

WINDS FROM JAPAN

The Licensing Executives Society Japan

Patent Linkage in Japan Vol. 3: Learning from Case Studies

By Yasuko TANAKA *

In [Vol. 1](#), we discussed how patent linkage works in Japan, and in [Vol. 2](#) we examined the 2025 reform brought about by two new notifications from the Ministry of Health, Labour and Welfare (MHLW). In this volume, we will introduce one of the most representative cases arising from issues related to patent linkage.

Before looking at the case, you need to keep in mind the following two points:

1. The Japanese patent linkage process offers no opportunity for litigation of the kind found under Hatch-Waxman; and
2. This is not a patent infringement suit brought after the launch of a generic drug.

You might think, "So what case are we going to look at?!" That is the right reaction! In Japan, some aspects of the law are hard to understand when you compare Japan's system with the patent linkage systems of other jurisdictions. We want readers around the world to know what actually happens in Japan, so that they are ready to enter the Japanese market. Now, let's get started.

Eribulin Mesilate Case (Nipro v. Eisai)¹

The originator drug is the anti-cancer drug Halaven® (API: Eribulin Mesilate).

Before the litigation, the generic company, Nipro, asked the originator, Eisai, whether it would enforce its patent rights based on Japanese Patents [6466339](#) and [6678783](#), filed after the approval of

the originator drug, if the generic product were approved. Eisai replied that it might do so.

After receiving Eisai's reply — and before its generic drug had been approved — Nipro (the generic company), separately from the patent linkage process, filed a declaratory action against Eisai in an attempt to obtain approval. It sought a declaratory judgment that the originator had no right to seek an injunction or damages — on the grounds that the patents were invalid and not infringed — and, in the alternative, that its product fell outside the technical scope of the patented inventions.

Decisions

In the first instance, the Tokyo District Court (TDC) did not reach the merits. Because of the [First Stage of the patent linkage](#), it reasoned, the generic drug was unlikely to be approved; and even if it were approved, the [Second Stage of the patent linkage — Prior Negotiation](#) — would follow before the drug price listing (DPL). The court therefore could not find it likely that the product would actually be listed and marketed, and saw no present danger to the plaintiff's legal position warranting a declaratory judgment. Then, the plaintiff appealed, but the IP High Court of Japan (IPHC) dismissed the appeal.

On appeal, Nipro also raised an argument based on the CPTPP (TPP11) Agreement. It contended that the First Stage of patent linkage can be

¹ TDC, August 30, 2022, 2021 (Wa) 13905; IPHC, May 10, 2023, 2022 (Ne) 10093

justified under Article 18.53(2) of that Agreement only if a declaratory action such as this one is brought in a case where patent infringement is in doubt, and the court recognizes the interest in seeking a declaratory judgment, and rules on the merits. On that basis, Nipro argued that such an interest should be recognized here. The IPHC rejected this argument, holding that Article 18.53(2) does not require a court, in these circumstances, to recognize the interest in seeking a declaratory judgment and to decide the case on the merits.

Takeaways

A declaratory action against the originator is not a workable way to clear patent linkage before approval. The obstacle the generic company complained of — that it could not get approved — was itself the reason the court found no need to decide the case. A rather ironic outcome, is it not?

The courts went further. If the generic applicant is dissatisfied with not being approved, they said, that is a dispute under public law between the applicant and the MHLW, not a private dispute with the originator. The proper defendant is the government.

This is legally coherent, but its practical value depends on whether a pharmaceutical company can realistically sue the regulator. In the United States and in several other jurisdictions, litigation between companies and government agencies is an ordinary feature of regulatory life. In Japan it is not. A pharmaceutical company's business rests on a continuing relationship with the MHLW across its entire portfolio — approvals, pricing, post-marketing obligations — and suing the ministry is, in commercial terms, close to unthinkable. The route the courts pointed to is open in law and closed in practice.

So, a generic applicant — including a biosimilar applicant — that is held up at the First Stage has, at present, no reliable route to have the underlying patent question decided before approval; and the alternative that the Eribulin Mesilate courts identified is one that Japanese business practice makes difficult to use.

Other cases

There are three further cases arising from patent linkage issues: two Aflibercept cases² and a Riva-roxaban case³. Those cases addressed whether an originator's act of notifying the MHLW that the generic applied for would infringe its patent rights could violate the Unfair Competition Prevention Act (UCPA). The court concluded that such acts did not violate the Act, because competition in the pharmaceutical market is not the kind of free competition that the UCPA is intended to protect. In light of these cases, an originator may notify the MHLW that a generic drug for which approval is sought would, if approved, infringe its patent rights.

Summary

Seen in that light, the Expert Panel System introduced on a trial basis in November 2025, which we described in [Vol. 2](#), is a first response to the very problem these cases exposed. Whether it is enough remains to be seen.

In the next volume, we will compare Japan's model with the systems of other jurisdictions. Stay tuned!

~~~~~  
\* *Editor / Patent Attorney, S-Cube Corporation/S-Cube International Patent Firm*

---

<sup>2</sup> TDC, October 28, 2024, 2024 (Yo) 30029 (First case); IPHC, August 13, 2025, 2025 (Ra) 10003 (Second case)

<sup>3</sup> TDC, October 29, 2025, 2025 (Wa) 70139

---

# AIPLA–LES Japan Joint Meeting 2026

By Mr. Roberto CARAPETO \*

LES Japan hosted the 19th AIPLA-LES Japan Joint in-person meeting on April 13, 2026, in Tokyo, continuing the long-standing and fruitful relationship between AIPLA and LES Japan. The joint meeting has become a valued annual opportunity for intellectual property professionals from both organizations to exchange views on timely legal and business issues, strengthen professional ties, and deepen international friendship. The 2026 meeting attracted a full room, with participation almost evenly divided between AIPLA and LES Japan members.

The 19th meeting in 2026 was moderated by Ms. Tomoko Noguchi of LES Japan. Following opening remarks by Mr. Shoei Imai, President of LES Japan, and Mr. Sal Anastasi, President of AIPLA, presenters from AIPLA and LES Japan shared insights on four highly relevant and engaging topics in intellectual property law and licensing practice. Topics were as below:

1. **【AIPLA】 Recent Decisions on the Patent Eligibility of AI**  
*Presented by Mr. Thomas Derbish*  
(Desmarais LLP)
2. **【LES】 Tokyo District Court's SEP Initiative: Establishing a Litigation Framework and FRAND Mediation**  
*Presented by Mr. Shogo Matsunaga*  
(Sonderhoff & Einsel law and Patent office)
3. **【AIPLA】 Ecofactor and the Evolving Evidentiary Standard for Proving Patent Damages**  
*Presented by Mr. Makoto Tsunozaki*  
(Knobbe Martens)
4. **【LES】 Inside the Role: Licensing Across APAC & EMEA in a Global Matrix Organization**  
*Presented by Mr. Mitsuaki Matsumura*  
(IBM Japan)

The first presentation, “Recent Decisions on the Patent Eligibility of AI,” was delivered by Mr. Thomas Derbish of Desmarais LLP on behalf of

AIPLA and offered a timely overview of recent U.S. case law on AI-related patent eligibility. Next, Mr. Shogo Matsunaga of Sonderhoff & Einsel Law and Patent Office, speaking for LES Japan, addressed “Tokyo District Court's SEP Initiative: Establishing a Litigation Framework and FRAND Mediation,” providing practical insights into recent Japanese developments in SEP dispute resolution.



*Ms. Tomoko Noguchi, Mr. Shoei Imai, Mr. Sal Anastasi, and Ms. Chikako Hashimoto*

The third presentation, “Ecofactor and the Evolving Evidentiary Standard for Proving Patent Damages,” was given by Mr. Makoto Tsunozaki of Knobbe Martens on behalf of AIPLA and examined recent U.S. developments concerning patent damages and comparable license evidence. The final presentation, “Inside the Role: Licensing Across APAC & EMEA in a Global Matrix Organization,” was delivered by Mr. Mitsuaki Matsumura of IBM Japan for LES Japan and shared engaging practical perspectives on licensing work within a global business organization.

One of the enduring strengths of this joint meeting is the lively exchange that follows each presentation, and the 2026 edition was no exception. The

four presentations covered diverse yet highly complementary themes, generating many thoughtful questions and comments from the audience. Discussions continued energetically during the reception at Benrishi-Kaikan, where participants from both organizations enjoyed the opportunity to reconnect, continue conversations sparked during the sessions, and further strengthen the close relationship between AIPLA and LES Japan.



*Mr. Thomas Derbish, Mr. Shogo Matsunaga, Mr. Makoto Tsunozaki, and Mr. Mitsuaki Matsumura*



The meeting concluded with closing remarks from Mr. Nick Mattingly, Chair of the IP Practice in Japan Committee of AIPLA, and Ms. Chikako Hashimoto, former President of LES Japan. I would like to express my sincere gratitude to all speakers and organizers for making this year's joint meeting such a success. Once again, the event fulfilled its important role as a forum for meaningful discussion, professional exchange, and warm international fellowship.

~~~~~

** Partner, Licks Attorneys*

2026 LES Japan Annual Meeting

By Yasuo FUJII *

LES Japan held its Annual Meeting on July 10th and 11th, 2026, in Nara City, Nara Prefecture. The Meeting was a great success with more than 230 participants!

Excursions

Before the Meeting started, on the morning of July 10th, the following two excursions took place in parallel.

(1) A golf competition was held at ASUKA Country Club, one of the most beautiful golf courses in Japan. Participants enjoyed not only playing golf but also the harmony of the surrounding nature.



Golf Course

(2) A guided tour took participants to: (i) a ceramic small dish (Akahada-ware) painting experience at Furuse Gyoza; (ii) lunch at Kamenoi Hotel; and (iii) a stroll through the traditional streets of Naramachi. Participants fully enjoyed the region's traditional crafts and culture.



Akahada-ware

Opening Ceremony

The Meeting, held under the theme of "Future Woven by Timeless Wisdom in the Ancient Capital of Nara", began with opening remarks by Mr. Shinya Hondo, Chair of the Organizing Committee. Mr. Shoei Imai, President of LES Japan, then officially declared the Meeting open.



Mr. Shinya Hondo



Mr. Shoei Imai

Keynote Speech 1

Mr. Motoshi Sobue, Project Professor at the Strategic Initiative for Research and Innovation, Nara Institute of Science and Technology, as well as CEO of both Nanolux Co. Ltd. and NeoCure Co. Ltd., delivered the first keynote speech, entitled "Leveraging Technology and Intellectual Property in Deep Tech Startups." He shared his fascinating experiences in managing two deep-tech startups, including expanding business through strategic pivots and acquiring patents. Participants gained valuable insights into both the challenges



Mr. Motoshi Sobue



Mr. Yuichi Takata

and excitement of sustaining and growing a long-term deep-tech business.

Keynote Speech 2

Mr. Yuichi Takata, Chief Researcher at the Data and Information Section, Department of Planning and Coordination, Nara National Research Institute for Cultural Properties, delivered the second keynote speech, entitled "Cultural Properties and IP Rights: For the Development of the Field in the Digital and AI Era." He introduced proactive initiatives addressing critical challenges, such as information overload and IP friction in archaeology and cultural preservation, improving operational efficiency through open data, and conducting cutting-edge research on castle stonewalls using digital technologies and AI. Participants warmly received his unique and passionate presentation.

Banquet

Following the keynote speeches, the Banquet opened with an address by LES Japan President Mr. Shoei Imai, a congratulatory speech by Mr. Takanori Nishimura, Deputy Governor of Nara Prefecture, and a toast by Ms. Ningling Wang, President of LES International. Participants enjoyed stimulating conversations while savoring a delicious buffet featuring Nara specialties and local sake. They were also treated to a traditional Gagaku music and dance, a classical performing art with over a millennium of history, presented by a local ensemble.



Banquet



Gagaku



Ms. Ningling Wang



Ms. Tomomi Fujita

After-Party (Friendship Night)

Following the Banquet's closing remarks by Ms. Tomomi Fujita, President-Elect of LES Japan, an after-party was held late into the night, providing members with further opportunities for friendly, face-to-face networking in a relaxed atmosphere.



After-Party

Concurrent Workshops

The second day of the Meeting (July 11th) opened with four concurrent workshops hosted by: (1) the U.S. Issues Working Group (WG) and the European Issues WG; (2) the Business Law and Intellectual Property Management WG; (3) the Academia and Industry R&D Collaboration Management WG; and (4) the IP Finance WG and Branding WG. Members attended the sessions that best aligned with their interests.



Workshop
Workshop

Panel Discussion

Following the workshops, a panel discussion was held on the theme "Intellectual Property Licensing Evolving with Generative AI and DX: Strategy Shift in AI-First Era." The panel featured four distinguished speakers: Ms. Kumiko Takemori (General Manager, Intellectual Property Department, Management Division, YUKIGUNI FACTORY CO., LTD.; The First License Committee Chairperson, Japan Intellectual Property Association), Mr. Keita Yonemori (Manager, Medical Intellectual Property Division, Intellectual Property Technology Center 1, Corporate Intellectual Property and Legal Headquarters, CANON INC.; The Second License Committee Chairperson, Japan Intellectual Property Association), Mr. Fumio Imoto (Senior Executive Professional / General Manager, IP Process Transformation Department, Intellectual Property Management and Rule Making/Standardization Division, NEC Corporation) and Mr. Hidenori Yorozu (President, Yorozu Intellectual Property Strategy Consulting Co-Representative, Generative AI Utilization Promotion Council, Intellectual Property & Intangible Assets Governance Association Former Corporate Officer, General Manager of the Intellectual Property Department at Daio Paper Corporation). The session was moderated by Ms. Chikako Hashimoto (Patent Attorney, Chief Manager, Trademark Department, Sakai International Patent Office Immediate Past President of LES Japan). The thought-provoking discussion inspired participants to reflect on the transformative role AI will play in the future.



Panel Discussion

Closing Ceremony

Finally, the Meeting concluded with a preview of the next year's LES Japan Annual Meeting in Kumamoto City, presented by Mr. Koichiro Yamashita, Chair-Elect of the Organizing Committee.



Mr. Koichiro Yam-

~~~~~  
\* Editor / Patent Attorney, Haruka Patent & Trademark Attorney

**By Koichiro YAMASHITA \***

### **Tokyo District Court Grants Injunction for Infringement of a FRAND-Encumbered Patent**

In its judgment of June 23, 2025, in *Pantech v. Google* (Case No. 2023 (Wa) 70501), the Tokyo District Court granted an injunction for infringement of a standard-essential patent (SEP) subject to a FRAND commitment. Previously, in its Grand Panel decision and judgment of May 16, 2014, in *Samsung v. Apple* (Case Nos. 2013 (Ra) 10007, 2013 (Ra) 10008, and 2013 (Ne) 10043), the Intellectual Property High Court held that seeking an injunction against a party willing to take a license on FRAND terms constitutes an abuse of rights under Article 1(3) of the Civil Code and is therefore impermissible. That precedent made it difficult to obtain an injunction for infringement of a FRAND-encumbered SEP.

In the present case, after disclosing its provisional view that the patent had been infringed, the court encouraged settlement negotiations concerning the plaintiff's global SEP portfolio. Both parties agreed to participate. Because the parties' proposed royalty-calculation methods (the plaintiff's revenue-based approach and the defendant's fixed-per-unit approach) were incompatible and difficult to reconcile, the court asked the defendant to submit a settlement proposal using the methodology adopted in the Grand Panel judgment. That methodology begins with the sales price and sales volume of the end product (the "Grand Panel Method"). However, the defendant asserted that its products encompassed a wide variety of models and that applying the Grand Panel Method would make the calculation excessively complex. It declined to disclose the sales price and sales volume for each product or submit a settlement proposal based on that method. The court therefore found that special circumstances existed indicating that the defendant was unwilling to take a license on FRAND terms, and it granted the injunction.

### **Tokyo District Court Issues SEP Litigation Guidelines to Facilitate Agreement on Global FRAND Royalty Rates**

In patent infringement actions involving standard-essential patents ("SEP litigation"), the Tokyo District Court will, in principle, encourage settlement at the first hearing and then schedule a structured, intensive series of settlement conferences.

Disputes over infringement (including claim construction) and invalidity are usually limited in scope, and the principal issue is often the abuse-of-rights defense, namely whether the defendant is willing to take a license on FRAND terms. If no settlement is reached and the settlement proceedings are terminated, both parties must promptly submit consolidated briefs and supporting evidence addressing the course and substance of the negotiations. The court will then determine, on the basis of those submissions, whether the abuse-of-rights defense has been established. Where infringement or invalidity is disputed, the court will set deadlines at the first hearing for two rounds of written submissions from each side: the plaintiff's opening submission, the defendant's response, the plaintiff's reply, and the defendant's sur-reply. The case will generally proceed on the written record, with a technical briefing session scheduled if necessary.

During settlement proceedings, the court will seek to prevent both hold-up and hold-out, establish a fair and neutral framework for the negotiations, and refine and present settlement proposals that take account of the course of the parties' negotiations and their respective positions. With respect to terms other than the global FRAND royalty rate, the parties must confer promptly after the first hearing and prepare a written agreement. If a settlement is reached, the agreement will be attached as an appendix to the settlement record.

In its complaint, the plaintiff must clearly explain its calculation methodology and propose a global FRAND royalty rate using a top-down approach, a comparable-license approach, or a combination of the two. In its answer, the defendant must specifically state whether it admits or denies the factual basis for the plaintiff's calculation, explain its objections to the plaintiff's methodology, present a counterproposal supported by its own calculation, and submit supporting evidence, including

sales volumes and sales revenue. If the defendant does not voluntarily submit the necessary evidence, the court may find that it is unwilling to take a license on FRAND terms.

### **Supreme Court of Japan Rules on Copyrightability of Mass-Produced Utilitarian Articles**

In a judgment delivered by its Second Petty Bench on April 24, 2026, in the *TRIPP TRAPP* case (Case No. 2025 (Ju) 356), the Supreme Court held: "Where the shape or other features of all or part of a mass-produced utilitarian article can be conceptually perceived, separately from the configuration derived from its function, as a creatively produced expression of thoughts or sentiments, the whole article or that part constitutes a

'work' in the artistic domain within the meaning of Article 2(1)(i) of the Copyright Act."

Applying that standard, the Supreme Court further held: "The shape or other features of all or part of the chair at issue can be perceived only as a configuration derived from its function as a children's chair; they cannot be perceived, separately from that configuration, as a creatively produced expression of thoughts or sentiments. Accordingly, the chair does not constitute a 'work.'" On that basis, the Supreme Court denied copyright protection for the chair.

~~~~~  
* Editor / Patent Attorney, Innoventier IP Attorneys

Editors' Note

This issue includes articles "Patent Linkage in Japan Vol. 3: Learning from Case Studies" by Ms. Yasuko TANAKA, "AIPLA-LES Japan Joint Meeting 2026" by Mr. Roberto CARAPETO, "2026 LES Japan Annual Meeting" by Mr. Yasuo FUJII, and "IP News from Japan" by Mr. Koichiro YAMASHITA.

<https://www.lesj.org/en/winds/new.php>

Thank you for supporting "*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:

<https://www.lesj.org/en/winds/backnumber/index.php#recentNum>

WINDS from Japan Editorial Board Members, 2026

Editor in Chief:

Yasuo FUJII

Editors:

Shoichi OKUYAMA;

Junichi YAMAZAKI; Kei KONISHI;

Naoki YOSHIDA; Mitsuo KARIYA;

Takao YAGI; Yoko NATSUME;

Dennis M. HUBBS; Yasuko TANAKA;

Koichiro YAMASHITA