

WINDS FROM JAPAN

The Licensing Executives Society Japan

Message from the New President

By Kenichi Nagasawa *



I would like to thank all of the LES Japan members for their understanding and cooperation on the various activities of LES Japan.

I am honored to announce that I was appointed as the 26th President at the LES Japan general meeting held on February 16th of this year. The responsibility of the long established society, seeing its 50th anniversary this year, makes me sanguine and encourages me to do my very best.

I would like to say a few words on my inauguration as President of LES Japan.

LES Japan is positioned as a local branch of the Licensing Executive Society International (LESI). I believe LES Japan is unique in that it has a more harmonized member composition among lawyers, patent attorneys, academia and industry, compared with its counterparts.

LES Japan provides numerous opportunities for its members to stay abreast of the industry as well as encourage communal interactions. Working group activities, which respond to the latest IP trends, works as a cue for members to start new communication networks. Timely seminars such as monthly regular sessions have welcomed speakers from various circles, including legal, industry and governmental organizations. The LES Japan web-sites and publications also publish thought-provoking content addressing myriad topics and from diverse view-points.

I would also like to thank my predecessors who have established such valuable features and would like to move them forward further. At the same time, I am looking forward to having more talks with members on how LES Japan should operate and take on any challenges for the next generation.

Our time is in a big swell of change and I believe these changes will have significant impacts on LES Japan and our industry globally.

Starting in 2020, the COVID pandemic is still raging worldwide, which has encouraged remote-working and web conferences. On the other hand, it is often pointed out that DX shift is not fast enough in Japan. It is expected that this change will further diversify people's preferences and needs.

Security issues among the US, China and Russia have been dangerously surfacing, which has made "economic security" an ordinary phrase. This is leading to many issues in areas such as supply chain and basic infrastructure development.

Environmental issues and human rights issues are also increasingly critical in the economic security context. On the technology development and business front, more attention is being attracted by changes of culture/value typically represented by Metaverse, which makes full use of NFT (Non Fungible Token) and XR (Cross Reality) and advancement of military industry and space industry, which is realizing use of revolutionary technology such as Quantum computers.

In order for our LES Japan to play a responsible role domestically and internationally under this time of big change as described above, I would like to introduce our policy for this year, following approval at the general meeting:

LES Japan has set forth its objective in article 3 of the LES Japan bylaws:

1. Improvement of professional ability and ethics of people who are responsible to licensing activities;
2. Better social recognition of licensing activity; and
3. Contribution to advancement of licensing activity and better transfer/exchange of intellectual property.

Per the guideline, in order to achieve the LES Japan's objectives above, we will focus on six themes (1) to (6) below to guide our activity (i.e. (i) Mutual exchanges among our members; (ii) Study and research of licensing activity; and (iii) Publication of the activity) set forth in article 4 of LES Japan bylaws, considering use of the online environment taking in account COVID's impact, positively taking on new challenges without hesitation.

(1) First, this year LES Japan will celebrate the 50th anniversary and I would like to use the opportunity to hold a Commemorative symposium in order to provide a chance for members to interact with each other and other IP related stakeholders.

Currently, it is scheduled for September 2022. I would also like to issue a 50th commemorative publication to publicize the LES Japan activities. I expect as early a publication as possible in 2023. I will also have commemorative sessions and round-table talks in addition to the commemorative symposium to make the publication more fruitful.

(2) Second, LES Japan's annual meeting, where members follow and share the latest IP trends, strengthen mutual exchange and make presentations for LES Japan activities of the year, will be held in Otsu, Shiga as a 50th commemorative anniversary meeting. This meeting will be a hybrid using online participation and carefully considering the COVID situation. We will well prepare various plans including keynote speeches and panel discussions, to make it as useful as possible, even if the meeting is only online.

(3) Third, in order to increase the benefit for members and to draw a picture of the desirable state of

the LES Japan in the future, we will encourage active discussions on untouched issues through task-forces having younger members involved. Using the insights obtained from these task forces, we will enact the valuable proposals coming out of such discussions.

(4) Fourth, for working groups operated by our members who play the fundamental role to support the operations of the LES Japan, we will make full use of online discussions to further improve the content of the works and encourage more members to participate. We will also prepare more opportunities to disseminate the fruits of their works.

(5) Fifth, for monthly study sessions and a practical license course, we will make full use of online sessions, select timely themes and provide training opportunities and study programs which should be of more benefit and interest for the members.

(6) Sixth, 2022 is the year where Mr. Ichiro Nakatommi and Ms. Junko Sugimura, both former chairs of the LES Japan will work as chair and vice chair of LESI. We will strongly support their international activities and actively contribute to LESI events and conferences.

We also have welcomed as an honorary advisor Mr. Yoshiyuki Iwai, former commissioner of the JPO and a current Chairman of the Japan Institute for Promoting Invention and Innovation.

In closing, I would like to make, with support from all the members, a more useful environment where all the members can make free and open activities and proposals, deepening ties with other bodies such as the Japan Business Federation (Keidanren) and the Japan Intellectual Property Association (JIPA).

Two years from now, I would appreciate having support and cooperation from you.

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\* *Head of Corporate Intellectual Property & Legal HQ, Head of Economic Security Office, Senior Managing Executive Officer, Canon Inc.*

# Inventorship of Experimenter: One of Co-First Authors But Not One of Co-inventors

By Yasuo Fujii, Ph.D.\*

There is no doubt about the importance of experimental results in the fields of biotechnology and chemistry. Therefore, most laboratories need excellent experimenters, who are sometimes graduate school students in university laboratories.

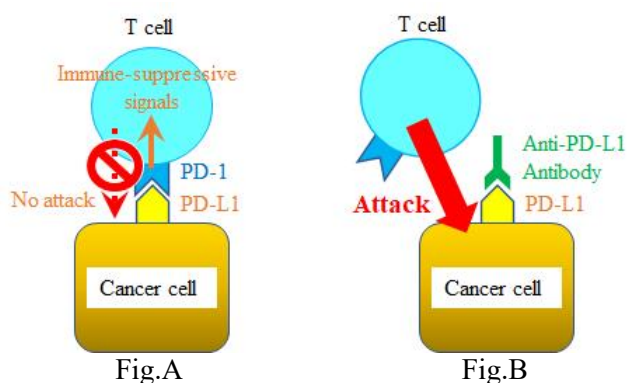
This article introduces a recent court case in Japan where a person who was engaged in experiments as a graduate school student, alleged inventorship.

## Background

The patent at issue is Japan Patent No. 5885764 (“the ’764 patent”) related to “an agent for treatment of cancer comprising, as an active ingredient, an anti-PD-L1 antibody that inhibits the immune-suppressive signal of PD-1.

The ’764 patent is one of several Japan patents that originated from one international application, where they are related to a medicine containing an anti-PD-1 antibody or an anti-PD-L1 antibody.

PD-1 is a receptor expressed on the surface of T cells, an immune system cell, which attacks cancer cells. On the other hand, some cancer cells express PD-L1, which bind to PD-1, on their surface. When PD-1 of a T cell binds to PD-L1 of a cancer cell (see Fig. A), an immune-suppressive signal is transmitted to the T cell and hence the T cell loses its ability to attack the cancer cell.



PD-1 was discovered in 1992 by Dr. Tasuku Honjo at Kyoto university, who is one of the co-inventors of the above-mentioned patents including the ’764 patent. The research team led by Dr. Honjo revealed that each of an anti-PD-1 antibody and an anti-PD-L1 antibody blocks the interaction between PD-1 and PD-L1 and activates the immune system against cancers by inhibiting the immune-suppressive signal (see Fig. B for anti-PD-L1 antibody).

In 2014, a medicine containing an anti-PD-1 antibody, named OPDIVO® (Nivolumab), was launched on the market for cancer immunotherapy by Ono Pharmaceuticals Co., Ltd. (“Ono”).

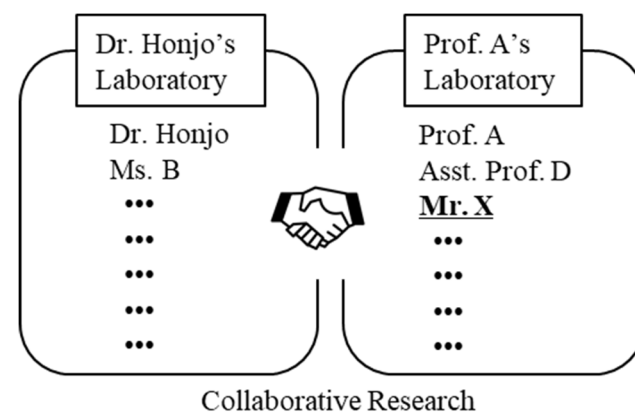
In 2018, Dr. Honjo won the Nobel Prize in Physiology or Medicine, with Dr. James P. Allison, for their discovery of cancer therapy by inhibition of negative immune regulation.

On the other hand, there was a dispute on inventorship of the U.S. patents corresponding to the above-mentioned Japan patents, where the courts held that Dr. Gordon Freeman and Dr. Clive Wood should be added as co-inventors (*Dana-Farber Cancer Institute v. Ono Pharmaceutical Co.*, No. 19-2050 (Fed. Cir. July 14, 2020)).

## District Court’s Holding

In 2017, a person (“Mr. X”) who was engaged in experiments for the research on PD-L1 and anti-PD-L1 antibodies sued alleging that he should be added as one of the co-inventors of the ’764 patent.

The Tokyo District Court carefully confirmed the facts. In 1999, Dr. Honjo started collaborative research on PD-L1 and anti-PD-L1 antibodies with the Professor (“Prof. A”) specializing in cancer immunity at Kyoto university.



In 2000, Mr. X joined the Prof. A’s laboratory as a graduate school student and started to be involved in the collaborative research.

In July 2002, a patent application, on which the above-mentioned patents including the ’764 patent claimed priority, was filed before the Japan Patent Office.

In September 2002, an academic paper entitled “Involvement of PD-L1 on tumor cells in the escape from host immune system and tumor immunotherapy

by PD-L1 blockade” was published in the *Proceedings of the National Academy of Sciences* (“PNAS paper”).

| '764 Patent                                           | PNAS paper                                                                                                             |
|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Inventors<br>Dr. Honjo<br>Prof. A<br>Ms. B<br>Mr. C   | Authors<br>Ms. B (co-first author)<br><b>Mr. X</b> (co-first author)<br>Asst. Prof. D<br>Mr. E<br>Dr. Honjo<br>Prof. A |
| Fig.1(A)<br>Fig.1(B)<br>Fig.2(A)<br>Fig.3(A)<br>Fig.5 | Fig.1B<br>Fig.1C<br>Fig.2AB<br>Fig.3A<br>Fig.4                                                                         |

The table above compares the co-inventors of the '764 patent and the co-authors of the PNAS paper. The table also lists the figures showing the results of experiments conducted by Mr. X, where the figures of the '764 patent respectively correspond to the figures of the PNAS paper.

As shown in the table, Mr. X is one of the co-first authors of the PNAS paper but not one of the co-inventors of the '764 patent, though they share several experimental results obtained by Mr. X.

In determination of whether Mr. X is one of the co-inventors of the '764 patent invention, the court firstly held that the '764 patent invention is based on the technical idea that an anti-PD-L1 antibody activates the immune system against cancers by inhibiting interaction between PD-1 and PD-L1.

Then the court proposed comprehensive consideration of facts including the following points:

- (i) contribution in conceiving the technical idea that an anti-PD-L1 antibody activates the immune system against cancers by inhibiting interaction between PD-1 and PD-L1;
- (ii) contribution in preparation and selection of anti-PD-L1 antibodies which inhibit interaction between PD-1 and PD-L1; and
- (iii) contribution in design and construction of experimental systems and degree of creative involvement in the experiments.

Regarding the point (i), Mr. X alleged that the relationship between the PD-1/PD-L1 interaction and the cancer treatment had been gradually recognized through his experiments. However, the court held that Mr. X was not involved in conceiving the above-held technical idea, since Dr. Honjo and Prof. A had already shared the above-held technical idea and had already begun concrete experiments to prove it before Mr. X joined the Prof. A's laboratory.

Regarding the point (ii), Mr. X alleged that his contribution in selecting anti-PD-L1 antibodies was

significant. However, the court held that though Mr. X actually played a certain role, the degree of his contribution was merely limited, since Assistant Professor (“Asst. Prof. D”) had already obtained hybridoma cells producing the anti-PD-L1 antibodies by instructions from Prof. A before Mr. X joined the Prof. A's laboratory.

Regarding the point (iii), Mr. X alleged that he conceived the experiments by himself. However, the court held that the series of experiments were designed and constructed by Prof. A and Asst. Prof. D from a logical and scientific point of view, and that Mr. X conducted the experiments with their advice and guidance.

Consequently, the court concluded that Mr. X was not found to be one of the co-inventors of the '764 patent.

### IP High Court's Holding

Mr. X appealed to the IP High Court. However, the IP High Court affirmed the District Court's conclusion, though it corrected some of the District Court's holdings.

The IP High Court held that the inventor should be a person who has conceived a technical idea of an invention specified in the claims or a person who has creatively been involved in a realization of the technical idea. Then the court also held that even if a person has been involved in experiments in a process of realization of the technical idea, the person is not an inventor if the involvement is not creative in relation to the technical idea of the invention.

Consequently the court concluded that Mr. X was not found to be one of the co-inventors of the '764 patent, since Mr. X's contribution in the experiments was not creative in relation to the technical idea of the patent invention.

### Inventorship of Experimenters

The more complex or advanced the technical idea on which an invention relies, the more important the experimenter's role providing experimental results supporting the invention.

On the other hand, according to the courts' holdings, even if an experimenter conducted many experiments important enough so that the results thereof are included in a patent specification, the experimenter is not deemed as an inventor without creative involvement in relation to the technical idea of the claimed invention.

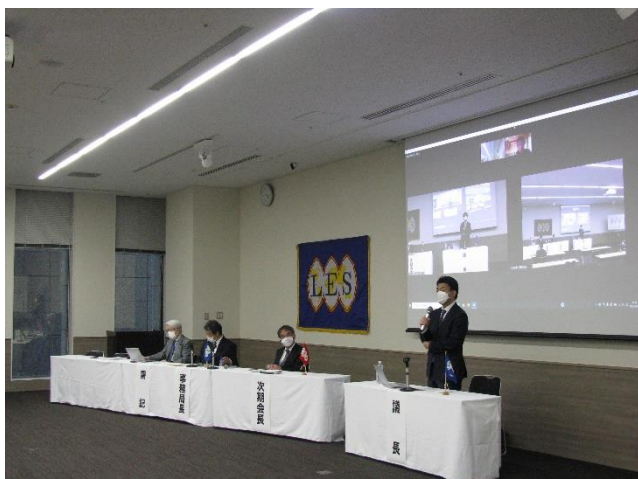
While it is not yet very clear what the creative involvement is, the court case introduced here has provided a certain standard in determining whether an experimenter is an inventor or not.

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* Editor / Patent Attorney, Haruka Patent & Trademark Attorney

2022 LES Japan Annual General Meeting

By Yasuo Fujii, Ph.D.*

The 2022 LES Japan Annual General Assembly was held on February 16th, 2022 in a hybrid manner that allowed the members to participate in person or online.



Tokyo Venue

Prior to deliberation of the bills, Chair Hiroki Saito, former President, summarized the activities of LES Japan in the previous two years, which had started amid the COVID-19 pandemic. In addition, Mr. Saito mentioned the significance of activities in this year of the 50th anniversary for LES Japan (LESJ). Finally, Mr. Saito, who is retiring as President due to the expiration of his term, expressed his sincere gratitude to all the members.



Chair Hiroki Saito, the former President

In deliberation of the bill, Mr. Kenichi Nagasawa, the new President, introduced the business plan of LESJ this year, including the 50th anniversary project in addition to the regular events.

Mr. Nagasawa further introduced his vision to seek an advanced role of LESJ in the society by seeking out more challenges. Specifically, Mr. Nagasawa proposed promoting communications with other organizations of industry, government and academia in Japan. Furthermore, since Mr. Ichiro Nakatomi and Ms. Junko Sugimura, former Presidents of LES Japan, are respectively becoming President and Vice President of LES International (LESI), Mr. Nagasawa emphasized providing more support to LESI and other national or regional societies, and he expected that the presence of LESJ would be increased.



Mr. Kenichi Nagasawa, the new President

LESJ is planning special events for celebrating its 50th anniversary this year, including a grand symposium inviting guests from various fields of Intellectual Property, and a special publication including articles about not only present issues and histories but also future visions.

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

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# *IP News from Japan*

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

## **Secret Patent Applications Coming to Japan**

A bill to establish a new law called Economic Security Promotion Act should pass the Diet and become a law soon. The new law should strengthen supply chains for stable procurement of semiconductors and other vital products. It also stipulates steps for preventing information leakage in the fields of nuclear power and military technologies.

With the new law, Japan seeks to align itself with the US and European countries, which have advanced measures in promoting economic security, as China's rise has intensified global technology competition.

The bill passed the House of Representatives on April 7th with support from the ruling LDP and its coalition partner, *Komeito*, as well as opposition parties, including the Constitutional Democratic Party of Japan (CDP). It is set to be voted on in the House of Councilors and is expected to pass soon.

The envisioned law has four pillars: securing stable supply of strategically important products and

natural resources, securing stable provision of core infrastructure services, supporting the development of important cutting-edge technologies, and keeping patent applications secret for sensitive technologies related to nuclear and military technologies.

Nuclear or military inventions made in Japan will have to be first filed in Japan. It will be possible for applicants to consult with the JPO to determine whether their invention would fall under the new requirement. An applicable application will be indicated as such within one year from the filing, and a renewable secrecy time will be also specified. The JPO will carry out initial screening and send candidate applications to the Cabinet Office, which will then consult with relevant agencies and individuals before making a final determination. According to the JPO, about ten patent applications are expected each year to be designated for the new rules. The applicants who have patent applications that are entered into this scheme will be compensated.

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* *Editor / Patent Attorney, Okuyama & Sasajima*

Editors' Note

This issue includes articles “Message from the New President” by Mr. Kenichi Nagasawa, “Inventorship of Experimenter: One of Co-First Authors But Not One of Co-inventors” and “2022 LES Japan Annual General Meeting” by Mr. Yasuo Fujii, and “IP News from Japan” by Mr. Shoichi Okuyama.

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/new.php>

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