Got a Broad Chemical Patent? Be Wary.

Idenix's Pharmaceuticals' patent (U.S. Patent No. 7,608,597) was invalidated for having a genus that was "too broad." The trial judge ruled that the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus. On appeal, the Federal Circuit upheld the trial judge's ruling of non-enablement. On January 19, 2021, the Supreme Court of the United States (SCOTUS) declined to review the Federal Circuit's decision to invalidate Idenix's patent.

This decision is likely to have effects across the pharmaceutical and biotech field. The Federal Circuit's ruling may narrow the scope of generic protection granted to pharmaceutical companies for novel drug scaffolds. Chemical genus claims are often used to deter "fast followers" from making small modifications to a drug's design to avoid patent coverage. In their amici briefs, both GlaxoSmithKline and Amgen argued that this narrowing would result in a decrease in innovation across the pharmaceutical space.

Idenix's patent claimed a method of treating Hepatitis C virus (HCV) infection by administering a class of synthetic nucleosides, β-D-2′-methylribofuranosyl nucleosides, also known as a "2'-methyl-up nucleosides". Idenix's patent covered any 2′-methyl-up nucleoside which fell within the claimed chemical genus that was effective in treating HCV. Idenix sued Gilead Sciences, alleging the '597 patent's claimed genus encompassed the compound sofosbuvir, an active ingredient in Gilead's hepatitis C drugs Sovaldi and Harvonis. In 2016, a Delaware jury agreed and awarded Idenix $2.5 billion. However, the district judge set aside the jury's verdict, ruling the patent was invalid on enablement grounds. The judge contended this genus was too broad, and the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus.

On appeal, the Federal Circuit determined the patent did not provide "meaningful guidance" or "useful blaze marks" to direct a person of skill to specific effective hepatitis C therapeutics within the claimed genus. That a person of ordinary skill in the art would not know, without undue experimentation, which 2′- methyl-up nucleosides would be effective for treating HCV. The court concluded that the working examples present in the patent were "very narrow, despite the wide breadth of the claims at issue" and were insufficient to enable such a broad genus.

Merck & Co. acquired Idenix Pharmaceuticals for $3.85 billion in 2014.

China Closer to Granting Patent Term Extensions?

A new draft amendment to Chinese Patent Law was submitted to the National People's Congress Standing Committee on June 28, 2020. Key provisions include the establishment of patent term adjustment (PTA) caused by delays in the patent office and patent term extension (PTE). Under the new draft amendment, a Patentee could receive up to 5 years of PTE, as long as the overall patent term does not extend beyond 14 years after approval of the drug, similar to PTE available in the United States

The proposed amendments in the draft also address many other weaknesses in biopharma IP protection in China. For example, these changes include litigation reform, including stronger and more efficient patent enforcement, an increase in the statutory limit on damages (up to CNY 5,000,000), and a 6-month grace period for public disclosures made for the benefit of the public during a national emergency.

Notably, the draft also provides for a delay of marketing approval of a new drug, if that new drug is subject to patent dispute. If a lawsuit is filed by an owner of a patent listed in China's "drug patent information registration platform" within 30 days of publication of a marketing approval application, the application is stayed for up to 9 months.

If implemented, these changes would make China a more attractive jurisdiction for life science innovators and biopharmaceutical investment opportunities from around the world.

This new draft is currently available for public comment until August 16, 2020.