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II Ca-Be-lly or Not II Ca-Be-lly: Is The Famous Cabilly II Antibody Patent Near Extinction?

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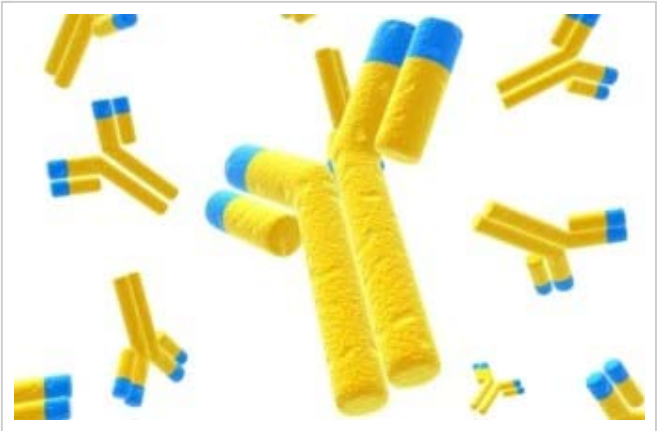

On February 5, 2016, the Patent Trial and Appeal Board (PTAB) issued a decision to institute an *Inter Partes* Review (IPR) of Genentech's "Cabilly II" patent (U.S. Patent No. 6,331,415). This triggered the one-month deadline for third parties to request joinder under 37 CFR § 42.122(b). Whether you are a licensee, or otherwise have a stake in the outcome of the Cabilly II, it may be prudent to consider your options before the March 5, 2016 deadline.

The Cabilly patents need no introduction – they are among the most famous in biotechnology, dating back to a 1983 filing by Shmuel Cabilly and others. The patents cover basic steps for manufacturing therapeutic antibodies and are widely commercialized – five of the top ten selling drugs in the world are currently therapeutic antibodies. Cabilly II alone was reportedly the subject of 70 different licenses granted between 1991 and 2013, with royalties from the patent family expected to reach one billion dollars annually by 2018, when the Cabilly patents are set to expire. Not surprisingly, Cabilly has faced numerous challenges, including an interference, reexamination, and multiple court challenges. The IPR petition for this latest challenge (IPR2015-01624) was filed on July 27, 2015 by Sanofi and Regeneron. Interestingly, on the date of the IPR filing on Cabilly II at the US Patent Office, Sanofi also filed a lawsuit seeking invalidity of Cabilly III (U.S. Patent No. 7,923,221) in the U.S. District Court for the Central District of California. To date, no IPR on Cabilly III has been filed.

Although Cabilly II survived past challenges, this instituted IPR may be the most difficult yet to shake off, given the recent statistics showing that only about 1 in 10 patents survives an IPR unscathed. By instituting the IPR, the PTAB panel has found that there is a reasonable likelihood that Sanofi and Regeneron would prevail with respect to at least one of the challenged claims. While patent owners argued that the same arguments were raised and fully addressed in prior proceedings, the Board held that the particular new combination of references upon which this proceeding is instituted was not previously addressed during prosecution or reexamination.

Those who have a stake in the outcome of this IPR, for example licensees, should carefully consider whether or not to request joinder by the March 5, 2016 deadline. A major benefit of joining the IPR is to continue the trial to Final Written Decision should the original parties to the IPR decide to settle and terminate the proceeding. Given the value of Cabilly II, settlement of the IPR is a real possibility.

In general, joinder requires filing an IPR petition along with a motion for joinder. Historically, joinders have been granted in about two thirds of such requests, so they are not automatic. Joinder is typically granted where the new petition does not raise new grounds, does not introduce new evidence, new issues or arguments, does not require additional discovery, and does not otherwise extend the instituted proceeding.