

WINDS FROM JAPAN

The Licensing Executives Society Japan

Heightened Due Diligence by Licensees?

– A Misconception about a Licensed Patent May Not Nullify the License Agreement –

By Kei KONISHI*



Many companies are well aware of the value of patent licensing. The exclusivity of patents requires companies that want to produce or sell their products which are covered by another's patent to obtain patent licenses from the patentees. It is, however, not surprising for a licensed patent to later be found to be irrelevant to the licensee's product, which raises a dispute between the licensee and the licensor. What if a licensed patent is invalidated or a licensee's product is found to be outside the scope of the licensed patent in later years? May a licensee seek monetary relief when a licensed patent is later found useless for operating its business?

The Intellectual Property High Court (IP High Court) recently rendered a landmark decision addressing these issues in favor of not licensees but licensors in the "Pebble Bed Bath" Case, 2008 (Ne) No. 10070 (decided on January 28, 2009).

Key Facts in the "Pebble Bed Bath" Case

At issue in this case was a patent directed to a certain construction of a "pebble bed bath" which has a flat surface made up of pebbles that are heated by hot water from underneath. By lying down or sitting on the top pebble layer of the

bath, a user could enjoy relaxation and therapeutic effects.

The patentee/licensor, a small business operating a public bath, granted a statutory exclusive license (the Patent Act, Art. 77) within certain areas of Japan to a small start-up business ("Licensee 1"). Licensee 1 paid royalties of 30 million JPY to the licensor.

Prior to their license agreement, the licensor and a non-exclusive licensee, a small business that had already started a pebble bed bath business together with the licensor ("Licensee 2"), explained to Licensee 1 that his product was the embodiment of the patent, and therefore, within the scope of the patent. They thus persuaded Licensee 1 to obtain a license for the purpose of producing and selling the pebble bed bath that was identical to Licensee 2's product. Believing that the patent license was crucial to his new business, Licensee 1 entered into a patent license agreement with the licensor and then, as a franchisee, launched in the market his pebble bed bath product, which was identical to Licensee 2's product. In fact, however, Licensee 1's product, as well as Licensee 2's product, was outside the scope of the licensed patent. It is noted that the patent license agreement contained a "non-restitution" clause that forbade Licensee 1 to assert restitution of a royalty payment "under any circumstances".

Since then, due to another dispute, the licensor terminated the non-exclusive patent license agreement with Licensee 2 and then filed a patent infringement lawsuit against Licensee 1. In response, the defendant (Licensee 1) filed a petition for invalidation of the licensed patent before the Japan Patent Office, and the licensed patent was conclusively determined to be invalid. Upon the licensed patent being invalidated, Licensee 1 sued the licensor claiming restitution of the already paid license royalties.

A Licensee's Misconception and Nullity of a License Agreement

Under the Japanese Patent Act, Art. 125, where a conclusive decision of patent invalidity is made binding, the invalidated patent is retroactively deemed never to have existed. A license agreement based on an invalidated patent between parties, however, does not automatically become null or cancellable as a matter of course according to precedents in Japan.

A licensee can assert nullity of a license agreement and thus assert restitution of the already paid license royalties because the paid royalties turn into unjust enrichment, provided that the licensee's misconception that brought him into the license agreement falls into a statutory "mistake in any element of the juristic act" (the Civil Code, Art. 95) that renders the license agreement null retroactively. According to the Civil Code, Art. 95, however, a licensee with a misconception may not assert nullity of the license agreement if he/she acted with gross negligence.

A key issue involved in the "Pebble Bed Bath" case was whether or not Licensee 1's misconceptions (i.e., that the patent was valid and Licensee 1's product was within the scope of the patent) fell into a statutory "mistake" under the Civil Code, Art. 95, which would lead to nullity of the patent license agreement and allow restitution of the already paid license royalties.

The Tokyo District Court Decision Affirming Restitution

In interpreting the "non-restitution" clause in the patent license agreement at issue, the Tokyo District Court held that the clause was to be construed as an agreement that the licensor had

no duty to make restitution of the already paid license royalties in case the patent was conclusively invalidated at a later date. Accordingly, the District Court declined Licensee 1's assertion for restitution of the already paid royalties based on his misconception that the patent was valid.

On the other hand, the District Court held that the "non-restitution" clause did not preclude Licensee 1 from asserting restitution of the royalties in the case of a statutory "mistake" concerning the license agreement. Accordingly, reasoning that Licensee 1 would not have entered into the license agreement if he had known that in fact his pebble bed bath product was outside the scope of the licensed patent, the District Court found statutory "mistake" in the fact that Licensee 1 came to believe that his product was within the scope of the patent as a result of the licensor's explanation. The District Court therefore ordered the licensor to retribute the already paid license royalties of 30 million JPY.

Reversal Decision at the IP High Court

On appeal, the IP High Court reversed the Tokyo District Court decision in part, ruling that commercial companies must pay due care in considering the patent to be licensed when entering into a patent license agreement. In particular, the IP High Court required that companies comprehensively consider, for example, the breadth of the patent at issue, the likelihood of future invalidation of the patent, and the degree of usefulness of the patent to contribute to the licensee's business by means of, for example, an expert opinion.

In light of the above higher standards, the IP High Court denied finding a statutory "mistake" in the fact that Licensee 1 came to believe that his product was within the scope of the patent as a result of the licensor's explanation. Further, the IP High Court stated that even if Licensee 1 was under a misconception concerning the license agreement in some respects, his gross negligence would forbid him from asserting the nullity of the license agreement.

Ultimately, the IP High Court reversed the District Court's order for restitution of paid royalties and declined all assertions brought by Licensee 1. Licensee 1, who relied solely on

the story from the licensor, conclusively lost the case.

Due Diligence Required for Possible Licensees

From a licensee's perspective, in light of the above IP High Court's precedent favoring the licensor, a licensee should conduct due diligence on a patent to be licensed when entering into a license agreement, in particular on the breadth and validity of the patent, and the correlation between the patent and the licensee's product,

even if the licensor gives certain assurances of the patent to be licensed. In that sense, to obtain an expert opinion might be helpful. Further, in negotiating terms and conditions of the license agreement, it is advisable to clarify the scope and limitations of the "non-restitution" clause.

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## “Post 2010 patent expiry. Strategies and challenges for pharmaceutical companies”

By **\*Bruno ROSSI**

Four industry licensing experts presented their views:

- ◆ Greg Wiederrecht, VP & Head, External Scientific Affairs, Worldwide Licensing & External Research, Merck & Co, Inc.
- ◆ Bruno Rossi, Head of Strategic Planning & Business Development, Bayer Yakuhin Ltd.
- ◆ Tetsushi Inada, Owner, Pharma-East Insight, Inc.
- ◆ Junichi Nakamichi, Representative Director and CEO, Sandoz K.K.

Our panel, conducted in English, attracted about 30 participants.

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Bruno Rossi introduced the panel and kicked off the topic with a reference to industry challenges formulated already in 2007, then zoomed to current headlines about healthcare reform in Japan (e.g., for a new pricing system) and in the USA, a key action point of President Obama.

Mr. Wiederrecht outlined the “Issues Facing Pharma”. The pharmaceutical market has drastically changed over the last few years. Industry regulators are more conservative, payer pressure on reimbursement has increased, the output research is lower, etc.

He showed how the loss of patent protection on blockbuster products goes beyond an impact

on sales and profit. It forces companies to adopt new strategies for growth, through more active licensing, partnering or acquisitions, entry into new segments, seeking growth from generics or the more difficult biosimilars – the fourth topic on our panel – and, finally, expansion into geographical territories. The best new regional growth opportunities today are in the so-called “pharmerging” markets of China, India, Russia, Latin America or Eastern Europe.

Another consequence is the consolidation of the pharmaceutical industry. Already, the seven major global pharmaceutical companies of 2004 trace their history to thirty independent companies in the 80's. Two major mergers are currently ongoing in the USA, with Pfizer in the process of acquiring Wyeth and Merck merging with Schering-Plough. Mr. Wiederrecht explained how, because of similar pressure, consolidation has reshaped Japan or, less widely known, biotech [*This is a strange juxtaposition. Why are “Japan” and “biotech” linked here?*] and why major Japanese companies have become avid acquirers.

In “A View from Japan”, Mr. Rossi underlined that Japanese companies are not isolated any more as they face the same challenges as their foreign competitors, even more so when they operate globally or compete with foreign companies in their home market. Safety has been an overriding concern of Japanese drug regulators, doctors and patients. Cost containment is a constant feature of the Japanese market. Signs point to recent interest in rewarding and funding prevention.

The Japanese pharmaceutical market shows, however, a few differences:

- ◆ A well-established national health insurance system (in contrast to the USA but closer to most European countries) but with unique weaknesses recently visible, e.g., in emergency services, obstetrics, pediatrics, organ transplants, etc.
- ◆ The delay in bringing modern drugs, medical technologies and vaccines to the country. This has moved beyond the negotiation agenda between governments; it is now a topic for public debate, known as the “drug lag”.
- ◆ Generics – relatively high-priced in Japan – have not had the same impact as in other western markets. Japan’s Ministry of Health continues to prefer price control and bi-annual price reductions rather than allowing market forces to keep costs in check, with only limited interest to analyze health outcomes.

Against all odds, and the backdrop of an economy struggling with recession, Japan is now returning to being a growth market sustained by the demand for new technologies (filling that “drug lag”), the country’s wealth and its universal health insurance coverage and access and finally, the pressure of an aging population.

To illustrate the challenge to specific companies, Mr. Rossi referred to a book<sup>1</sup> “The Shock of the Year 2010 for the Pharmaceutical Industry”, written by Fumiyoshi Sakai, financial analyst at Credit Suisse, who follows the pharmaceutical industry.

Biotech – Mr. Inada addressed in detail the contribution from biotech companies in sharing the innovation risk. The challenges of the biotech sector amplified in 2008 with the financial crisis. The contribution of biotech to the discovery and development of innovative drugs is now firmly established but the sudden squeeze on funding puts more pressure on this business model.

Mr. Inada argued the case for a new approach: proof of relevance, not simply proof of concept. Against a more demanding environment, from R&D funding to regulatory approval, “validating

new targets and mechanisms is less important than demonstrating clinical differentiation”.

Biotech success stories abound in the USA while, as our healthcare workgroup showed at previous LES panel discussions in 2007 and 2008, the environment for biotech is less favorable in Japan.

Biosimilars – When we confirmed Mr. Nakamichi as our fourth speaker, who would have thought that the Ministry of Health, Labor and Welfare would approve somatropin, Sandoz’s human growth hormone, as Japan’s first biosimilar, one week before the LES annual meeting in Kyoto?

Biological products represent a major sub-segment of the world pharma market, worth about US\$100 billion today with annual growth prospects of 10%, faster than the expected growth of other drugs. By 2013, half of the global sales of pharmaceutical products reaching patent expiry will be from biologics. Mr. Nakamichi commented that several companies have publicly stated their ambitions in biosimilars or “follow-on biologics”, with Sandoz having one of the best records so far.

He guided us through the regulatory pathway for biosimilars and the regional differences. The EU has a clear regulatory path. This regulatory leadership gives EU-based manufacturers a solid basis to address legitimate concerns about quality, safety and efficacy. Japan has recently clarified and publicized its regulatory path while the debate is still on-going in the USA.

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After these individual presentations, we had ample time for questions. All four speakers concurred that opportunities are there in spite of the challenges in the industry. While some companies may be better equipped than others, the choice of strategies is wide open. Core to many options, licensing and partnering remain two critical skills and opportunities.

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¹ Published in Japanese by Kanki Shuppan.

IP News from Japan

By Shoichi OKUYAMA*

Generics Fight IP Headwinds

On May 29, 2009, the Third Division of the Intellectual Property High Court (IP High Court), presided over by Judge Toshiaki Iimura, rendered three decisions for the same group of cases, reversing decisions the Japan Patent Office (JPO) had issued against Takeda Pharmaceutical to reject its applications for patent term extensions (case Nos. 2008 (gyo-ke) 10458, 10459 and 10460). One of the subject patents (Japanese patent No. 3677156) relates to a drug made up of a fast-release composition and a surrounding slow-release composition containing three particular components, without specifying what the active component is. In fact, the products that were the subject of the new approvals in question contained morphine hydrochloride, an active component that has long been known. Based on such approvals for the slow-release drugs Takeda obtained in September 2005, it applied for patent term extensions. The JPO rejected these applications, essentially because the active component was not at all new.

The system of patent term extension started in Japan in 1988. Since then, extensions have been granted for new active components. Takeda has challenged this practice based on the argument that such practice was not based on relevant provisions in the patent law.

The new IP High Court decision will make it easier for originators to obtain patent term extensions based on patents related to a new formulation of a conventional active component. This decision reverses the JPO's current practice and clearly contradicts earlier decisions of the IP High Court and its predecessor. For example, the IP High Court affirmed the JPO's rejection of a patent term extension for a patent related to a long-term slow-release formulation of a prostate cancer drug as recently as in July 2007 (case No 2005 (gyo-ke) 10311). The inconsistent legal interpretations will have to eventually be resolved by the Supreme Court, but the logic of this new decision is very straightforward and convincing if we look at the patent law statutes.

It is evident from this decision that the current JPO practice and court decisions that supported it represent somewhat skewed interpretations of statutes that were made to strike a balance between the interests of originators and those of generic makers.

On a different front, the section related to pharmaceuticals in the Examination Guidelines published by the JPO will be revised. Based on a report prepared by the commission set up for the reform of patent protection for medical and diagnostic methods, the JPO will make new dosage regimens and administrations of a conventional drug patentable if they show remarkable effects over the prior art. Owing to opposition from physicians, medical or diagnostic methods will not become patentable subject matters, despite repeated attempts by interested parties, but the government decided to slightly expand the range of patentable subject matters and, for this purpose, to revise the JPO Examination Guidelines. A draft of the revised Guidelines has already been published for public scrutiny.

Although the Japanese government has recently been promoting the use of generic drugs to reduce health care costs in a rapidly aging society, current trends in patent law appear to be against generics in patent law.

Qualcomm Dealt with a C&D Order by JFTC

The Japan Fair Trade Commission (JFTC) issued a cease and desist (C&D) order against Qualcomm, a wireless telecommunications R&D company based in San Diego, on September 30, 2009 for unfair trade practices. In July, the JFTC warned Qualcomm of an anticipated C&D order to give it an opportunity to file a brief in rebuttal. This is a result of a three-year investigation over license agreements with Japanese companies for mobile phone CDMA technologies Qualcomm had developed. The JFTC objected to non-assertion provisions and royalty-free licenses granted on Japanese licensees' intellectual property in agreements Qualcomm had with Japanese licensees as unfair trade practices under the Antimonopoly Law. Qualcomm may appeal this decision, or else it

will have to revise its agreements with Japanese licensees. An English translation of the C&D order is available from the website of the JFTC (<http://www.jftc.go.jp/>)

Innovation Network Corporation of Japan Starts with Huge Funding

A new government-funded company called Innovation Network Corporation of Japan (INCJ) was established in July with a fund of 900 million U.S. dollars from the government plus 100 million U.S. dollars from the private sector.

It also has a government guarantee for an additional 9 billion U.S. dollars. The purpose of the company is to fund private initiatives for research and development projects based on technologies developed by universities, ventures, and small or large companies. It is expected that the company will also help such projects obtain intellectual property rights.

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## **Editors' Note**

We trust that the articles included in this issue will prove useful in providing you with up-to-date information on a variety of IP issues in Japan. If you require further information on the articles included in this issue you may visit the web site of the Japan Patent Office at: <http://www.jpo.go.jp/index.htm>.

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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