtained a production method patent (the “Patent”).

After the expiration of the substance patent, Chugai filed a lawsuit against generic drug companies (the “Defendants”) who imported and sold maxacalcitol products requesting an injunction on the sale of the Defendants’ products as being produced by methods infringing Claim 13 of the Patent (the “Case”). After filing the Case, Claim 13 of the Patent was corrected.

The corrected Claim 13 recites an invention for a production method of producing a chemical compound from a starting material (vitamin D structure or 20-position alcohol compound at the steroid ring structure) by reacting the starting material with a reagent to obtain an intermediate, and then treating the intermediate with a reducing agent to produce the objective substance (the “Patented Invention”).

The Defendants’ (generic drug companies’) methods do not literally fulfill a constituent feature of the Patented Invention, which uses a compound of a cis-form vitamin D structure as a starting material but uses a compound of a trans-form of vitamin D, which is a geometric isomer of the cis-form vitamin D structure instead. The Defendants’ methods literally meet all other constituent features of Claim 13.

For this reason, a judgment of literal infringement was denied. The major issue in the Case was whether the Defendants’ methods constitute infringement under the doctrine of equivalents. The court of the first instance found that the Defendants are liable for patent infringement under the doctrine of equivalents (the Tokyo District Court decision of December 24, 2014 (*Hanrei Jiho*, No. 2258, p. 106)). The Defendants appealed this judgment to the Intellectual Property High Court. The Grand Panel of the Intellectual Property High Court affirmed the District Court’s decision (Intellectual Property High Court, Grand Panel decision of March 25, 2016 (Supreme Court of Japan website (Japanese), 2015 (Ne) 10014)).

### (2) IP High Court Grand Panel Decision

The Grand Panel of the IP High Court found patent infringement under the doctrine of equivalents for a pharmaceutical case for the first time ever.

The Supreme Court decision on the Ball Spline case (Supreme Court judgment dated February 24, 1998, *Minshu*, Vol. 52, No. 1, p. 113) established the following five requirements for finding patent infringement under the doctrine of equivalents, which is applicable when a claim includes a portion which is close to but not literally met by the accused product or method:

- i) Non-essential part  
The difference is not an essential part of the patented invention.
- ii) Replaceability  
If the claim element in question is replaced with the element in the accused product or method, the purpose of the invention can be

achieved and the same operational advantage can be attained.

iii) Ease of conceiving (ease of replacement)

A person skilled in the art could have easily conceived of the replacement at the time when the accused product was manufactured or the accused method was practiced.

iv) The accused product or method was not easily conceived from the prior art

The accused product or method is not identical to the publicly known technology at the time of patent filing, or a person skilled in the art could not have easily conceived of the accused product or method from the publicly known technology at the time of patent filing.

v) No special circumstances, such as intentional exclusion

There are no special circumstances, for example, the accused product or method was not intentionally excluded from the scope of the patented invention during prosecution of the patent.

The Grand Panel of the Intellectual Property High Court considered whether each of the five requirements for applying the doctrine of equivalents was met. The Grand Panel focused especially on the First Requirement (non-essential part) and the Fifth Requirement (no special circumstances), which are often the reasons why patent infringement under the doctrine of equivalents is denied. This judgment set forth important guidelines for interpreting the First and Fifth Requirements.

**a) First Requirement of the Doctrine of Equivalents**

The Grand Panel illustrated a way for determining the essential part of a patented invention, as follows:

“[T]he essential part of a patented invention should be determined based on the description in the claim and the specification, in particular, through a comparison with the prior art disclosed in the specification. i) If the degree of contribution of the patented invention is evaluated as greater than that of the prior art, the essential part of the patented invention should be considered as a broader concept with respect to the relevant portion of the claim description (... the Patented Invention is an example of this type). ii) If the degree of contribution of the patented invention is evaluated as not greater than that of the prior art, the essential part should be considered to have almost the same meaning as described in the claim.” (Emphasis added)

The Grand Panel noted that other prior art should be considered if the description is insufficient with respect to the problem which could not be resolved by the prior art:

“However, if the description of the specification regarding the problem which could not be resolved by the prior art is objectively insufficient in light of the prior art as of the filing date (or the priority date), a characterizing portion constituting a unique technical idea of the patented invention that is not seen in the prior art should be determined by taking into the consideration also the prior art which was not disclosed in the specification. In this case, the essential part of the patented invention is considered closer to the claim description in comparison to a case where the essential part is determined only based on the description of the claim and the specification, and therefore the scope of equivalents should be narrower.” (Emphasis added)

The Grand Panel also noted:

“[I]n a determination of the First Requirement, that is, a determination on whether the different portion is a non-essential part of the patent invention, it is not appropriate to first divide the claim elements into an essential part and a non-essential part and then conclude that the doctrine of equivalents is not applicable to the claim elements which are determined as essential parts. Instead, it is necessary to first determine whether the accused product or method has the essential part of the patented invention and then conclude that the difference is not an essential part if the accused product or method is recognized to have the essential part. Even if the accused product or method has a difference other than the characterizing portion constituting a unique technical idea which is not seen in the prior art, this fact cannot be a reason for denying the fulfillment of the First Requirement.”

**b) Fifth Requirement of the Doctrine of Equivalents**

The Grand Panel clarified that the special circumstance of the Fifth Requirement should not be found to apply solely because the applicant did not describe a different structure in the claim, even if the applicant could have easily conceived of the different structure at the time of patent filing.

“In this regard, even if there is a different structure which is outside the scope of a claim and can be easily conceived by a person skilled in the art as of the filing date as substantially identical with the structure stated in the claim and the applicant could thus have also easily conceived of the different structure as of the filing date, this fact alone cannot serve as a reason for alleging that the applicant’s failure to state the different structure in the claim falls under the “special circumstances” in the Fifth Requirement of the doctrine of equivalents.”

This is because, ... i) ... the substantive value of a patented invention extends to the art which a person skilled in the art could have easily conceived as substantially identical with the structure stated in a claim even if it was not stated in the claim. ii) In addition, ... originally, the applicant should draft a claim in just proportion with the scope of the invention disclosed in the specification... However, in some cases, it should be harsh to require the applicant to prepare a claim covering all possible infringing embodiments which may be implemented in the future and a specification supporting such a claim with limited time under the first-to-file patent system. On the other hand, in many cases, a third party who has learned the invention described in the specification can easily conceive of an embodiment having the essential part of the patented invention but not being included in the scope of the literal interpretation of the claim.

In light of the aforementioned situation, even if a person skilled in the art could have easily conceived of a different structure which is outside the scope of a claim as of the filing date, it is not reasonable to simply exclude the different structure from the application of the doctrine of equivalents.” (Emphasis added.)

Further, the Grand Panel indicated exceptional cases where the application of the doctrine of equivalents is denied by the Fifth Requirement of the doctrine of equivalents as follows:

“However if the applicant is objectively and externally considered as having recognized a different structure which is outside the scope of a claim as of the filing date (for example, the applicant is considered to have described the different structure in the specification or the applicant described the different structure in a technical paper published at the time of patent filing), the applicant’s failure to state the different structure in the claim is considered to fall under the “special circumstances” in the Fifth Requirement.

In the aforementioned cases, it can be understood that the patentee intentionally excluded the different structure from the scope of the claim. That is, the patentee admitted that the different structure does not fall within the technical scope of the patented invention or the patentee behaved as if he/she had objectively acknowledged so. In this situation, reliance by a third party who understands as such should be protected. Therefore, the patentee is not permitted to subsequently allege the application of the doctrine of equivalents in relation to the accused product or method incorporating the different structure in light of the doctrine of estoppel.” (Emphasis added.)

### (3) Analysis

The fact that the Grand Panel of the Intellectual Property High Court found patent infringement under the doctrine of infringement in the field of pharmaceuticals is significant. The Court’s clear explanation of the correct interpretation of the five requirements of the doctrine of equivalents (especially the interpretation of the First and Fifth Requirements, as stated above, where there was previously a split among the lower courts), means that the judgment will have a major impact on the practice of patent infringement arguments based on the doctrine of equivalents generally, and in pharmaceutical cases specifically.

In the interpretation of the First Requirement, the Court found that, if the description of the problem to be solved in the specification is insufficient, the characterizing portion will be determined in taking account of prior art not stated in the specification, and the scope of the doctrine of equivalents to be applied will become narrower. When drafting the specification it is therefore recommended to describe sufficiently the problems to be solved in comparison with the prior art. Further, the Court showed examples of “special circumstances” where the Fifth Requirement of the doctrine of equivalents is not satisfied, such as when it is considered that the applicant described the accused structure in the specification or when the applicant disclosed the accused structure in technical papers published at the time of patent filing whereas the applicant did not describe the accused structure in the patent claim.

Applicants need to pay attention to this judgement as it relates to the description in the specification at the time of filing. Especially, with respect to the latter point, if the applicant is a company, then the “applicant” might be considered inclusive of employees of the company, and therefore, it will be important to manage matters related to technical papers by related persons before and after the patent application.

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*\*Attorney at Law, Mori Hamada & Matsumoto*

# 2017 LES Japan General Assembly

By Kazuaki Okimoto\*

LES Japan held its 2017 General Assembly on February 15, 2017 at the Kasumigaseki Common Gate West in Toranomon, Tokyo.

Prior to the General Assembly, we had a two-hour special seminar presented by an invited lecturer, Mr. Hideo Toyoda, President of Panasonic IP Management Co., Ltd. Mr. Toyoda discussed the use of Panasonic's intellectual property to profit from IP, and the reorganization of the management structure of the IP department. He also touched on reformation of the IP department (Photo 1). Since Panasonic has quickly rejuvenated its business by reorganizing IP management, his lecture was very impressive and persuasive.



(Photo 1: Seminar)

During the General Assembly of LES Japan, followed by this seminar, we discussed, item by item, income and expenditures, activities, and human affairs of LES Japan in 2016, and plans for 2017 (Photo 2). The plans of LES Japan were approved unanimously.



(Photo 2: General Assembly Discussion)

Following the General Assembly, we had a reception (Photo 3) and five of the distinguished guests gave speeches:

- Ms. Patricia Bunye, President, LES International
- Mr. Setsuo Iuchi, Secretary-General, Intellectual Property Strategy Headquarters, Cabinet Office
- Dr. Keisuke Isogai, Director-General, Commissioner's Secretariat, Agency for Cultural Affairs
- Mr. Yoshinori Komiya, Commissioner, Japan Patent Office
- Mr. Misao Shimizu, Chief Judge of the Intellectual Property High Court



(Photo 3: Networking Reception)



(Photo 4: From the left, Mr. Makoto Ogino, President-Elect of LES Japan; Ms. Patricia Bunye, President of LES International; Ms. Junko Sugimura, President of LES Japan; and Dr. Ichiro Nakatomi, Immediate Past President of LES Japan)



(Photo 5: Speech by Mr. Komiya)



(Photo 6: Speech by Mr. Shimizu)

Other invited distinguished guests were as follows:

Mr. Toshio Mamiya, Director-General, Policy Planning and Coordination Department, Japan Patent Office

Ms. Takako Nakamura, Director, Policy Planning and Research Division, Japan Patent Office

Mr. Takeshi Nakano, Director, Legislative Affairs Office, Japan Patent Office

Ms. Makiko Takabe, Judge of the Intellectual Property High Court

Mr. Kazuhide Shimasue, Judge of the Tokyo District Court

Mr. Tamotsu Shoji, Judge of the Tokyo District Court

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## *IP News from Japan*

**By Shoichi Okuyama, Ph.D.\***

### **Cyber-Attack Shuts Down JPO J-PlatPat Database for One Week**

In the late afternoon of March 9, 2017, JST, all functions of the official Japan Patent Office database for patents, trademarks, and designs, J-PlatPat, suddenly shut down due to cyber-attack on its server system, Apache Struts 2. The database was restarted at 9:00 a.m. on March 17, 2017. Japanese users had to access similar services provided by WIPO or EPO instead. The National Center for Industrial Property Information and Training, INPIT, which actually operates the system, announced that no confidential information was leaked in this incident because J-PlatPat is solely for dissemination of public IP information. Another Japanese government-run database, J-Stage, which is for academic documents, was shut down for five days because of a similar cyber-attack.

### **Infringing “Summary Websites”**

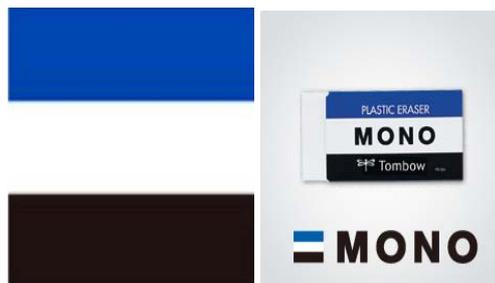
Websites that summarize information for specific topics, so-called “summary websites”, are very popular among net users. A major information and game service provider, DeNA, announced that it shut down a large number of its summary websites that collect and post specific information, such as about health issues. In these sites, according to a third-party committee commissioned by DeNA, about 21,000 articles and 742,043 images posted were suspected of copyright infringement. Also, at least ten articles were found to violate the Pharmaceuticals and Medical Devices Act, which prohibits the provision of medical advice by those who are not medical doctors. The company promised to compensate for each incident of copyright infringement. The author guidelines DeNA used contained some language that suggests use of texts and images from other sites without authorization.

## Music Schools Voice against JASRAC

JASRAC (Japanese Society for Rights of Authors, Composers and Publishers), which is by far the largest rights management organization in Japan for musical works, met with strong opposition from private music schools when it tried to collect royalties for the use of music in classrooms. In Japan, there are a large number of music schools managed by major musical instruments companies, such as Yamaha and Kawai. They buy copyrighted musical scores and provide lessons to students of all ages. According to JASRAC, such students pay tuition and play music for an audience of fellow students, and therefore, the schools have to pay royalties for performance of musical works JASRAC manages. An association of these musical schools strongly objected to the proposed royalty of about 2.5% of tuition, and declared they would bring their case before a court if negotiations failed.

### Two Color Marks Allowed for the First Time

On March 1, 2017, the JPO announced that it allowed two color trademarks for the first time. Since April 1, 2015, the JPO has been accepting trademark applications for non-traditional marks such as for sounds, colors, positions, motions, and holograms. Almost 1500 applications have so far been filed, and among them, 492 applications are for color marks. After careful review, the JPO has allowed the first two cases. More than 200 registrations have already been made for other types of non-traditional marks.



Allowed color mark Erasers in Cl. 16. Product ad. Tombow Pencil



Allowed color mark Retail services in Cl. 35 Shop Seven Eleven Japan Co., Ltd.

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\* Editor / Patent Attorney, Okuyama & Sasajima

## Editors' Note

This issue includes articles relating to “IP High Court Applied Doctrine of Equivalents in Pharmaceutical Field First Time Ever”; “2017 LES Japan General Assembly” and “IP News from Japan.”

Thank you for your support of “Winds from Japan.” This newsletter will continue to provide you with useful information on activities at LES Japan and up-to-date information on IP and licensing activities in Japan.

If you would like to refer to any back issues of our newsletters, you can access them via the following URL: <http://www.lesj.org>

(MK)

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