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Janssen Biotech Unable To Rewrite History and Save Remicade Patent

By Jeff Nichols

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The Federal Circuit on Tuesday affirmed a Patent Trial and Appeal Board ("PTAB") decision invalidating a patent on the autoimmune disease drug Remicade for double patenting.

Remicade, which has sales of more than $4 billion a year, is prescribed for treating arthritis, Crohn's disease and other inflammation-related ailments. In 2016, Pfizer and Celltrion Healthcare Co. Ltd. launched Inflectra, a biosimilar version of Remicade, which Janssen said infringed a number of its patents.

The Court's decision upholds the PTAB's decision affirming the Examiner's determination in an ex parte reexamination that the claims in US Patent No. 6,284,471 are unpatentable for obviousness-type double patenting based on at least two other Janssen patents.

The patent at issue was filed in February 1994 as a continuation-in-part of two earlier filed applications. During the reexamination proceeding, Janssen amended the patent in a way that it argued converted the application from a continuation-in-part to a divisional application, rendering the patent subject to the safe harbor provision under 35 U.S.C. §121. The safe harbor provision provides:

A *patent issuing on* an application with respect to which a requirement for restriction under this section has been made, or on an *application filed as a result of* such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, *if the divisional application is filed before the issuance of the patent on the other application.*

35 U.S.C. §121 (emphasis added).

The Examiner, the PTAB, and the Federal Circuit disagreed with Janssen's safe harbor arguments. According to the Federal Circuit, "[w]e . . . find no reason, under the plain language of [the statute] or under our precedent, to permit Janssen now, by amendment, to acquire the benefit of the safe harbor . . . . A patent owner cannot retroactively bring its challenged patent within the scope of the safe-harbor provision by amendment in a reexamination proceeding."

Circuit Judges Sharon Prost, Jimmie Reyna and Evan Wallach sat on the panel for the Federal Circuit.