

Patent Map of the Bioavailability Related Pharmaceutical Compositions

KIPO Pharm. Exam. Div.

Korean Intellectual Property Office.

Bioavailability of some drugs has been tested for determining their bioequivalence to their comparison drugs. The huge formulation and composition studies of drugs have been done to improve their bioavailability. Therefore the patent application numbers related to bioavailability have been increased for last 20 years.

In case of Korea 340 cases of the patent have been applied from 1982 to 2005. Especially the patent application no. was tremendously increased in from 2001 to 2003 as shown in Figure 1. This result is strongly related to the medical reform system of Korea enacted in 2000. Many pharmaceutical companies need bioequivalence data of their generic drugs to sell them continuously in the market after enactment of the medical reform system.

One successful case of the bioavailability related pharmaceutical compositions development is the cyclosporin microemulsion to improve cyclosporin's absorption rate (patent application no. ; 1994-0013945 applied from Hanmi). The market share price in 2004 year is about 72 billion won.

In case of USA 500 cases of the patent have been published from 1976 to 2004. The patent publication no. was tremendously increased from 1994 to 2002 as shown in Figure 2. This result would be strongly related to the Hatch-Waxman Act enacted in 1984. The purposes of the Hatch-Waxman Act prevent to lose patent terms of original drugs due to the approval process at the FDA and to bring generic drugs to the market more quickly after expire date of the original drug's patent term. Therefore, the companies of brand(original) drugs applied many patents related to the drug composition to protect their brand drugs from the generic drugs. The companies of the generic drugs applied many patents to bring their generic drugs to the market as soon as the patent terms of the original drugs expired.

Norvatis and Pfizer companies applied the bioavailability related patent most in all companies. Firstly, the patent from Korea is published in 1994.

In case of Japan only PAJ data base was used to extract the bioavailability related patent. 230 cases of the patent have been applied in from 1980 to 2004. The tendency of patent application from 1983 to 2004 except 1992 and 1994 was not much changed in each year as shown in Figure 3. The Japanese companies tend to apply their patent steadily in their need.

In case of EPO 148 cases of the patent have been applied from 1980 to 2004. The patent application no. was steadily increased in 1980-2003 as shown in Figure 4.

Pfizer applied their patent most in all companies. This company applied 8 cases in 2001 and 2002. Pfizer's high application in these years is consistent with the tendency in USA as said above.

This patent maps said that the patent application or publication tendency in each country was a

little different according to their technological basis or systematic situations.

This statistical data will play an important role in establishing the direction of drug development for scientists in the pharmaceutical fields .

Bioavailability; Bioequivalence; Patent Map; Patent

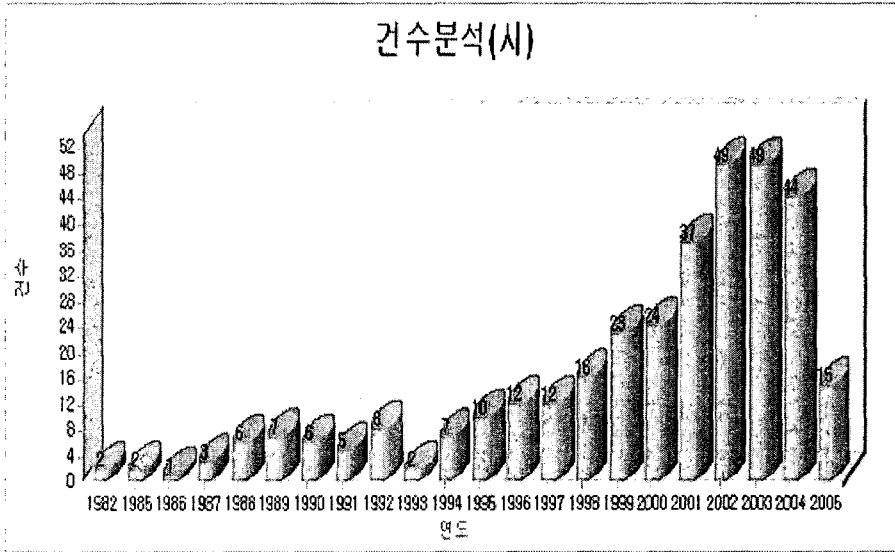


Figure 1. Patent Application Number of Bioavailability related Pharmaceutical Compositions in Korea

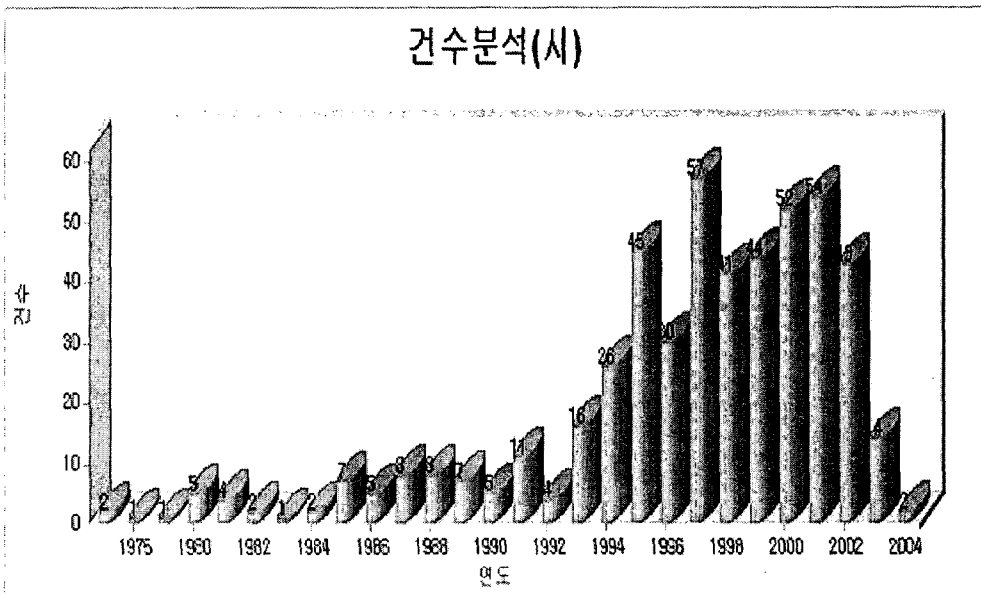


Figure 2. Patent Application Number of Bioavailability related Pharmaceutical Compositions in USA

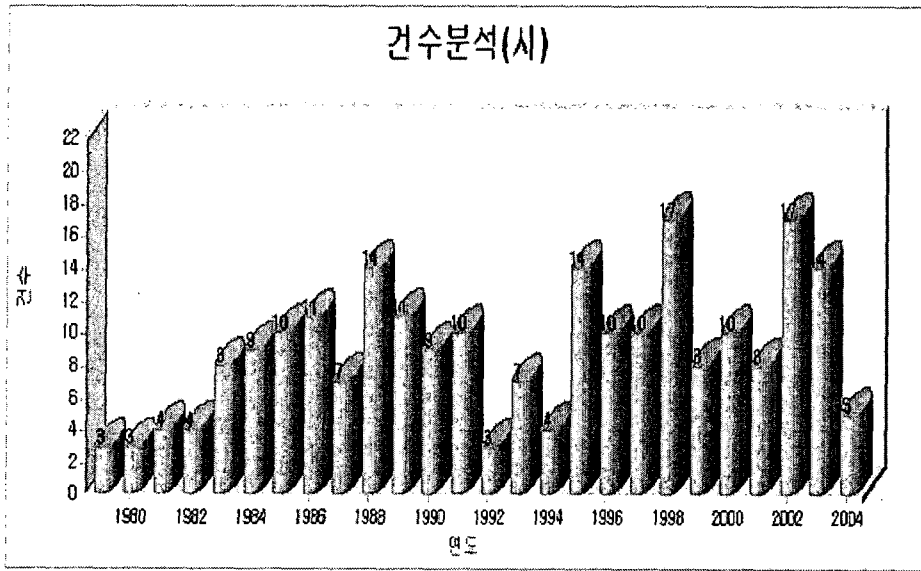


Figure 3. Patent Application Number of Bioavailability related Pharmaceutical Compositions in Japan

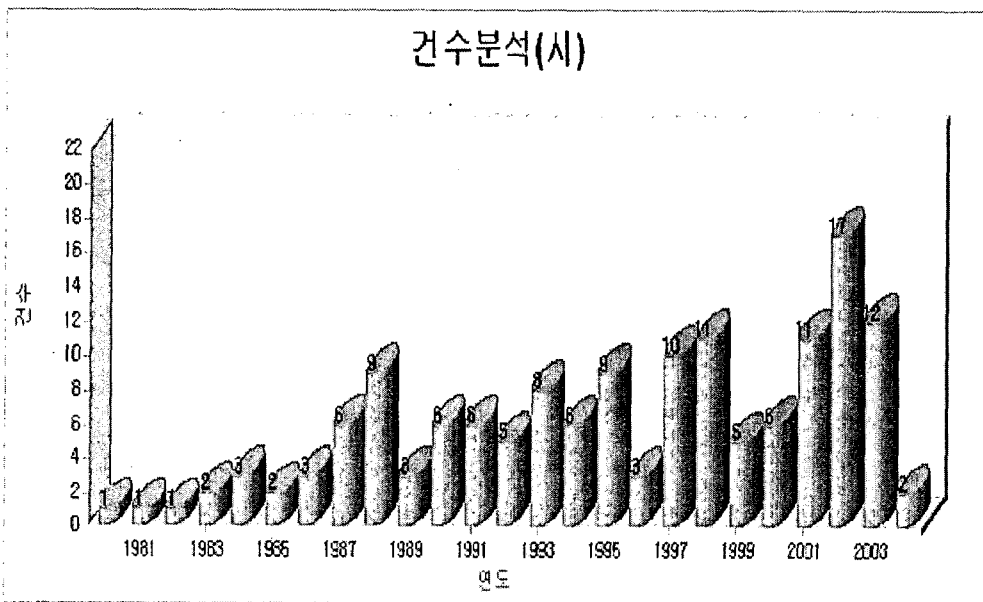


Figure 4. Patent Application Number of Bioavailability related Pharmaceutical Compositions in EPO