



WINDS FROM JAPAN

The Licensing Executives Society Japan

Pravastatin Sodium Case, Product-by-Process Claiming Practice: Supreme Court Overrules the Grand Panel of the IP High Court

By Shoichi Okuyama, Ph.D.*

The Supreme Court of Japan rendered two decisions that would greatly modify product-by-process claim drafting and interpretation practice (*Pravastatin Sodium Case* decisions, June 5, 2015, the Second Petty Bench of the Supreme Court of Japan, case Nos. 2012(ju)1204 and 2012(ju)2658). Japan's highest court *reversed* the Grand Panel¹ of the IP High Court. The two decisions upset the current practice and efforts toward international harmonization. Two points were emphasized in the opinion of the Court:

Products made by a Different Process Infringe the Claim: “[E]ven if a patent claim concerning a product invention recites the manufacturing process of a product, the technical scope of the patented invention should be determined to cover products that have the same structure and characteristics, etc., as those of the product made in accordance with the manufacturing process.”

Product-by-Process Claims When Only Way to Define a Product: “[W]hen patent claims concerning a product invention recite the manufacturing process of a product, such claims would satisfy the requirement [that] “the invention be clear” according to Article 36(6)(ii), Patent Act, only if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing.”

In fact, the Supreme Court adhered to the theory it created years ago that a product claim should be, as a rule, delimited by the structure or characteristics of the inventive product despite the fact that in 1994, Article 36 of the Patent Act was amended to allow for more flexibility in claim drafting. The Supreme Court allowed the use of product-by-process limitations in the claims only if it is impossible or utterly impractical to define the invention without using such limitations at the time of filing. In order to justify above-mentioned two theses, it created a new category of the lack of clarity under Article 36(6)(ii).

As a result of these Supreme Court decisions, the Japan Patent Office now have to make sure, if it finds a product-by-process limitation in a claim, that it was impossible or impractical to define the invention without using the product-by-process limitation, while it is quite certain that this question will come back during patent infringement litigation in any case.

The Supreme Court *Lipase Decision* (1991): The Supreme Court in this decision recognized the importance of the public notice function of patent claims. Citing the *Lipase Decision*, the Court in the *Pravastatin Sodium Case* reiterated the public notice function of patent claims. In the earlier *Lipase Decision* the Supreme Court rejected the idea of reading a limitation from the specification into pending claims. The Tokyo High Court (now IP High Court) read “lipase” in the claim as the species “Ra lipase” because all examples in the specification were for Ra lipase. The *Lipase Decision* was an appeal from a JPO decision to reject the application.

¹ The Grand Panel consists of the heads of the four divisions that exist in the IP High Court plus one less senior judge.

The Supreme Court stated that:

When the patentability requirements according to Article 29(1) and (2), Patent Act; that is, the novelty and inventive step of an invention found in a patent application are reviewed, the gist of the invention in the application has to be determined in order for the invention to be compared with prior art defined in Article 29(1). Unless special circumstances exist, this determination of the gist has to be made based on the recitations in the claims. Only if special circumstances exist such as when the technical meaning of a recitation in the claim cannot be understood without ambiguities, or when it is apparently clear that such recitation is an error with reference to the detailed description of the invention in the specification, it is permitted to refer to the detailed description of the invention in the specification.

Justice Yamamoto's Sharply Worded Concurrence: Justice Tsuneyuki Yamamoto, who started his career as a bureaucrat at the Ministry of International Trade and Industry (now the Ministry of Economy, Trade and Industry), concurred with the Judgment but strongly criticized the majority opinion.

He pointed out that the Patent Act was amended in 1994 with respect to Article 36(5)(ii), which required that patent claims must "set forth only the features indispensable for the constitution the invention." The corresponding provision after the amendment is found in Article 36(5), which requires that claims must set forth "all matters which an applicant for a patent considers necessary in defining an invention." Noting discussions made in the report of the council responsible for the amendment and also quotations from the current examination guidelines published by the Japan Patent Office, he noted that the amendment and current JPO practice allow functional and process limitations in patent claims, while product-by-process claims are also subject to other patentability requirements such as clarity of claims and novelty.

He noted that the majority opinion would upset such interpretation of the Patent Act and also the current examination practice. He also pointed out that, in a large number of cases, if the format of product-by-process claims is not used, claims become rather unclear. He gave an exemplary claim which recites that "a cell produced by introducing a certain gene into a certain cell in a certain way." He argued that such a claim is very easy to understand for a skilled person. On the other hand, if the cell has to be defined in terms of structure or characteristics, the resulting claim would be understandable to no one. This is against the ideal of the Patent Act which aims at a proper balance between the protection of inventions and public use.

He also cautioned that if product-by-process claims are allowable only "if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing" as in the majority opinion, it would become practically impossible to use process-by-process limitations.

He also questioned the expansive interpretation of Article 36(6)(ii) (clarity requirement) by stating that: "According to the majority opinion, if product-by-process claims are refused or invalidated as violating the clarity requirement when such claims do not satisfy the requirement that it is impossible or impractical to specify the claimed product without a process limitation goes far beyond the traditional interpretation of Article 36(6)(ii), and such new interpretation is clearly wrong."

Justice Yamamoto agreed with the majority opinion in that the product-by-process claim should also cover products that are not made by the recited process. He also agreed to remand the case back to the IP High Court.

Two Decisions: The two Supreme Court decisions were handed down on the same day. A Hungarian subsidiary of Teva Pharmaceutical Industries, Ltd. separately sued two Japanese companies, Kyowa Hakko Kirin Co., Ltd. and Tohri Company Ltd., for infringement of a Japanese patent it owns, patent No. 3737801. The first case involving Kyowa Hakko Kirin resulted in the Grand Panel decision of the IP High Court, which addressed the issue of infringement of a product-by-process claim. The other case involving Tohri lead to another IP High Court decision rendered by an ordinary panel of three judges. The main issue in the second decision was an invalidity defense - the lack of inventive step. The second decision (case No. 2012(ju)2658) is just a paraphrased version of the first decision (case No. 2012(ju)1204), and they are substantially the same. In this paper, we base our analysis on the first decision involving Kyowa Hakko Kirin.

Implications for Product-by-Process Claiming: Under these new Supreme Court decisions, the Japan Patent Office now has to examine patent applications containing product-by-process claims to determine whether or not any circumstances exist under which it was impossible or impractical to directly identify the structure or characteristics of the product at the time of filing. The burden rests on the applicant to show such circumstances existed as of the filing date. It is generally not easy to show that something is impossible to accomplish while it may be easier to show the contrary. Also, the applicant may have to make sure that the structures or characteristics of, say,

antibiotics, microorganisms or modified cells are described in detail in the patent application, although claims identifying such structures or characteristics may be more difficult to understand. Inventions in such fields like metals, alloys, semiconductors, or even mechanical engineering may face problems if claims contain some language that suggests use of a process.

Questioning the Validity of Existing Patents:

The validity of existing patents that have product-by-process limitations in the claims may have to be questioned.

Interim Guidelines published on July 6, 2015:

On July 6, 2015, the Japan Patent Office published a document entitled "Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims." An English summary version was also prepared and published by the JPO. It can be found at the JPO website. According to this document, if the applicant argues in writing that it was impossible or impractical to identify the invention in terms of its structure or characteristics at the time of filing, the examiner is encourage to take the face value of the argument and allow the application as a rule.

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*\* Editor / Patent Attorney, Okuyama & Sasajima*

# LES Japan 38th Annual Summer Conference 2015 in Sendai

By Mitsuo Kariya\*

LES Japan 38<sup>th</sup> Annual Summer Conference 2015 was held on 3<sup>rd</sup> and 4<sup>th</sup> of July 2015 in Sendai city, Miyagi prefecture, which is the largest city in the northeast region of Japan. LES Japan held an annual conference in this region for the first time since the M9 earthquake and tsunami on March 11, 2011. Although no trace was found in the downtown of Sendai city where this conference was held, the maritime area was still under reconstruction. The total number of participants for the conference reached 200, including more than 35 participants from abroad.

The Conference started with opening remarks by Mr. Chikashi Tamura, Chair of the Organizing Committee, and Dr. Ichiro Nakatomi (photo 1), President of LES Japan. Mr. Tamura introduced the theme of the conference, “Look Forward” which expresses our determination of moving forward with people in this region. Dr. Nakatomi discussed his expectation of LES Japan’s contributions to reconstruction after the disaster and creation of new industries.



photo 1

Opening Remarks by Dr. Nakatomi

LES Japan had an honor of having Mr. James Sobieraj (photo 2), President of LESI and Ms. Patricia Bunye, President-elect of LESI at this conference.



photo 2

Speech by Mr. Sobieraj

The first program of the Conference was a keynote speech, “International Maritime Trade and Environment” by Mr. Yoshikazu Kawagoe (photo 3), Executive Officer and General Manager of Technology, Mitsui O.S.K. Lines, Ltd. This company is known for having voluntarily sent a passenger ferry to provide sufferers with bath and food shortly after they lost their homes. Mr. Kawagoe discussed his initiatives of reducing loads on the environment in maritime trades.



photo 3

Speech by Mr. Kawagoe

The second program was a guest speech, “Power of Tohoku will change Japan” by Mr. Kuniaki Fukui (photo 4), Chief Executive Officer, Nippon Zenyaku Kogyo Co., Ltd. He led the company to change the business model from formulation to new drug development by struggling for 29 years while rebuilding the company’s facilities which were completely destroyed by the earthquake. He also connected other affected companies with universities to change them from subcontractors to R&D oriented companies and contributed to increase the number of employees in the region.



photo 4

Speech by Mr. Fukui

The third program was a guest speech, “Making of Greek Sculpture – Actual Condition of Ancient Workshop” by Dr. Kyoko Haga (photo 5), Associate

Professor, Faculty of Literature Study, Graduate School of Tohoku University. Her scientific study using 3D scanning clarified the sculptor of a famous statue which has been disputed among academics for a long time.



photo 5  
Speech by Dr. Haga

The participants were impressed with the remarkable efforts by the distinguished speakers to vitalize people, industries and academics in the affected area.

The banquet started with a message from Miyagi Prefectural Governor conveyed by Mr. Masahiro Wako (photo 6), Director General of Miyagi Prefecture. Judge Misao Shimizu (photo 7) from the IP High Court gave a congratulatory speech.



photo 6  
Speech by Mr. Wako



photo 7  
Speech by Judge Shimizu

All participants enjoyed precious moments for chatting and networking with selected drinks and a good combination of local foods and international foods (photo 8). In the middle of the banquet, Mr. Torahiko Maki (photo 9), ex-Vice President of LES Japan was commended for his numerous long-term contributions to the society.



photo 8  
Guest table at the banquet



photo 9  
Award to Mr. Maki

The participants also enjoyed a traditional local dance, “Suzume-Odori” (photo 10) performed by a student dance team from Miyagi University.



photo 10  
Dance performance

On the second day, four workshops (photo 11) were organized by working groups of LES Japan. Latest IP topics were discussed by: 1) “University Network for Innovation and Technology Transfer”; 2) Asian Issues WG; 3) Healthcare WG; and 4) Trade Secret WG.



photo 11  
Workshop

After the workshops, a panel discussion (photo 12) was held based on the theme of “Toward the Future of the Judicial System for IP” by Judge Misao Shimizu, the IP High Court; Judge Taek Soo Kwon, who is now retired from the Seoul High Court; Mr. Masataka Kamiyanagi, IP Advisor, Seiko Epson Corp.; Dr. Shoichi Okuyama, Patent Attorney, Okuyama & Sasajima; Mr. Junichi Yamazaki, Attorney at Law, Miyake & Yamazaki; and Ms. Junko Sugimura, President-elect of LES Japan.

This panel discussion was planned as a celebration of the 10<sup>th</sup> anniversary of the IP High Court. The panelists discussed the past 10 years IP situation in Japan, contributions of the IP High Court and prospects of IP circumstances. The participants

were encouraged by the active and positive discussions among the knowledgeable panelists.



photo 12  
Panel discussion

The conference concluded successfully with a closing speech by Mr. Eiichiro Kubota, Chair of the Organizing Committee for the next year announcing the 2016 LES Japan Annual Summer Conference in Matsuyama city, Ehime prefecture.

We look forward to seeing you in Matsuyama next year.

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IP News from Japan

By Shoichi Okuyama, Ph.D.*

JPO and USPTO to Collaborate in Searches

The Japan Patent Office (JPO) and the United States Patent and Trademark Office (USPTO) agreed to launch a Bilateral Collaboration Search Pilot (CSP) program from August 1, 2015. The JPO and USPTO will share search results and patentability opinions, and give the search results to the applicants within six months from the request for the CSP program, after which substantive examination will be carried out by each office. Applicants who wish to acquire patents in Japan (JP) and the U.S.A. using the CSP program should file a request. The first office, either the JPO or USPTO, will carry out a search and send the search results to the second office together with a patentability opinion. The second office will carry out a search and give its search results to the first office together with its opinion. After the combined search results are given to the applicants, substantive examination will start in each patent office independently.

Amendments to Patent and Trade Secret Laws Become Laws

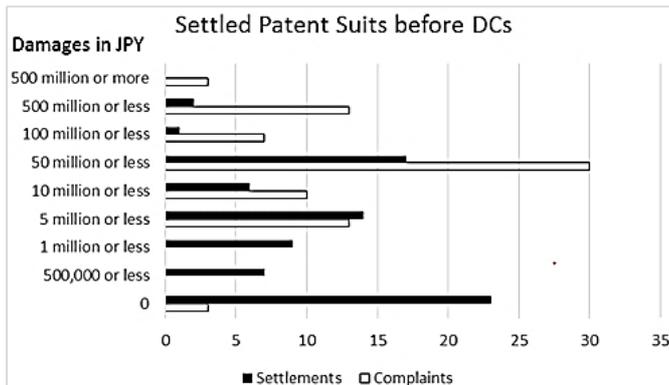
On July 3, 2015, bills to amend the Patent and Trademark Acts and Unfair Competition Prevention Act passed the Diet, and they became laws upon their promulgation on July 10, 2015. There are two major components in the amendments to the Patent Act: the new employee invention scheme and the accession to the Patent Law Treaty. Japan also will join the Singapore Treaty on the Law of Trademarks. The Unfair Competition Prevention Act was amended to give stronger protection to trade secrets. The new laws will take effect within one year from the promulgation. Rules and guidelines will be drafted for these amendments soon, and details will emerge in a few months.

True Picture of Court Settlements in Patent Disputes Emerges for the First Time

The Institute of Intellectual Property (IIP), a semi-governmental research institute, published in March 2015 a report commissioned by the JPO on the current status of patent infringement lawsuits in Japan.

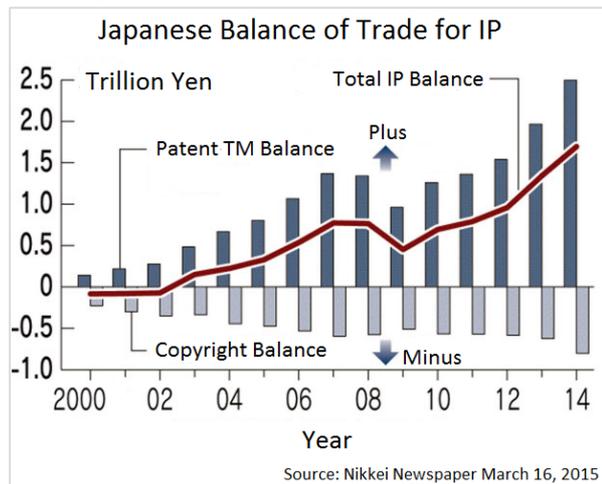
This nearly 500-page report is replete with statistical and survey data, but most notably the true picture of settlements before the courts became clear. About 27% of patent infringement lawsuits end up with settlements before the district courts, while 44% end with court decisions. However, very little was known as to the conclusions of such settlements. Often, a judge pulls out numbers from his division, and reports a much higher percentage of cases resulting in a win for patentees in settled cases without providing any details while the decision-based win rate for patentee is somewhere between 20-25% in recent years. The courts provided the IIP with raw data for recent three years (2011-2013), and the IIP report shows the true picture of settled cases. About a half of the settled cases include some provisions for performance of injunctions, and the distribution of payments are shown in the graph below.

Of the 79 court settled cases, patentees received JPY 5 million (about \$40,000) or less in 47 cases, with a significant number of cases resulting in zero payment (23). A larger percentage of the settled cases seem to favor patentees as compared with the total decision-based win rate (20-25%), but the recovery of litigation costs is still difficult for patentees before Japanese courts.



Balance of Tech Trade Keeps Improving

The Japanese balance of trade based on intellectual property continues to increase. In particular, the balance of technology trade is improving. However, if we look closely at the breakdown, about 80 % of technology trade income comes from overseas subsidiaries of Japanese companies. It seems there is still a long way to go if Japanese companies wish to enjoy the fruits of R&D by way of international licensing. (One trillion yen is currently about US\$ 8 billion.)



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 \* Editor / Patent Attorney, Okuyama & Sasajima

## Editors' Note

This issue includes articles relating to a Supreme Court decision relating to Product-by-Process claims; the 2015 LES Japan Annual Conference in Sendai 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>

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