



PATENT WATCH

Stelara safe after IL-12 antibody dispute

AbbVie has lost a patent dispute in which it tried to show that Janssen's Stelara (ustekinumab) — an antibody binding to interleukin-12 (IL-12) and IL-23 that is marketed for the treatment of psoriasis and psoriatic arthritis — infringed on two patents describing IL-12-targeting antibodies owned by AbbVie. Instead, a US appeals court held that two AbbVie patents (US 6914128 and US 7504485) were invalid because AbbVie had tried to claim more types of IL-12 antibodies in the '128 and '485 patents than it had actually invented.

AbbVie's patents claimed a class or genus of fully human IL-12 antibodies that consisted of about 300 members with a range of IL-12-binding affinities; Stelara fell within this genus. Janssen asserted that although the patents tried to claim a large genus of antibodies, the antibodies that were actually described in the patents were limited to a group of closely related, structurally similar antibodies that are all derived from the same lead antibody, and so were not representative of the large genus that was claimed. Because of this asserted discrepancy between what was claimed and what was described in the patents, Janssen said that the patents failed to meet the so-called 'written description' requirement of patent law, which states that a patent must adequately describe the technology that is sought to be patented in order to show that a person really has invented it.

By contrast, AbbVie argued that the described antibodies did reflect the entire genus, largely because these antibodies had a range of binding affinities that matched the range of binding affinities in the entire genus. But the appeals court disagreed, noting that the patents did not give "any example, or even the possibility" of antibodies

other than those having VH3-type heavy chains and λ -type light chains, and so were not representative of the claimed genus of antibodies. Moreover, the court noted that Stelara "differs considerably" compared to the antibodies described in the '128 and '485 patents, as Stelara has VH5-type heavy chains and κ -type light chains and only about 50% sequence similarity in the variable regions.

Of general interest to patents claiming biologics, the court also highlighted that patents that describe an invention in terms of its function — such as an antibody that modulates the activity of a cytokine — rather than its structure are vulnerable to invalidity challenges based on a lack of adequate written description, especially "where it is difficult to establish a correlation between structure and function for the whole [claimed] genus". However, this judgement contrasted with the outcome of a similar case between AbbVie and Janssen in Canada, where a court held that functionally describing the IL-12 antibodies was adequate to show that AbbVie invented the general concept of using an IL-12 antibody to treat psoriasis, and so was entitled to patent protection for a genus of IL-12 antibodies.

As a result of this decision, Janssen is free to continue marketing Stelara in the United States, where it had reported sales of ~US\$0.9 billion in 2013.

AbbVie versus Janssen: <http://www.ca9.uscourts.gov/images/stories/opinions-orders/13-1338.Opinion.6-27-2014.1.PDF>

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