



China's Patent Re-Examination Board Says Pharmaceutical Salts Not Patentable Over Pure Compounds

In July 2013, the Patent Re-Examination Board of China's State Intellectual Property Office invalidated the U.S. biotech company, Gilead Sciences', Chinese patent covering Tenofovir Disoproxil Fumarate (TDF or PMPA), which is the active ingredient in Gilead Sciences' drug for treating HIV, AIDS and hepatitis B – sold in the market under the trade name Viread. The Chinese patent, CN 100384859C, has claims that cover a genus of compounds (including Tenofovir and Tenofovir Disoproxil) and their pharmaceutically acceptable salts, isomers and hydrates, second medical use with the compounds, and methods for making these compounds. Although the Re-Examination Board's decision has not been published, it is believed that the Board sided with the patent challenger and accepted its argument that the active ingredient of Viread does not possess an inventive step over prior art, a Czech patent issued in 1985. Specifically, the challenger argued that compared to the prior art disclosure, the active ingredient of Viread, i.e., the fumarate salt, only renders Tenofovir Disoproxil better bioavailability and makes the compound easier to be absorbed, not more. Gilead Sciences has the option to appeal but has not indicated its intention.

Several years ago, the Re-Examination Board made the same finding against Pfizer's Chinese patent on Viagra. However, the Board's decision was overturned by the Beijing Intermediate People's Court on appeal. In view of the precedent of the Viagra case, it appears that Gilead Sciences may appeal the Re-Examination Board's decision to the Beijing Intermediate People's Court to see how the Court would decide this case.

Claims on methods for treating a disease are not patentable subject matter in China. As such, applicants for Chinese patents are usually left with claims directed to compounds or compositions, methods for making the compounds or compositions, and second medical use claims. Both the Viagra and Viread decisions by the Re-Examination Board illustrate how important it is for Chinese patent applicants to not only draft simple compound or composition claims, but also consider other forms of composition claims.

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