A novel touch

Japan enjoys an innovative biotech industry. Osamu Yamamoto of Yuasa and Hara reveals what patent owners need to know during prosecution

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How capable is the Japanese biotechnology industry of taking advantage of innovations in this area?

There are two issues in Japan deemed to be of particular importance: regenerative medicine and personalised medicine.

Japan is a world leader in research for regenerative medicine. Japan currently holds about one third of all patents globally in this field. Stem cell researcher Shinya Yamanaka received the joint Nobel Prize for Medicine in 2012 with UK scientist John Gurdon. On 25 November 2014, new regulations for accelerating approval of regenerative therapeutics in Japan were implemented, meaning companies are now able to receive conditional marketing approval and generate revenue from regenerative products while trials are being conducted. The new framework is expected to enhance opportunities for commercialisation of medicinal products in Japan.

Personalised medicine helps to deliver precisely targeted, predictable and highly effective medicine customised for individual patients. Due to a growing understanding of genetics, it will be possible to provide improved diagnoses, safer drug prescribing, and more effective treatment of diseases and conditions. Further, diagnostic modalities and biomarkers have been intensively developed for personalised medicine. Innovation in these areas is underway in Japan.

How progressive is Japanese patent law in terms of patentable subject matter, particularly where biotech is concerned?

Correlation-based medical diagnostics are essential for the development of personalised medicine. However, a claim directed to a diagnostic method that involves observing a natural correlation has not been eligible as a matter for patent due to the Prometheus decision handed down by the US Supreme Court. Without the burden of such a decision, in Japan patents are routinely issued in the field of correlation-based medical diagnostics.

If something exists in nature, but needs to be isolated artificially, that same thing once isolated is entitled to the protection of a patent. Examples are chemical substances isolated from plants, microorganisms, and genes.

Medical use, and second medical use, of a known compound is also patentable in Japan. New plant varieties and animals may be patented provided that all requirements for patentability are complied with.

Any invention that is liable to injure public order, morality or public health cannot be patented. However, in Japan patentability of transgenic animals is not deemed problematic. For example, a patent for a Harvard mouse was granted in Japan.

For an invention to be patented that invention must be capable of industrial application. Inapplicable inventions include methods of surgery, therapy or human diagnosis. However, as for diagnosis inventions, in many cases it is possible to draft claims in such a manner that avoids a rejection being issued on ground of lack of industrial applicability.

Claims covering an invention that address a dosage schedule or amount may suffice to distinguish such an invention over the prior art, and if an unexpected remarkable effect is attained by the invention, it will be deemed that the invention does involve inventive step. This means that a new dosage schedule may be patentable.

What is the key case law in biotech, and what development of this law is required in order to enhance protection of Japanese biotech innovation?

Product-by-process claim drafting and interpretation practice were greatly modified as a result of the Pravastatin Sodium case decisions (Japan Supreme Court, 5 June 2015, Case Nos 2012(ju)1204 and 2012(ju)2658). Japan's highest court reversed the Grand Panel of the IP High Court; and in doing so, two main points were emphasised by the court.

Product-by-process claims can be drafted, only if circumstances exist under which it is impossible or entirely impractical to directly identify a structure or characteristics of a product at the time of filing. Otherwise, the claim will be rejected on grounds of lack of clarity. Even though product-by-process claims are limited by and defined by a process, determination of patentability is based on the product itself. A technical scope of a product-by-process claim should be determined to cover products that have the same structure and characteristics, as those of the product made in accordance with the manufacturing process.

These should be considered because it is often either difficult or impossible to identify the structure or characteristics of the product for biotech inventions.

What are your key tips for prosecuting biotechnology patents in Japan?

Historically, Japan was criticised for prolonged examination, especially in relation to pioneering biotech inventions, the net result of such examination was a short patent term. But times have changed.

Now, accelerated examination, including the Patent Prosecution Highway, is actively used in Japan. An interview with a patent examiner is often highly effective in successfully prosecuting complex biotech cases, by facilitating understanding of an invention under examination and resolving possible issues that may otherwise prevent the application.

Extending patent exclusivity for biopharma is highly important. It is essential to file the first patent application early on, with attention paid to the drafting of the application so as to avoid creating prior art problems. The reason behind this is that a patent application at an early stage containing only limited experiment data will limit a scope of any claim that can be obtained, taking into account the relatively strict support and enablement requirements imposed by the Japanese Patent Office.

If claims in later-filed applications are novel and inventive over those of an earlier filing even after publication of the earlier patent application, it may be possible to obtain patents with later stage developments containing detailed experiment data for specific drug candidates, and thereby enjoy a longer term of patent coverage for specific biopharmaceuticals. **IPPro**

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