

# Kluwer Patent Blog

## Japan: The IP High Court has clarified that the Japanese Bolar exemption covers clinical testing for not only “generic” but also “innovator” drugs

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In the pharma industry, constant battles have been taking place for many decades between innovators and generics. More recently, battles among innovators have also started to occur. This post concerns a case which may have an impact on the development strategies of innovators, as well as licensing strategies of universities and public research institutions which do not commercialize patented drugs by themselves.

In the case at hand (*X (individual) v. Amgen K.K.; The IP High Court Case No.: 2020 (Ne) 10051; Decision date: February 9, 2021*), a Japanese subsidiary of Amgen (“**Amgen**”) was sued by patentee X (an individual) who asserted that Amgen’s clinical trial in Japan for an innovator drug infringed X’s patent. X is one of the inventors of the patent and a researcher in a US university. The patent was originally filed by two US private entities and the US university, but X obtained the right regarding the patent application and then the patent was granted. Amgen was conducting a clinical trial in the form of a “bridging study” to obtain a marketing approval for an innovator drug of Talimogene Laherparepvec (“**T-VEC**”), which had been approved in US and Europe. There was no doubt that T-VEC fell within the technical scope of X’s patented invention. Amgen sought protection under the research exemption, and the court ruled in favor of Amgen.

The main issue in this case was whether or not clinical testing for “innovator” drugs was covered by the research exemption under Section 69(1) of the Japanese Patent Act. In relation to this, the Japanese Supreme Court had rendered a decision on April 16, 1999 in *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.; The Supreme Court Case No. 1998 (ju) 153*, that, under Section 69(1) of the Japanese Patent Act, a clinical testing for “generic” drugs during the patent term does not constitute patent infringement. The reasoning was that if clinical testing of generic drugs were not allowed during the patent term, third parties, i.e., generic drug companies, would not be able to freely practice the patent (including commercial sale of generic drugs) for a considerable period of time even after the expiry of the patent, which goes against the spirit of the patent system. The ruling of the Supreme Court, which is sometimes called the Japanese *Bolar* exemption, was clearly limited to clinical trials of generic drug companies for use of a patent of an innovator drug company. In the *Amgen* case, the IP High Court ruled in this case that such

Supreme Court's reasoning applies not only to generic drugs, but also to innovator drugs. The IP High Court also found that the testing activities conducted by Amgen did not go beyond the scope of a clinical trial necessary to obtain a marketing approval of T-VEC.

The next question is the scope of this IP High Court decision. Does the research exemption apply to clinical testing absolutely required for obtaining a marketing approval for an innovator drug, to clinical trials in general, or even to clinical studies? Should the patent be a substance patent for an active ingredient? How about patents regarding antibodies, DNAs, and methods regarding medicines and medical devices? These new questions have not been answered yet.

According to this case, even if you are a patentee of a pharmaceutical invention, it does not mean that you have exclusive rights during the patent term to conduct clinical testing for new drugs using the invention — even during the patent term, other innovator-drug companies will be able to conduct clinical testing using the disclosed invention under the research exemption, and it is possible that they may even obtain marketing approval earlier than you. If the research exemption applies to a wider scope of clinical trials, licensees may start to reconsider if they actually need these licenses and licensors may lose their source of income. Pharmaceutical companies and academia are carefully watching the development of this IP High Court case as well as discussions regarding the scope of the Japanese *Bolar* exemption.

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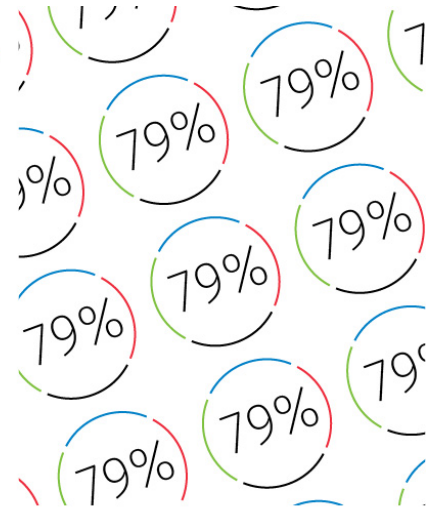
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