



Pharmaceutical Research Tools in Japan

The research-based pharmaceutical industry is a key asset for the Japanese economy. Japan represents around 13% of the world pharmaceutical production and 11% of the worldwide pharmaceutical market. This industry employs over 190,000 locally. Japan stands out as a competitive pharmaceutical industry, and an internationally attractive environment for drug development. This was achieved with the implementation and enforcement of intellectual property rights in line with international standards.

Several economic indicators show that the Japanese pharmaceutical sector is losing competitiveness compared to the United States of America. The MHLW has adopted a “*Vision for the Pharmaceutical Industry*” which aims to improve the international competitiveness of the Japanese pharmaceutical sector. To achieve the goals set as part of this initiative, careful attention should be given to ensure strong and effective intellectual property standards, and to avoid their erosion.

We were informed that discussions are taking place in Japan regarding models to introduce compulsory licensing mechanisms with regard to pharmaceutical research tool patents (or similar measures which would have the effect of unilaterally and compulsorily depriving patent holders from their rights).

EFPIA would stress the following:

- There is no substantial evidence that research tools patents inhibit research or scientific progress in practice¹. Many companies voluntarily licence research tool patents on fair commercial terms. Further, the research tools themselves are often made available in the ordinary course of business practice.

The current system of compulsory licensing under Japanese law, which generally reflects the TRIPs Agreement, is carefully balanced as it is conceived as an **exceptional mechanism** to address emergency situations or abuse. Compulsory licensing is to be used only in a very limited set of circumstances (e.g., in situations where a patent owner has abused the right, or impeded the ability of a Government to take emergency action).

- EFPIA does not believe that research tool patents should be subject to specific compulsory licensing mechanisms that do not apply to other types of patents. Certainly, EFPIA sees no reason for any rules or laws which allow for systematic or automatic compulsory licensing of research tool patents. Research tool patents should be treated in the same way as any other patent, so that compulsory licences

¹ See, for example, Gene patenting and medical research: a view from a pharmaceutical company; Stott & Valentine; Nature Reviews Drug Discovery **3** 364-368 (2004) and the references therein.

are only allowed where there is an abuse of patent rights or to allow emergency action.

- More extensive use of compulsory licensing will threaten the research-based pharmaceutical and life science technologies sector in Japan by **creating legal and economic uncertainty, undermining the incentives** for local and international firms to engage in innovative activities. Companies will reconsider making investments in the country's pharmaceutical and life science technologies sector, preventing amongst other innovative activities the elaboration of tools to identify treatments to cure diseases prevalent in Japan and internationally.
- Because there is no evidence that research tool patents are causing specific problems, there is no benefit to be gained from more extensive compulsory licensing provisions for them. To the contrary, to introduce such provisions will reduce the incentives to invest in research in Japan and will damage Japan's reputation for being a supporter of strong intellectual regimes.

Therefore, research tools should not be subject to particular compulsory licensing standards. The current legislative framework provides for the necessary safeguards to ensure that research tools are readily available. Weakening of intellectual property protection in Japan would have as adverse reaction to deter investment in pharmaceutical innovation from local and international companies.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the research-based pharmaceutical industry operating in Europe. Its members comprise 25 national pharmaceutical industry associations and 43 pharmaceutical companies involved in the research, development and manufacturing of medicinal products for human use.

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