
Japan IP High Court to Decide Patent Term Extension Again

On February 14, 2014, the Japan IP High Court announced they had selected *Genentech, Inc. vs. the JPO* as the 9th Grand Panel case to clarify one of the requirements for patent term extension*.

The case concerns four appeals of the JPO Appellate Board's decisions to reject Genentech's four applications for patent term extension. These decisions are based on two patents (JP 3398382, JP 3957765) and the second marketing authorization for bevacizumab (Avastin®), an antibody used as an anti-cancer drug. The issue is whether patent term extension should be approved, when an additional marketing authorization concerns only an addition to "Dosage and Administration" while "Indication and Usage" remains unchanged.

	Indication and Usage	Dosage and Administration
1st MA (April 2007)	unresectable, advanced or recurrent colon or rectum cancer	5 mg/kg or 10 mg/kg of bevacizumab to an adult i.v. every 2 weeks or more in association with another antineoplastic agent
2nd MA (September 2009)	unresectable, advanced or recurrent colon or rectum cancer	5 mg/kg or 10 mg/kg of bevacizumab to an adult i.v. every 2 weeks or more in association with another antineoplastic agent <u>7.5 mg/kg of bevacizumab to an adult i.v. every 3 weeks or more in association with another antineoplastic agent</u> (Underlined portion was newly authorized and added)

Chugai Pharmaceuticals, an exclusive licensee for the patents, obtained the second marketing authorization in September 2009. Genentech applied for patent term extension. After the examiner's rejection, the JPO Appellate Board rejected the application again, and Genentech appealed. The case was heard on February 24, 2014, and will be decided shortly.

* http://www.ip.courts.go.jp/eng/hanrei/g_panel/index.html

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