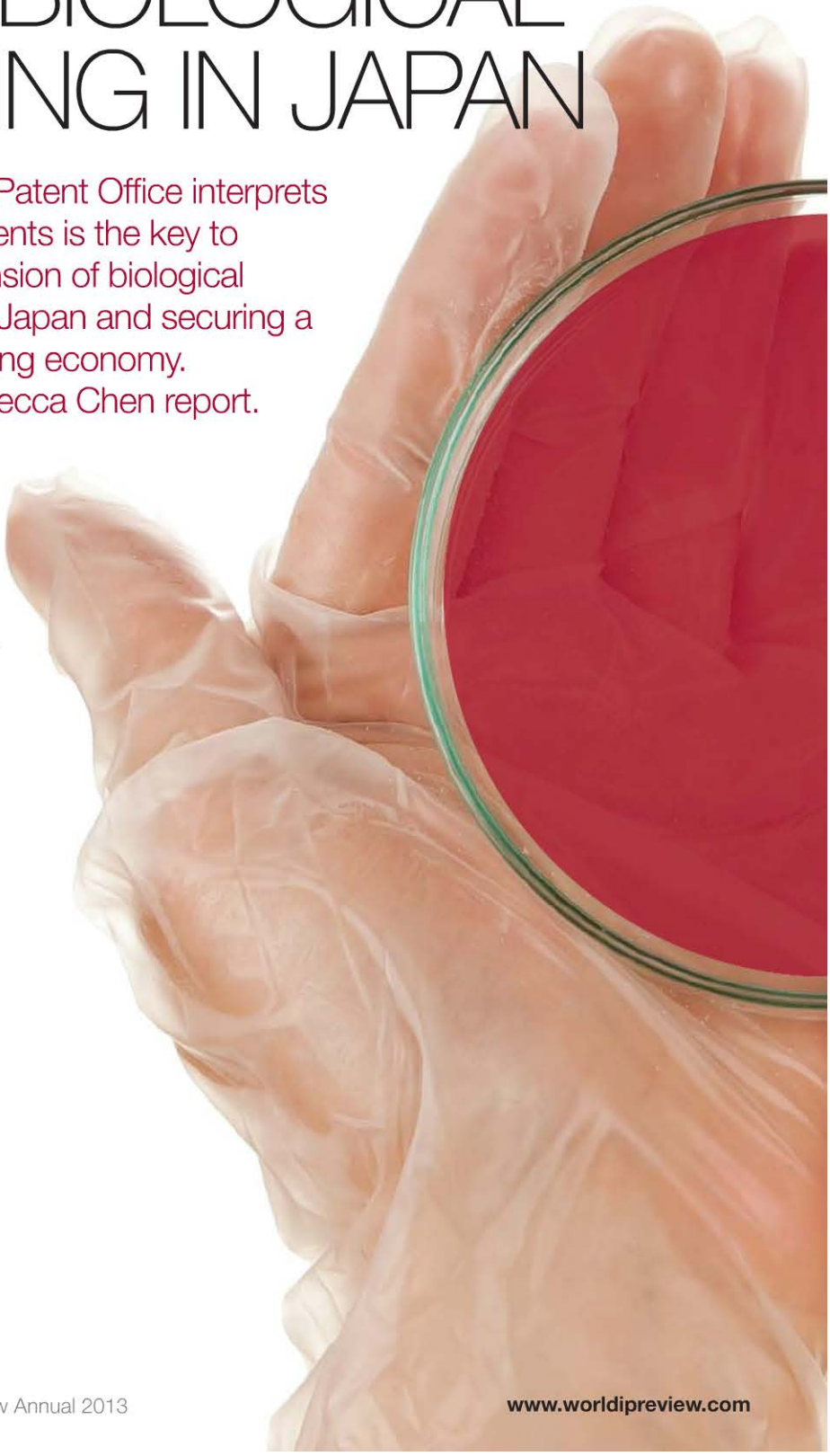
IPS CELL TECHNOLOGY SPURS BIOLOGICAL PATENTING IN JAPAN

Understanding how the Patent Office interprets specific patent requirements is the key to capitalising on the expansion of biological invention patentability in Japan and securing a market within this booming economy. Kenji Sugimura and Rebecca Chen report.



Developments in induced pluripotent stem (iPS) cell technology have opened the door to clinical applications with huge implications to the healthcare market. To capitalise on this booming market in Japan, firms need to understand how to draft patent applications that best protect this new biotechnology.

Biotechnology is an invention-intensive industry that relies heavily on the protection of IP, especially patents. Although biotechnology offers novel solutions to medical, agricultural and environmental industries, developing biological inventions is risky. Inventors and investors risk enormous financial, time and labour commitments. Developers rely on the period of market exclusivity conferred by patents to recoup investments in R&D.

Japan's booming biotech industry

Japan is a leader in the biotechnology sector. The boom in Japan's biotechnology industry was propelled by the award of the 2012 Nobel Prize in Physiology or Medicine to Professor Shinya Yamanaka and his colleague, Sir John Gurdon, for "the discovery that mature cells can be reprogrammed to become pluripotent" in October 2012. In January this year, Prime Minister Shinzo Abe further fuelled Japan's biotech boom by promising an economic stimulus package that includes $223 million-worth of funding for research in the iPS cells field.

As a leader in biotechnology innovation, Japan has the second highest patent application filing rate in the world, second only to the US. Biotechnology is a growing sector in Japan. The fastest growing

Japanese biotechnology companies have seen their values triple since the start of 2013. This growth in the biotechnology field represents a high-value market for foreign companies.

Patenting biological inventions

Under the umbrella of biotechnology, biological inventions, like iPS cell technology, are examined according to general examination guidelines for patents. In response to requests for additional clarity, the Japan Patent Office (JPO) set forth specific guidelines for biological-related inventions. Through the years, the JPO has continued to amend these guidelines to bring greater clarity to new technologies. The result of these amendments has been a broadening of the scope of patentability within the biotechnology industry.

Understanding how the JPO interprets specific patent requirements is the key to capitalising on this expansion of biological invention patentability and securing a market within this booming economy. This article will highlight key issues to note when patenting biological inventions in Japan.

Requirement for industrial applicability

The Japanese Patent Act requires that all patentable inventions be "industrially applicable". Essentially, inventions must have market or commercial potential to be patentable. The JPO explicitly lists "medical activities" among inventions that fall outside the scope of industrially applicable inventions, meaning that methods of surgery, therapy and the diagnosis of human diseases cannot be patented.

Some people have incorrectly assumed that this designation means all medical technology cannot be patented in Japan. This is a misunderstanding, as most inventions in the field of medical technology can be characterised as devices, substances and other products that constitute patentable subject matter.

The JPO continues to revise patent examination guidelines regarding industrial applicability, further clarifying the scope of patentability as it includes or excludes specific emerging technologies.

Methods for manufacturing medical materials from raw material collected from a human body were added to the realm of patentable subject matter in 2003. In 2009, the JPO added illustrative examples of patentable "methods for manufacturing medical material" to include methods of inducing differentiation and induction of human iPS cells.

Methods for controlling the operation of a medical device were also added to the scope of patentable subject matter in 2003 and further expanded in 2005. With regard to these types of method patents, it is important to note that the claim language must be drafted in a way to claim the function of the medical device as a method of controlling the device, not as a method for the function of the device. The claim language should also avoid any step with an action taken by medical personnel or the influence on a human body by the device.

Methods for gathering various kinds of information from the human body were included in the examination guideline as patentable subject matter in 2009. Care must be given while drafting these claims to avoid including any step that involves the judging of the physical or mental condition of the subject human body or the prescription, treatment or surgery plan of the subject human body.

These amendments have significantly broadened the scope of biotechnology patentability in Japan. Consequently, claims should be drafted according to the newest examination standards in order to provide the broadest possible protection.

Claim scope

The Japan Patent Act requires that the invention, as set forth in the claims, is clearly defined. The JPO has established standards for such clarity by outlining the various ways in which genes, vectors, recombinant vectors, transformants, fused cells, recombinant proteins and monoclonal antibodies may be described in a claim. The claim scope of inventions related to a gene or a protein corresponding to a gene was broadened to allow claims to encompass genes or proteins that share sequence similarity.

Patent rights in the past were rigidly narrow—protecting patents only if DNA or protein sequences matched base by base or unit by unit. However, it is known that sequences do not need to match completely for an equivalent functional effect. Patents now protect protein amino acid sequences and gene nucleic acid sequences to allow for small "substitution, deletion or addition" in the sequence or include sequences that have enough similarity that they anneal or 'hybridise' with the original sequence.

In practice, the expression "substitution, deletion or addition" is understood to refer to a modification within a limited range of usually fewer than 10 units. When claiming an invention related to a gene or a protein corresponding to a gene, the "substitution, deletion or addition" language should be used to broaden the scope of protection. If this language was not used in an original patent of a key invention, it may be advisable to file a divisional application to the original patent containing the "substitution, deletion or addition" language. Before this change, patentees had to rely on the doctrine of equivalents to defend their patent rights. Now, patents can be drafted using this language to better protect their inventions.

Enablement requirement

A patent specification must be written so it enables a person of ordinary skill in the art to which the invention pertains to carry out the invention. In order to satisfy this requirement, a person of ordinary skill in the art must be able to reproduce the invention. Regarding biological inventions, the person must be able to reproduce the biological material, such as a protein, gene, recombinant vector, or cell, on the basis of the description in the specification.

If the biological material cannot be produced, the applicant must deposit the biological material to the National Institute of Bioscience and Human Technology (NIBH) before filing the application and submit a deposit certificate issued by the NIBH, or provide a copy of a receipt issued by the international depository authority under the Budapest Treaty. Failing to deposit such biological material will result in the JPO rejecting an application for failing to satisfy the enablement requirement.

> "WHEN CLAIMING AN INVENTION RELATED TO A GENE OR A PROTEIN CORRESPONDING TO A GENE, THE 'SUBSTITUTION, DELETION OR ADDITION' LANGUAGE SHOULD BE USED TO BROADEN THE SCOPE OF PROTECTION."

Prior art and advantageous effect

The applicant is required to describe the technical field and prior art to which the invention pertains within the specifications. This requirement aims to highlight the technical significance of the invention and may clarify a problem that the invention will solve.

The prior art should be disclosed so that it explains the current state of the art and the problem to be solved. Although it doesn't have to, the applicant should then describe an advantageous effect, not exhaustive, of the claimed invention over the relevant prior art. The explanation of such an advantageous effect will be taken into account as support for the existence of an inventive step. This is of particular importance where combinations of publicly known processes or materials are used to create a new invention with an advantageous effect that could not have been foreseen.

Public order

Last, when considering patenting biological inventions, applicants should be aware of Article 32 of the Patent Act, which prohibits the patenting of an invention that is likely to harm public policy or public health. In practice, patents for inventions that include the step of destroying a human embryo have been rejected under Article 32. This morality provision has not, however, been used to prohibit the patenting of methods of culturing or differentiating already established embryonic stem cell lines. Although patent applicants may easily overcome Article 32, with respect to iPS cells, it is important they are mindful of such mitigating factors when devising a patent strategy.

Capturing the booming market

Given the substantial growth of its biotechnology industry and its expansion of patentable subject matter, Japan holds tremendous opportunities for companies seeking to expand their biotechnology markets. Understanding the patent landscape as it pertains to biotechnology in Japan will enable companies to tailor patent applications appropriately to capture this booming industry. ■

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